UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Jennifer Noonan Edmonds, attest that I am the Director, Policy Analysis and Communications, Office of Air Quality Planning and Standards, Office of Air and Radiation of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

May 9, 1986, Contact Report – D. Newton and S. Srebro, MRI, to M. Popescu, Johnson & Johnson, International, 4 pages

November 14, 1989, Contact Report -- Val deOlloqui, MRI, to David Carwell, Sherwood Medical, 2 pages

November 11, 1986, Contact Report – M. Cassidy, MRI, to C. Predmore, Sherwood, 2 pages

November 17, 2003, J&J Stack Test Report, 126 pages

January 28, 2020, Attachment – Performance Test, 155 pages

Subscribed under the penalty of perjury on this 17th day of July, 2023.

JENNIFER EDMONDS Digitally signed by JENNIFER EDMONDS
Date: 2023.07.17 15:46:14 -04'00'

Jennifer Noonan Edmonds, Director
Policy Analysis and Communications
Office of Air Quality Planning and Standards
Office of Air and Radiation

CERTIFICATION OF TRUE COPY

I, Jennifer Clark, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Clark, Jennifer Digitally signed by Clark, Jennifer
Date: 2023.07.20 17:03:24 -04'00'

Jennifer Clark
Associate General Counsel
General Law Office
Office of General Counsel

OAR Box 1158

Prepped by Ryan Dugan

Document Number:

207) II-E-314

Docket Number:

A-88-03

A-88-03

II E 314

CONTACT REPORT--MRI Project No. 7712-K

From: David L. Newton and Sharon Srebro
Environmental Engineering Department

Date of Contact: 5/9/86 and 10/04/88 (for revisions)

Contacted by: Telephone

Company/Agency: Johnson & Johnson, International
New Brunswick, New Jersey

Telephone Number: (201) 524-2978
Fax (201) 214-0332
214-0334

CONFIRMATION

RESPONSE See attached Telecon

WRITTEN ☐
VERBAL ☒
NONE ☐

Person(s) Contacted/Title(s)

Mr. Miron G. Popescu, Technical Advisor

A followup call to confirm the information in the original contact report (see attached) was conducted October 4, 1988, by Sharon Srebro. Mr. Popescu provided verbal revisions that are incorporated in this version of the report. (see also telecon dated October 4, 1988, Sharon Srebro with Miron Popescu.)

CONTACT SUMMARY:

I called Mr. Popescu to discuss EO sterilization processes and EO emissions from sterilization chamber evacuation cycles and aeration cycles.

Mr. Popescu said that one can fairly accurately model EO behavior in an empty sterilization chamber by using ideal gas relationships. For example, if a 600 ft^3 chamber is charged with 50 lb of 80/20 EO/CO_2 mix at an operating pressure of 0.9 atm, the EO concentration would be approximately 1,000 mg/ℓ. If the chamber is evacuated to 1 in. Hg absolute (or 0.03 atm absolute), approximately 0.81 lb of sterilant gas are left in the chamber, or approximately 49 lb of sterilant gas are removed.

I asked Mr. Popescu how such a calculation would compare with actual data. Mr. Popescu responded that measurement data were available, and that typically one would measure concentrations of 600,000 to 700,000 ppmv at about 6 in. from the stack exit during the first evacuation cycle.

Mr. Popescu said that the common practice of vacuum pulsing (pulsating purge) only serves to remove EO adsorbed on the chamber walls, but does not remove EO absorbed in the product to any significant extent. He said that this practice helps to lower worker exposure to EO when the chamber doors are opened and products unloaded. He said that vacuum pulsing would remove perhaps another 10 percent of the remaining 0.81 lb in the hypothetical case discussed earlier. This would result in maximum stack concentrations of 3,000 to 4,000 ppmv.

Mr. Popescu said that a 3 to 7 day aeration period is typical for products after they have been removed from the sterilization chamber. During aeration, products may be exposed to heat and airflow, but according to Mr. Popescu, time is the essential element for removing absorbed EO from the product. He said that FDA requires that EO concentrations in most products be no higher than 250 ppmw. Certain surgical implants may require lower concentrations. Mr. Popescu said that roughly 80 percent of the material originally absorbed by the product is desorbed within 7 days.

Mr. Popescu said that a good contact for information on absorption of EO and EO chemistry during sterilization processes is Mr. Ed Gunsales at the Johnson & Johnson plant in Valley Forge, Pennsylvania. He can be reached at (215) 337-2400.

CONTACT REPORT--MRI Project No. 7712-K

From: David L. Newton, Environmental Engineering Department

Date of Contact: 5/9/86

Contacted by: Telephone

Company/Agency: Johnson & Johnson, International
New Brunswick, New Jersey

Telephone Number: (201) 524-5483

Person(s) Contacted/Title(s)

Mr. Miron G. Popescu, Technical Advisor

CONTACT SUMMARY:

I called Mr. Popescu to discuss EO sterilization processes and EO emissions from sterilization chamber evacuation cycles and aeration cycles.

Mr. Popescu said that one can fairly accurately model EO behavior in the sterilization chamber by using ideal gas relationships. For example, if a 600 ft^3 chamber is charged with 50 lb of 80/20 EO/CO_2 mix at an operating pressure of 0.9 atm, the EO concentration would be approximately 1,000 mg/ℓ. If the chamber is evacuated to 1 in. Hg absolute (or 0.03 atm absolute), approximately 1.81 lb of sterilant gas are left in the chamber, or approximately 48 lb of sterilant gas are removed.

I asked Mr. Popescu how such a calculation would compare with actual data. Mr. Popescu responded that measurement data were available, and that typically one would measure concentrations of 600,000 to 700,000 ppmV at about 6 in. from the stack exit during the first evacuation cycle.

Mr. Popescu said that the common practice of vacuum pulsing (pulsating purge) only serves to remove EO adsorbed on the chamber walls, but does not remove EO absorbed in the product to any significant extent. He said that this practice helps to lower worker exposure to EO when the chamber doors are opened and products unloaded. He said that vacuum pulsing would remove perhaps another 10 percent of the remaining 1.81 lb in the hypothetical case discussed earlier. This would result in maximum stack concentrations of 3,000 to 4,000 ppmV.

Mr. Popescu said that a 3 to 7 day aeration period is typical for products after they have been removed from the sterilization chamber. During aeration, products may be exposed to heat and air flow, but according to Mr. Popescu, time is the essential element for removing absorbed EO from the product. He said that FDA requires that EO concentrations in products be no higher than 250 ppmV. Mr. Popescu said that roughly 80 percent of the material originally absorbed by the product is desorbed within 7 days.

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OAR Box 1158

Prepped by Ryan Dugan

Document Number:

255) II-E-362

Docket Number:

A-88-03

A-88-03

II E 362

CONTACT REPORT--MRI Project No. 7723

From: Val deOlloqui, Environmental Engineering Department

Date of Contact: 11/14/89

Contacted by: Telephone

Company/Agency: Sherwood Medical
400 Maple Street
Commerce, Texas 75428

Telephone Number: (214) 886-3153

Person(s) Contacted/Title(s)

David Carwell, Engineer III

CONFIRMATION Feb 7 1990

REF

WRITTEN ☐
VERBAL ☐
NONE ☑

CONTACT SUMMARY:

Mr. Carwell was contacted to clarify his company's response to the July 1989 information collection request and to require about rear exhausts on their sterilizers. He explained that 95 percent of all the ethylene oxide used was processed through the scrubber which has an efficiency of 98 percent. This efficiency was determined from an independent test that was conducted. He said that the rest of the EO was absorbed into the product (2 percent of total) and offgased in the aeration room (3 percent). The aeration room vent total included all of the vents around the door as well as the rear exhaust and aeration room vents. No estimate was given to the percentage of EO that was vented out of the rear exhaust.

OAR Box 1936

Prepped by Charmelle Mathews

Document Number:

332) II-E-162

Docket Number:

A-88-03

A-88-03
II-E-162

CONTACT REPORT--MRI Project No. 7723-K

From: Margery A. Cassidy, Environmental Engineering Department

Date of Contact: 11/25/86

Contacted by: Telephone

Company/Agency: Hospital Products Division of Sherwood Medical
108 North Main Street
Sherburne, New York 13460

Telephone Number: (607) 674-2635

Person(s) Contacted/Title(s)

Carolyn Predmore

CONTACT SUMMARY:

[Note that this company is no longer part of Chesebrough-Pond's. They are now called "Hospital Products Division of Sherwood Medical"]. Tom Napper, the contact listed on the Section 114 Information Request, referred me to Carolyn Predmore to discuss the issues in question.

Ms. Predmore said that the values for net ethylene oxide used per year for chamber No. 4 on page 3 (17,270 and 1,662 lb/yr) were taken from their 1986 product budget projection. The value presented for calculated emissions on page 7a under 3c (34,437 lb/yr) was calculated on the basis of a report from York Labs and represents a worst-case, full capacity value. Therefore, the values on page 3 are more realistic and should be used for our purposes, according to Ms. Predmore.

With regard to the apparent discrepancy in sterilizer No. 4 efficiency values, Ms. Predmore said that the values were from the York Lab report and that for the 100 percent ethylene oxide mixture, an efficiency of 99.998 percent is correct. For the 12/88 mixture, the efficiency is 99 percent even though they are used in the same chamber.

CONFIRMATION MAR. 26, 1987

RESPONSE APR 2, 1987

WRITTEN ✓
VERBAL ☐
NONE ☐

ETHICON

a ***Johnson & Johnson*** company
3348 Pulliam Street
San Angelo, TX 76905-4403

RN 101649804

RECEIVED
NOV 18 2003
FIELD OPERATIONS
REGION 7

November 17, 2003

To: Mr. Sam Madison
Emissions Evaluator
Texas Commission on Environmental Quality
3300 North A Street
Building 4, Suit 107
Midland, TX 79707

Subject: Submittal of source test reports for Ethylene Oxide Scrubbers and Catalytic Oxidizers

Reference: FOP Permit No. O-02452
NSR Permit No. 20178
Account No. TG-0079-G

Dear Mr. Madison:

During September 15 through 19, 2003, Professional Environmental Services, Inc. (PES) conducted emissions testing for the scrubbers and catalytic oxidizers at the plant located in San Angelo, Texas. This testing was performed to satisfy the requirements of Title 30 Texas Administrative Code chapter 122 and the FOP. The attached reports indicate that all units tested were over 99% efficient, as required by the Clean Air Act.

Ethicon appreciates your active participation in pre-planning the tests and guiding us in making the testing process successful. Attached are two copies of the final report from PES Inc. It is my understanding that after completing your review, you will forward one copy of the report with your remarks to the TCEQ Region 8 office in San Angelo, Texas. I also understand that EPA Region 6 does not need a copy, Ethicon may voluntarily send them a copy.

As you review the reports and have any questions, please contact me at (325) 482-5419, Harry Johantgen at (325) 482-5710 or Dennis Becvar of PES at (626) 962-3278.

It was a pleasure working with you.

Sincerely,

Tahseen Khan

Attachments
CC: Marcia Brown
Mason West
Harry Johantgen

My doc/noncfc- Stack test result to Sam Madison TCEQ.doc TK/Nov.17'03
UPS Tracking: 1Z 771 532 0143014405

RECEIVED
NOV 1 8 2003
FIELD OPERATIONS
REGION 7

SOURCE TEST REPORT:

EMISSIONS TESTING OF THE EAST AND WEST ETO ABATORS AND EAST AND WEST FLUID BED SCRUBBERS

Conducted On:

September 15-18, 2003

Conducted At:

ETHICON, Inc.
3348 Pulliam Street
San Angelo, Texas 76905

PES Project No. 1070.001

Conducted By:

PROFESSIONAL ENVIRONMENTAL SERVICES, INC.
5027 Irwindale Avenue, Suite 100
Irwindale, California 91706
Telephone: 626-962-3278

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APPENDIX C PROCESS DATA FOR EAST AND WEST SCRUBBERS
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APPENDIX E TEST EQUIPMENT CALIBRATION DATA

SOURCE TEST REPORT:

EMISSIONS TESTING OF THE EAST AND WEST ETO ABATORS AND EAST AND WEST FLUID BED SCRUBBERS

EXECUTIVE SUMMARY

State and Federal Operating permits limit ethylene oxide (EtO) emissions from the sterilization operations at Ethicon's San Angelo, Texas, facility. The emissions from the EtO sterilization processes are controlled by catalytic oxidizers (abators) and fluid bed scrubbers. During the week of September 15, 2003, Professional Environmental Services, Inc., Irwindale, California, conducted source emissions testing of the two abators and two scrubbers that are used to reduce EtO emissions to the atmosphere. For the determination of destruction efficiency by each abator, pure EtO was injected from a compressed gas cylinder connected to the inlet duct. Samples were collected simultaneously at the inlet and outlet of each abator and analyzed by a gas chromatograph operated on site. The inlet concentrations averaged 137 and 160 parts per million by volume, dry basis (ppmvd), for the west and east abators respectively; and, the outlet concentrations were less than 0.1 ppmvd, yielding an overall efficiency of >99% for both abators. Due to safety considerations, the inlet concentration of EtO to the scrubbers could not be sampled directly; therefore, the destruction efficiency of the scrubbers was determined by monitoring process conditions to determine the inlet concentrations, and by direct sampling of the exhaust of the scrubber during the period when EtO was evacuated from a loaded sterilizer to its scrubber. The inlet EtO to each scrubber averaged 30.4 pounds of EtO, and at the outlet the emissions averaged less than 0.0013 pounds per evacuation cycle, yielding an overall efficiency of >99% for each scrubber. To satisfy the requirements of the operating permit granted by the US EPA, one test run was conducted without product in the chamber. This test also yielded a control efficiency of greater than 99% with an inlet loading of 30.3 pounds of EtO.

On Thursday, September 18, 2003, Mr. Sam Madison of the Texas Commission on Environmental Quality (TCEQ) visited the site and was given a debriefing of the source testing accomplished to date and a tour of the facility.

CONTACT INFORMATION

Facility:	**Ethicon** 3348 Pulliam Street San Angelo, TX 76905
Contacts:	Mr. Tahseen Khan, Environmental Engineer Telephone: 325-482-5419 Fax: 325-482-5233 email: tkhan2@ethus.jnj.com Mr. Harry Johantgen , Process Engineer Telephone: 325-482-5701 Fax: 325-482-5662 email: hjohantg@ethus.jnj.com
Agency:	**Texas Commission on Environmental Quality** Compliance and Enforcement Division Midland Regional Office 3300 North A Street Building 4, Suite 107 Midland, TX 79707
Contact:	Mr. Sam Madison, Emissions Evaluator Telephone: 432-570-1359 Fax: 432-570-4795 email: smadison@tnrcc.state.tx.us
Permit Information:	TCEQ Permit No. O-02452 USEPA Tile V Permit (40 CFR, Part 63, Subpart O) Account Number: TG-0079-G
Source Test Contractor:	**Professional Environmental Services, Inc.** 5027 Irwindale Avenue, Suite 100 Irwindale, CA 91706
Contact:	Mr. Dennis Becvar, Senior Project Manager Telephone: 626-962-3278 Fax: 626-962-5905 email: dbecvar@mpowercom.net

SOURCE TEST REPORT:

EMISSIONS TESTING OF THE EAST AND WEST ETO ABATORS AND EAST AND WEST FLUID BED SCRUBBERS

SECTION 1
INTRODUCTION

1.1 SUMMARY OF SOURCE TESTING PROGRAM

During the week of September 15, 2003, Professional Environmental Services, Inc. (PES), Irwindale, California conducted source emissions testing on the non-CFC ethylene oxide (EtO) sterilization operations at Ethicon's San Angelo, Texas, facility. This facility manufactures various medical sutures and other products used by the medical profession. Texas Commission on Environmental Quality (TCEQ) has issued a Federal Operating Permit (No. O-02452), under the Federal Clean Air Act as required by Title III of the Clean Air Act Amendments of 1990, 40 CFR, Part 63, Subpart O. A Texas New Source Review (NSR) Permit No. 20178, is also in force under the Texas Clean Air Act section 382.0511(b).

Emissions to the atmosphere from the EtO sterilization operations are controlled by two fluid scrubbers and two Donaldson EtO catalytic oxidation devices (EtO abators). The non-CFC operations incorporate six automated sterilizers which use 100 percent EtO as the sterilant. The purpose of this testing program was to determine the control efficiency of the east and west Donaldson EtO abators and the east and west fluid bed scrubbers.

Samples were collected into Tedlar bags simultaneously at the inlet and outlet of each EtO abator. Since the concentrations of EtO at the inlet vary depending on the evacuation cycles of the various sterilizers, the inlet concentrations were increased by injecting EtO directly into the inlet duct from a compressed gas cylinder containing 100% EtO. The concentration of EtO at the inlet was varied by partially opening the valve on the cylinder of pure gas and adjusting a second valve until an in-line rotometer indicated a constant flow. The EtO destruction efficiency of each abator was determined by immediately analyzing samples collected into evacuated Tedlar bags with a gas chromatograph (GC) operated on site.

The second component to this testing program was to determine the efficiency of the fluid bed scrubbers. Samples of EtO at the scrubber exhaust were collected into Tedlar bags during the entire evacuation cycle of a sterilization chamber. The amount of EtO at the inlet of the scrubbers was determined by using data from various process instrumentation and mass balance calculations. Three test runs were conducted on the scrubbers during sterilization of product in the chamber; and as required by US EPA, one test run was conducted while an empty chamber was charged with EtO evacuated to the scrubber.

The sampling and analytical procedures used for this testing program are based on standard procedures established by EPA and TCEQ.

1.2 SCHEDULE FOR TESTING PROGRAM

The following table summarizes the various tasks and schedule for this testing program:

Date	Time	Description
Sept 15, 2003	0730-0900	facility security/safety training
	0930-noon	test equipment set-up and connection of the cylinder of EtO to the west abator inlet duct
	1330-1500	pre-test calibration of GC
	1530-1730	sample collection/analysis west abator (inlet/outlet)
	1730-1815	post-test calibration of GC
Sept 16, 2003	0830-0930	pre-test calibration of GC
	0930-1000	sampling equipment set-up and connection of EtO cylinder to the east abator inlet duct
	1000-1130	sample collection/analysis east abator (inlet/outlet)
	1130-1215	post-test calibration of GC
	1215-1330	sampling of Sterilizer O – East Scrubber
	1330-1415	sample analysis
	1415-1530	post-test calibration
	1950-2047	sampling of Sterilizer T – West Scrubber
	2047-2145	sample analysis
	2145-2200	post-test calibration
Sept 17, 2003	0043-0031	sampling of Sterilizer U – West Scrubber (aborted test-wrong scrubber column)
	0045-0030	sample analysis
		no post test calibration
	0800-0830	pre-test calibration
	0905-1035	sampling of Sterilizer T – West Scrubber (empty chamber)
	1035-1115	post-test calibration
	1337-1417	sampling of Sterilizer U – West Scrubber
	1430-1500	sample analysis
	1500-1645	post-test calibration
Sept 18, 2003	1100-1400	meeting with Sam Madison-TCEQ
	1400-1600	equipment tear-down and packing

SECTION 2
SOURCE DESCRIPTION

2.1 PROCESS DESCRIPTION

The following is a brief overview of the non-CFC operations at Ethicon. A detailed description will not be provided herein due to the possibility of releasing proprietary information.

In the non-CFC facility Ethicon operates six 100-percent EtO sterilizers and two fluid bed scrubbers. The identification of the sterilizers and respective scrubbers are as follows:

Vessel	Sterilization Process	Scrubber
Sterilizer O	Primary	east
Sterilizer M	Secondary	east
Sterilizer N	Secondary	east
Sterilizer T	Primary	west
Sterilizer U	Primary	west
Sterilizer V	Secondary	west

A normal sterilization cycle begins when the medical products are loaded into the sterilization chamber. The chamber door is closed and hermetically sealed. Air is pumped from the chamber by a vacuum pump; the vacuum pulled depends on the type of product and packaging. Steam is injected to heat and humidify the product while vacuum is maintained. Next, nitrogen is injected to dilute any remaining oxygen in the chamber. When the nitrogen charge is completed the oxygen concentration is measured to ensure that it is within a safe limit before the EtO is introduced. Once it is determined that the oxygen limits have been satisfied the chamber is charged with pure EtO from the EtO Dispensing Facility (EDF) through a make-up tank. The chamber is pressurized with a combination of EtO and Nitrogen to a pressure of 90 kPa or greater. At the completion of the exposure, a vacuum pump exhausts the EtO to one of two scrubber systems. Once the sterilization cycle is completed, the product is transferred from the chamber into either a vacuum dryer or aeration vessel, depending on the type of packaging. Product from the primary sterilization process is moved to a vacuum dryer where a vacuum is pulled on the product for approximately 12 hours to draw out any residual EtO from the packaging. Product from the secondary sterilization process is moved to an aeration room for approximately 8 hours to allow sufficient time for EtO to off-gas. The vacuum dryer and aeration chamber are both maintained under negative pressure and exhausted to the Donaldson abators.

2.2 CONTROL EQUIPMENT DESCRIPTION

2.2.1 Abators

Emissions from the vacuum dryers and aeration rooms are exhausted through two Donaldson abators. The EtO gas stream is heated by a heat exchanger and introduced to the

FIGURE 2.1
EQUIPMENT DIAGRAM OF AN ABATOR

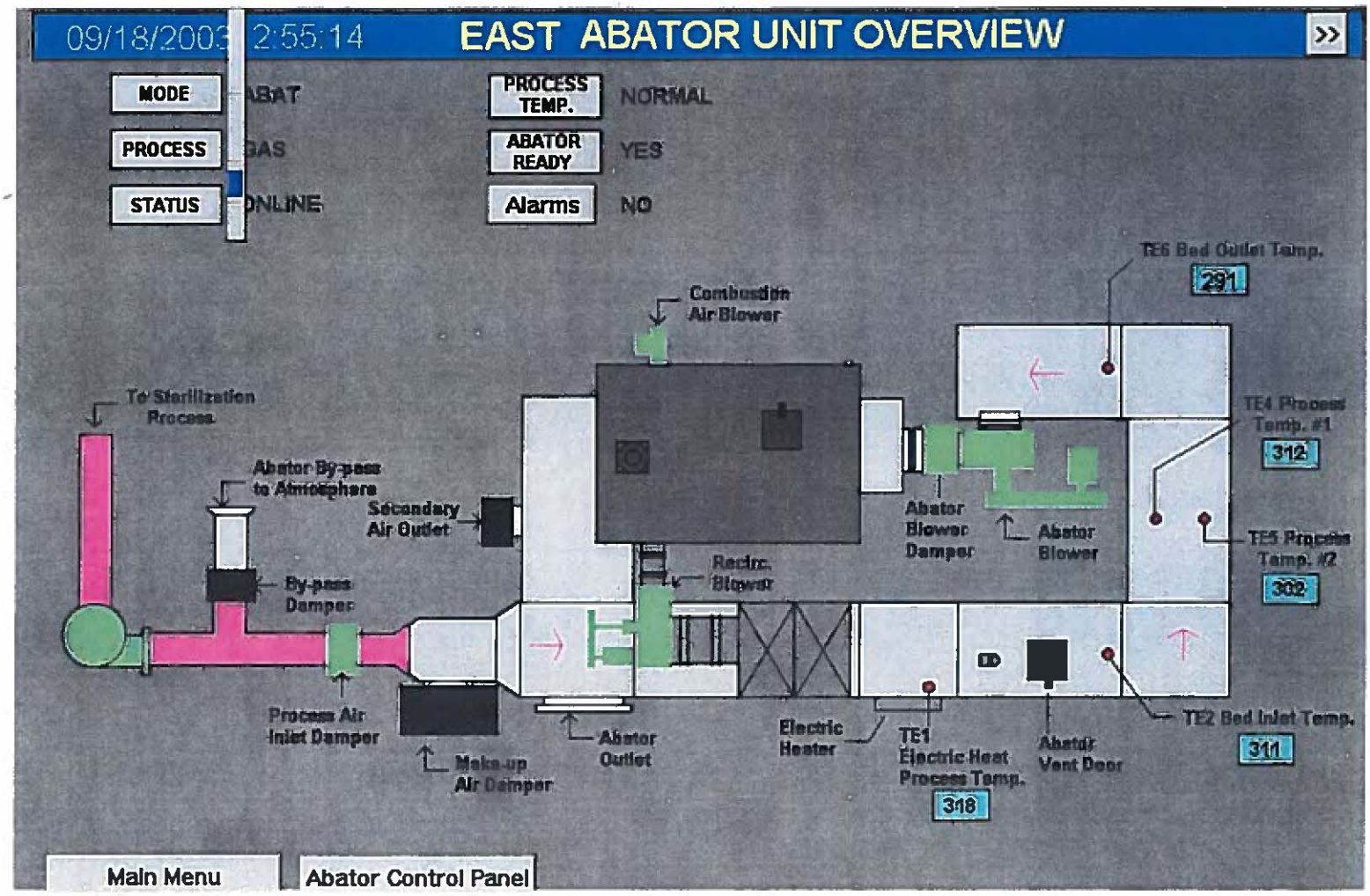
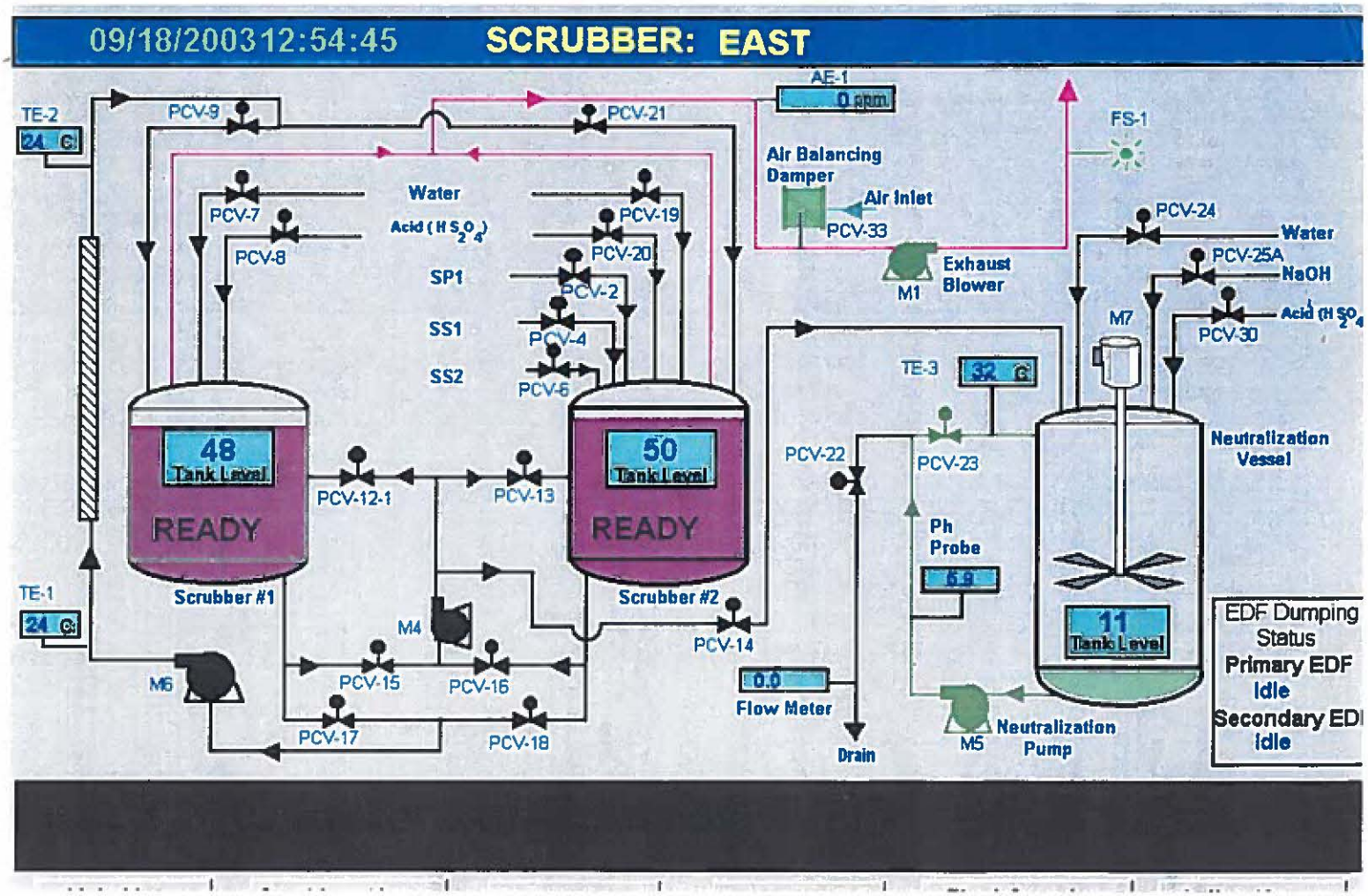


FIGURE 2.2
EQUIPMENT DIAGRAM OF A SCRUBBER



catalyst bed within the Abator. Additional heating of the gas stream is by natural gas fired burners or, as alternate, electric heat. The heated gas stream is then passed through a catalyst bed. Oxygen and EtO migrate through the catalyst bed by diffusion and are absorbed into the pores of the catalyst. Oxidation of the EtO takes place at these sites converting the EtO to carbon dioxide and water vapor. The reaction products are desorbed from the catalyst pores and passed through a heat exchanger for heat recovery, and then to the atmosphere.

The oxidation temperature at the outlet of the catalyst beds is continuously monitored and recorded to ensure that the manufacturer's recommended minimal operating temperature range of 270°F - 280°F is maintained and complies with the State's Permit requirement. Continuous monitoring as defined by the permit, requires that a reading is to be taken every fifteen minutes. The abators are required to reduce EtO emissions to the atmosphere by at least 99%. These requirements are in both the Federal Operating Permit and the New Source Review permit.

While 40 CFR, Part 63, Subpart O, does not require an initial performance test for the abators, Section 63.362(b)(4) requires facilities to comply with at least one work practice standard. Ethicon standard practice is to conduct an annual performance test on both abators. If the efficiency is less than 99%, the catalyst is removed and sent to the manufacturer for regeneration as soon as practicable, but no later than 180 days after the test. Included in this testing program was the determination to verify that each abator has an efficiency of at least 99%.

2.2.2 Scrubbers

The plant operates two identical acid-water scrubber systems to control EtO emissions from the sterilization chambers. The scrubbers are designated as East and West and were manufactured by Damas, and are Model 1000-2-6-HE-SR units. Each unit is comprised of two tanks. Scrubber tanks designated as A and B (or SC1 and SC2) are for the East Scrubber; and, tanks C and D (or SC1 and SC2) are for the West Scrubber. Both sets of scrubbers are configured identical to one another, similar dimensions, and operating parameters. Each of the four tanks contains three bladders. Each scrubber has one tank continuously on-line and one tank on standby status. For both scrubbers, only one column is on-line at a time with the alternate column serving as backup when it is determined that maintenance is required on the column that is in service.

Each sterilizer chamber is charged through a make-up tank. As EtO is absorbed into the product, the make-up tank compensates for pressure drop occurring due to absorption by the product. EtO is delivered to the chamber from the make-up tank until the pressure inside the chamber stabilizes. At the conclusion of the sterilization cycle, the EtO in the chamber is delivered through the scrubber during a tank evacuation cycle.

Process flow diagrams of the various sterilization operations, scrubbers, and the abator systems are presented are Figures 2.3 through 2.4.

FIGURE 2.3
PROCESS FLOW DIAGRAM FOR
PRIMARY STERILIZATION ENVIRONMENTAL OPERATIONS

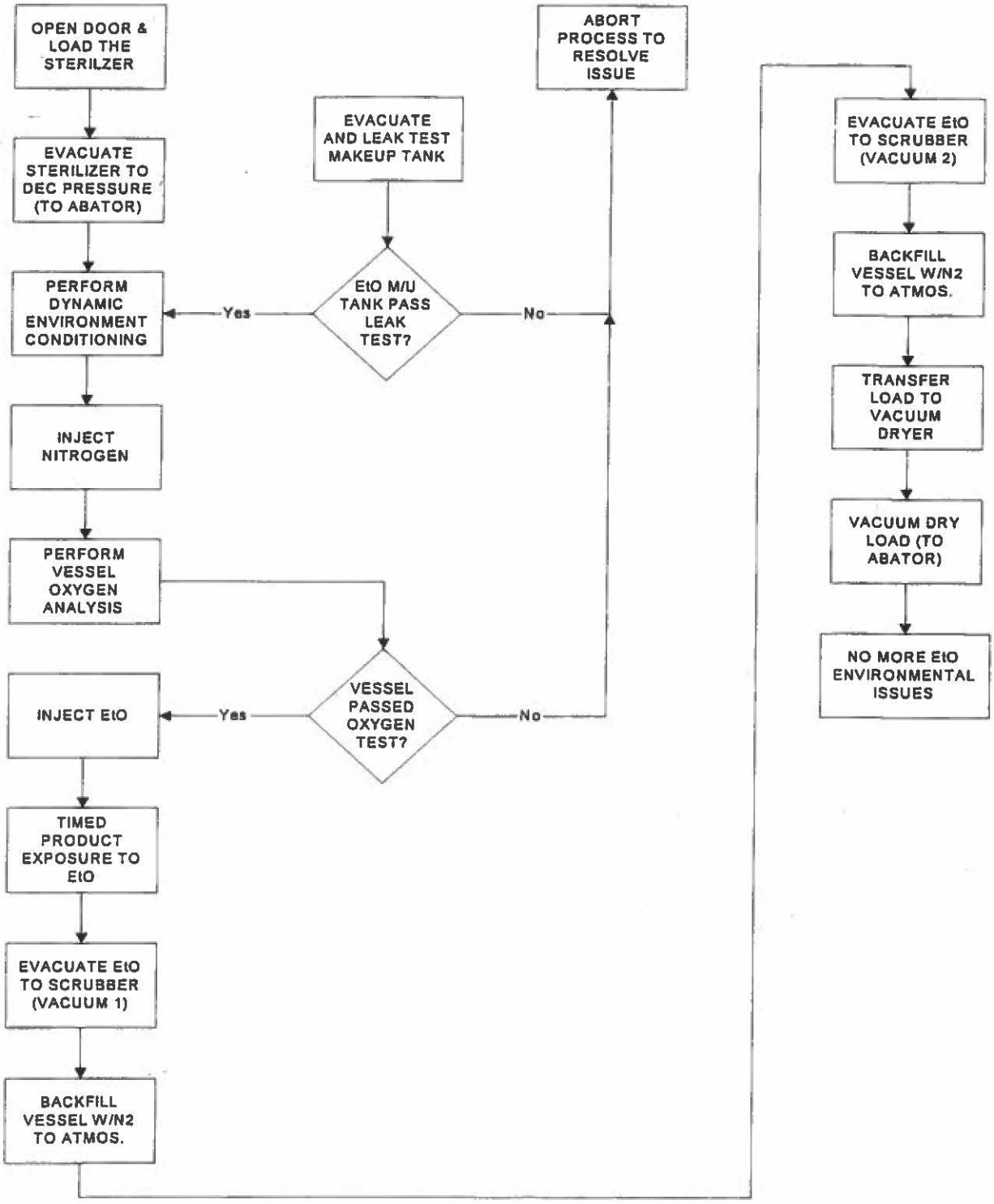
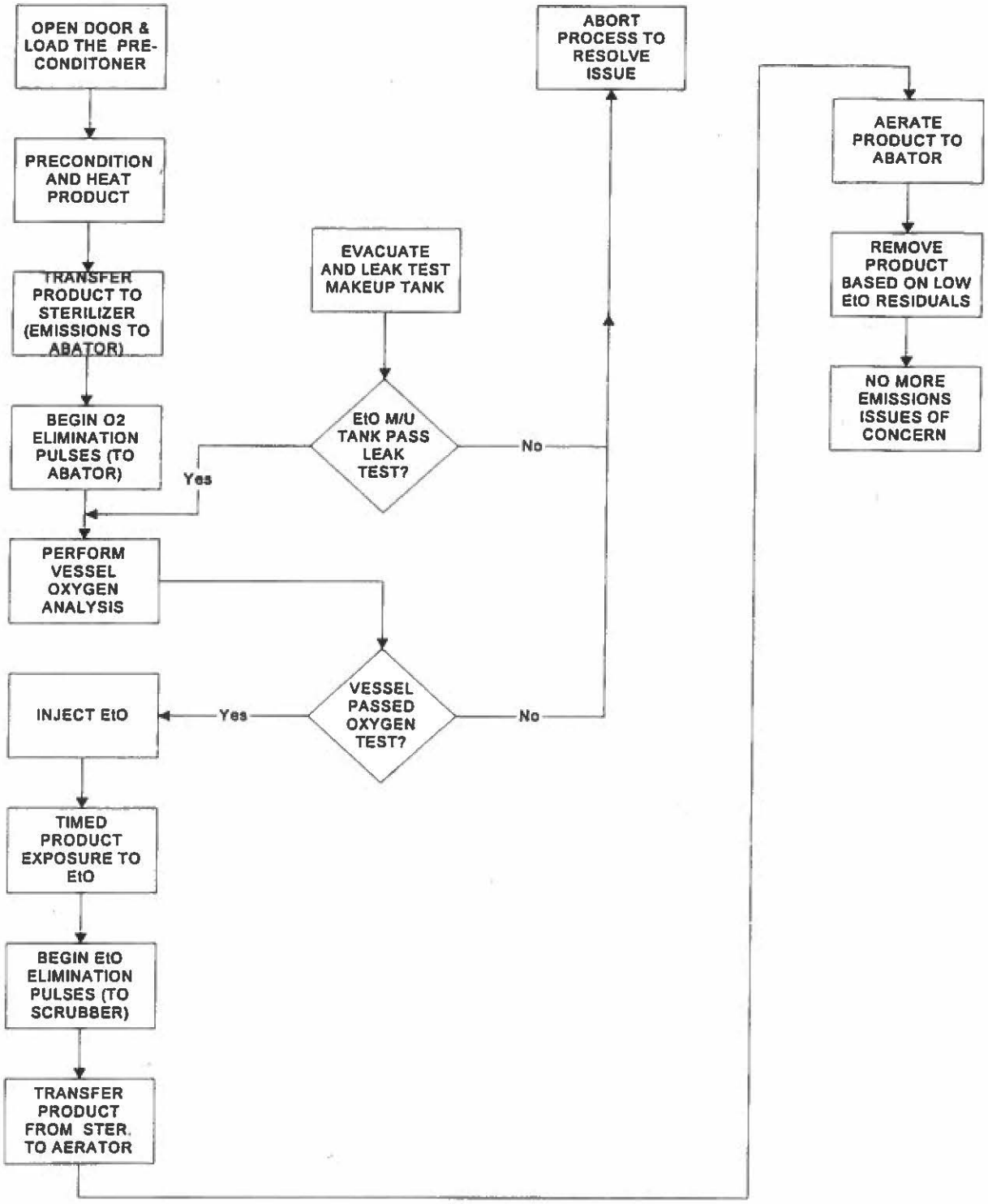


FIGURE 2.4
PROCESS FLOW DIAGRAM FOR
SECONDARY STERILIZATION ENVIRONMENTAL OPERATIONS



SECTION 3
TESTING METHODOLOGY

3.1 SAMPLE COLLECTION

3.1.1 Abators

Samples were collected into evacuated 10 liter Tedlar bags through sampling connections located in the inlet and exhaust ducts on each of the two abators. The inlet and outlet samples were collected through a Teflon tube connected directly into Tedlar bags. The bags were installed in air tight chambers and filled by withdrawing air from inside the chamber allowing the bags to be filled as result of the differential pressure created between the sample probe and the exterior surface of the bag. The outlet samples were collected simultaneously with the inlet samples over a period of approximately five to ten minutes. The inlet samples were collected by inserting the Teflon tubing one third of the way into the inlet duct; the samples at the abator exhaust were collected from a permanently installed sampling array positioned across the duct cross-sectional area. A diagram showing the setup of the sampling equipment is shown in Figure 3.1. The sample bags were analyzed immediately after sample collection on a Perkin Elmer gas chromatograph operated on site.

3.1.2 Scrubbers

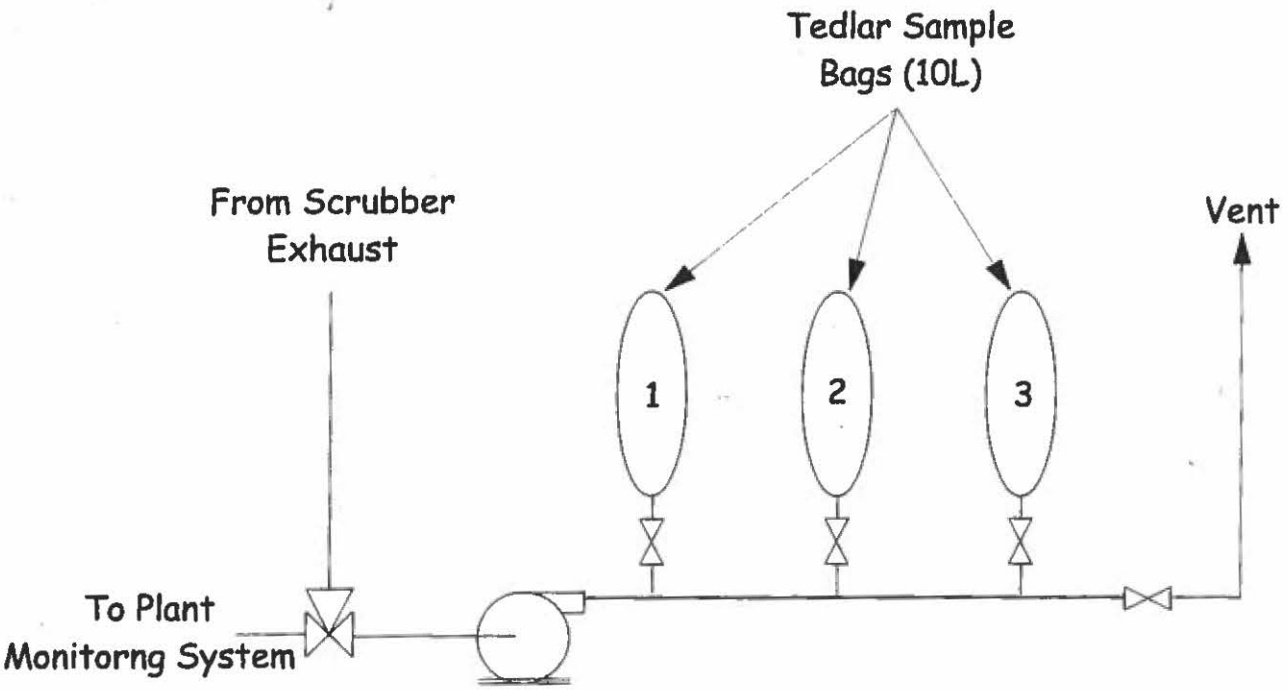
Samples from the scrubbers were collected from stainless steel tubing permanently installed in the scrubber exhaust duct. The stainless steel tubing is normally used to deliver sample to the Ethicon on-line EtO monitoring system. A three-way valve installed in the stainless steel tubing was used to divert the exhaust gas sample from the monitoring system to the PES sampling system. The sampling system included a Teflon lined diaphragm pump with a manifold/valve system connected to the outlet of the pump. Three Tedlar bags were connected to the manifold system and were filled when a sterilizer charged with EtO was evacuated to the scrubber. The first bag was filled during the period when the sterilizer pressure went from 90 kPa to approximately 45 kPa; the second bag was filled during the period when the sterilizer pressure was reduced from 45 kPa to 10 kPa; and the third bag was filled while the sterilizer pressure was reduced from 10 kPa to approximately zero. The bags were filled over a period of approximately 70-80 minutes. Information regarding the sterilizer pressure was communicated to the sampling team by the control room via hand held radios. A diagram showing the setup of the sampling equipment is shown in Figure 3.1. The sample bags were analyzed immediately after sample collection on the gas chromatograph operated on site.

3.2 DESCRIPTION OF GAS CHROMATOGRAPH MONITORING SYSTEM

The EtO analysis was conducted following the procedures of EPA Method 18 utilizing a gas chromatograph (GC) operated on site. Each Tedlar bag sample was analyzed within fifteen minutes of sample collection. The GC is a dual channel, Auto-system Model, manufactured by Perkin Elmer, equipped with Arnel 6-port sample/injection valves, flame ionization detectors, a microprocessor controller, and a dual channel integrator.

FIGURE 3.1

DIAGRAM OF SCRUBBER EXHAUST SAMPLING SET-UP



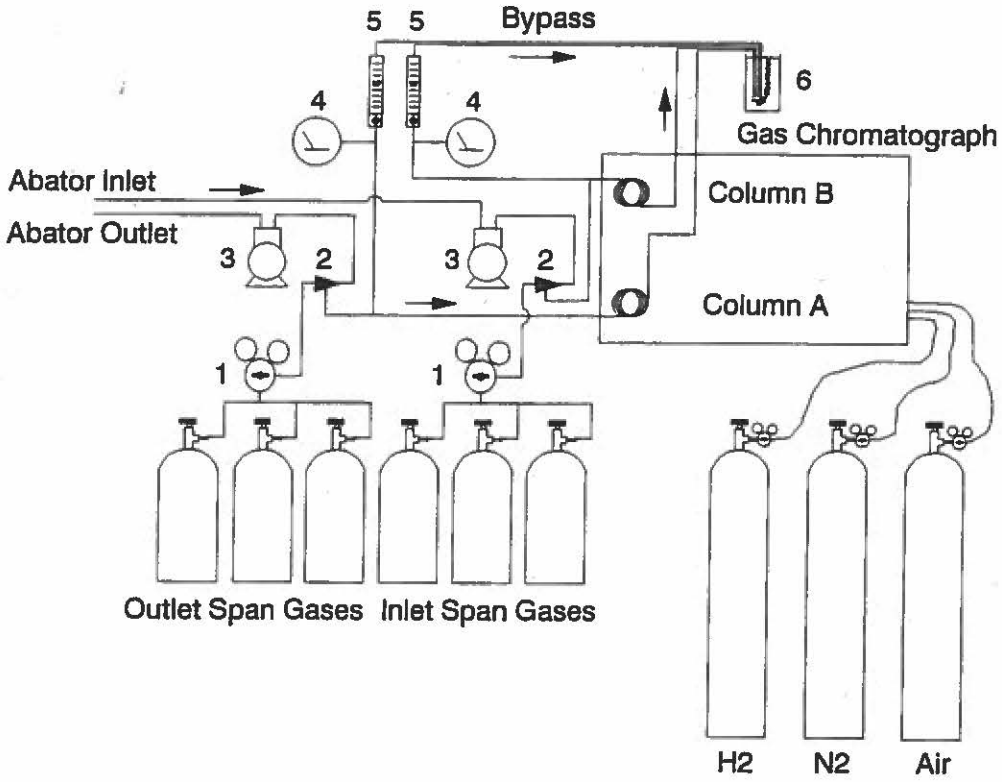
Note:

Bag 1 Filled between 90-45 kpa
Bag 2 Filled between 45-10 kpa
Bag 3 Filled between 10-0 kpa

Chromatogram data were displayed on a 16-inch CRT and archived on a hard disk drive. The chromatographic columns were manufactured by Supelco, six feet long, 0.125" OD stainless steel, and packed with 10 percent SP-1000 on 60/80 mesh Carbopack B. The carrier gas was ultra pure nitrogen. The columns were operated at 45°C, the injectors at 200°C, the detectors at 250°C, and the sample valve at 150°C. For each channel, the sample was delivered to the GC through a heated loop of 1/8-inch Teflon tubing by way of a Thomas, Teflon-lined sampling pump, and sample distribution manifold that incorporated a 0-5 "H_2O Magnehelic gage, and a bypass rotometer, to deliver sample and calibration gases to the sample loop under isopiestic conditions. The pump was located upstream of the sample loop and the Magnehelic monitored the backpressure of the sample loop created either by the pump in the sample mode or by the calibration gas from the pressurized cylinder in the span mode. The backpressure was regulated by varying the flow through the bypass flow meter and a three-way valve selected either the sample pump or span gas cylinder. The EtO bypassed was vented through an impinger/scrubber containing 1N sulfuric acid to act as a safety scrubber. Before testing, the GC was calibrated with low, mid, and high span gases. The inlet channel was calibrated with 98, 2129, and 5000 ppmv EtO span gases. The outlet channel was spanned with 1.09, 5.1, and 10.1 ppmv EtO span gases. The GC setup for the on site sample analyses is presented in Figure 3.2

FIGURE 3.2

DIAGRAM OF GAS CHROMATOGRAPH



1. Span Gas Regulator
2. 3-Way Sample Valve
3. Sample Pump
4. Back Pressure Magnehelic
5. Bypass Flow Meter
6. Acidic Scrubber

SECTION 4
RESULTS

The results of the source testing for each of the abators are summarized in Table 4.1. Both of the units demonstrated control efficiencies within regulatory requirements for the destruction of ethylene oxide. The overall destruction efficiency was greater than 99.9% for both units with inlet concentrations ranging from a low of 130 ppm v/v to a maximum inlet concentration of 209 ppm v/v.

The results of the scrubber testing are presented in Table 4.2. Both scrubbers demonstrated EtO control efficiencies of greater than 99%. The average weight of ethylene oxide charged to a sterilizer loaded with product was 30.36 lbs; and the charge of ethylene oxide to the empty chamber was 28.38 lbs. The scrubber efficiency was determined by measuring the concentration of EtO at the scrubber exhaust over the entire period of evacuation. The period of evacuation was determined by monitoring the initial pressure in the sterilizer prior to starting the vacuum pump. The pressure in the chamber was 94 kPa when the pump was started, and approximately 1 kPa when the sampling was terminated.

The exhaust gas flow at the scrubber exhaust was based on the amount of nitrogen that was present in the sterilizer chamber before introducing the ethylene oxide. Since, ethylene oxide is the only gas which reacts with the scrubber solution to form ethylene glycol as it passes through the scrubber solution, it is safe to assume that all of the nitrogen passes through the scrubber and into the atmosphere. Since only the ethylene oxide is reacted and absorbed by the scrubber, it assumed that all of the nitrogen passes through the scrubber and into the atmosphere. The weight of nitrogen was determined by the initial pressure in the sterilizer and the final pressure of nitrogen, approximately 42 kPa before ethylene oxide was introduced into the chamber. Since the flow of nitrogen was in the range of 3 cubic feet per minute, it was impossible to measure this flow with a Pitot tube following EPA Reference Methods 1-4. As an alternative, a hot wire anemometer was positioned in the exhaust duct but the velocity of the exhaust was still significantly less that the accuracy of the instrument. The instrument full scale range was 600 fpm, and the exhaust gas velocity of nitrogen during evacuation was less than 7 fpm. The data used in the calculation of the nitrogen flow are summarized in Table 4.3.

The laboratory results of scrubber samples collected before and after the testing program are presented in Table 4.4.

The gas chromatography sample run data are summarized in Tables 4.5 through Table 4.7 for the data collected September 15-17, 2003 respectively.

Additional data such as copies of the various chromatograms and other supporting data are located in the Appendices.

TABLE 4.1

RESULTS OF SOURCE TESTING THE EAST AND WEST ABATORS

Conducted on: September 15-16, 2003

Unit Tested	Inlet Concentration (ppm v/v)	Outlet Concentration (ppm v/v)	Efficiency (%)
West Abator (tested on Sept.15)			
Test No. 1	~~135~~ 152.2	<0.10	>99.9
Test No. 2	~~145~~ 190	<0.10	>99.9
Test No. 3	~~130~~ 162	<0.10	>99.9
Average	~~137~~ 168	<0.10	>99.9
East Abator (tested on Sept. 16)			
Test No. 1	~~132~~ 134	<0.10	>99.9
Test No. 2	~~209~~ 210	<0.10	>99.9
Test No. 3	~~140~~ 141	<0.10	>99.9
Average	~~160~~ 162	<0.10	>99.9

TABLE 4.2

RESULTS OF SOURCE TESTING
FLUID BED SCRUBBERS

Conducted on: September 16-17, 2003

Date	Time	Vessel	Scrubber	Inlet EtO (lbs)	Outlet EtO (lbs)	Efficiency (%)
9/16/03	1215-1320	Sterilizer O (loaded)	East	30.36	0.0005	>99.99
9/16/03	1950-2047	Sterilizer T (loaded)	West	30.58	0.0017	>99.99
9/17/03	0043-0131	Sterilizer U (loaded)	West	aborted test	aborted test	aborted test
9/17/03	0905-1035	Sterilizer T (empty)	West	28.38	0.0021	>99.99
9/17/03	1327-1417	Sterilizer U (loaded)	West	30.14	0.0029	>99.99

$99.816 = \frac{28.38 - .0021}{28.38} \times 100$

$100 - ($

$\frac{.0029}{30.14} = \frac{-9.621765E-5}{1.000000}$

$= 99.99037\ \%$ $(e \times 100)$

$\frac{.0021}{28.38} = \frac{7.399677\cancel{6}6702E-5}{1.0000}$

$= 99.9926\ \%$ $(e \times 100)$

$99.99 = \frac{30.14 - .0029}{30.14} \times 10$

TABLE 4.3
NITROGEN EXHAUST GAS FLOW
FROM STERILIZERS THROUGH FLUID BED SCRUBBERS

Parameter	Test 1	Test 2	Test 3	Test 4
Date	9/16/2003	9/16/2003	9/17/2003	9/17/2003
Clock Time	1215-1320	1950-2047	0905-1035	1327-1417
Sterilizer	O	T	T (empty)	U
Scrubber	East	West	West	West
Minutes for Evacuation	65	57	90	50
Pressure Initial				
kPa [1]	3.73	3.72	3.73	3.73
psia [2]	0.541	0.539	0.541	0.541
Pressure Final				
kPa [3]	42.3	43.0	42.3	42.4
psia [2]	6.134	6.235	6.134	6.148
Chamber Temperature				
deg C	34	35	36	34
deg F [4]	93	95	97	93
Weight of Nitrogen [5]				
Kg	6.85	6.98	6.85	6.87
lbs [6]	15.08	15.36	15.08	15.12
Volume of Nitrogen				
cubic meters	5.89	6.00	5.89	5.91
cubic feet [7]	208.1	211.9	208.1	208.6
Exhaust Rate				
cubic meters per minute	0.091	0.105	0.066	0.118
cubic feet per minute [8]	3.20	3.72	2.31	4.17
EtO in scrubber exhaust				
ppmvd	21	69	88	122
lbs/evacuation [9]	0.0005	0.0017	0.0021	0.0029

[1] Initial Pressure from process data

[2] psia = kPa x 0.145 psia/kPa

[3] Final Pressure form process data

[4] deg F = (9/5 deg C) + 32

[5] Nitrogen (Kg) = (kPa final-kPa initial) x 144 x cubic meters of chamber/(1545/mw N_2) x (Temp Chamber + 273)

Nitrogen (lbs) = (psia final - psia initial) 144 x cubic ft of chamber / (1545/mw N_2) x (Temp Chamber + 460)

[6] lbs = kg x 2.2 lbs/kg

[7] cubic feet of nitrogen = lbs of N_2 x 13.80 cf/lb

[8] cubic feet = cubic meters x 35.3 cubic feet/cubic meter

[9] lbs/evacuation = ppmvd x cubic feet of N_2 x MW of N_2 x 2.60 x 10^{-9} lbs/lbmole-ppmvd

molecular weight of nitrogen = 28.01 mole wt

molecular weight of ethylene oxide = 44.05 mole wt

volume of empty chamber = 475 cubic feet

TABLE 4-4
RESULTS OF SCRUBBER SOLUTION ANALYSES [1]

Date	Scrubber	Parameter	Results
9/17/03	B	Ph	0.3
		Ethylene Glycol	281,000 mg/L
	D	pH	0.2
		Ethylene Glycol	305,000 mg/L
9/22/03	B	pH	0.2
		Ethylene Glycol	330,000 mg/L
	D	pH	0.2
		Ethylene Glycol	326,000 mg/L

[1] Sampled and analyzed by Enviro-Tech Laboratories, Inc., San Angelo, Texas

TABLE 4.5
GAS CHROMATOGRAPHY RUN SUMMARY
ETHICON, INC.
SEPTEMBER 15, 2003

Chromatogram	Channel A (outlet)	Channel B (inlet)
ETO00001	Calibration set-up	Calibration set-up
ETO00002	Calibration set-up	Calibration set-up
ETO00003	Calibration set-up	Calibration set-up
ETO00004	Calibration set-up	Calibration set-up
ETO00005	Calibration set-up	Calibration set-up
ETO00006	Calibration set-up	Calibration set-up
ETO00007	1.01 ppm Low Cal	98.1 ppm Low Cal
ETO00008	1.02 ppm Low Cal	98.5 ppm Low Cal
ETO00009	1.01 ppm Low Cal	98.2 ppm Low Cal
ETO00010	1.01 ppm Low Cal	98.8 ppm Low Cal
ETO00011	1.01 ppm Low Cal	98.4 ppm Low Cal
ETO00012	5.21 ppm Mid Cal	2,129 ppm Mid Cal
ETO00013	5.15 ppm Mid Cal	2,130 ppm Mid Cal
ETO00014	5.13 ppm Mid Cal	2,131 ppm Mid Cal
ETO00015	10.12 ppm High Cal	5,020 ppm High Cal
ETO00016	10.12 ppm High Cal	5,023 ppm High Cal
ETO00017	10.15 ppm High Cal	5,023 ppm High Cal
ETO00018	<100 ppb West Abator Run 0	14 ppm West Abator-Preliminary
ETO00019	<100 ppb West Abator Run 1	152 ppm West Abator
ETO00022	<100 ppb West Abator Run 1	151 ppm West Abator
ETO00021	<100 ppb West Abator Run 1	153 ppm West Abator
ETO00022	<100 ppb West Abator Run 2	191 ppm West Abator
ETO00023	<100 ppb West Abator Run 2	188 ppm West Abator
ETO00024	<100 ppb West Abator Run 2	190 ppm West Abator
ETO00025	<100 ppb West Abator Run 2	190 ppm West Abator
ETO00026	<100 ppb West Abator Run 3	160 ppm West Abator
ETO00027	<100 ppb West Abator Run 3	162 ppm West Abator
ETO00028	<100 ppb West Abator Run 3	165 ppm West Abator
ETO00029	1.01 ppm Low Cal	100.3 ppm Low Cal
ETO00030	1.02 ppm Low Cal	102.0 ppm Low Cal
ETO00031	1.02 ppm Low Cal	101.0 ppm Low Cal
ETO00032	5.23 ppm Mid Cal	2,129 ppm Mid Cal
ETO00033	5.16 ppm Mid Cal	2,129 ppm Mid Cal
ETO00034	5.34 ppm Mid Cal	2,128 ppm Mid Cal
ETO00035	10.12 ppm High Cal	5,001 High Cal
ETO00036	10.24 ppm High Cal	5,002 High Cal
ETO00037	10.12 ppm High Cal	5,001 High Cal

TABLE 4.6
GAS CHROMATOGRAPHY RUN SUMMARY
ETHICON, INC.
SEPTEMBER 16, 2003

Chromatogram	Channel A (outlet)	Channel B (inlet)
ETO00038	1.00 ppm Low Cal	101.9 ppm Low Cal
ETO00039	1.01 ppm Low Cal	102.0 ppm Low Cal
ETO00040	1.01 ppm Low Cal	101.0 ppm Low Cal
ETO00041	5.13 ppm Mid Cal	2,129 ppm Mid Cal
ETO00042	5.12 ppm Mid Cal	2,127 ppm Mid Cal
ETO00043	5.12 ppm Mid Cal	2,129 ppm Mid Cal
ETO00044	10.14 ppm High Cal	5,006 ppm High Cal
ETO00045	10.14 ppm High Cal	5,007 ppm High Cal
ETO00046	10.10 ppm High Cal	5,008 ppm High Cal
ETO00047	<100 ppb East Abator Run 1	140 ppm East Abator
ETO00048	<100 ppb East Abator Run 1	132 ppm East Abator
ETO00049	<100 ppb East Abator Run 1	130 ppm East Abator
ETO00050	<100 ppb East Abator Run 2	211 ppm East Abator
ETO00051	<100 ppb East Abator Run 2	210 ppm East Abator
ETO00052	<100 ppb Abator Run 2	208 ppm East Abator
ETO00053	<100 ppb East Abator Run 3	142 ppm East Abator
ETO00054	<100 ppb East Abator Run 3	140 ppm East Abator
ETO00055	<100 ppb East Abator Run 3	140 ppm East Abator
ETO00056		35 ppm Bag 1 East Scrubber - O
ETO00057		34 ppm Bag 1 East Scrubber - O
ETO00058		19 ppm Bag 2 East Scrubber - O
ETO00059		19 ppm Bag 2 East Scrubber - O
ETO00060		9.2 ppm Bag 3 East Scrubber - O
ETO00061		9.1 ppm Bag 3 East Scrubber - O
ETO00062		98 ppm Bag 1 West Scrubber -T
ETO00063		99 ppm Bag 1 West Scrubber –T
ETO00064		67 ppm Bag 2 West Scrubber – T
ETO00065		65 ppm Bag 2 West Scrubber – T
ETO00066		41 ppm Bag 3 West Scrubber – T
ETO00067		42 ppm Bag 3 West Scrubber – T
ETO00068		aborted sample wrong scrubber
ETO00069		aborted sample wrong scrubber
ETO00070		aborted sample wrong scrubber
ETO00071	1.01 ppm Low Cal	101.2 ppm Low Cal
ETO00072	1.00 ppm Low Cal	101.1 ppm Low Cal
ETO00073	1.00 ppm Low Cal	101.3 ppm Low Cal
ETO00074	5.24 ppm Mid Cal	2,119 ppm Mid Cal
ETO00075	5.12 ppm Mid Cal	2,119 ppm Mid Cal
ETO00076	5.14 ppm Mid Cal	2,118 ppm Mid Cal
ETO00077	10.12 ppm High Cal	5,002 ppm High Cal
ETO00078	10.31 ppm High Cal	5,000 ppm High Cal
ETO00079	10.23 ppm High Cal	5,001 ppm High Cal

TABLE 4.7
GAS CHROMATOGRAPHY RUN SUMMARY
ETHICON, INC.
SEPTEMBER 17, 2003

Chromatogram	Channel A (outlet)	Channel B (inlet)
ETO00080		101.9 ppm Low Cal
ETO00081		101.5 ppm Low Cal
ETO00082		2,128 ppm Mid Cal
ETO00083		2,129 ppm Mid Cal
ETO00084		5,005 ppm High Cal
ETO00085		5,003 ppm High Cal
ETO00086		119 ppm Bag 1 West Scrubber-T empty
ETO00087		120 ppm Bag 1 West Scrubber-T empty
ETO00088		86 ppm Bag 2 West Scrubber-T empty
ETO00089		87 ppm Bag 2 West Scrubber-T empty
ETO00090		59 ppm Bag 3 West Scrubber-T empty
ETO00091		54 ppm Bag 3 West Scrubber-T empty
ETO00092		185 ppm Bag 1 West Scrubber-U
ETO00093		185 ppm Bag 1 West Scrubber-U
ETO00094		98 ppm Bag 2 West Scrubber-U
ETO00095		99 ppm Bag 2 West Scrubber-U
ETO00096		81 ppm Bag 3 West Scrubber-U
ETO00097		80 ppm Bag 3 West Scrubber-U
ETO00098		99.3 ppm Low Cal
ETO00099		99.5 ppm Low Cal
ETO00100		2,129 ppm Mid Cal
ETO00101		2,128 ppm Mid Cal
ETO00102		5,001 ppm High Cal
ETO00103		5,005 ppm High Cal

APPENDIX A

FEDERAL AND STATE OPERATING PERMITS

Robert J. Huston, *Chairman*
R. B. "Ralph" Marquez, *Commissioner*
Kathleen Hartnett White, *Commissioner*
Margaret Hoffman, *Executive Director*

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

April 21, 2003

Mr. Rudy Rodriguez
Plant Manager
Ethicon, Inc.
3348 Pulliam Street
San Angelo, Texas 76905

Re: Effective Permit Approval
Initial Issuance
Project Number: 3766
Permit Number: O-02452
Ethicon, Inc.
San Angelo Plant
San Angelo, Tom Green County
Account Number: TG-0079-G

Dear Mr. Rodriguez:

The effective federal operating permit (FOP) for Ethicon, Inc., San Angelo Plant is enclosed. This FOP constitutes authority to operate the emission units identified in the FOP application.

All site operating permits are subject to public petition for 60 days following the expiration of the 45-day U.S. Environmental Protection Agency (EPA) review. The public petition period for the FOP extends from February 8, 2003 until April 8, 2003. If the EPA receives a valid petition and objects to the above-referenced permit, you will be notified promptly by the Texas Commission on Environmental Quality (TCEQ).

It should be noted that from the date of this letter Ethicon, Inc., San Angelo Plant must operate in accordance with the requirements of Title 30 Texas Administrative Code Chapter 122 (30 TAC Chapter 122) and the FOP. Some of the terms and conditions contained in the FOP include recordkeeping conditions, reporting conditions (which includes deviation reporting), and compliance certification conditions. All reports, along with any questions regarding the reports, shall be forwarded to the TCEQ's San Angelo Regional Office, 622 S. Oakes, Suite K, San Angelo, Texas 76903-7013.

Consistent with 30 TAC Chapter 122, Subchapter C, the permit holder shall submit an application to the Air Permits Division (APD) for a revision to an FOP for those activities at a site which change, add, or remove one or more FOP terms or conditions. The permit holder shall also submit an application to the APD for a revision to a permit to address the following: the adoption of an applicable requirement previously designated as federally enforceable only; the promulgation of a new applicable requirement; the adoption of a new state-only requirement; or a change in a state-only designation.

In addition, please note that 30 TAC Chapter 122 was revised on November 20, 2002, with an effective date of December 11, 2002. In part, this revision amended the definition of applicable requirement to include certain sections of 30 TAC Chapter 101. In accordance with the November 20, 2002 adoption, the attached permit has been revised to reflect the new applicable requirements.

Thank you again for your cooperation in this matter. If you have questions concerning the review or this notice, please contact Mr. Tomas Ennis at (512) 239-3553.

Sincerely,

for Margaret Hoffman
Executive Director
Texas Commission on Environmental Quality

MH/TE/jp

cc: Mr. Tahseen Khan, Staff Environmental Engineer, Ethicon, Inc., San Angelo
Mr. John Haagensen, Environmental Engineer, Ethicon, Inc., San Angelo
Mr. Mark Newman, Air Program Manager, Region 8 - San Angelo

Enclosure: Effective Permit

cc: Ms. Mary Stanton, U.S. Environmental Protection Agency, Region 6, Dallas

FEDERAL OPERATING PERMIT

A FEDERAL OPERATING PERMIT IS HEREBY ISSUED TO

Ethicon, Inc.

AUTHORIZING THE OPERATION OF

San Angelo Plant
Surgical & Medical Instruments

LOCATED AT

Tom Green County, Texas

LATITUDE 31° 28' 18" LONGITUDE 100° 23' 10"

Account Number: TG-0079-G

This permit is issued in accordance with and subject to the Texas Clean Air Act (TCAA), Chapter 382 of the Texas Health and Safety Code and Title 30 Texas Administrative Code Chapter 122 (30 TAC Chapter 122), Federal Operating Permits. Under 30 TAC Chapter 122, this permit constitutes the permit holder's authority to operate the site and emission units listed in this permit. Operation of the site and emission units listed in this permit are subject to all additional rules or amended rules and orders of the Commission pursuant to the TCAA.

This permit does not relieve the permit holder from the responsibility of obtaining New Source Review authorization for new, modified, or existing facilities in accordance with 30 TAC Chapter 116, Control of Air Pollution by Permits for New Construction or Modification.

The site and emission units authorized by this permit shall be operated in accordance with 30 TAC Chapter 122, the general terms and conditions, special terms and conditions, and attachments contained herein.

This permit shall expire five years from the date of issuance. The renewal requirements specified in 30 TAC § 122.241 must be satisfied in order to renew the authorization to operate the site and emission units.

Permit No: O-02452 Issuance Date: April 21, 2003

Margaret Hoffman

Executive Director

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GENERAL TERMS AND CONDITIONS

The permit holder shall comply with all terms and conditions contained in 30 TAC § 122.143 (General Terms and Conditions), 30 TAC § 122.144 (Recordkeeping Terms and Conditions), 30 TAC § 122.145 (Reporting Terms and Conditions), and 30 TAC § 122.146 (Compliance Certification Terms and Conditions).

The permit holder shall comply with 30 TAC Chapter 116 by obtaining a New Source Review authorization prior to new construction or modification of emission units located in the area covered by this permit.

All reports required by this permit shall be forwarded to the Texas Commission on Environmental Quality (TCEQ) regional office for your site. For reports submitted, please include a cover letter which identifies the following information: company name, primary TCEQ account number, site name, area name (if applicable), and Air Permits Division permit number.

SPECIAL TERMS AND CONDITIONS:

Emission Limitations and Standards, Monitoring and Testing, and Recordkeeping and Reporting:

1. Permit holder shall comply with the following requirements:

   A. Emission units (including groups and processes) in the Applicable Requirements Summary attachment shall meet the limitations, standards, equipment specifications, monitoring, recordkeeping, reporting, testing, and other requirements listed in the Applicable Requirements Summary attachment to assure compliance with the permit.

   B. The textual description in the column titled "Textual Description" in the Applicable Requirements Summary attachment is not enforceable and is not deemed as a substitute for the actual regulatory language. The Textual Description is provided for information purposes only.

   C. A citation listed on the Applicable Requirements Summary attachment, which has a notation [G] listed before it, shall include the referenced section and subsection for all commission rules, or paragraphs for all federal and state regulations and all subordinate paragraphs, subparagraphs and clauses, subclauses, and items contained within the referenced citation as applicable requirements.

   D. The permit holder shall comply with the applicable requirements of 40 CFR Part 63, Subpart O and 30 TAC Chapter 113, Subchapter C, Division 6. The specific 40 CFR Part 63, Subpart O standards, as well as, monitoring, testing, recordkeeping, and reporting requirements that apply to the emission unit under 30 TAC Chapter 113, Subchapter C, Division 6 Section 113.200 are depicted in the attached applicable requirements summary table for 40 CFR Part 63, Subpart O.

2. The permit holder shall comply with the following sections of 30 TAC Chapter 101, (General Rules):

   A. Definitions of §101.1, insofar as the terms defined in this section are used to define the terms used in other applicable requirements;

   B. Circumvention under §101.3;

   C. Sampling under §101.8, if such action has been requested by the TCEQ;

   D. Sampling Ports under §101.9, if such action has been requested by the TCEQ;

   E. Emissions Inventory Requirements of §101.10;

   F. Emission Event Reporting and Recordkeeping Requirements of §101.201;

   G. Scheduled Maintenance, Startup, and Shutdown Reporting and Recordkeeping Requirements of §101.211;

   H. Operational Requirements of §101.221;

   I. Demonstrations under §101.222; and

   J. Actions to Reduce Excessive Emissions under §101.223.

3. Permit holder shall comply with the following requirements of 30 TAC Chapter 111:

   A. For visible emissions from stationary vents constructed after January 31, 1972, the permit holder shall comply with the following requirements:

      (i) 30 TAC § 111.111(a)(1)(B) (relating to Requirements for Specified Sources);

      (ii) 30 TAC § 111.111(a)(1)(F)(ii), (iii), or (iv); and

      (iii) The permit holder shall also comply with the following periodic monitoring requirements for the purpose of annual compliance certification under 30 TAC § 122.146:

      An annual observation of stationary vents which are required to comply with 30 TAC § 111.111(a)(1)(B) shall be conducted at least once during each 12-month certification period. Visible emission observations are not required for stationary vessels (which includes both storage and process vessels), tanks, reservoirs, distillation columns, decanters, or other containers holding a VOC, and water separators which separate material containing a VOC since these types of emission units are unable to exceed the opacity limitations in 30 TAC § 111.111(a)(1)(B) due to the characteristics of a VOC.

The observations must occur at least once during each 12-month certification period. Visible emissions observations shall be made and recorded. However, if liquid fuel is fired for a period greater than or equal to 24 consecutive hours, the permit holder shall conduct an observation of the stationary vent for each such period to determine if visible emissions are observed. Documentation of the observations shall be maintained.

Visible emissions shall be determined with each stationary vent in clear view of the observer. The observer shall be at least 15 feet, but not more than 0.25 miles, away from each stationary vent during the observation. For outdoor locations, the observer shall select a position where the sun is not directly in the observer's eyes. When condensed water vapor is present within the plume, as it emerges from the emissions outlet, observations must be made beyond the point in the plume at which condensed water vapor is no longer visible. When water vapor within the plume condenses and becomes visible at a distance from the emissions outlet, the observation shall be evaluated at the outlet prior to condensation of water vapor.

If visible emissions are not present during the annual observation or firing of liquid fuel, the RO may certify that the source is in compliance with the applicable opacity requirement in 30 TAC § 111.111(a)(1) and (a)(1)(B). Documentation of the observations shall be maintained.

However, if visible emissions are present during the annual observation or firing of liquid fuel, the permit holder shall either list this occurrence as a deviation on the next deviation report as required under 30 TAC § 122.145(2) or conduct the appropriate opacity test specified in 30 TAC § 111.111(a)(1)(F) to determine if the source is in compliance with the opacity requirements. If an opacity test is performed and the source is determined to be in compliance, the RO may certify that the source is in compliance with the applicable opacity requirement. However, if an opacity test is performed and the source is determined to be out of compliance, the permit holder shall list this occurrence as a deviation on the next deviation report as required under 30 TAC § 122.145(2).

Some vents may be subject to multiple visible emission or monitoring requirements. All credible data must be considered when certifying compliance with this requirement even if the observation or monitoring was performed to demonstrate compliance with a different requirement.

4. The permit holder shall comply with the following requirements for units subject to any subpart of 40 CFR Part 60, unless otherwise stated in the applicable subpart:

   A. Title 40 CFR § 60.7 (relating to Notification and Recordkeeping);

   B. Title 40 CFR § 60.8 (relating to Performance Tests);

C. Title 40 CFR § 60.9 (relating to Availability of Information);

D. Title 40 CFR § 60.11 (relating to Compliance with Standards and Maintenance Requirements);

E. Title 40 CFR § 60.12 (relating to Circumvention);

F. Title 40 CFR § 60.13 (relating to Monitoring Requirements);

G. Title 40 CFR § 60.14 (relating to Modification);

H. Title 40 CFR § 60.15 (relating to Reconstruction); and

I. Title 40 CFR § 60.19 (relating to General Notification and Reporting Requirements).

5. The permit holder shall comply with the following requirements for units subject to any 40 CFR Part 63 for Source Categories unless otherwise stated in the applicable subpart:

A. Title 40 CFR § 63.4 (relating to Prohibited Activities and Circumvention);

B. Title 40 CFR § 63.5 (relating to Construction and Reconstruction);

C. Title 40 CFR § 63.6 (relating to Compliance with Standards and Maintenance Requirements);

D. Title 40 CFR § 63.7 (relating to Performance Testing Requirements);

E. Title 40 CFR § 63.8 (relating to Monitoring Requirements);

F. Title 40 CFR § 63.9 (relating to Notification Requirements);

G. Title 40 CFR § 63.10 (relating to Recordkeeping and Reporting Requirements); and

H. Title 40 CFR § 63.15 (relating to Availability of Information and Confidentiality).

6. For sterilization facilities subject to ethylene oxide emission standards in 40 CFR Part 63, Subpart O, the permit holder shall comply with the following requirements (Title 30 TAC Chapter 113, Subchapter B, Division 6 incorporated by reference):

A. Title 40 CFR § 63.360(a) (relating to General Provisions of Subpart A); and

B. Title 40 CFR § 63.367(b) (relating to Recordkeeping Requirements).

New Source Review Authorization Requirements

7. Permit holder shall comply with the requirements of New Source Review authorizations issued or claimed by the permit holder for the permitted area, including permits, permits by rule, standard permits, flexible permits, special permits, permits for existing facilities including Voluntary Emissions Reduction Permits and Electric Generating Facility Permits issued under 30 TAC Chapter 116, Subchapter I, or special exemptions referenced in the New Source Review Authorization References attachment. These requirements:

   A. Are incorporated by reference into this permit as applicable requirements.

   B. Shall be located with this operating permit.

   C. Are not eligible for a permit shield.

8. In addition to the New Source Review authorizations specifically listed in the New Source Review Authorization Reference attachment, the permit holder shall comply with the appropriate Permits By Rule (PBR) claimed or issued prior to 1991. To facilitate identification of any pre-1991 PBRs in this permit, a list of potential PBRs that may apply has been included in the attachment "Additional Permits By Rule In Effect Prior to 1991 That May Apply to This Operating Permit." The permit holder shall revise this permit to specify which PBRs are applicable at the next permit action on or after six months following the issuance date of this permit.

9. The permit holder shall comply with the general requirements of 30 TAC Chapter 106, Subchapter A or the general requirements, if any, in effect at the time of the claim of any PBR.

10. Changes to qualified facilities meeting the criteria of 30 TAC Chapter 116 § 116.116(e) are incorporated in this operating permit by reference until these changes are incorporated in the appropriate NSR permit. The permit holder shall provide documentation and notification as required by 30 TAC § 116.117 for these changes.

Compliance Requirements.

11. The permit holder shall certify compliance with all permit terms and conditions using, at a minimum, but not limited to, the continuous or intermittent compliance method data from monitoring, recordkeeping, reporting, or testing required by the permit and any other credible evidence or information. The certification period may not exceed 12 months and the certification must be submitted within 30 days after the end of the period being certified.

Protection of Stratospheric Ozone

12. Owners and operators of a site subject to Title VI of the FCAA Amendments shall meet the following requirements for protection of stratospheric ozone.

A. Any on site servicing, maintenance, and repair on refrigeration and nonmotor vehicle air-conditioning appliances using ozone-depleting refrigerants shall be conducted in accordance with 40 CFR Part 82, Subpart F. Owners or operators shall ensure that repairs or refrigerant removal are performed only by properly certified technicians using certified equipment. Records shall be maintained as required by 40 CFR Part 82, Subpart F.

Permit Location

13. The permit holder shall maintain a copy of this permit and records related to requirements listed in this permit on site.

ATTACHMENTS

Applicable Requirements Summary

New Source Review Authorization References

APPLICABLE REQUIREMENTS SUMMARY

Unit Summary 9

Applicable Requirements Summary 10

Unit Summary

Unit/Group/ Process ID No.	Unit Type	Group/Inclusive Units	SOP Index No.	Regulation	Requirement Driver
PRO-EAST	Sterilization Source Attributes	EPN-5 EPN-20	63O-1	40 CFR Part 63, Subpart O	Sterilization Chamber Vent = Acid Scrubber
PRO-EAST	Sterilization Source Attributes	EPN-5 EPN-20	63O-2	40 CFR Part 63, Subpart O	Aeration Room Vent = Catalytic or Thermal Oxidizer
PRO-WEST	Sterilization Source Attributes	EPN-10 EPN-21	63O-1	40 CFR Part 63, Subpart O	Sterilization Chamber Vent = Acid Scrubber
PRO-WEST	Sterilization Source Attributes	EPN-10 EPN-21	63O-2	40 CFR Part 63, Subpart O	Aeration Room Vent = Catalytic or Thermal Oxidizer
ETHSA1	Storage Tanks/vessels	N/A	60KB	40 CFR Part 60, Subpart Kb	No changing attributes.

Applicable Requirements Summary

Unit/Group/Process		SOP Index No.	Pollutant	Emission Limitation/Standard or Equipment Specification		Textual Description (See Special Term and Condition 1.B.)	Monitoring And Testing Requirements	Recordkeeping Requirements (30 TAC § 122.144)	Reporting Requirements (30 TAC § 122.145)
ID No.	Type			Name	Citation				
PRO-EAST	EP	63O-1	ETHYLENE OXIDE	40 CFR Part 63, Subpart O	§ 63.362(c) § 63.363(f)	Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.	[G]§ 63.363(a) § 63.363(b) § 63.363(b)(1) [G]§ 63.363(b)(2) [G]§ 63.364(a) [G]§ 63.364(b) § 63.364(e) § 63.365(a) § 63.365(b) [G]§ 63.365(b)(1) [G]§ 63.365(c) [G]§ 63.365(e)	[G]§ 63.364(b) § 63.367(a)	[G]§ 63.366(a) [G]§ 63.366(b) [G]§ 63.366(c)
PRO-EAST	EP	63O-2	ETHYLENE OXIDE	40 CFR Part 63, Subpart O	§ 63.362(d) § 63.363(f)	A source using 10 tons shall reduce emissions from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.	[G]§ 63.363(a) § 63.363(b)(3) [G]§ 63.363(b)(4) § 63.363(c) § 63.363(c)(1) § 63.363(c)(2) § 63.363(c)(3) [G]§ 63.364(a) [G]§ 63.364(c) § 63.364(e) § 63.365(a) [G]§ 63.365(c) [G]§ 63.365(d)	§ 63.364(c) § 63.367(a) § 63.367(d)	[G]§ 63.366(a) [G]§ 63.366(b) [G]§ 63.366(c)
PRO-WEST	EP	63O-1	ETHYLENE OXIDE	40 CFR Part 63, Subpart O	§ 63.362(c) § 63.363(f)	Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.	[G]§ 63.363(a) § 63.363(b) § 63.363(b)(1) [G]§ 63.363(b)(2) [G]§ 63.364(a) [G]§ 63.364(b) § 63.364(e) § 63.365(a) § 63.365(b) [G]§ 63.365(b)(1) [G]§ 63.365(c) [G]§ 63.365(e)	[G]§ 63.364(b) § 63.367(a)	[G]§ 63.366(a) [G]§ 63.366(b) [G]§ 63.366(c)

Applicable Requirements Summary

Unit/Group/Process		SOP Index No.	Pollutant	Emission Limitation/Standard or Equipment Specification		Textual Description (See Special Term and Condition 1.B.)	Monitoring And Testing Requirements	Recordkeeping Requirements (30 TAC § 122.144)	Reporting Requirements (30 TAC § 122.145)
ID No.	Type			Name	Citation				
PRO-WEST	EP	63O-2	ETHYLENE OXIDE	40 CFR Part 63, Subpart O	§ 63.362(d) § 63.363(f)	A source using 10 tons shall reduce emissions from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.	[G]§ 63.363(a) § 63.363(b)(3) [G]§ 63.363(b)(4) § 63.363(c) § 63.363(c)(1) § 63.363(c)(2) § 63.363(c)(3) [G]§ 63.364(a) [G]§ 63.364(c) § 63.364(e) § 63.365(a) [G]§ 63.365(c) [G]§ 63.365(d)	§ 63.364(c) § 63.367(a) § 63.367(d)	[G]§ 63.366(a) [G]§ 63.366(b) [G]§ 63.366(c)
ETHSA1	EU	60KB	VOC	40 CFR Part 60, Subpart Kb	§ 60.110b(c)	Except for §60.116b(a)-(b), vessels meeting the specified design capacities and maximum true vapor pressure are exempt from General Provisions and from provisions of this subpart.	§ 60.116b(a) § 60.116b(b)	§ 60.116b(a) § 60.116b(b)	None

NEW SOURCE REVIEW AUTHORIZATION REFERENCES

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New Source Review Authorization References by Emission Unit 15

Additional Permits By Rule In Effect Prior to 1991 Potentially Applying to This Operating Permit 16

New Source Review Authorization References

The New Source Review authorizations listed in the table below are applicable requirements under 30 TAC Chapter 122 and enforceable under this operating permit.

PSD Permits	NA Permits
PSD Permit No.:	NA Permit No.:
Title 30 TAC Chapter 116 Permits, Special Permits, and Other Authorizations (Other Than Permits By Rule, PSD Permits, or NA Permits) for the Application Area.	
Authorization No.: 20178	Authorization No.:
Authorization No.:	Authorization No.:
Permits By Rule (30 TAC Chapter 106) for the Application Area	
Number: 106.102	Version No./Date: 09/04/2000
Number: 106.103	Version No./Date: 09/04/2000
Number: 106.122	Version No./Date: 09/04/2000
Number: 106.183	Version No./Date: 09/04/2000
Number: 106.227	Version No./Date: 09/04/2000
Number: 106.242	Version No./Date: 09/04/2000
Number: 106.261	Version No./Date: 09/04/2000
Number: 106.262	Version No./Date: 09/04/2000
Number: 106.263	Version No./Date: 11/01/2001
Number: 106.265	Version No./Date: 09/04/2000
Number: 106.266	Version No./Date: 09/04/2000
Number: 106.371	Version No./Date: 09/04/2000
Number: 106.372	Version No./Date: 09/04/2000
Number: 106.418	Version No./Date: 09/04/2000
Number: 106.472	Version No./Date: 09/04/2000
Number: 106.473	Version No./Date: 09/04/2000
Number: 106.511	Version No./Date: 09/04/2000
Number: 106.533	Version No./Date: 11/26/1997
Number: 106.533	Version No./Date: 09/04/2000
Number: PBR-068	Version No./Date: 04/05/1995

New Source Review Authorization References

Number: PBR-086	Version No./Date: 08/11/1989
Number: PBR-478	Version No./Date: 09/12/1989
Municipal Solid Waste and Industrial Hazardous Waste Permits With an Air Addendum09/04/2000	
Permit No.:	Permit No.:
Permit No.:	Permit No.:
Permit No.:	Permit No.:
Permit No.:	Permit No.:

New Source Review Authorization References by Emissions Unit

The following is a list of 30 TAC Chapter 116 New Source Review (NSR) authorizations for emission units listed elsewhere in this operating permit. The NSR authorizations are applicable requirements under 30 TAC Chapter 122 and enforceable under this operating permit. If the unit is grandfathered from 30 TAC Chapter 116 New Source Review authorization requirements then "GF status" will be put in the New Source Review Authorization column of the following table.

Unit/Group/Process ID No.	Emission Unit Name /Description	New Source Review Authorization
ETHSA1	Diesel Storage Tank	PBR-086 / 09/12/1989
PRO-EAST	East Sterilization Process	NSR-20178
PRO-WEST	West Sterilization Process	NSR-20178

Note: The grandfathered status for shown units in this table reflects the status represented by the applicant on Form OP-REQ1 (Area-wide Applicability Determinations) or Form OP-SUM (Individual Unit Summary) and has not been reviewed to determine validity of the claim of grandfathered status.

Additional Permits By Rule In Effect Prior to 1991
Potentially Applying to This Operating Permit

GENERAL			
Facilities (Emission Limitations)	106	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	124	-	5/12/81, 9/23/82
Facilities (Emission and Distance Limitations)	118	-	7/15/88, 8/11/89
Replacements of Facilities	111	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
Repairs and Maintenance	70	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	80	-	12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
ANALYSIS AND TESTING			
Pilot Plants	76	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	90	-	4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
AGGREGATE AND PAVEMENT			
Portable Rock Crushers	73	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
Bulk Mineral Handling	91	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	108	-	1/8/80, 5/12/81, 9/23/82
Asphalt Concrete Plants	99	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	117	-	1/8/80, 5/12/81, 9/23/82
Asphalt Silos	122	-	7/15/88,8/11/89
COMBUSTION			
Boilers, Heaters, and Other Combustion Devices	7	-	9/23/82, 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
MANUFACTURING			
Semiconductor Manufacturing	115	-	7/15/88, 8/11/89
FEED, FIBER and FERTILIZER FEED			
Grain Handling, Storage and Drying	74	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	88	-	9/23/82
MIXERS, BLENDERS AND PACKAGING			
Chlorine	81	-	7/15/88, 8/11/89
OIL AND GAS			
Salt Water Disposal (Petroleum)	65	-	4/25/86, 7/15/88, 8/11/89
Oil and Gas Production Facilities	66	-	4/25/86, 7/15/88, 8/11/89
Gas Dehydration Units	72	-	1/8/80, 5/12/81, 9/23/82
	63	-	1/11/85, 7/26/85
Gas Oil Separators	73	-	1/8/80, 5/12/81, 9/23/82
	64	-	1/11/85, 7/26/85
Gas-fired Emulsion Treaters	74	-	1/8/80, 5/12/81, 9/23/82
	65	-	1/11/85, 7/26/85
Free Water Knockouts	75	-	1/8/80, 5/12/81, 9/23/82
	66	-	1/11/85, 7/26/85
Tank Battery for Sweet Crude	103	-	1/8/80, 5/12/81, 9/23/82
	87	-	1/11/85,7/26/85
Tank Battery for Sour Crude	104	-	1/8/80, 5/12/81, 9/23/82
	88	-	1/11/85,7/26/85
Tank Battery	93	-	5/5/76

Cryogenic Natural Gas Liquid Separators	105	- 1/8/80, 5/12/81, 9/23/82
	89	- 1/11/85,7/26/85

PLANT OPERATIONS

Cooling Water Units	8	- 12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	9	- 5/8/72
Refrigeration Systems	103	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	121	- 5/12/81, 9/23/82
Lime Slaking Facilities	121	- 7/15/88, 8/11/89
Aqueous Solutions for Electrolytic and Electroless Processes	41	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	46	- 12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
	47	- 5/8/72

PLASTICS, FIBERGLASS AND RUBBER

Thermoset Resin Facilities	113	- 4/25/86, 7/15/88, 8/11/89
Conveyance and Storage of Plastic and Rubber Material	27	- 4/25/86, 7/15/88, 8/11/89
Equipment for Mixing Plastic and Rubber (with solvent)	48	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	54	- 9/23/82
Equipment for Mixing Plastic and Rubber (no solvent)	46	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	52	- 12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
	53	- 5/8/72
Fiberglass Reinforced Plastics Manufacturing	115	- 1/8/80, 5/12/81, 9/23/82

SERVICE INDUSTRIES

Uranium Recovery Facilities	95	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	112	- 1/8/80, 5/12/81, 9/23/82
Ethylene Oxide Sterilizers	89	- 7/15/88, 8/11/89
Printing Presses	13	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	14	- 1/8/80, 5/12/81, 9/23/82

SURFACE COATING

Surface Coat Facility (Paint Spray Booth)	75	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	89	- 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
Automobile Restoration Facility	116	- 4/25/86, 7/15/88, 8/11/89

SURFACE PREPARATION

Dry Abrasive Cleaning	102	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	120	- 5/12/81, 9/23/82
Degreasing Units	107	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	125	- 9/23/82

TANKS, STORAGE AND LOADING

Organic and Inorganic Liquid Loading and Unloading

	51	- 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	57	- 12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
	58	- 5/8/72

Organic Liquid Loading and Unloading			
	53	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	60	-	12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
	61	-	5/8/72
Hydrochloric Acid	78	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	94	-	1/11/80, 5/12/81, 9/23/82
Acid Storage	14	-	1/11/85, 7/26/85
	15	-	12/1/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
	16	-	05/08/1972
Pressurized Tanks or Tanks Vented to a Firebox	82	-	7/26/85, 4/25/86, 7/15/88, 8/11/89
	98	-	1/8/80, 5/12/81, 9/23/82
Pressurized Tanks or Tanks Vented to Control	83	-	7/26/85, 4/25/86, 7/15/88, 8/11/89
	99	-	1/8/80, 5/12/81, 9/23/82
LPG Storage Containers	87	-	9/17/73, 4/4/75, 5/5/76
Anhydrous Ammonia Storage	84	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	100	-	1/8/80, 5/12/81, 9/23/82
Storage Tank and Change of Service	86	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	102	-	1/8/80, 5/12/81, 9/23/82
THERMAL CONTROL DEVICES			
Dual Chamber Incinerators	2	-	5/8/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82 7/26/85, 4/25/86, 7/15/88, 8/11/89
Flares	80	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	96	-	1/8/80, 5/12/81, 9/23/82
Direct Flame Incinerators	88	-	7/15/88, 8/11/89
Pathological Waste Incinerators	90	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	106	-	1/8/80, 5/12/81, 9/23/82
Heat Cleaning Devices	87	-	7/15/88, 8/11/89
TURBINES AND ENGINES			
Stationary Engines and Turbines	6	-	1/8/80, 5/12/81, 9/23/82, 1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
Gas Turbines	82	-	12/1/72, 5/8/72, 9/17/73, 4/4/75, 5/5/76
WASTE PROCESS AND REMEDIATION			
Water and Wastewater Treatment	61	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	69	-	12/1/72, 5/8/72, 9/17/73, 4/4/75, 5/5/76, 1/8/80, 5/12/81, 9/23/82
	70	-	5/8/72
Water and Soil Remediation	68	-	7/15/88, 8/11/89
Municipal Solid Waste Landfill/Transfer	110	-	1/11/85, 7/26/85, 4/25/86, 7/15/88, 8/11/89
	129	-	9/23/82

APPENDIX A

Acronym List 20

ACRONYM LIST

The following abbreviations or acronyms may be used in this permit:

30 TAC Chapter 112 ..... Title 30 Texas Administrative Code Chapter 112
40 CFR Part 60, Appendix A ..... Title 40 Code of Federal Regulations Part 60, Appendix A
ACFM ..... actual cubic feet per minute
AMOC ..... alternate means of control
ARP ..... Acid Rain Program
ASTM ..... American Society of Testing and Materials
B/PA ..... Beaumont/Port Arthur (nonattainment area)
CAM ..... Compliance Assurance Monitoring
CD ..... control device
COMS ..... continuous opacity monitoring system
CVS ..... closed-vent system
D/FW ..... Dallas/Fort Worth (nonattainment area)
DR ..... Designated Representative
ElP ..... El Paso (nonattainment area)
EP ..... emission point
EPA ..... U.S. Environmental Protection Agency
EU ..... emission unit
FCAA Amendments ..... Federal Clean Air Act Amendments
FOP ..... federal operating permit
GF ..... grandfathered
gr/100 scf ..... grains per 100 standard cubic feet
HAP ..... hazardous air pollutant
H/G ..... Houston/Galveston (nonattainment area)
H_2S ..... hydrogen sulfide
ID No. ..... identification number
lb/hr ..... pound(s) per hour
MMBtu/hr ..... Million British thermal units per hour
MRRT ..... monitoring, recordkeeping, reporting, and testing
NA ..... nonattainment
N/A ..... not applicable
NADB ..... National Allowance Data Base
NO_x ..... nitrogen oxides
NSPS ..... New Source Performance Standard (40 CFR Part 60)
NSR ..... New Source Review
ORIS ..... Office of Regulatory Information Systems
Pb ..... lead
PBR ..... Permit By Rule
PM ..... particulate matter
ppmv ..... parts per million by volume
PSD ..... prevention of significant deterioration
RO ..... Responsible Official
SO_2 ..... sulfur dioxide
TCEQ ..... Texas Commission on Environmental Quality
TSP ..... total suspended particulate
TVP ..... true vapor pressure
U.S.C. ..... United States Code
VOC ..... volatile organic compound

APPENDIX B

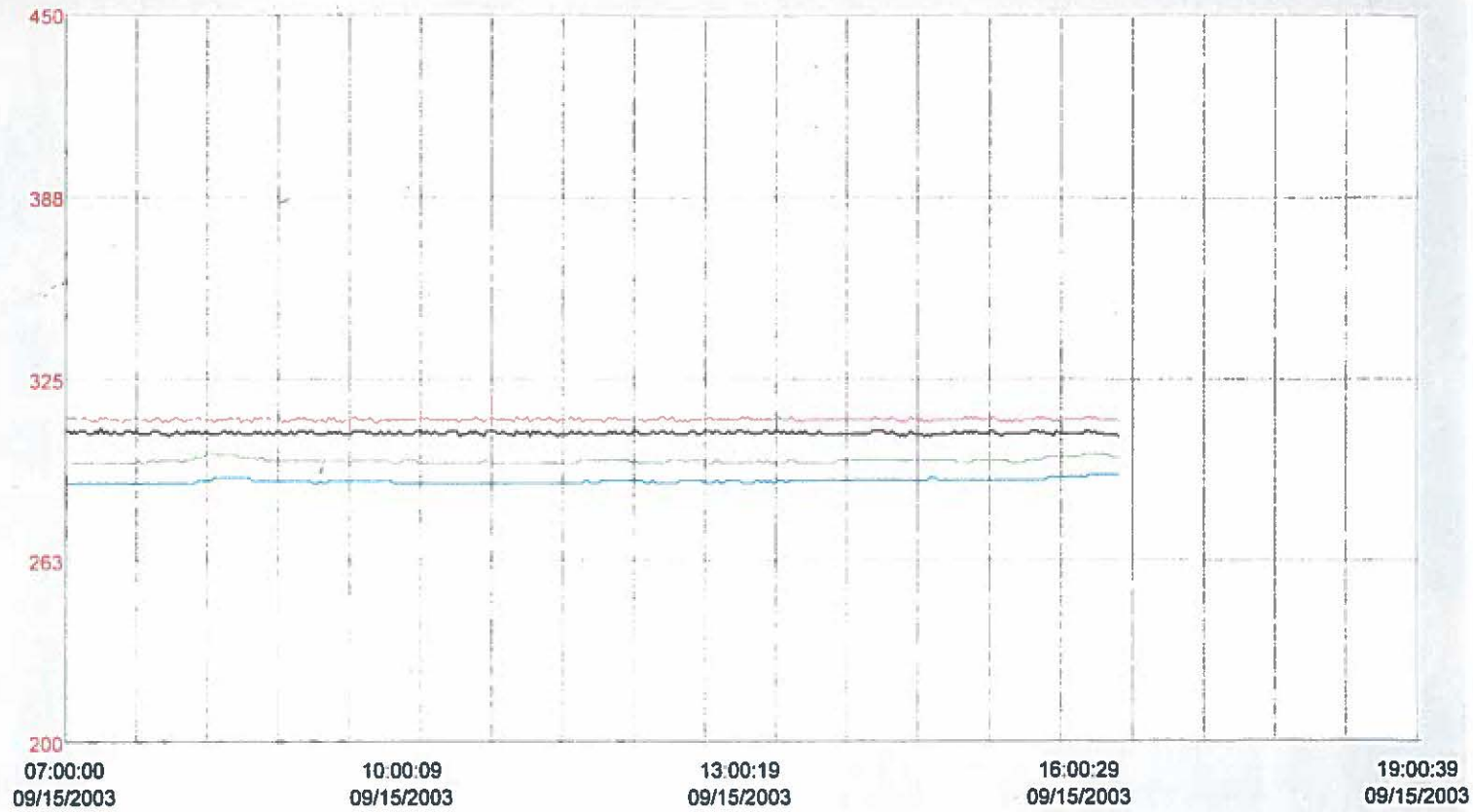
EAST AND WEST ABATOR DATA

GAS CHROMATOGRAPHY RUN SUMMARY
ETHICON, INC.
SEPTEMBER 15, 2003

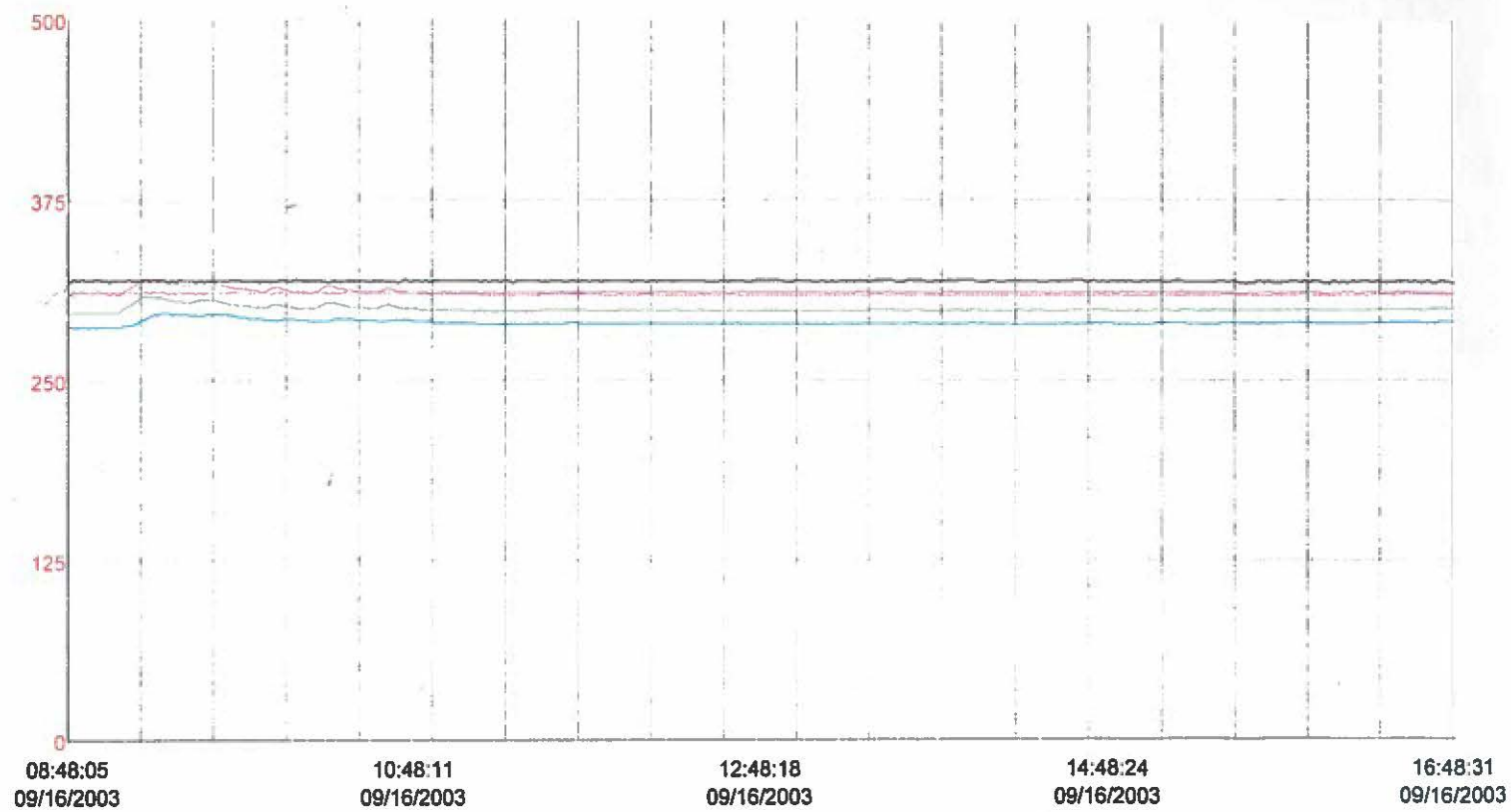
Chromatogram	Channel A (outlet)	Channel B (inlet)
ETO00001	Calibration set-up	Calibration set-up
ETO00002	Calibration set-up	Calibration set-up
ETO00003	Calibration set-up	Calibration set-up
ETO00004	Calibration set-up	Calibration set-up
ETO00005	Calibration set-up	Calibration set-up
ETO00006	Calibration set-up	Calibration set-up
ETO00007	1.01 ppm Low Cal	98.1 ppm Low Cal
ETO00008	1.02 ppm Low Cal	98.5 ppm Low Cal
ETO00009	1.01 ppm Low Cal	98.2 ppm Low Cal
ETO00010	1.01 ppm Low Cal	98.8 ppm Low Cal
ETO00011	1.01 ppm Low Cal	98.4 ppm Low Cal
ETO00012	5.21 ppm Mid Cal	2,129 ppm Mid Cal
ETO00013	5.15 ppm Mid Cal	2,130 ppm Mid Cal
ETO00014	5.13 ppm Mid Cal	2,131 ppm Mid Cal
ETO00015	10.12 ppm High Cal	5,020 ppm High Cal
ETO00016	10.12 ppm High Cal	5,023 ppm High Cal
ETO00017	10.15 ppm High Cal	5,023 ppm High Cal
ETO00018	<100 ppb West Abator Run 0	14 ppm West Abator-Preliminary
ETO00019	<100 ppb West Abator Run 1	152 ppm West Abator
ETO00022	<100 ppb West Abator Run 1	151 ppm West Abator
ETO00021	<100 ppb West Abator Run 1	153 ppm West Abator
ETO00022	<100 ppb West Abator Run 2	191 ppm West Abator
ETO00023	<100 ppb West Abator Run 2	188 ppm West Abator
ETO00024	<100 ppb West Abator Run 2	190 ppm West Abator
ETO00025	<100 ppb West Abator Run 2	190 ppm West Abator
ETO00026	<100 ppb West Abator Run 3	160 ppm West Abator
ETO00027	<100 ppb West Abator Run 3	162 ppm West Abator
ETO00028	<100 ppb West Abator Run 3	165 ppm West Abator
ETO00029	1.01 ppm Low Cal	100.3 ppm Low Cal
ETO00030	1.02 ppm Low Cal	102.0 ppm Low Cal
ETO00031	1.02 ppm Low Cal	101.0 ppm Low Cal
ETO00032	5.23 ppm Mid Cal	2,129 ppm Mid Cal
ETO00033	5.16 ppm Mid Cal	2,129 ppm Mid Cal
ETO00034	5.34 ppm Mid Cal	2,128 ppm Mid Cal
ETO00035	10.12 ppm High Cal	5,001 High Cal
ETO00036	10.24 ppm High Cal	5,002 High Cal
ETO00037	10.12 ppm High Cal	5,001 High Cal

GAS CHROMATOGRAPHY RUN SUMMARY
ETHICON, INC.
SEPTEMBER 16, 2003

Chromatogram	Channel A (outlet)	Channel B (inlet)
ETO00038	1.00 ppm Low Cal	101.9 ppm Low Cal
ETO00039	1.01 ppm Low Cal	102.0 ppm Low Cal
ETO00040	1.01 ppm Low Cal	101.0 ppm Low Cal
ETO00041	5.13 ppm Mid Cal	2,129 ppm Mid Cal
ETO00042	5.12 ppm Mid Cal	2,127 ppm Mid Cal
ETO00043	5.12 ppm Mid Cal	2,129 ppm Mid Cal
ETO00044	10.14 ppm High Cal	5,006 ppm High Cal
ETO00045	10.14 ppm High Cal	5,007 ppm High Cal
ETO00046	10.10 ppm High Cal	5,008 ppm High Cal
ETO00047	<100 ppb East Abator Run 1	140 ppm East Abator
ETO00048	<100 ppb East Abator Run 1	132 ppm East Abator
ETO00049	<100 ppb East Abator Run 1	130 ppm East Abator
ETO00050	<100 ppb East Abator Run 2	211 ppm East Abator
ETO00051	<100 ppb East Abator Run 2	210 ppm East Abator
ETO00052	<100 ppb Abator Run 2	208 ppm East Abator
ETO00053	<100 ppb East Abator Run 3	142 ppm East Abator
ETO00054	<100 ppb East Abator Run 3	140 ppm East Abator
ETO00055	<100 ppb East Abator Run 3	140 ppm East Abator
ETO00056		35 ppm Bag 1 East Scrubber - O
ETO00057		34 ppm Bag 1 East Scrubber - O
ETO00058		19 ppm Bag 2 East Scrubber - O
ETO00059		19 ppm Bag 2 East Scrubber - O
ETO00060		9.2 ppm Bag 3 East Scrubber - O
ETO00061		9.1 ppm Bag 3 East Scrubber - O
ETO00062		98 ppm Bag 1 West Scrubber -T
ETO00063		99 ppm Bag 1 West Scrubber –T
ETO00064		67 ppm Bag 2 West Scrubber – T
ETO00065		65 ppm Bag 2 West Scrubber – T
ETO00066		41 ppm Bag 3 West Scrubber – T
ETO00067		42 ppm Bag 3 West Scrubber – T
ETO00068		aborted sample wrong scrubber
ETO00069		aborted sample wrong scrubber
ETO00070		aborted sample wrong scrubber
ETO00071	1.01 ppm Low Cal	101.2 ppm Low Cal
ETO00072	1.00 ppm Low Cal	101.1 ppm Low Cal
ETO00073	1.00 ppm Low Cal	101.3 ppm Low Cal
ETO00074	5.24 ppm Mid Cal	2,119 ppm Mid Cal
ETO00075	5.12 ppm Mid Cal	2,119 ppm Mid Cal
ETO00076	5.14 ppm Mid Cal	2,118 ppm Mid Cal
ETO00077	10.12 ppm High Cal	5,002 ppm High Cal
ETO00078	10.31 ppm High Cal	5,000 ppm High Cal
ETO00079	10.23 ppm High Cal	5,001 ppm High Cal



SCDM01:MN12030.F_CV	TE2 Bed Inlet Temperature	311
SCDM01:MN12031.F_CV	TE6 Bed Outlet Temperature	291
SCDM01:MN12033.F_CV	TE5 Process Temperature #2	298
SCDM01:MN12034.F_CV	TE1 Electric Heat Process Temperature	306



SCDM01:LN12030.F_CV	TE2 Bed Inlet Temperature	311
SCDM01:LN12031.F_CV	TE6 Bed Outlet Temperature	289
SCDM01:LN12032.F_CV	TE4 Process Temperature #1	309
SCDM01:LN12033.F_CV	TE5 Process Temperature #2	298
SCDM01:LN12034.F_CV	TE1 Electric Heat Process Temperature	319

Data File C:\HPCHEM\3\DATA\ECON03\ETO00007.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.88237e4	5.37738e-5	1.01222		EtO

Totals : 1.01222

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00008.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.90318e4	5.37759e-5	1.02345		EtO

Totals : 1.02345

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00009.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.88250e4	5.37738e-5	1.01229		EtO

Totals : 1.01229

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00010.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.580	VV	1.88242e4	5.37738e-5	1.01225		EtO

Totals : 1.01225

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00011.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.88194e4	5.37737e-5	1.01199		EtO

Totals : 1.01199

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00012.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	9.66427e4	5.39309e-5	5.21203		EtO

Totals : 5.21203

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00013.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	9.54676e4	5.39304e-5	5.14861		EtO
Totals :				5.14861		

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00014.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	9.51639e4	5.39303-5	5.13222		EtO

Totals : 5.13222

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00015.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.87606e5	5.39493e-5	10.12122		EtO

Totals : 10.12122

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00016.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.87627e5	5.39493e-5	10.12234		EtO
Totals :				10.12234		

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00017.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.88139e5	5.39494e-5	10.15000		EtO

Totals : 10.15000

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00018.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.585	VV	1.88985e3	5.20253e-5	0.09832		EtO
Totals :				0.09832		

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00019.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.90542e3	5.20411e-5	0.09916		EtO

Totals : 0.09916

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00020.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.83037e3	5.19621e-5	0.09511		EtO

Totals : 0.09511

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00021.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.64934e3	5.17418e-5	0.08534		EtO

Totals : 0.08534

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00022.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.580	VV	1.70697e3	5.18170e-5	0.08845		EtO

Totals : 0.08845

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00023.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.61191e3	5.16901e-5	0.08332		EtO

Totals : 0.08332

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00024.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.580	VV	1.83834e3	5.19708e-5	0.09554		EtO
Totals :				0.09554		

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00025.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.76015e3	5.18820e-5	0.09132		EtO

Totals : 0.09132

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00026.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.75829e3	5.18798e-5	0.09122		EtO

Totals : 0.09122

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00027.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.588	VV	1.79887e3	5.19270e-5	0.09341		EtO

Totals : 0.09341

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00028.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.88818e3	5.20235e-5	0.09823		EtO

Totals : 0.09823

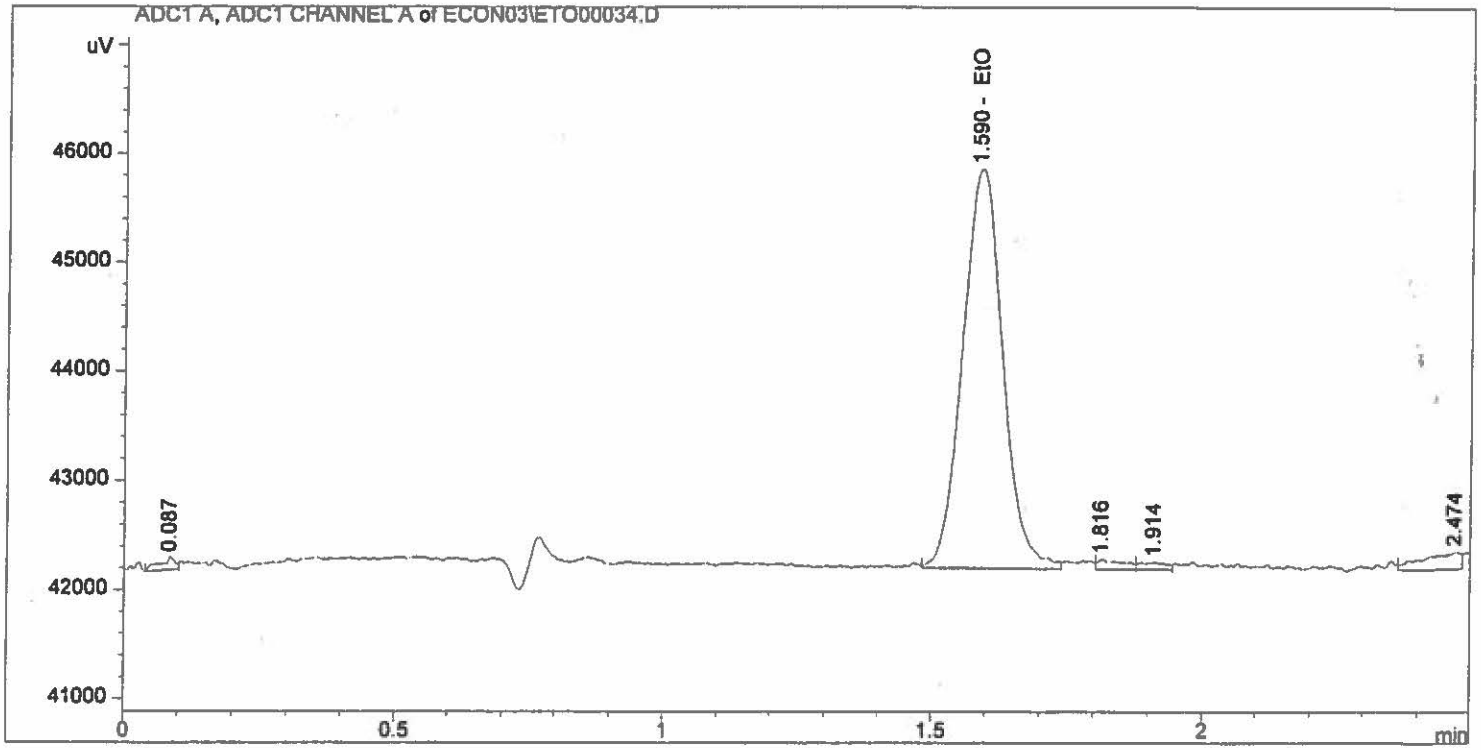
*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00029D

Injection Date	: 9/15/03 3:44:19 PM	Seq. Line :	-
Sample Name	:	Vial :	-
Acq. Operator	: Becvar/Barreda	Inj :	-
		Inj Volume :	Manually

Acq. Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/10/03 2:08:14 PM by Becvar/Barreda
Analysis Method : C:\HPCHEM\3\METHODS\ECONEX03.M
Last changed : 9/23/03 1:26:11 PM by Becvar/Barreda
(modified after loading)

HYDROCARBON SPECIATION
50@3/20/340@1
15mx0.53mmid rtx-1



External Standard Report

Sorted by Signal

Calib. Data Modified	:	Tuesday, September 23, 1903 1:23:51 PM
Multiplier	:	1.000000
Dilution	:	1.000000
Uncalibrated Peaks	:	compound name not specified

Data File C:\HPCHEM\3\DATA\ECON03\ETO00029D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.590	VV	1.87844e4	5.37734e-5	1.01010		EtO

Totals : 1.01010

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00030.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.90282e4	5.37759e-5	1.02326		EtO

Totals : 1.02326

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00031.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.90460e4	5.37761e-5	1.02422		EtO

Totals : 1.02422

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00032.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	9.70187e4	5.39311e-5	5.23232		EtO

Totals : 5.23232

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00033.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	9.57511e4	5.39306e-5	5.16391		EtO

Totals : 5.16391

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00034.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	9.90693e4	5.39318e-5	5.34299		EtO

Totals : 5.34299

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00035.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.631	VV	1.89642e5	5.39496e-5	10.23111		EtO

Totals : 10.23111

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00036.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.600	VV	1.89848e5	5.39496e-5	10.24223		EtO

Totals : 10.24223

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00037.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.598	VV	1.87604e5	5.39493e-5	10.12112		EtO

Totals : 10.12112

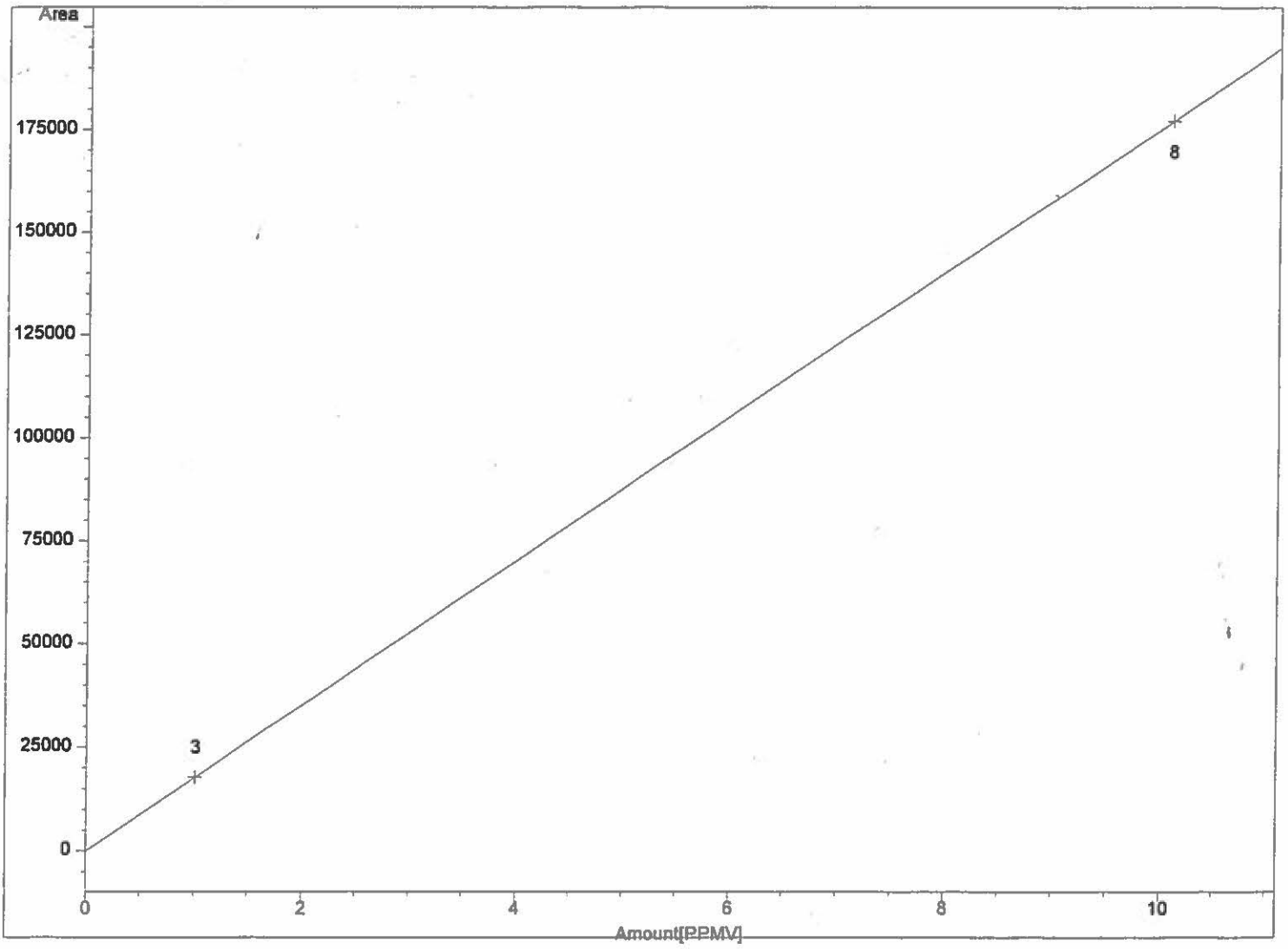
*** End of Report ***

Method C:\HPCHEM\3\METHODS\ECONEX03.M

==========

Calibration Curve

==========



EtO at exp. RT: 1.645
ADC1 A, ADC1 CHANNEL A
Correlation: 1.00000
Residual Std. Dev.: 52.46602
Formula: y = mx + b
m: 17552.87695
b: 35.00136
x: Amount
y: Area

==========

Data File C:\HPCHEM\3\DATA\ECON03\ETO00038.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.76641e4	5.68578e-5	1.00434		EtO

Totals : 1.00434

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00039D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.77380e4	5.68583e-5	1.00855		EtO

Totals : 1.00855

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00040.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.585	VV	1.78291e4	5.68589e-5	1.01374		EtO

Totals : 1.01374

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00041.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.585	VV	9.00007e4	5.69486e-5	5.12541		EtO

Totals : 5.12541

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00042.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	8.99642e4	5.69486e-5	5.12333		EtO

Totals : 5.12333

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00043.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	8.99615e4	5.69486e-5	5.12318		EtO

Totals : 5.12318

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00044.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.77941e5	5.69595e-5	10.13546		EtO

Totals : 10.13546

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00045.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.78039e5	5.69595e-5	10.14100		EtO

Totals : 10.14100

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00046.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.77354e5	5.69595e-5	10.10201		EtO

Totals : 10.10201

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00047.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.56614e3	5.56975e-5	0.08723		EtO

Totals : 0.08723

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00048.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.60476e3	5.57281e-5	0.08943		EtO

Totals : 0.08943

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00049.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.580	VV	1.64127e3	5.57558e-5	0.09151		EtO

Totals : 0.09151

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00050.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.63811e3	5.57534e-5	0.09133		EtO

Totals : 0.09133

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00051.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.67462e3	5.57800e-5	0.09341		EtO
Totals :				0.09341		

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00052.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.78994e3	5.58567e-5	0.09998		EtO

Totals : 0.09998

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00053.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.583	VV	1.56860e3	5.56995e-5	0.08737		EtO

Totals : 0.08737

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00054.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.583	VV	1.60546e3	5.57287e-5	0.08947		EtO

Totals : 0.08947

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00055.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.60089e3	5.57251e-5	0.08921		EtO

Totals : 0.08921

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00071.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.78008e4	5.68587e-5	1.01213		EtO

Totals : 1.01213

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00072.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	1.76179e4	5.68575e-5	1.00171		EtO

Totals : 1.00171

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00073.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.583	VV	1.75917e4	5.68574e-5	1.00022		EtO

Totals : 1.00022

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00074.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.580	VV	9.20584e4	5.69491e-5	5.24264		EtO

Totals : 5.24264

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00075.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	8.99347e4	5.69485e-5	5.12165		EtO

Totals : 5.12165

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00076.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.584	VV	9.03133e4	5.69486e-5	5.14322		EtO

Totals : 5.14322

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00077.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.583	VV	1.79275e5	5.69596e-5	10.21143		EtO

Totals : 10.21143

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00078.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.581	VV	1.81036e5	5.69597e-5	10.31174		EtO

Totals : 10.31174

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00079.D

Signal 1: ADC1 A, ADC1 CHANNEL A

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.582	VV	1.79638e5	5.69596e-5	10.23211		EtO

Totals : 10.23211

*** End of Report ***

Intercept	Area	Concentration	notes
5393.68359	155842	98.1	low cal
5393.68359	156456	98.5	low cal
5393.68359	155995	98.2	low cal
5393.68359	156916	98.8	low cal
5393.68359	156302	98.4	low cal
5393.68359	3270477	2129	mid cal
5393.68359	3272011	2130	mid cal
5393.68359	3273544	2131	mid cal
5393.68359	7704181	5020	high cal
5393.68359	7708782	5023	high cal
5393.68359	3022140	5023	high cal
5393.68359	2692.588	14.3	West Abator
5393.68359	238964	152.3	West Abator
5393.68359	237124	151.1	West Abator
5393.68359	240345	153.2	West Abator
5393.68359	298929	191.4	West Abator
5393.68359	294175	188.3	West Abator
5393.68359	296935	190.1	West Abator
5393.68359	297396	190.4	West Abator
5393.68359	251233	160.3	West Abator
5393.68359	253841	162.0	West Abator
5393.68359	258441	165.0	West Abator
5393.68359	159216	100.3	low cal
5393.68359	158909	100.1	low cal
5393.68359	161343	101.7	low cal
5393.68359	3270477	2129	mid cal
5393.68359	3270477	2129	mid cal
5393.68359	3270220	2129	mid cal
5393.68359	7675043	5001	high cal
5393.68359	7676576	5002	high cal
5393.68359	7675043	5001	high cal
5884.5459	161782	101.9	low cal
5884.5459	161983	102.0	low cal
5884.5459	160405	101.0	low cal
5884.5459	3263047	2129	mid cal
5884.5459	3259988	2127	mid cal
5884.5459	3262760	2129	mid cal
5884.5459	7664578	5006	high cal
5884.5459	7666107	5007	high cal
5884.5459	7667637	5008	high cal
5884.5459	220377	140.2	East Abator
5884.5459	207985	132.1	East Abator
5884.5459	204925	130.1	East Abator
5884.5459	329056	211.3	East Abator
5884.5459	327470	210.2	East Abator
5884.5459	324563	208.3	East Abator
5884.5459	223743	142.4	East Abator
5884.5459	220377	140.2	East Abator
5884.5459	220224	140.1	East Abator

2	Scrubber O
3	Scrubber O
1	Scrubber O
1	Scrubber O
	Scrubber O
	Scrubber O
2	Scrubber T
5	Scrubber T
2	Scrubber T
4	Scribber T
3	Scrubber T
0	Scrubber T
	aborted sample
	aborted sample
	aborted sample
2	low cal
1	low cal
3	low cal
9	mid cal
9	mid cal
8	mid cal
2	high cal
0	high cal
1	high cal
.9	low cal
.5	low cal
8	mid cal
9	mid cal
5	high cal
3	high cal
.2	Scrubber T-MT
.5	Scrubber T-MT
1	Scrubber T-MT
1	Scrubber T-MT
3	Scrubber T-MT
4	Scrubber T-MT
.3	Scrubber U
.2	Scrubber U
2	Scrubber U
2	Scrubber U
3	Scrubber U
4	Scrubber U
3	low cal
5	low cal
29	mid cal
28	mid cal
01	high cal
05	high cal

Data File C:\HPCHEM\3\DATA\ECON03\ETO00017.D

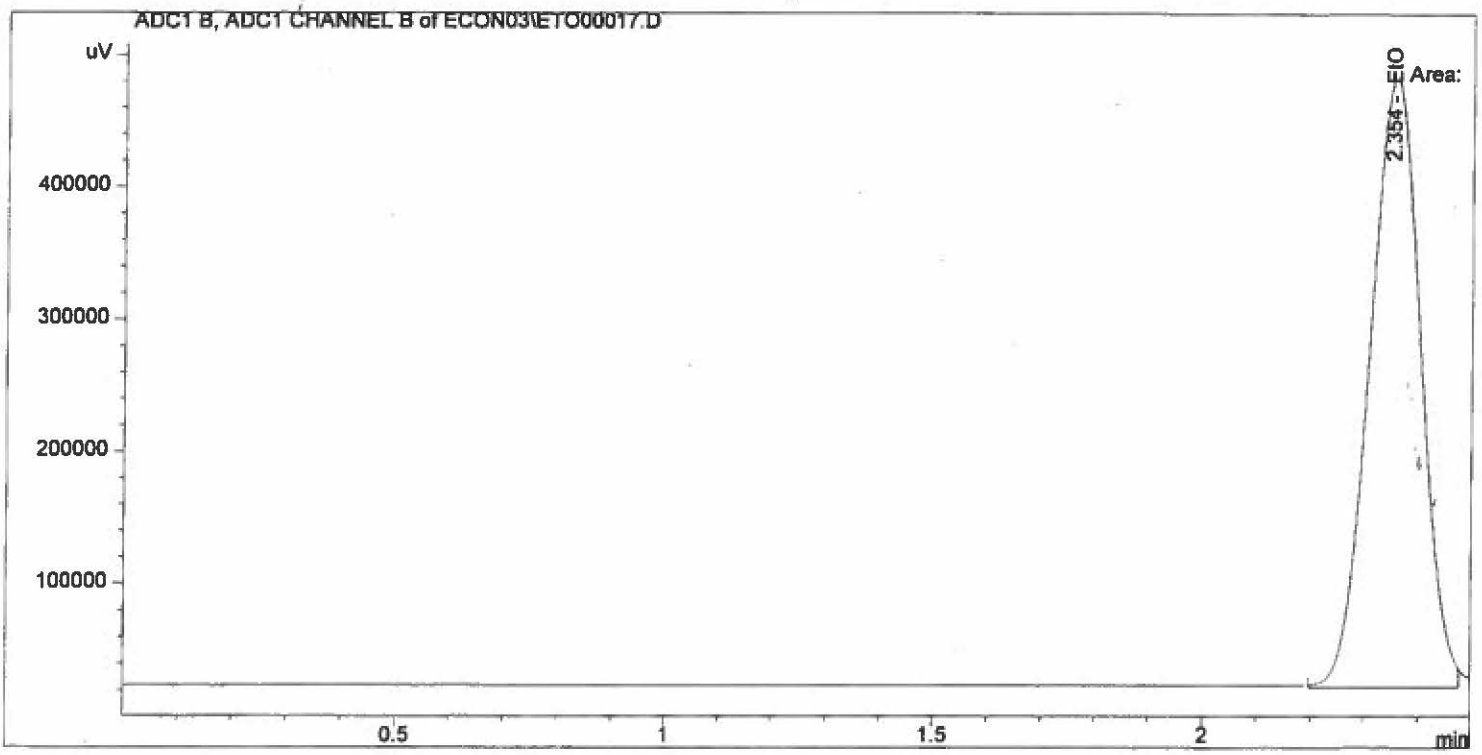
OK

==========

Injection Date : 9/15/03 11:06:30 AM
Sample Name :
Acq. Operator : Becvar/Barreda

Seq. Line : -
Vial : -
Inj : -
Inj Volume : Manually

Acq. Method : C:\HPCHEM\3\METHODS\ECONEX03.M
Last changed : 9/10/03 2:24:12 PM by Becvar/Barreda
Analysis Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/22/03 2:48:08 PM by Becvar/Barreda
(modified after loading)



==========

External Standard Report

==========

Sorted by Signal
Calib. Data Modified : Monday, September 22, 1903 2:39:37 PM
Multiplier : 1.000000
Dilution : 1.000000
Uncalibrated Peaks : compound name not specified

Data File C:\HPCHEM\3\DATA\ECON03\ETO00017.D

OK

Signal 1: ADC1 B, ADC1 CHANNEL B

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
2.354	MM	3.02214e6	1.66202e-3	5022.85840		EtO

Totals : 5022.85840

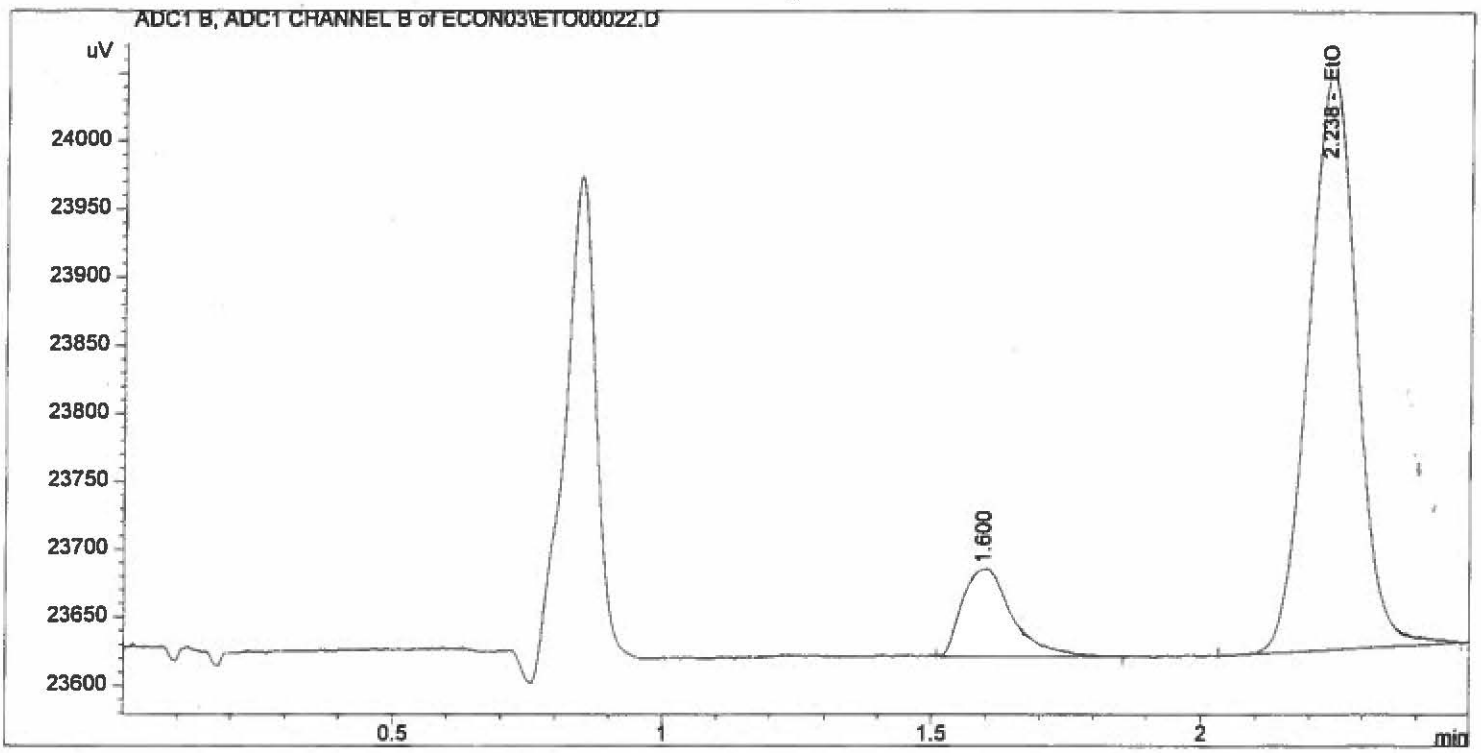
==========

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00018.D

Injection Date	: 9/15/03 1:38:00 PM	Seq. Line :	-
Sample Name	:	Vial :	-
Acq. Operator	: Becvar/Barreda	Inj :	-
		Inj Volume :	Manually

Acq. Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/10/03 2:08:14 PM by Becvar/Barreda
Analysis Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/22/03 2:52:02 PM by Becvar/Barreda
(modified after loading)



External Standard Report

Sorted by Signal
Calib. Data Modified : Monday, September 22, 1903 2:51:19 PM
Multiplier : 1.000000
Dilution : 1.000000
Uncalibrated Peaks : compound name not specified

Da ile C:\HPCHEM\3\DATA\ECON03\ETO00018.D

Signal 1: ADC1 B, ADC1 CHANNEL B

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.600	VV	412.91803	0.00000	0.00000		?
2.238	PBA	2692.58813	5.30059e-3	14.27231		EtO

Totals : 14.27231

==========

*** End of Report ***

Method C:\HPCHEM\3\METHODS\ECONIN03.M ECIN03A

==========

Calibration Table

==========

ETO-A

Calib. Data Modified : Monday, September 22, 1903 3:10:08 PM

Calculate : External Standard
Based on : Peak Areas

Rel. Reference Window : 10.000 %
Abs. Reference Window : 0.300 min
Rel. Non-ref. Window : 5.000 %
Abs. Non-ref. Window : 0.100 min
Default Multiplier : 1.000000 (if not set in sample table)
Default Dilution : 1.000000 (if not set in sample table)
Default Sample Amount : 0.000000 (if not set in sample table)
Calculate Uncal. Peaks: compound name not specified
Partial Calibration : Yes, identified peaks are recalibrated
Correct All RTs : No, only for identified peaks

Curve Type : Linear
Origin : Included
Weight : Equal

Recalibration Settings:
Average Response : Average all calibrations
Average RT : Floating Average New 75%

Calibration Report Options :
Printout of recalibrations within a sequence:
Calibration Table after Recalibration
Normal Report after Recalibration
If the sequence is done with bracketing:
Results of first cycle (ending previous bracket)

Signal 1 : ADC1 B, ADC1 CHANNEL B

RT [min]	Sig	Lvl	Amount [PPMV]	Area	Amt/Area	Ref	Grp	Name
1.636	1	3	98.00000	1.61343e5	6.07403e-4			EtO
		5	2129.00000	3.27022e6	6.51027e-4			

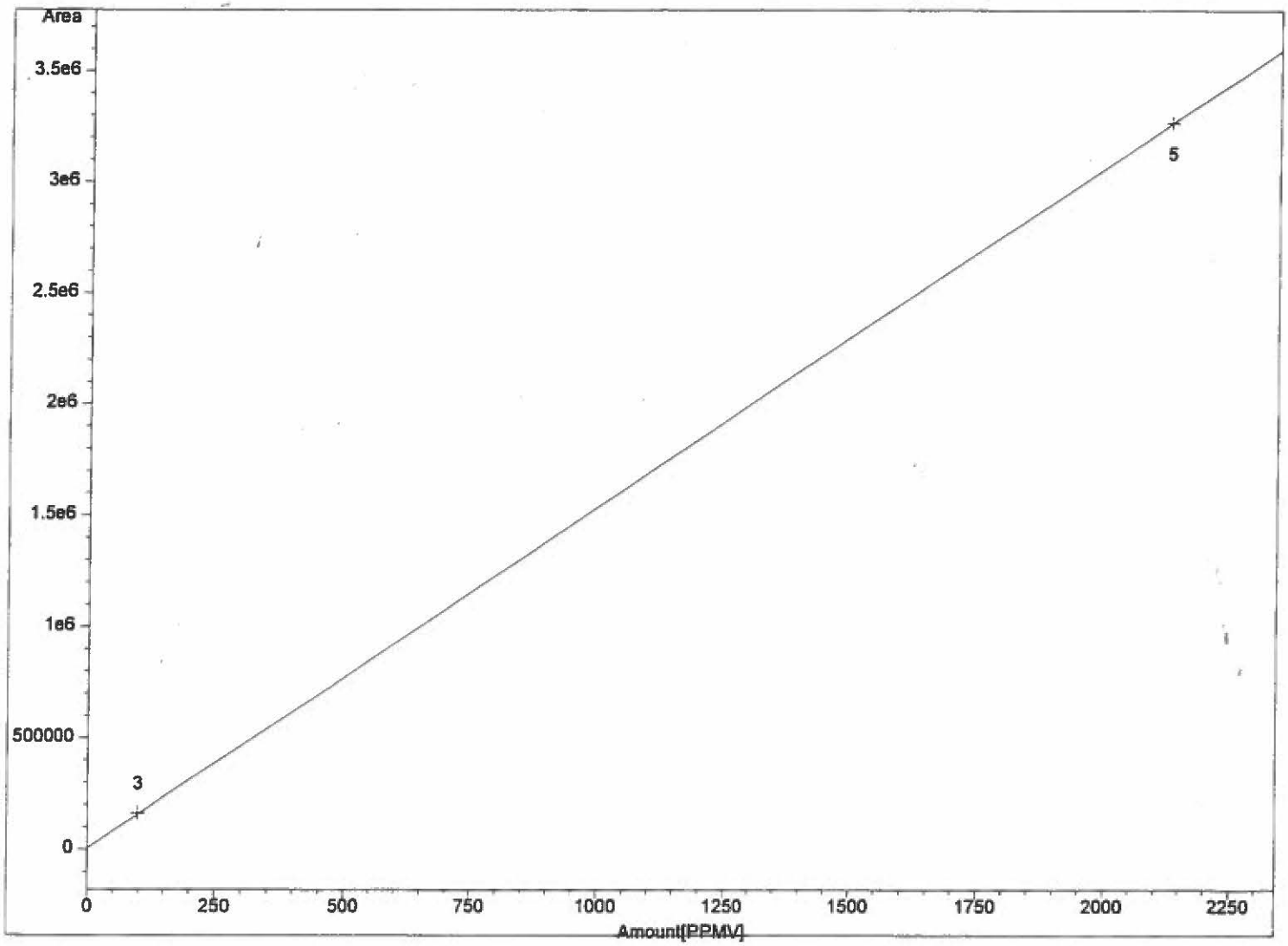
==========

Method C:\HPCHEM\3\METHODS\ECONIN03.M

==========

Calibration Curve

==========



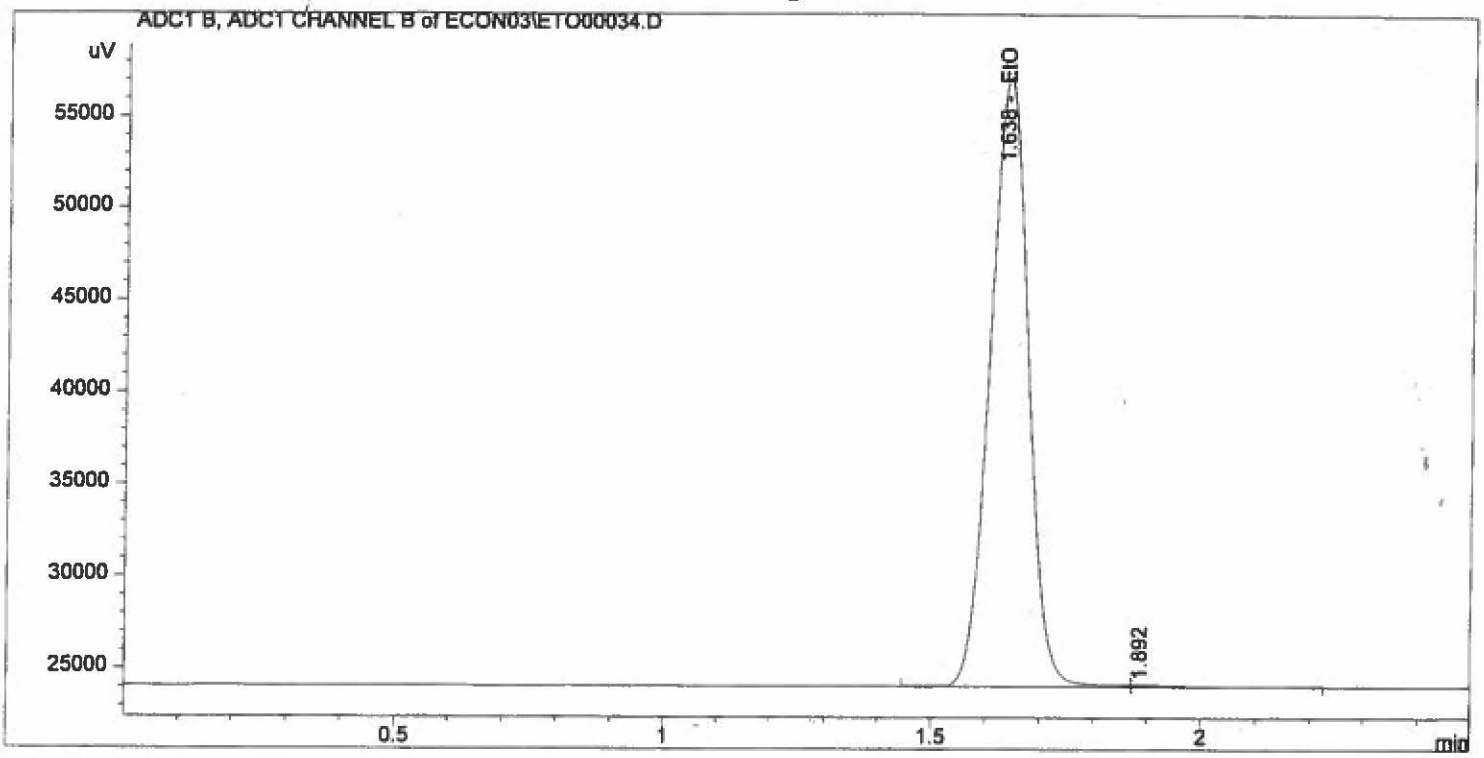
EtO at exp. RT: 1.636
ADC1 B, ADC1 CHANNEL B
Correlation: 1.00000
Residual Std. Dev.: 7818.35011
Formula: y = mx + b
m: 1533.62305
b: 5393.68359
x: Amount
y: Area

==========

Data File C:\HPCHEM\3\DATA\ECON03\ETO00031.D

Injection Date	: 9/15/03 3:44:19 PM	Seq. Line :	-
Sample Name	:	Vial :	-
Acq. Operator	: Becvar/Barreda	Inj :	-
		Inj Volume :	Manually

Acq. Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/10/03 2:08:14 PM by Becvar/Barreda
Analysis Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/22/03 3:14:26 PM by Becvar/Barreda
(modified after loading)



External Standard Report

Sorted by Signal
Calib. Data Modified : Monday, September 22, 1903 3:10:08 PM
Multiplier : 1.000000
Dilution : 1.000000
Uncalibrated Peaks : compound name not specified

Data File C:\HPCHEM\3\DATA\ECON03\ETO00031.D

Signal 1: ADC1 B, ADC1 CHANNEL B

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.638	VV	1.61343e5	6.30253e-4	101.68666		EtO
1.892	VV	735.29828	0.00000	0.00000		?

Totals : 101.68666

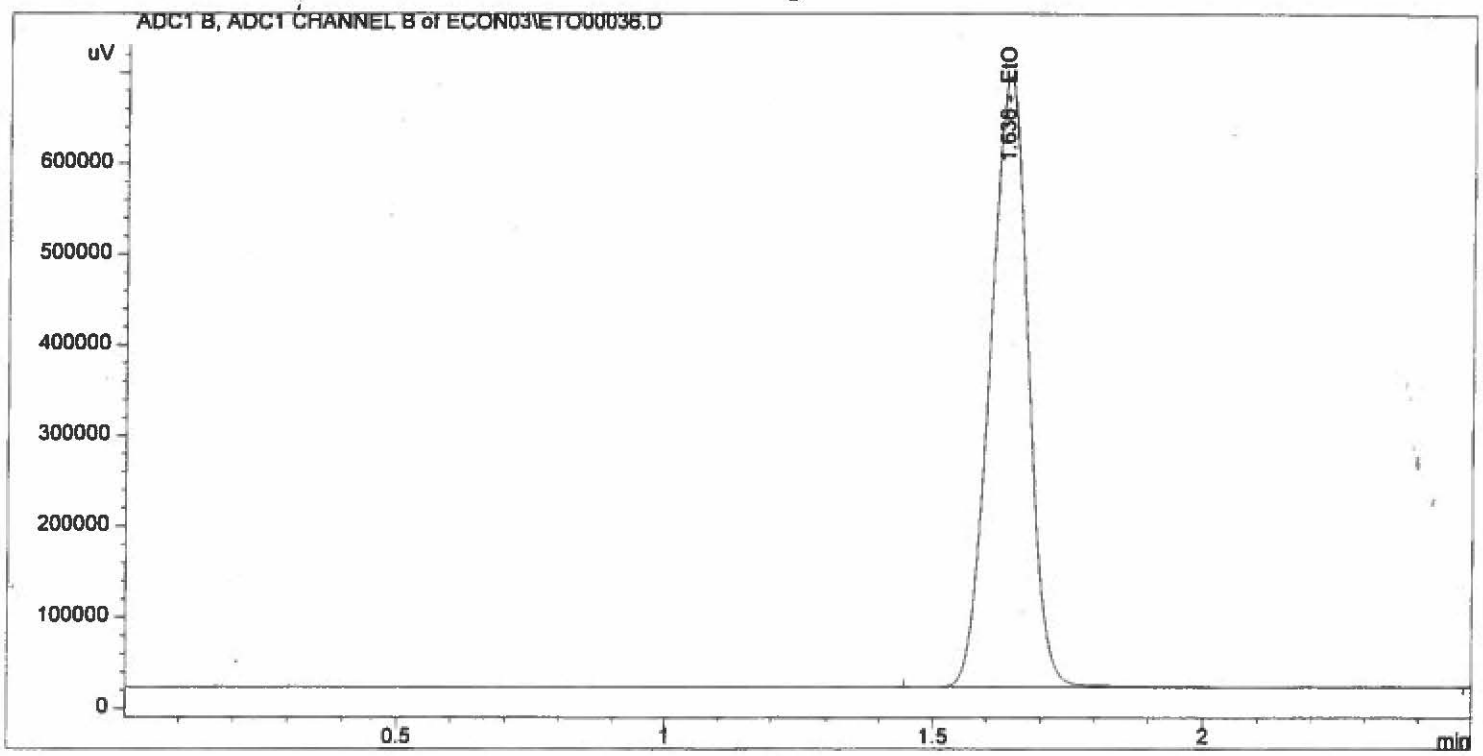
==========

*** End of Report ***

Data File C:\HPCHEM\3\DATA\ECON03\ETO00034.D

Injection Date	: 9/15/03 3:51:15 PM	Seq. Line :	-
Sample Name	:	Vial :	-
Acq. Operator	: Becvar/Barreda	Inj :	-
		Inj Volume :	Manually

Acq. Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/10/03 2:08:14 PM by Becvar/Barreda
Analysis Method : C:\HPCHEM\3\METHODS\ECONIN03.M
Last changed : 9/22/03 3:12:51 PM by Becvar/Barreda
(modified after loading)



External Standard Report

Sorted by Signal
Calib. Data Modified : Monday, September 22, 1903 3:10:08 PM
Multiplier : 1.000000
Dilution : 1.000000
Uncalibrated Peaks : compound name not specified

Data File C:\HPCHEM\3\DATA\ECON03\ETO00034.D

Signal 1: ADC1 B, ADC1 CHANNEL B

RT [min]	Type	Area [uV*s]	Amt/Area	Amount [PPMV]	Grp	Name
1.636	PBA	3.27022e6	6.50975e-4	2128.83032		EtO

Totals : 2128.83032

==========

*** End of Report ***

January 28, 2020

Re: EPA Subpart O ARV and SCV Compliance Test Report

To: Rubén Martínez Vargas

Customed Quality Assurance Director

Customed

ruben.martinez@prhospital.com

Call Box 158

Carolina, P.R. 0098-0158

787-622-5151 * 7634

Dear Mr. Vargas:

Attached is one copy of the final test report for the above referenced testing program. We understand that you will submit the required copies of this report to the Puerto Rico Environmental Quality Board for review. Should there be any questions concerning the enclosed report, please contact me at (484) 252-4335.

Respectfully,

L. Christopher Heilner

L. Christopher Heilner

Owner, LCH Consulting Associates, LLC

Final Test Report
2019 for Destruction Removal Efficiency of Ethylene Oxide Emissions from Sterilization Chamber Vents and Sterilization Aeration Room Vents

Puerto Rico Hospital | Customed
7 Igualdad Street
Fajardo Puerto Rico 00738
January 28, 2020

Prepared for:

Rubén Martínez Vargas
Customed Quality Assurance Director
Customed
ruben.martinez@prhospital.com
Call Box 158
Carolina, P.R. 0098-0158
787-622-5151 * 7634

For submittal to:
Puerto Rico Environmental Quality Board

Prepared by:

L. Christopher Heilner
Owner
LCH Consulting Associates, LLC
88 Glocker Way PMB 287
Pottstown, Pennsylvania 19465

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CERTIFICATION OF ACCURACY AND COMPLETION

I, Mr. L. Christopher Heilner, as the LCH Consulting Associates report author, certify under penalty of law that I believe the information provided in this document is true, accurate and complete. I am aware that there are significant civil and criminal penalties, including the possibility of fine or imprisonment, or both, for submitting false, inaccurate, or incomplete information.

Signed: L. Christopher Heilner Date: 01/28/2020

L. Christopher Heilner
Owner
LCH Consulting Associates
Telephone: (484) 252-4335

1.0 EXECUTIVE SUMMARY

This stack test report aims to satisfy Customed's PREQB permit and EPA Subpart O requirements. LCH Consulting Services, LLC (LCH) of Pottstown, Pennsylvania, was retained to perform the compliance stack test and this resulting final test report. The following provides contact, facility, permit, and source information:

1.1 CONTACT SUMMARY

Facility (Customed) Responsible Official

Rubén Martínez Vargas
Customed Quality Assurance Director
Customed
ruben.martinez@prhospital.com
Call Box 158
Carolina, P.R. 0098-0158
787-622-5151 * 7634

Regulatory Agency (PREQB) Contact

Luis R. Sierra Torres, PE
Chief Inspection and Compliance Division
Air Quality Area
Puerto Rico Environmental Quality Board
Air Quality Division
PO Box 11488
San Juan PR 00910

Stack Test Contractor

Mr. L. Christopher Heilner
LCH Consulting Services, LLC
88 Glocker Way PMB 287
Pottstown, PA 19465
484-252-4335 phone
chris@lchconsulting.com

1.2 PERMIT AND SOURCE SUMMARY

1.2.1 Applicable Regulation – 40CFR63.360 Subpart O: Ethylene Oxide Emissions Standards for Sterilization Facilities

PREQB Permit Number	XXXX
LCH Project Number	P101419
Process Description	Commercial Ethylene Oxide sterilization facility including pre-conditioning, exposure and aeration of medical products
Emission Points	EP1 Sterilization Chamber Vent • Chamber 1 1212.8 ft^3 usable volume using 43-60 pounds EtO per cycle EP2 Aeration Room Vent • 14 Pallet Aeration Room
Control Devices	Advanced Air Technologies SN021126 Acid Gas Scrubber • SCV EP1 Controlled by scrubber • Liquor is 10% H_2SO_4/40% Ethylene Glycol • Liquor pH is monitored and was 0.45 at time of testing • Reaction Tank 1 was 72.2" at time of testing • Reaction Tank 2 was 17.0" at time of testing Advanced Air Technologies Safe Cell II Model DR-490A • ARV EP2 Controlled by Safe Cell • Media is maintained by quarterly M18 ETO sampling • 14 Pallets of product in aeration 60 minutes prior to sampling
Control Efficiency SCV (E1) ARV (E2)	99% removal or less than 1ppm for Subpart O compliance • 2 sample runs during the chamber's simultaneous first evacuations for SCV • Empty chamber with normal maximum EtO loading for SCV test 1 • Chamber with product and normal cycle for SCV test 2

- 3 sixty minute sample runs for ARV after 14 pallets of product in aeration for 60 minutes

Test Methods	40CFR60 Appendix A • Method 1 – Determination of Sampling Locations • Method 2 – Volumetric Flow Rate Determination of Stack Gases • Method 3 – Molecular Weight Determinations of Stack Gases • Method 4 – Determination of Stack Gas Moisture Content (Saturation by Psychometric Chart) • Method 18 – EtO by gas chromatography – integrated bag sample, on-site gas chromatography, flame ionization detector (FID) • Subpart O 40CFR63.365(b) calculations
Test Dates	January 9th and 10th of 2020

Table 1 SCV Subpart O Results

Table 1 – Summary of Results SCV1 Destruction Removal Efficiency Advanced Air Technology Scrubber SN 021126 Customed, Inc. Fajardo, Puerto Rico January 9th, 2020									
Run	Date	Chamber	Mass EtO Charged to Chambers (pounds)	Percent Chamber Gas Evacuated (%)	Scrubber Outlet Gas Volume (dscf)	Scrubber Outlet EtO Concentration (ppm)	Mass of EtO at Scrubber Inlet (pounds)	Mass of EtO at Scrubber Outlet (pounds)	DRE (%)
1	1/9/2020	1	43.0	63.92%	205.0	12.5	27.49	0.00029	99.9989%
2	1/9/2020	1	60.4	63.98%	240.6	16.2	38.64	0.00044	99.9988%
								Average Removal Efficiency	**99.9989%**

Table 2 ARV Subpart O Results

Table 2 - Summary of Results ARV Emissions Advanced Air Technology Dry Bed Scrubber Customed, Inc. Fajardo, Puerto Rico January 9th, 2020				
Run	Date	Start Time	Time End	Outlet Concentration (PPM)
1	1/9/2020	21:03	22:03	0.410
2	1/9/2020	22:07	23:07	0.637
3	1/9-10/2020	23:11	00:11	0.616
			average	**0.555**

2.0 PROCESS DESCRIPTION

Chamber 1 manufactured by Vacudyne is used to sterilize medical products. The chamber was advanced to "sterilant removal" phase to create a worst-case scenario to challenge Customed's AAT scrubber system. The in-chamber sterilization cycle includes pre-conditioning, sterilization and aeration. The typical cycle for sterilization includes four vacuum and nitrogen injection pulses to remove air, injection of clean steam for humidification, ethylene oxide charge, injection of additional nitrogen, three nitrogen washes i.e. evacuations all of which are vented to the Scrubber system. Process run records are available in Attachment F.

The Customed scrubber system provides pollution control with an exothermic reaction between ethylene oxide and sulfuric acid. The scrubber consists of a reaction tank, spray nozzles, demister pad and a packed tower. Scrubber pH, glycol and reaction tank levels were monitored before and after the test program. Scrubber process data was collected by Scrubber and is available in Attachment F.

Sterile product is transferred to the aeration room for the final degassing. The aeration room vent (ARV, EP2) is controlled by an Advanced Air Technologies Safe Cell II dry bed scrubber. The system uses media beads to scrub the ethylene oxide from atmospheric emissions. 14 pallets of product were transferred after the second SCV test cycle. The product was in aeration for sixty minutes prior to starting the emissions tests.

3.0 SCOPE AND OBJECTIVES

The objective of the testing program was to satisfy the EQB permit for ongoing compliance of the existing dry bed ARV scrubber and to determine scrubber performance existing SCV scrubber.

The performance of the scrubber system was determined by testing the sterilization chamber vent. The highest concentration at the abator occurs at the start of the initial evacuation. The test procedures of 40CFR63.365 (b) are suitable to demonstrate the compliance status of the Scrubber. 63.365(b) reads: *"Efficiency at the sterilization chamber vent. The following*

procedures shall be used to determine the efficiency of all types of control devices used to comply with 63.362(c) sterilization chamber standard."

Subpart O was written based on technologies that destroy ETO immediately as it is exhausted from the chamber. With the scrubber system, ETO enters the packed tower and scrubber liquor is sprayed over packing material and circulated through the reaction tans. As per Subpart O, the greatest ETO concentrations are emitted from the first evacuation of the sterilization chambers. Volumetric flow was determined on a minute basis from the beginning of the first evacuation until the completion of the final evacuation. This was between 8 and 11 minutes. Moisture was reported as saturated at the Scrubber balance outlet temperature.

EPA test methods strive to demonstrate performance under a worst case scenario. The facility operated at normal maximum loading for the performance test. Customed used a cycle with no product in the chamber and sampling only pre-aeration cycle phases are the most conservative in terms of loading as there is no product mass or product packaging to retain ETO. This results in more ETO coming from the first purge cycle as compared to a cycle with product present. The second SCV test was performed with product in the chamber. This condition yielded very similar results and allowed Customed to continue commercial operations during testing.

4.0 FIELD TESTING PROGRAM

4.1 Testing Location and Traverse Points

Sampling for the SCV was conducted at the outlet of the scrubber. The location was accessed via manlift and crane. One port was used, single point traverse was used. The nature of the process does not allow flow except for chamber releases. Timing of the processes did not allow for a traverse or cyclonic flow check determination. The stack inside geometry was determined for Method 1 compliant single point sampling locations. This point of average velocity was used for flow determinations during each sampling run. This data is available in Attachments E.

Sampling for the ARV was conducted at the outlet of the AAT dry bed scrubber. Only concentrations of ethylene oxide were determined and reported at the ARV.

4.2 Testing Summary

Testing was conducted according to the U.S. EPA Federal Register 40 CFR 60 Appendix A. The following procedures were utilized at the SCV scrubber exhaust stack.

Procedures[1]

Method 1:	Sample and Velocity Traverses for Stationary Sources
Method 2:	Determination of Stack Gas Velocity and Volumetric Flow Rate
Method 3:	Determination of Stack Gas Molecular Weight
Method 18:	Volatile Organic Compounds by Gas Chromatography

Two test runs were performed for each emission parameter. Some emission parameters where possible, were determined concurrently. All test runs include concurrent gas flow rate determinations by EPA Methods 1, 2, and 3. Regarding Method 3 sampling, the option to use the molecular weight of 30.00 for test parameters as the chamber atmosphere is essentially ambient air heated with steam was used.

Gas flow rate determined by EPA Methods 1, 2, and 3 concurrently with emissions sampling were used to calculate lb/hr emission rates. This information available in Attachment E.

The average of the two test runs were compared to the allowable emission limits to determine compliance.

Detailed descriptions of the sampling trains, analyzers, and procedures are provided in Section 4.4.

Equations that will be used for test calculations are presented in Attachment A.

[1]Source: U.S. EPA, *Federal Register*, Title 40 Part 60, Appendix A

4.3 PROCESS OPERATIONS AND EMISSION TESTING

During each sample run the following process data were confirmed

1. Scrubber pH, Glycol Percentage and Reaction Tank Level
2. Amount of Ethylene Oxide Charged
3. Sterilization Cycle Parameters
4. Sterilization Chamber Conditions

This information is available in Attachments F and G.

4.4 SAMPLING PROCEDURES

The following sections provide descriptions of sampling procedures and the sampling trains that were used for emissions testing.

4.4.1 Gas Flow and Temperature Measurements

Gas Flow Measurement were made with Standard Pitot (velocity) tube connected to an inclined manometer and digital pressure transducers. The static pressure was measured using the same Pitot tube and manometer. A Chrome-Alumel thermocouple attached to a digital indicator was used to measure the gas temperature at each traverse point.

This information can be found in Attachment E.

4.4.2 Oxygen and Carbon Dioxide Emission Concentration Determinations

Oxygen (O_2) and carbon dioxide (CO_2) emission concentrations could be determined by EPA Method 3 *Determination of Oxygen and Carbon Dioxide Concentrations in Emissions from Stationary Sources*. Oxygen and CO_2 emission concentrations were used primarily for the determination of gas molecular weight required for gas flow rate calculations. For this reason, we did not perform any actual molecular weight determinations and Method 3 was used to assign a molecular weight of 30.00, which is thought to be appropriate as this is essentially thermoelectrically heated air. Molecular weight will be the same at the inlet and the outlet and thus cancel each other out for destruction efficiency calculations.

4.4.3 Determination of Ethylene Oxide Emissions

Procedures outlined in 40 CFR 60 Methods 18 and Subpart O 40CFR63.365 (b) calculations will be used to determine Ethylene Oxide emission concentrations, and are discussed as follows:

SCV ETO samples were collected and analyzed using the Integrated Bag Sampling and analysis procedure of Method 18 section 8.2.1.1. An un-heated Teflon sample line and stainless-steel sample probe was placed in the scrubber outlet stack connecting to a Teflon line to a 100% Teflon (new sample bags were employed for each sample) sample bag inside a rigid stainless steel evacuated canister. A sample rate of approximately .25 liters per minute was established and the sampling system was purged without a bag in line for as long as possible prior to sampling. A bag was installed immediately prior to sampling and the sample was collected by evacuated canister technique over the duration of the entire first evacuation of the four chambers used for testing purposes.

ARV ETO were collected using the direct interface procedure of Method 18. A Teflon sample line was connected to a Teflon pump to extract a sample from ARV AAT outlet at approximately 20LPM. A slip stream of .25LPM was introduced to the GC sampling valve for continuous integrated sampling. Three sample runs of sixty minutes each and 14 to 16 three minute chromatograms were performed. Prior to sampling a direct interface recovery study was performed, available in table 4. After both SCV and ARV sampling a calibration drift assessment was performed available in table 3.

4.5 SAMPLE ANALYSES

All samples were analyzed onsite by L. Christopher Heilner of LCH operating a GC FID. All QA/QC measures inherit to the analyzer and the methodology were followed.

4.5.1 GC Description

Samples were analyzed by gas chromatography using an SRI 8610C gas chromatograph with dual column, dual detector (PID and FID) with heated sample loops, injectors and 3 meter packed columns. Gas in the sample loop was injected directly into the GC's analytical columns

by the gas sampling valve. The GC was operated with carrier gas flow of 18 ml/minute and column temperature of 130˚C. The carrier gas was ultra-high purity helium. Hydrogen and air were used to maintain the FID. ETO eluted at approximate 0.8-0.9 minutes.

4.5.2 Calibration Standards

Three cylinders of calibration standard, ETO in nitrogen, in concentrations of 1000.0, 100, 10 and 1 ppm were used to create an FID calibration curve to calculate ETO concentration in ppm given instrument response in millivolts. Calibration standards were analyzed in triplicate and the average value of the samples will be calculated. An analytical result was considered valid if its value is within 5% of the average value. Calibration curves are found in Attachment B. Calibration standard certificates are found in Attachment H.

A calibration curve was generated using Microsoft Excel chart function by constructing a linear XY-Scatter graph that solves the quadratic equation of the line Y=mX+b where "y" is the calculated concentration of EtO, "x" is the instrument response, "m" is the constant and "b" is the y-coordinate intercept. The option forcing the graph through zero was enabled so "b" = zero. The least squared R^2 value and the equation of the line was shown. An R^2 value of 95% is acceptable according to Method 18. The gas chromatograph routinely exceeds the 95% R^2 value. The GC/FID showed a 99.9999+% R^2 value and a 0.1807 and .1847 (ARV) y-value. This information is found on the calibration curve in Attachment B.

4.5.3 Chromatograms

The chromatogram log sheet is a Microsoft Excel spreadsheet that transposes run information in an easy to read format and provides the calculating capabilities to assess the QA/QC requirements of the method. The chromatograms were logged by the file path directory of the hard drive storage. This information is found in Attachment C.

The chromatograms were automatically printed at the conclusion of each analysis in .pdf format. Each chromatogram includes information identifying the type of analysis, i.e. set up, calibration, sample, recovery study, date and time of analysis, comments, retention time and integrated peak area. The results are in units of millivolts. Field corrections initiated by the operator were not necessary. The chromatograms can be found in Attachment D.

4.5.4 QA/QC Measures

4.5.4.1 Calibration Drift Assessment

The mid-range calibration standard was analyzed at the conclusion of testing and the results were compared to the initial analysis to determine if calibration drift has occurred. A 5% deviation between results is allowable. The SRI gas chromatograph has historically met the 5% criteria. The table below illustrates the results of the calibration drift assessments.

Table 3 Calibration Drift Assessment
Advance Air Technology Acid Gas Scrubber SCV DRE Test
Customed, Inc. Fajardo, Puerto Rico
January 9th, 2020

Date	Unit Tested	Detector	Concentration EtO Standard (ppm)	Initial Response (millivolts)	Final Response (millivolts)	Calibration Drift (%)
9-Jan	SCV	FID	100	561.3	542.4	3.48%
10-Jan	ARV	FID	10	57.2	56.4	1.40%

4.5.4.2 Direct Interface and Teflon Sampling Bag Recovery Study

The sample from the outlet SCV scrubber was used to perform the sample bag recovery study. The sample was spiked with the 100ppm calibration and analyzed immediately following spiking. The sample was allowed to age for 2 hours and reanalyzed to establish the sample stability in the sampling bag. The results were found to be in compliance and are illustrated in the table below.

TABLE 4 - BAG RECOVERY STUDY
AAT Acid Gas Scrubber DRE Test
Customed, Inc. Fajardo, Puerto Rico
January 9th, 2020

Test Date	Test Site	Run No.	Calc. Conc. EtO in Bag "u" (ppm)	Initial Spiked Bag EtO Conc. (ppm)	Conc. of Spike Added to Bag "s" (ppm)	Aged Bag EtO Conc. "t" (ppm)	R Value "R"
1/9/2020	Customed	1	12.46	55.48	43.02	55.67	1.00

$R = (t - u) / s$ R must fall within 0.7 and 1.3

Where:

R = the average fraction recovered

t = bag concentration after being spiked and allowed to "age"

u = bag concentration before being spiked

s = increase in bag concentration

Prior to sampling from the outlet ARV scrubber, a direct interface recovery study was performed. A bag of 10ppm calibration gas introduced at the inlet of the sampling system and analyzed in triplicate to determine the integrity of the sampling system. The results were found to be in compliance and are illustrated in the table below.

Table 5 - Direct Interface Sample Train Recovery Study
Lesni CatOx Performance Test
Boston Scientific, Dorado, Puerto Rico
June 13-14, 2019

Date	Detector	Concentration EtO Standard (ppm)	Instrument Response		Recovery Efficiency (%)
			Cylinder Direct Inject (millivolts)	Direct Interface Sample Train Inject (millivolts)	
9-Jan	FID	10	57.17	57.46	0.50%

ATTACHMENT A

EQUATIONS

Equation 1: Outlet ETO concentrations

$$Wo = (Q * Mol.Wt. * C) / (10^6 * Mol.Vol.)$$

Where:

Wo	**=**	**Mass of EtO released from abator to atmosphere**
Q	**=**	**Total volume of gas at the outlet of the abator (scf)**
Mol.Wt.	**=**	**Molecular Weight of ETO 44.05 (lb/lb-mol)**
C	**=**	**Concentration EtO in sample (ppmv)**
Mol.Vol.	**=**	**Molar volume: 385.32 scf/lb-mol at STP**
10^6	**=**	**Conversation factor for parts per million**

Equation 2: Mass Emission Rates

$$Q = T * (1 – B_{ws}) * V_s * A * ((T_{std} * P_s)/ (T_s * P_{std}))$$

Where:

T	**=**	**Duration of test in minutes**
B_{ws}	**=**	**Water vapor proportion by volume**
V_s	**=**	**Stack gas velocity in feet per second**
A	**=**	**Cross-sectional area of the stack in SQFT**
T_{std}	**=**	**528(˚R) - *standard temperature***
P_s	**=**	**Absolute stack Pressure ("Hg)**
T_s	**=**	**Stack Temperature (˚R)**
P_{std}	**=**	**29.92"Hg - *standard pressure***

Equation 3: Destruction/Removal Efficiency

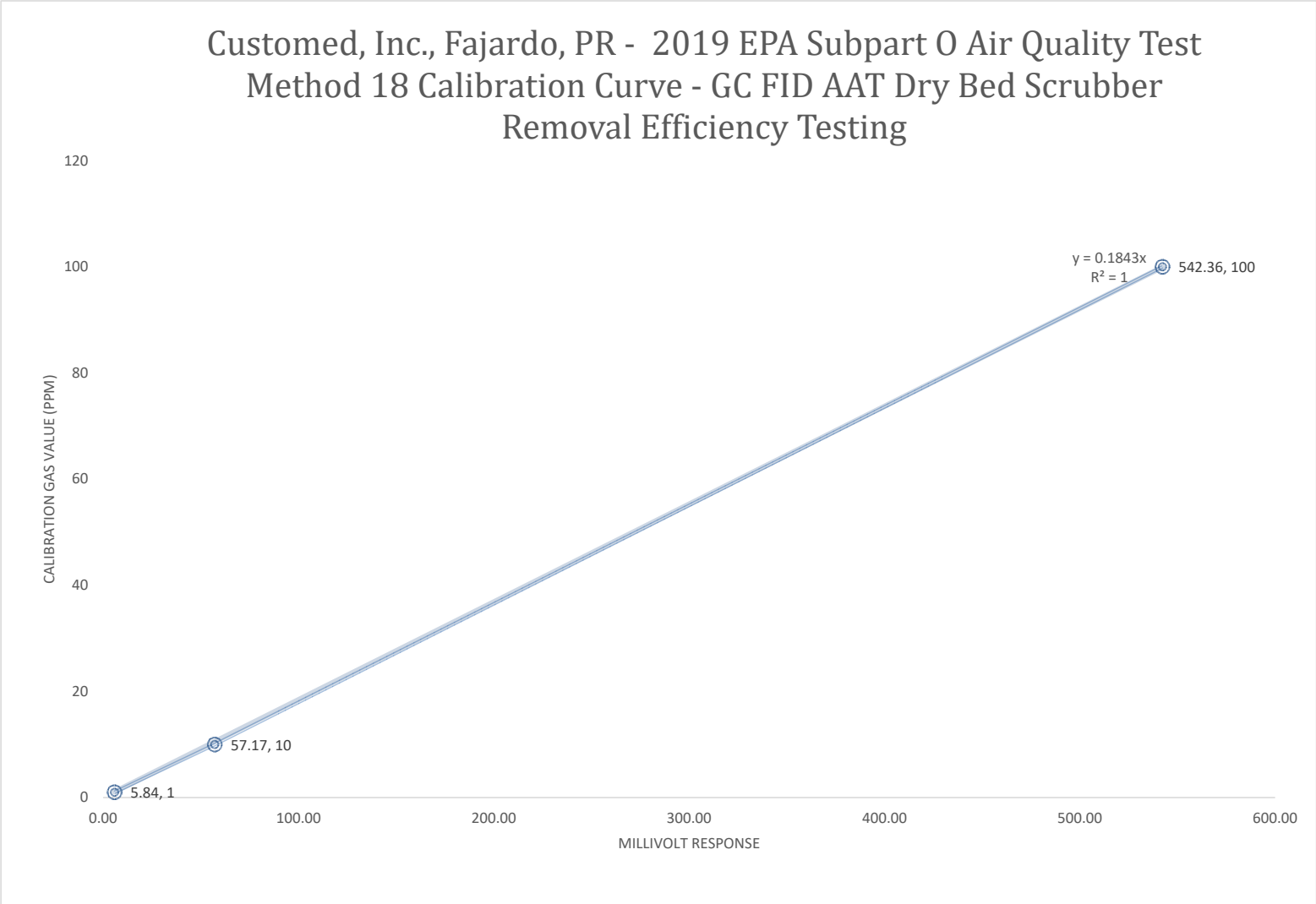
$$DRE = [(W_i – W_o)/W_i] * 100$$

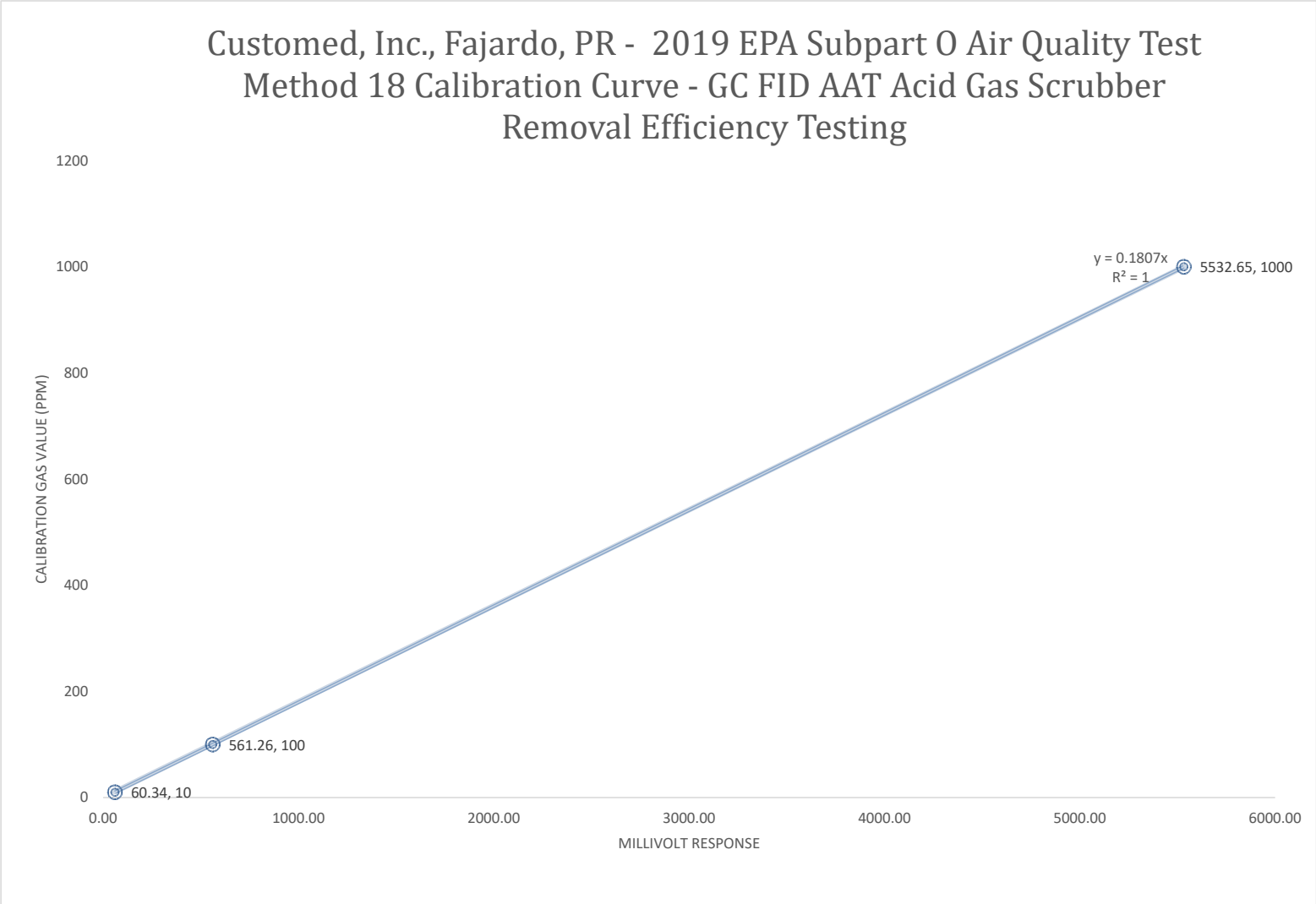
Where:

W_i	**=**	**Mass of EtO at inlet of balance, Subpart O Calculation**
W_o	**=**	**Mass of EtO at outlet of the abator**

ATTACHMENT B

CALIBRATION CURVES


Customed, Inc., Fajardo, PR - 2019 EPA Subpart O Air Quality Test
Method 18 Calibration Curve - GC FID AAT Dry Bed Scrubber
Removal Efficiency Testing
CALIBRATION GAS VALUE (PPM)
MILLIVOLT RESPONSE
y = 0.1843x
R² = 1
542.36, 100
57.17, 10
5.84, 1
0
20
40
60
80
100
120
0.00
100.00
200.00
300.00
400.00
500.00
600.00


Customed, Inc., Fajardo, PR - 2019 EPA Subpart O Air Quality Test Method 18 Calibration Curve - GC FID AAT Acid Gas Scrubber Removal Efficiency Testing
CALIBRATION GAS VALUE (PPM)
MILLIVOLT RESPONSE
y = 0.1807x
R² = 1
5532.65, 1000
561.26, 100
60.34, 10
0
200
400
600
800
1000
1200
0.00
1000.00
2000.00
3000.00
4000.00
5000.00
6000.00

ATTACHMENT C

CHROMATOGRAM LOGSHEET

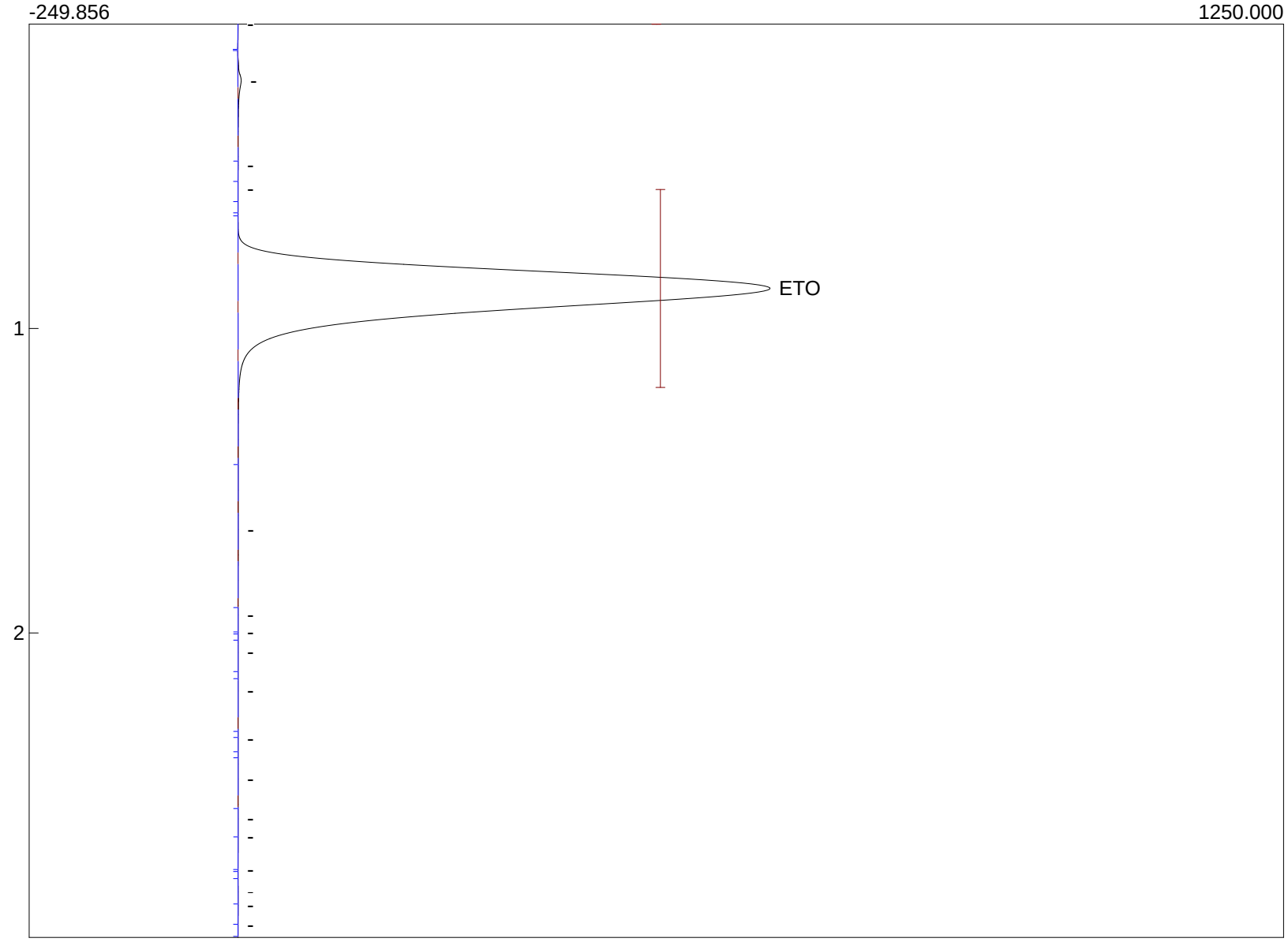
Customed, Inc. Fajardo, Puerto Rico								
Advanced Air Technology Acid Gas Scrubber SCV Subpart O Test								
Chromatogram Logsheet								
Date	fp	type	description	retention time	response	average	score	calc'd conc
01/09/20	840			0.866	5523.8		1.00	
	843	cal	1000ppm Calibration Gas	0.876	5522.2		1.00	
	844			0.863	5552.0	5532.65	1.00	1003.2
01/09/20	859			0.880	563.6		1.00	
	860	cal	100ppm Calibration Gas	0.880	559.9		1.00	
	861			0.883	560.3	561.26	1.00	101.2
01/09/20	873			0.883	60.6		1.00	
	874	cal	10ppm Calibration Gas	0.883	59.9		0.99	
	875			0.886	60.5	60.34	1.00	10.9
01/09/20	881			0.956	68.5		1.00	
	883	Sample	Scrubber Test One	0.960	68.1		0.99	
	884			0.946	68.9	68.54	1.01	12.5
01/09/20	887			0.956	89.7		1.00	
	888	Sample	Scrubber Test Two	0.970	89.5		1.00	
	889			0.956	89.4	89.56	1.00	16.2
01/09/20	891		Recovery Study Initial Scrubber	0.873	306.1		1.00	
	894	QA	Test 1 Bag Sample Spiked with	0.873	306.9		1.00	
	896		100ppm Calibration Gas	0.873	308.2	307.04	1.00	55.5
01/09/20	905		100ppm Calibration Gas	0.883	542.3		1.00	
	906	Cal	Drift Test	0.883	542.0		1.00	
	907			0.873	542.8	542.36	1.00	98.0
01/09/20	928		Recovery Study Final Scrubber	0.863	309.8		1.01	
	929	QA	Test 1 Bag Sample Spiked with	0.863	307.4		1.00	
	930		100ppm Calibration Gas	0.876	307.1	308.08	1.00	55.7

Customed, Inc. Fajardo, Puerto Rico								
Advanced Air TechnologyDry Bed Scrubber ARV Subpart O Test								
Chromatogram Logsheet								
Date	fp	type	description	retention time	response	average	score	calc'd conc
01/09/20	905	cal	100ppm Calibration Gas	0.883	542.3		1.00	
	906			0.883	542.0		1.00	
	907			0.873	542.8	542.36	1.00	99.96
01/09/20	914	cal	10ppm Calibration Gas	0.873	57.2		1.00	
	915			0.873	57.6		1.01	
	916			0.873	56.7	57.17	0.99	10.54
01/09/20	919	cal	1ppm Calibration Gas	0.873	5.9		1.01	
	920			0.866	5.8		0.99	
	921			0.860	5.9	5.84	1.01	1.076
01/09/20	936	cal	10ppm Direct Interface Recovery Study	0.873	56.7		0.99	
	937			0.860	58.0		1.01	
	938			0.873	57.7	57.46	1.00	10.589
01/10/20	1220	cal	10ppm Calibration Drift Test	0.863	56.3		1.00	
	1221			0.863	56.8		1.01	
	1223			0.876	56.0	56.38	0.99	10.4
01/09/20	943	ARV Run 1 01/09/20 2103 to 2203		1.116	0.0245			0.00
	944			1.117	0.0045			0.00
	945			1.106	0.0057			0.00
	946			1.146	0.0108			0.00
	947			1.073	0.0710			0.01
	948			0.000	0.0000			0.00
	949							0.00
	950			0.743	4.7220			0.87
	951			0.740	4.0366			0.74
	952			0.736	4.2074			0.78
	953			0.743	3.9635			0.73
	954			0.736	3.8808			0.72
	955							0.00
	956							0.00
	957			0.753	3.7207			0.69
	958			0.750	4.2847			0.79
					2.226			0.410
01/09/20	959	ARV Run 2 01/09/20 2207 to 2307		0.740	3.6765			0.68
	960			0.743	3.5402			0.65
	961			0.743	3.5765			0.66
	962			0.743	3.3196			0.61
	963							0.00
	964			0.743	3.2937			0.61
	965			0.753	3.6320			0.67
	966			0.756	4.0763			0.75
	967			0.753	3.9118			0.72
	968			0.753	3.2680			0.60
	969			0.740	3.8742			0.71
	970			0.746	3.3550			0.62
	971			0.740	3.1113			0.57
	972			0.740	3.0844			0.57
	973			0.740	3.0844			0.57
	974			0.740	3.0760			0.57
					3.459			0.637
01/09/20	975	ARV Run 3 01/09/20 2311 to 0011		0.743	3.7324			0.69
	976			0.743	2.7842			0.51
	977			0.753	2.9044			0.54
	978			0.753	2.8986			0.53
	979			0.750	3.4024			0.63
	980			0.753	3.3888			0.62
	981			0.740	3.4320			0.63
	982			0.740	4.5250			0.83
	983			0.740	3.3899			0.62
	984			0.736	3.3160			0.61
	985			0.736	3.4900			0.64
	986			0.753	3.8158			0.70
	987			0.750	3.0318			0.56
01/10/20	988			0.750	3.1634			0.58
	989			0.753	3.1552			0.58
	990			0.753	3.0843			0.57
					3.345			0.616

ATTACHMENT D

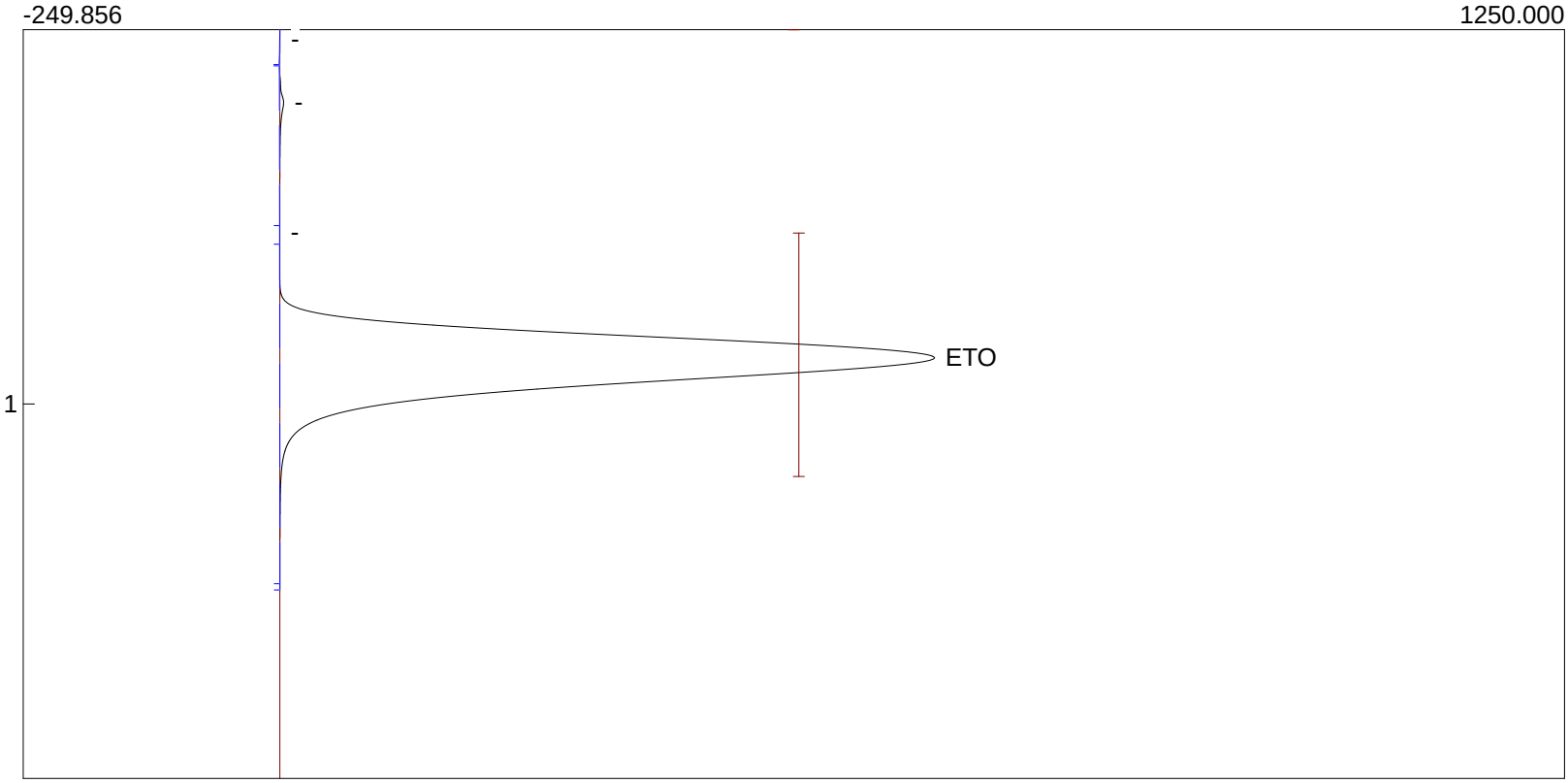
CHROMATOGRAMS

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 07:20:52
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_840. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 1000ppm Calibration gas



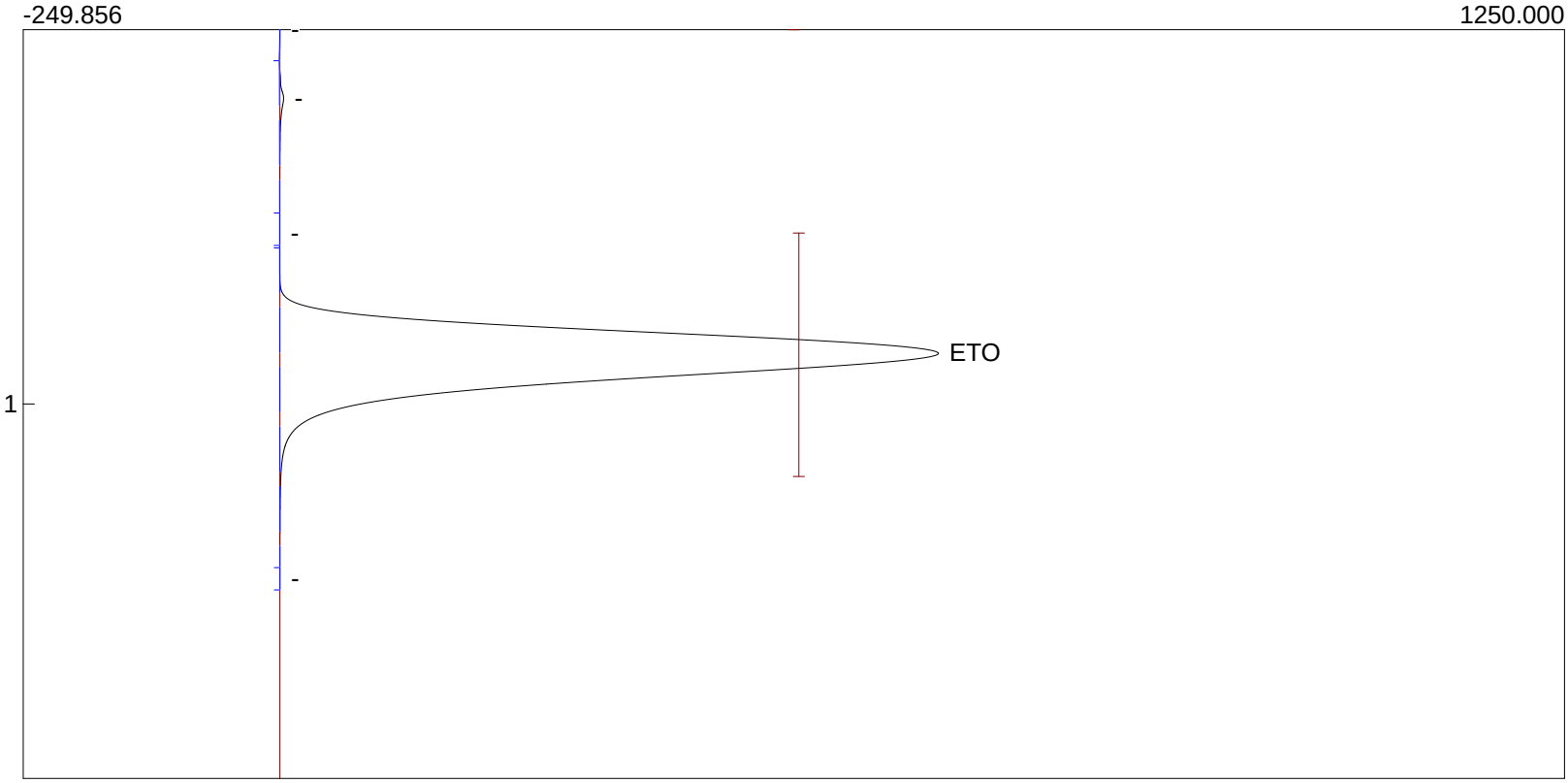
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.866	5523.7774
1			5523.7774

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 07:28:28
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_843. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 1000ppm Calibration gas



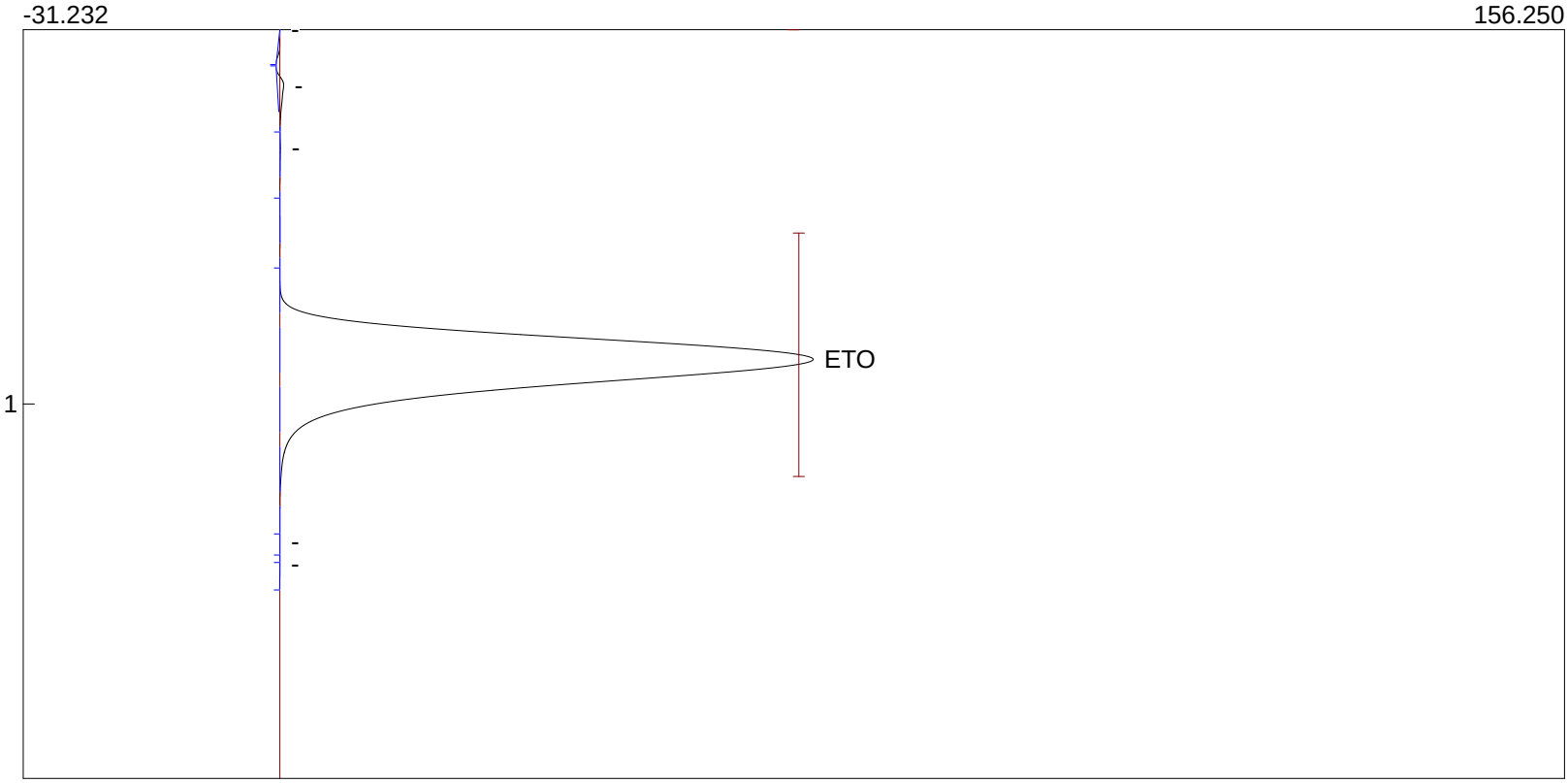
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.876	5522.1816
1			5522.1816

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 07:30:05
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_844. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 1000ppm Calibration gas



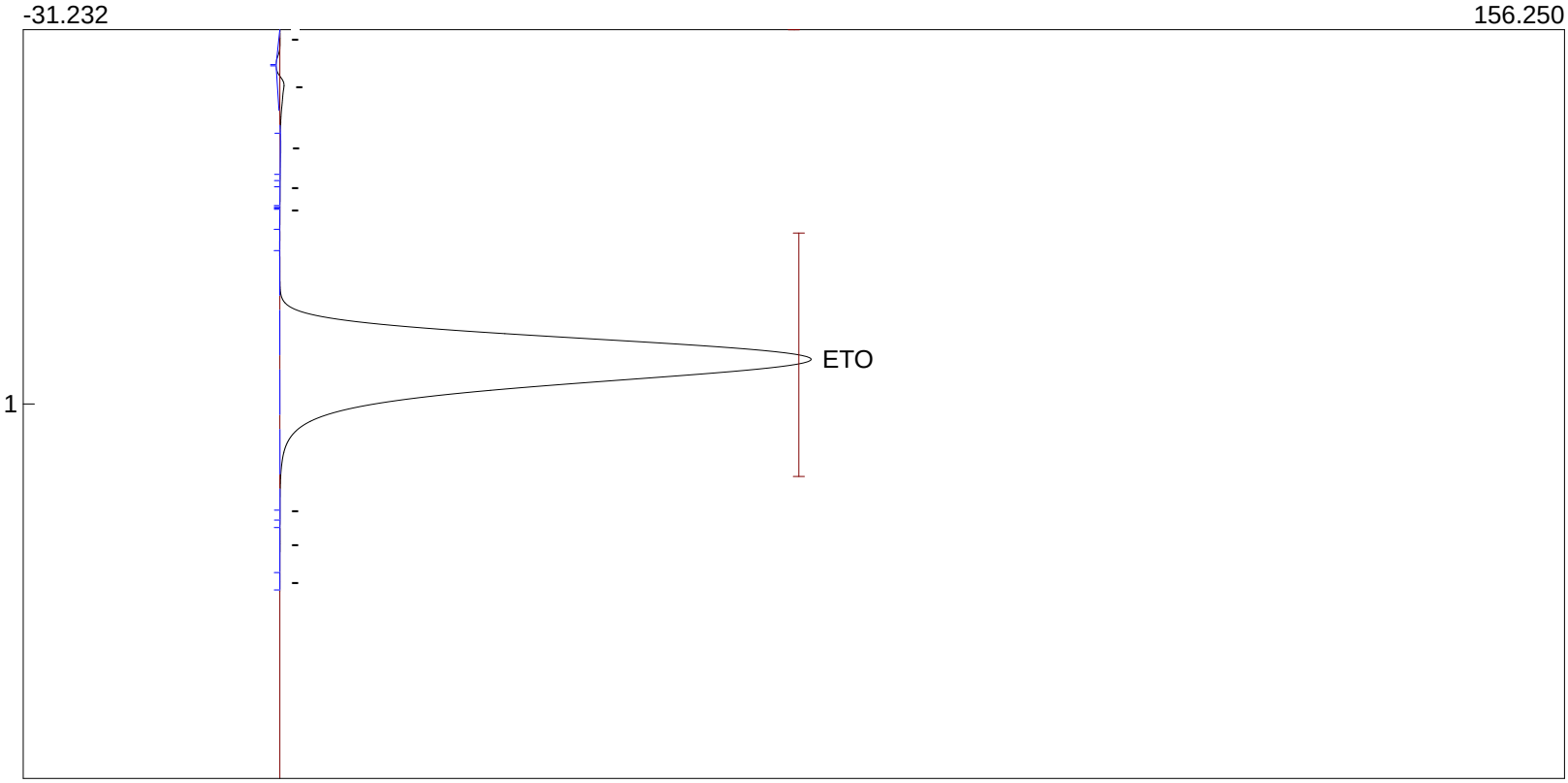
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	5551.9872
1			5551.9872

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 07:57:09
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_859. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 100ppm Calibration gas



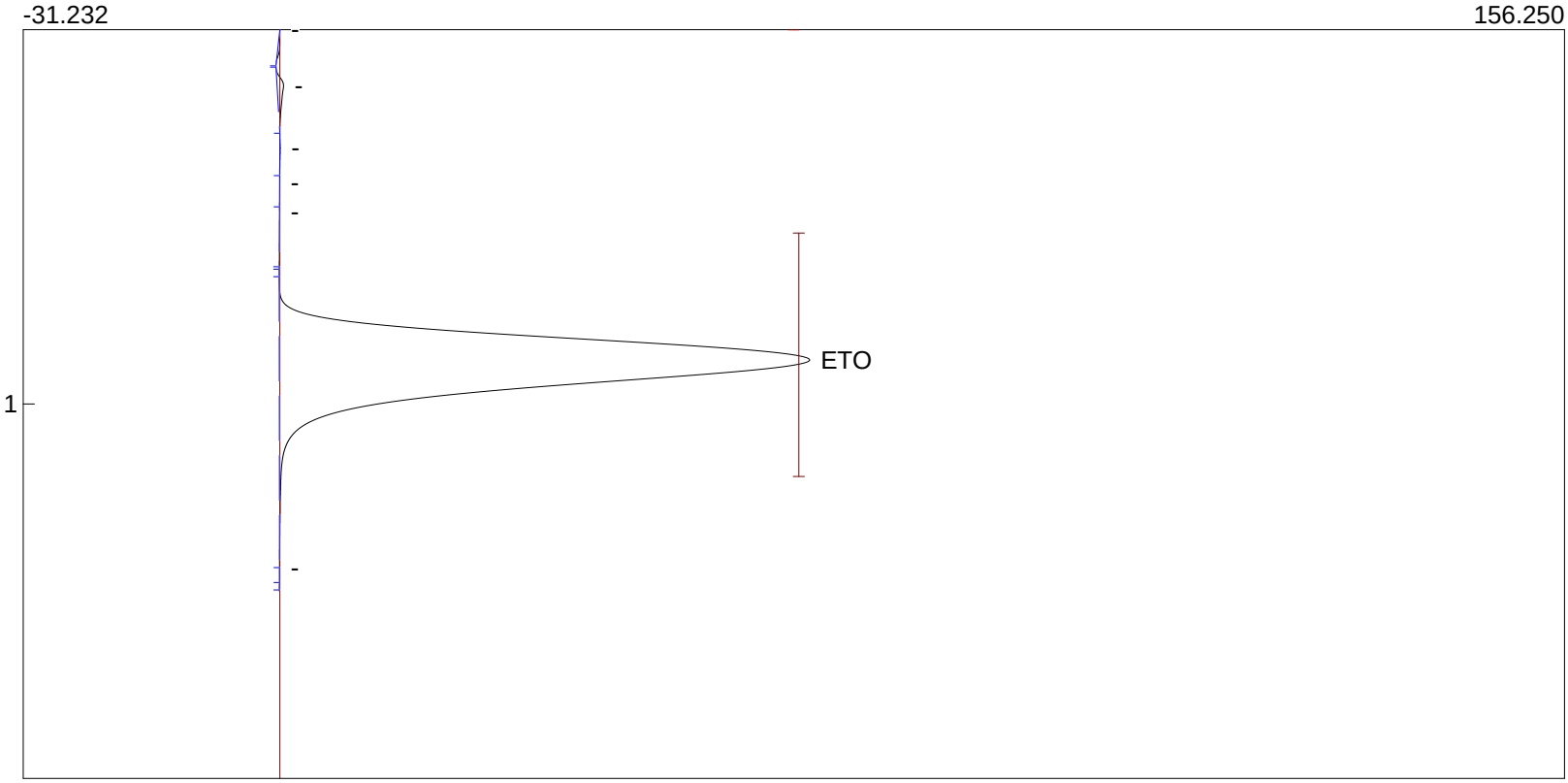
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.880	563.6214
1			563.6214

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 07:58:45
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_860. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 100ppm Calibration gas



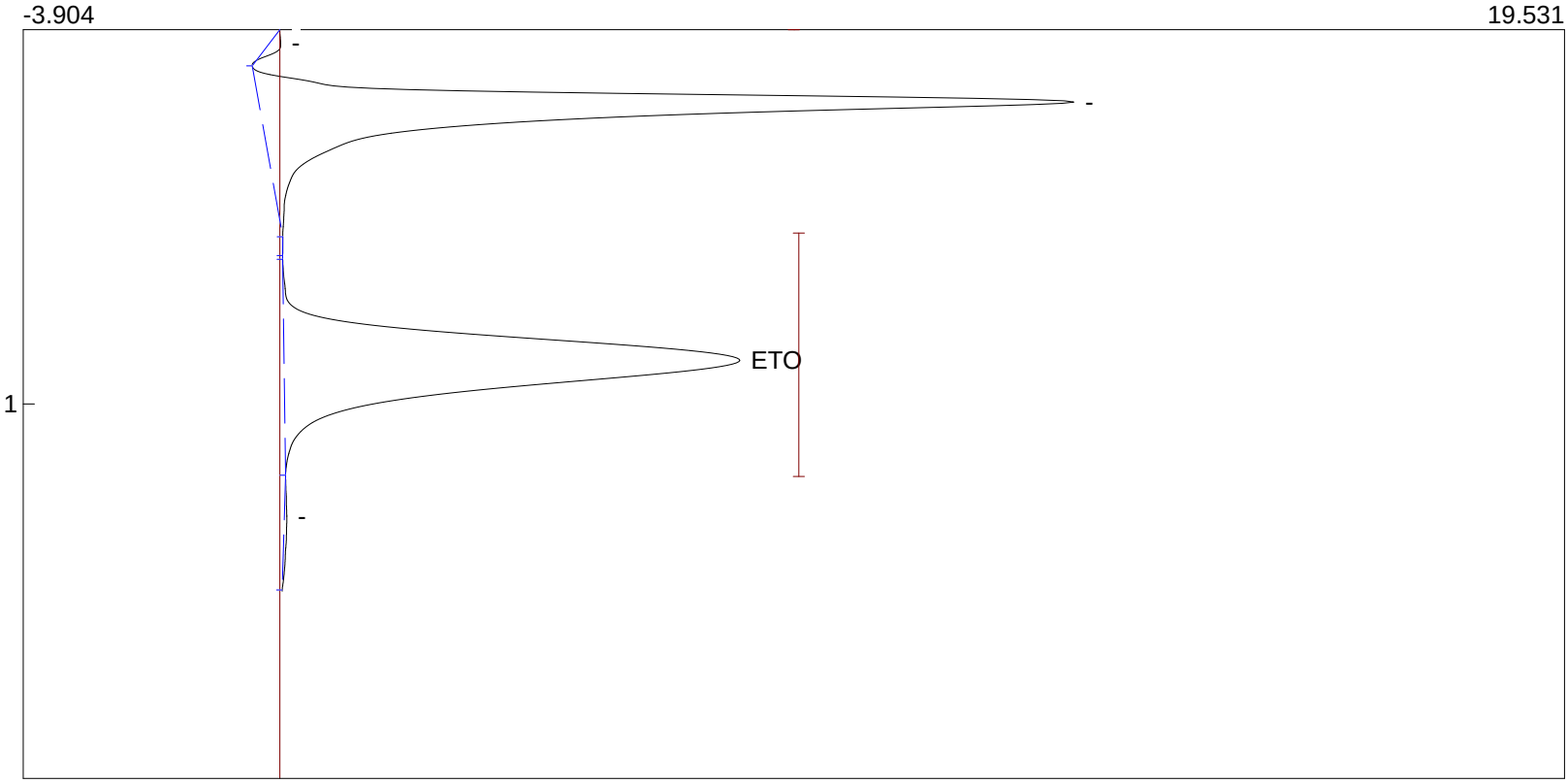
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.880	559.8958
1			559.8958

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:00:32
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_861. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 100ppm Calibration gas



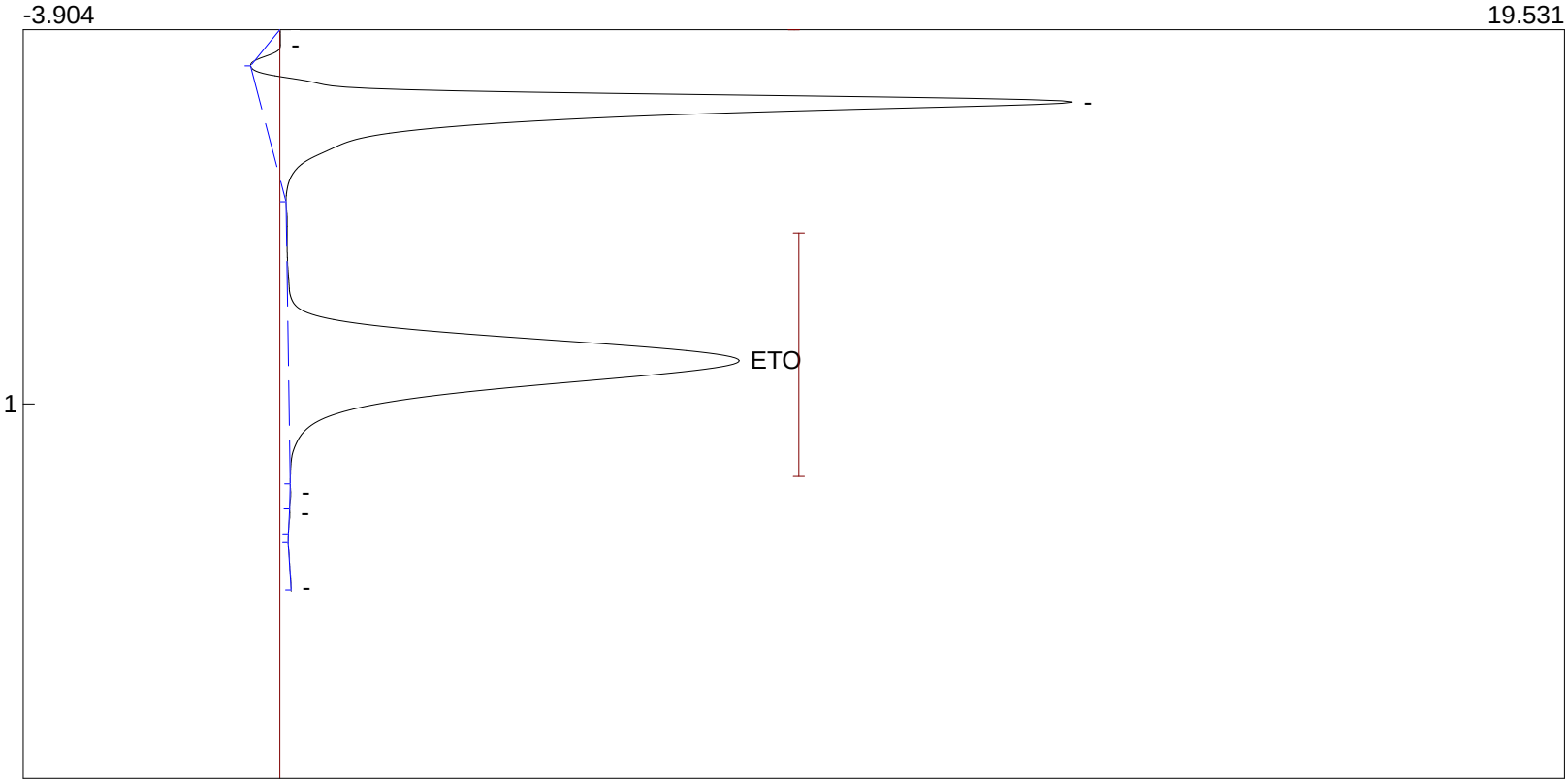
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	560.2599
1			560.2599

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:23:44
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_873. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10ppm Calibration gas



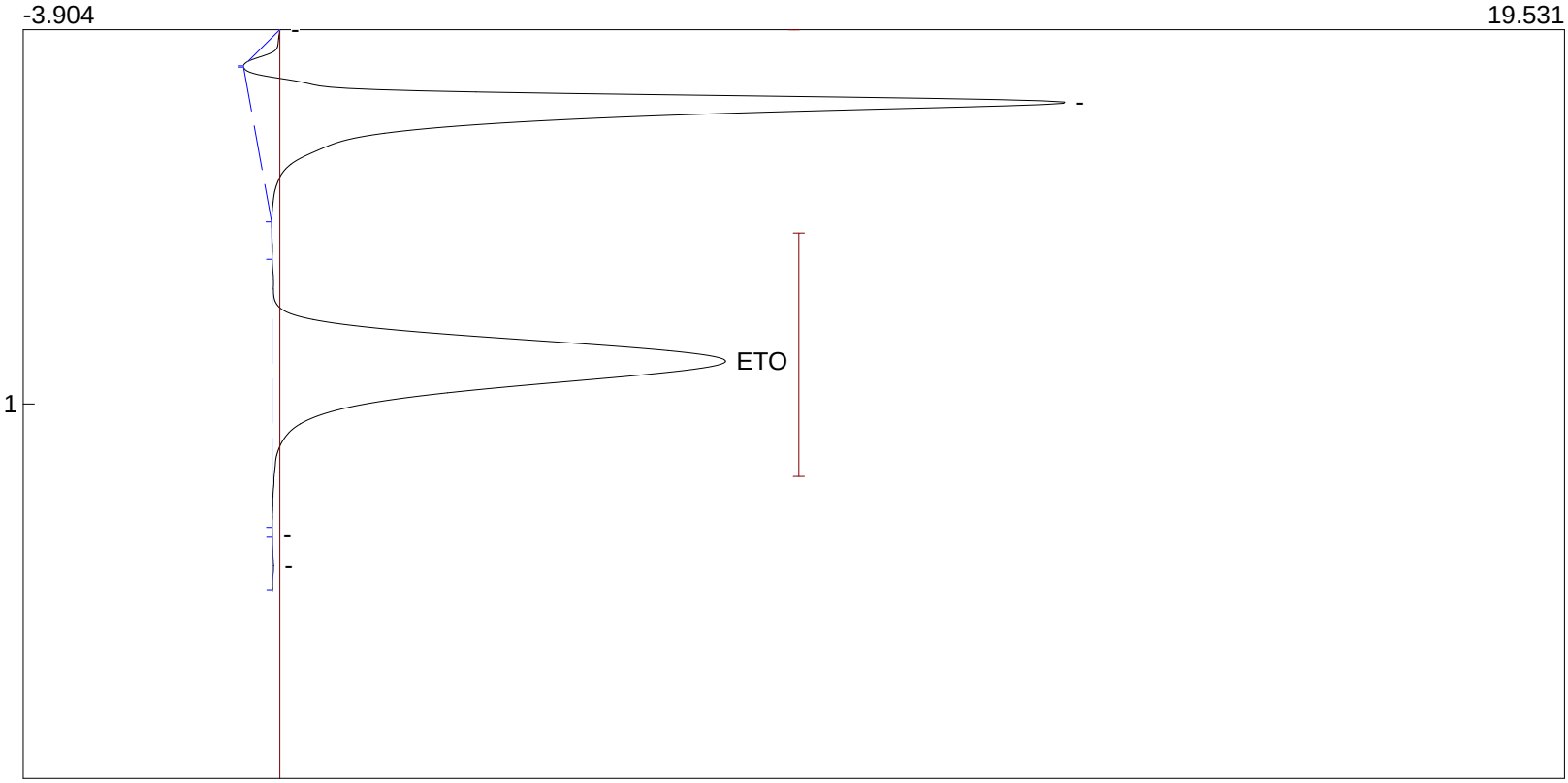
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	60.6194
1			60.6194

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:25:17
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_874. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10ppm Calibration gas



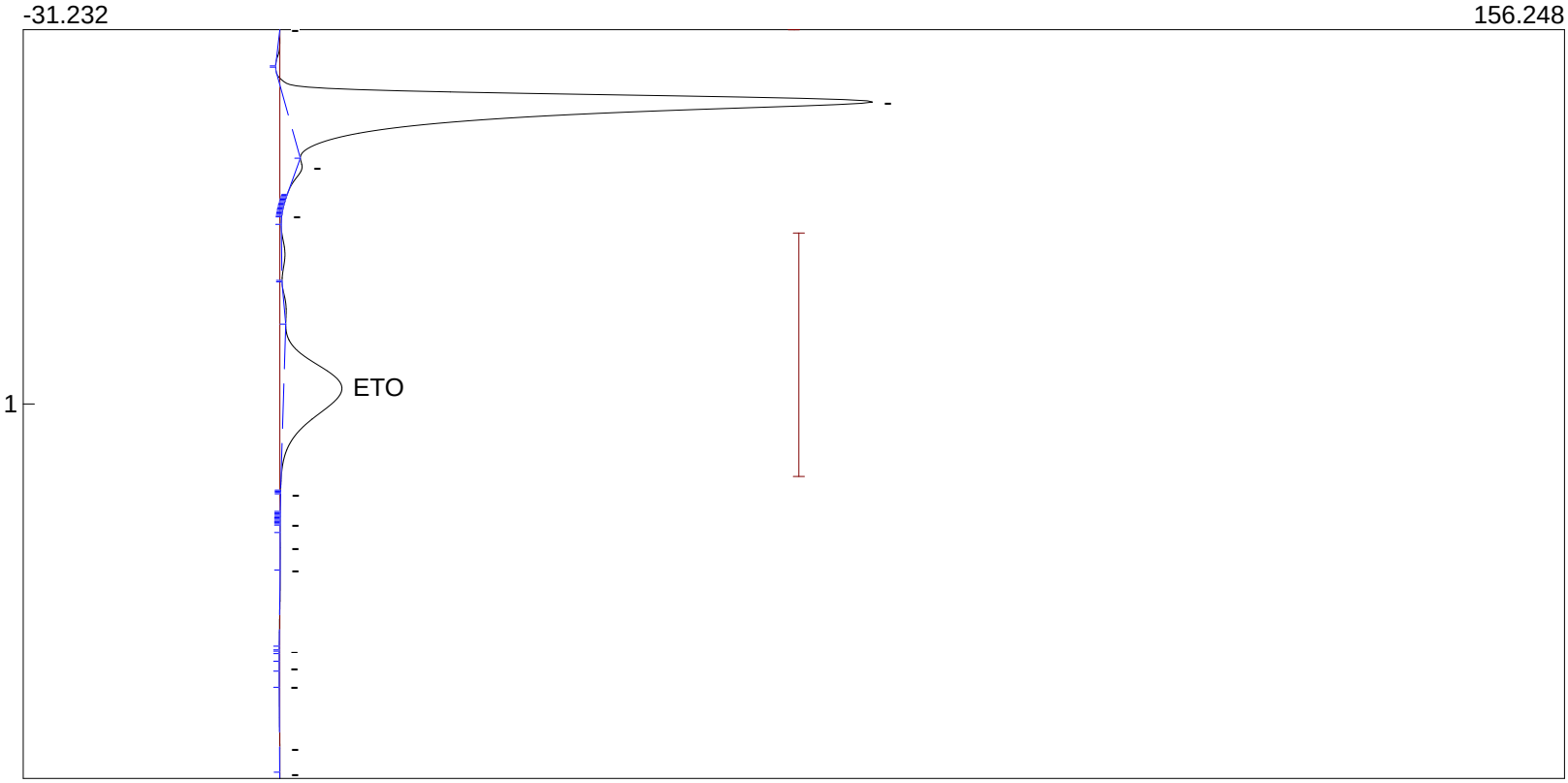
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	59.9244
1			59.9244

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:26:55
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_875. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10ppm Calibration gas



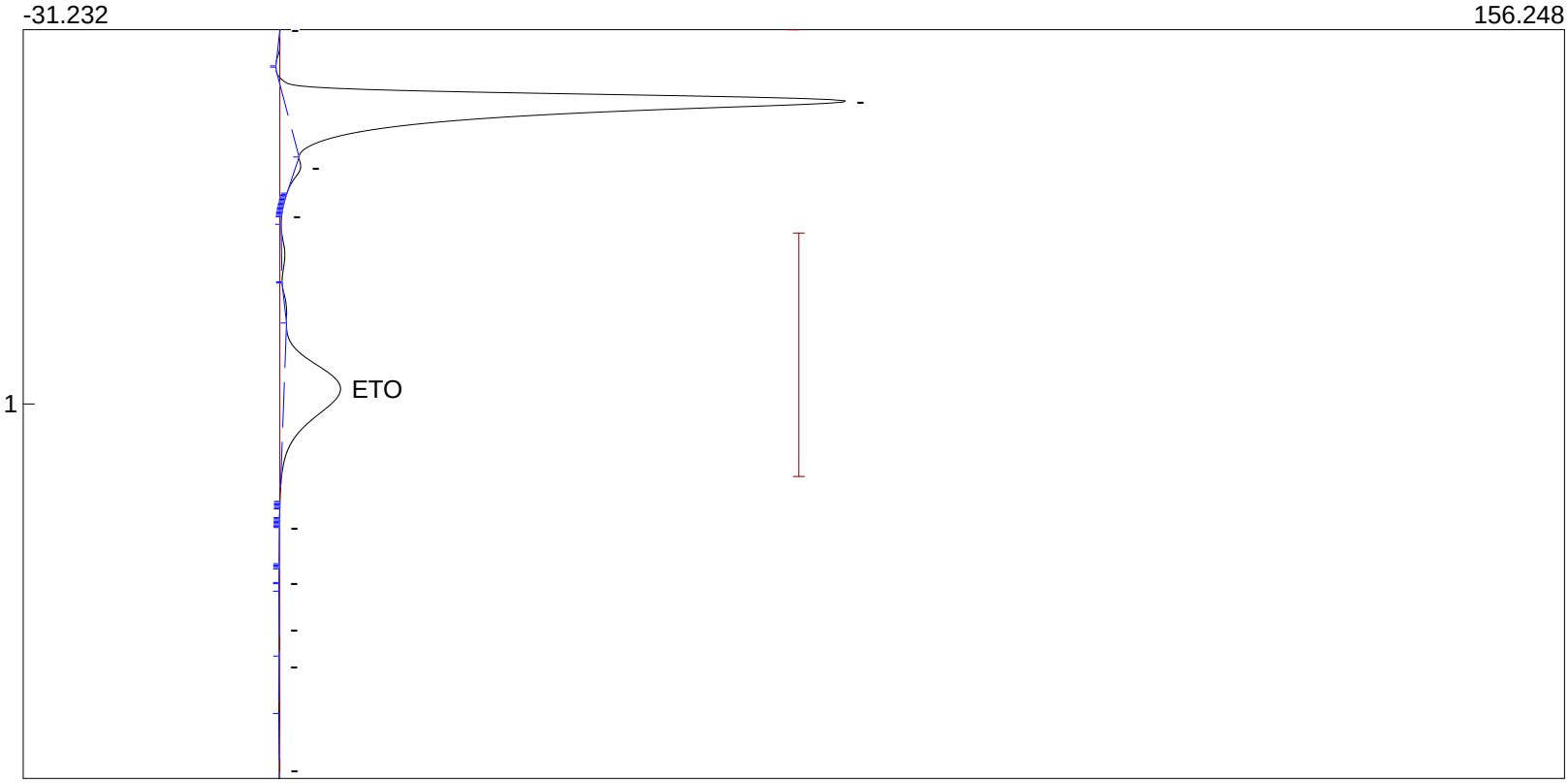
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.886	60.4624
1			60.4624

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:45:50
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_881. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 1



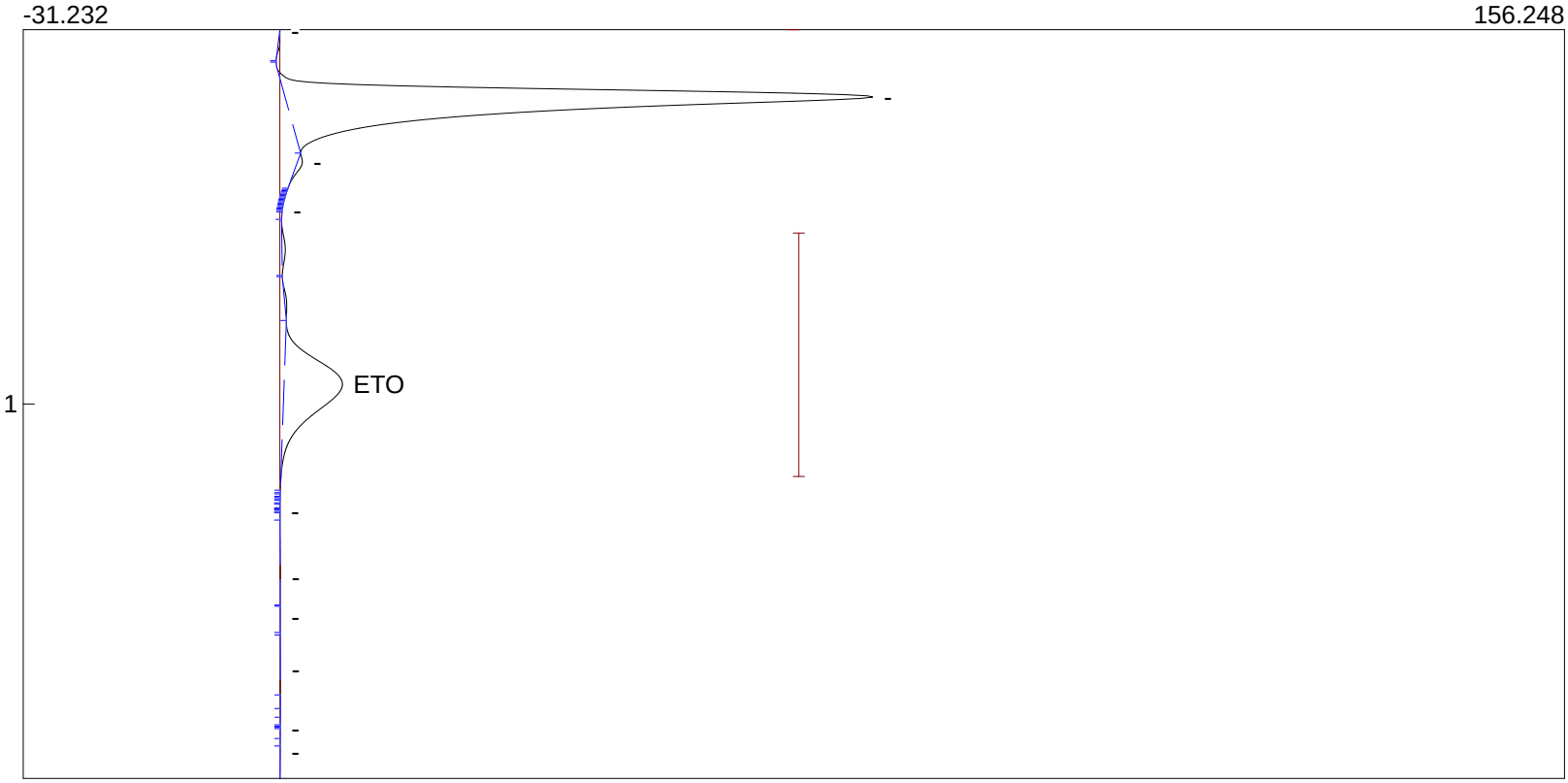
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.956	68.5463
1			68.5463

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:52:54
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_883. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 1



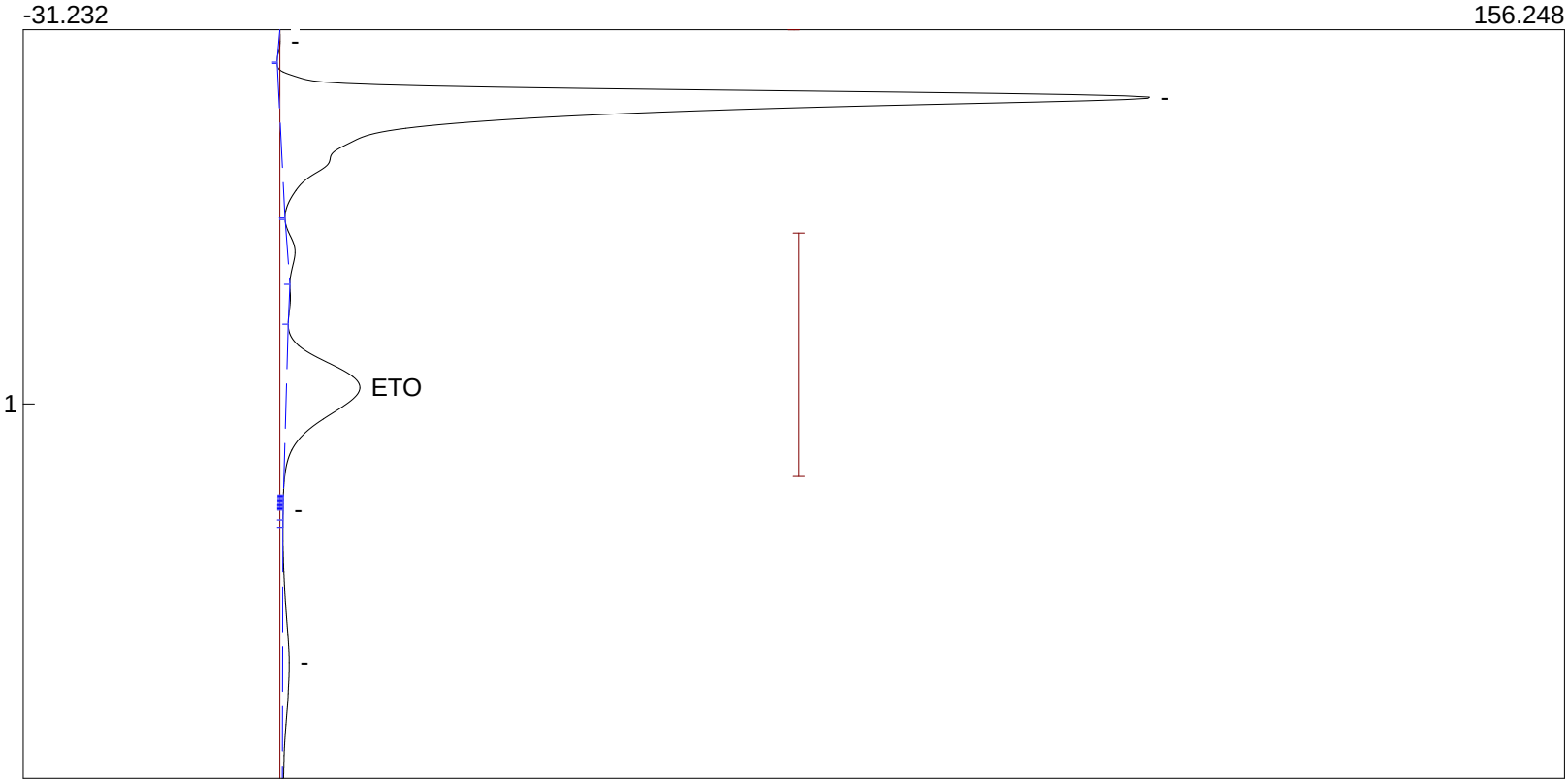
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.960	68.1342
1			68.1342

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 08:56:42
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_884. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 1



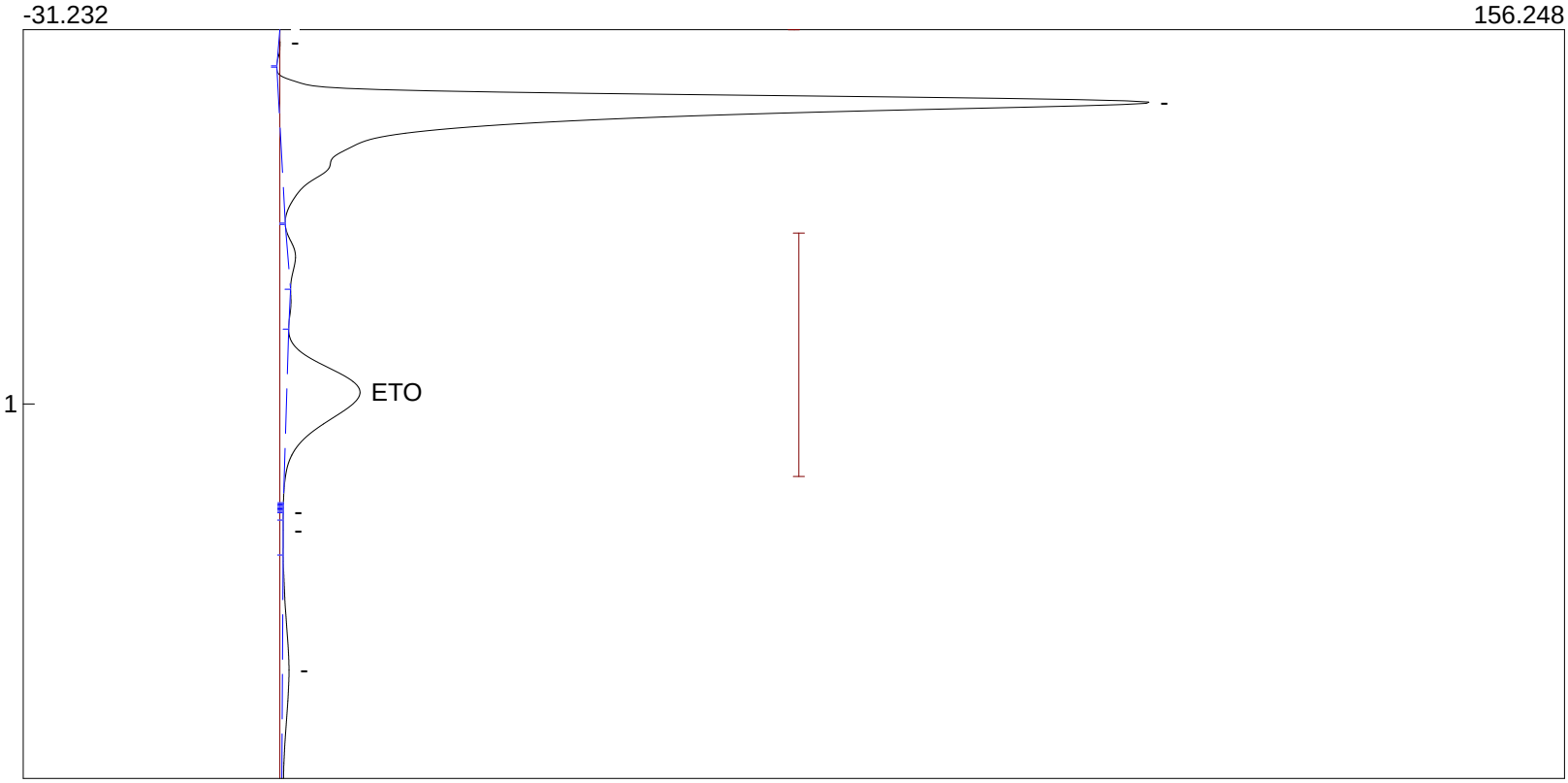
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.946	68.9414
1			68.9414

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 16:24:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_887. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 2



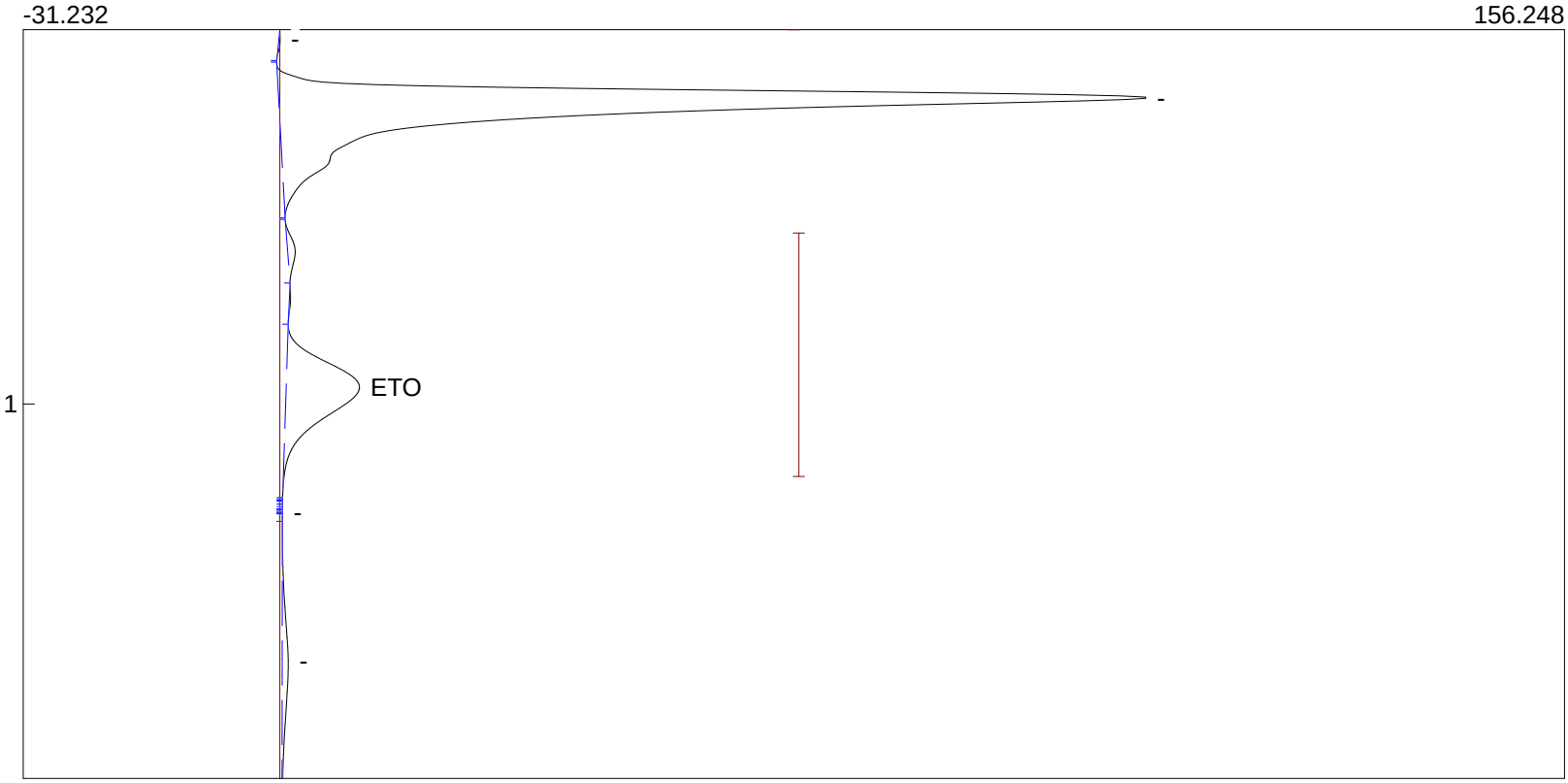
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.956	89.7374
1			89.7374

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 16:28:02
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_888. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 2



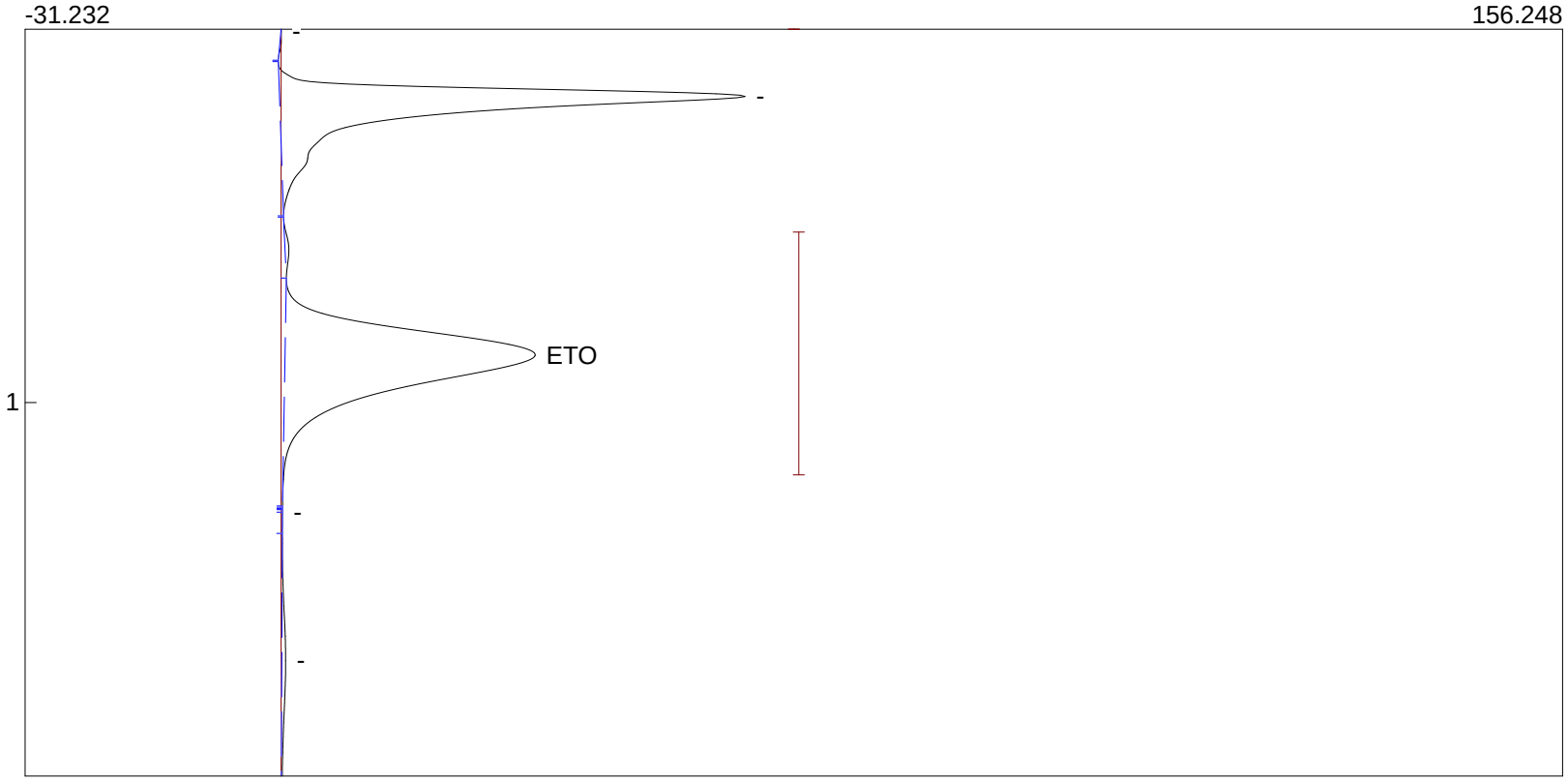
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.970	89.5103
1			89.5103

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 16:31:32
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_889. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 2



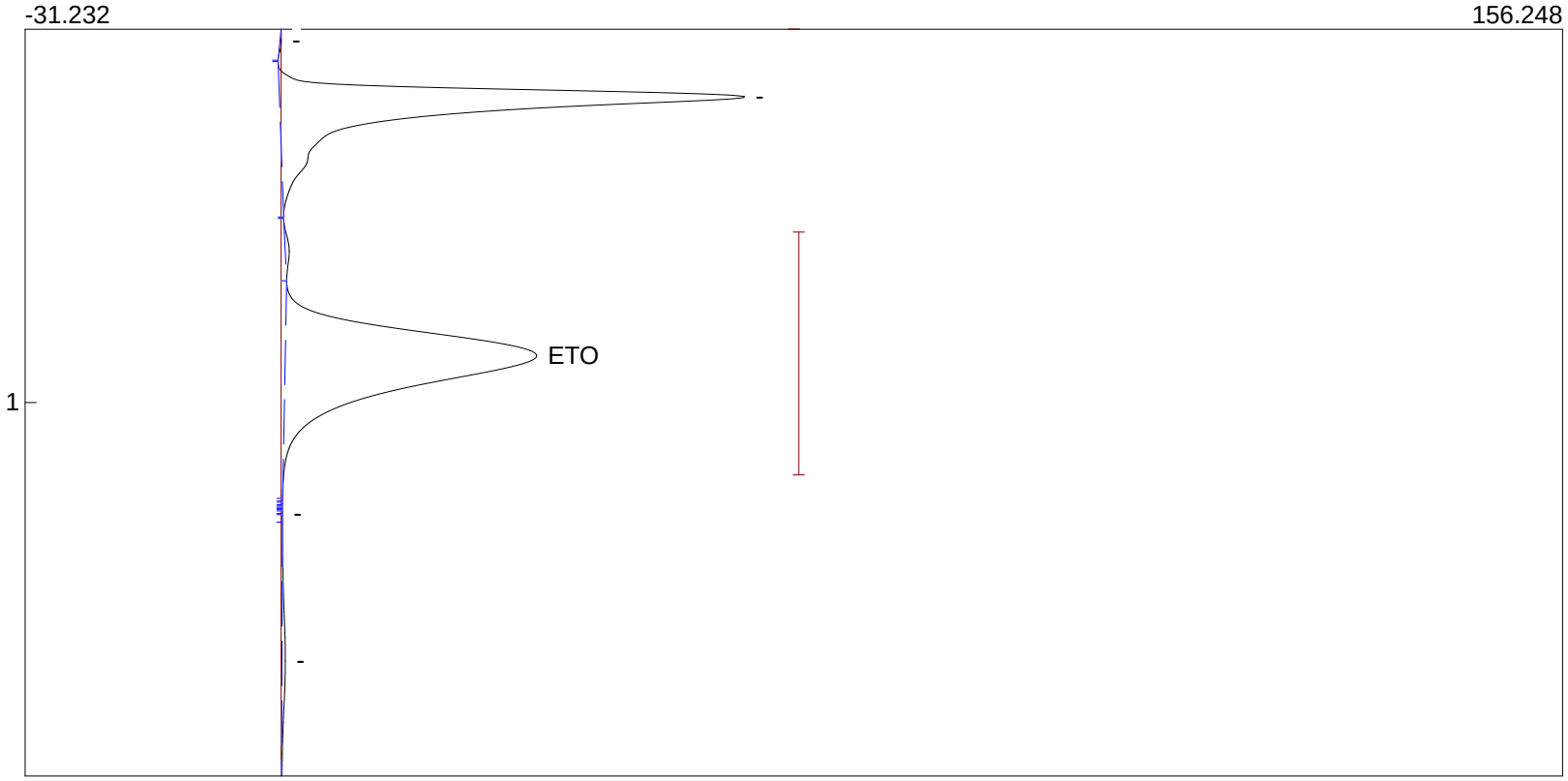
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.956	89.4434
1			89.4434

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 16:43:10
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_891. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 2
Recovery Study Initial



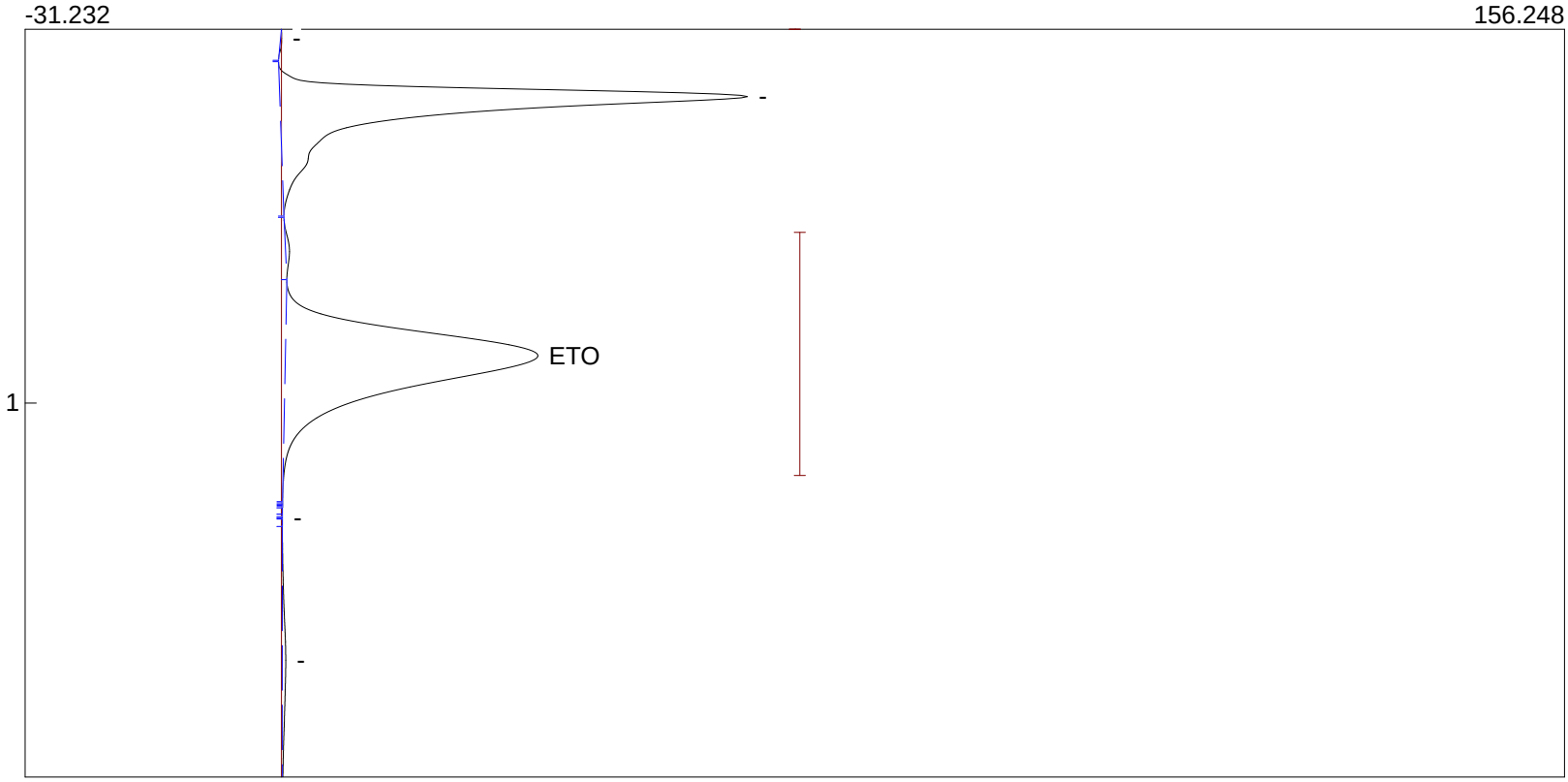
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	306.0619
1			306.0619

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 16:54:17
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_894. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 2
Recovery Study Initial



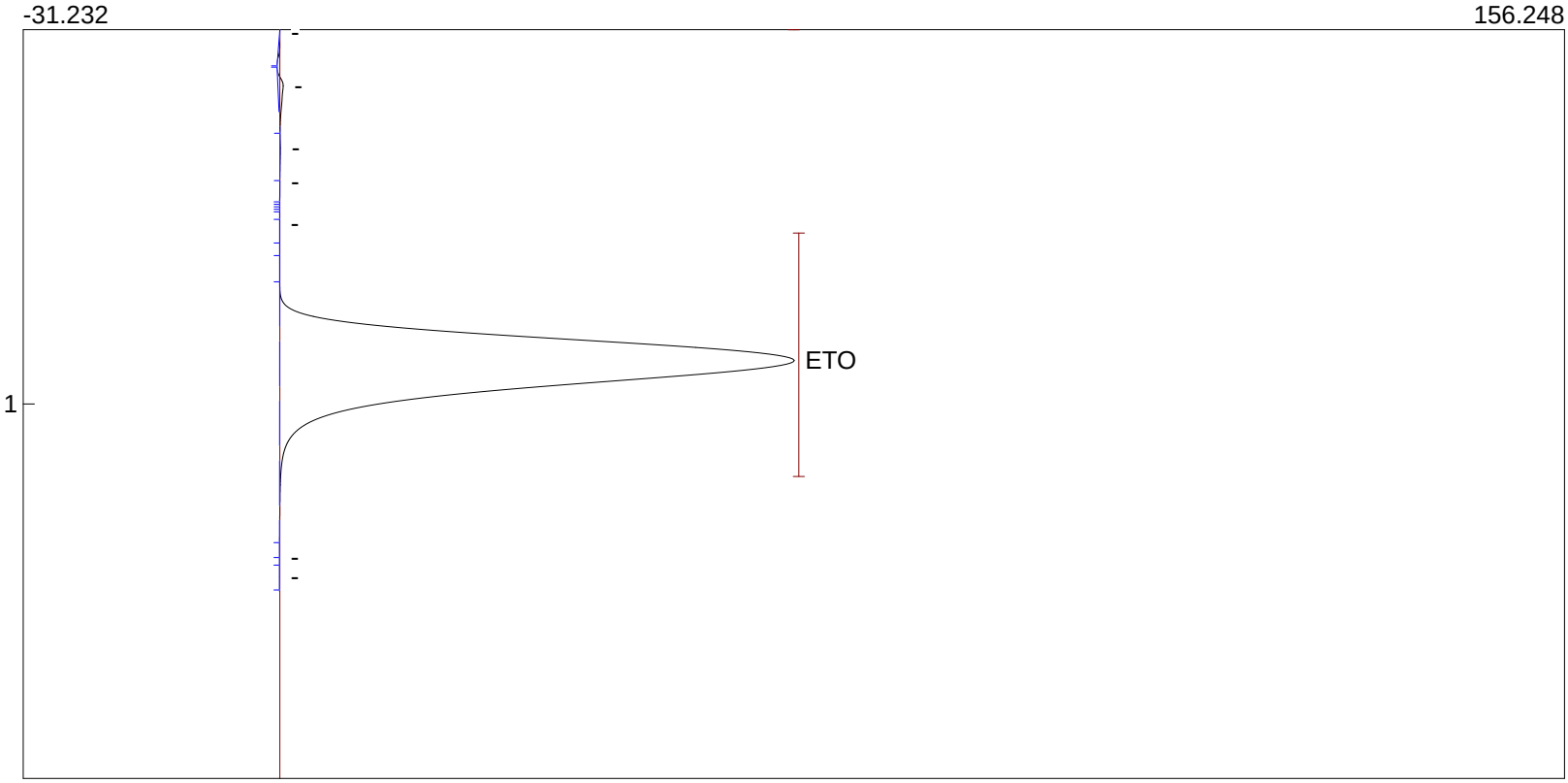
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	306.8794
1			306.8794

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:01:15
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_896. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Scrubber Test 2
Recovery Study Initial



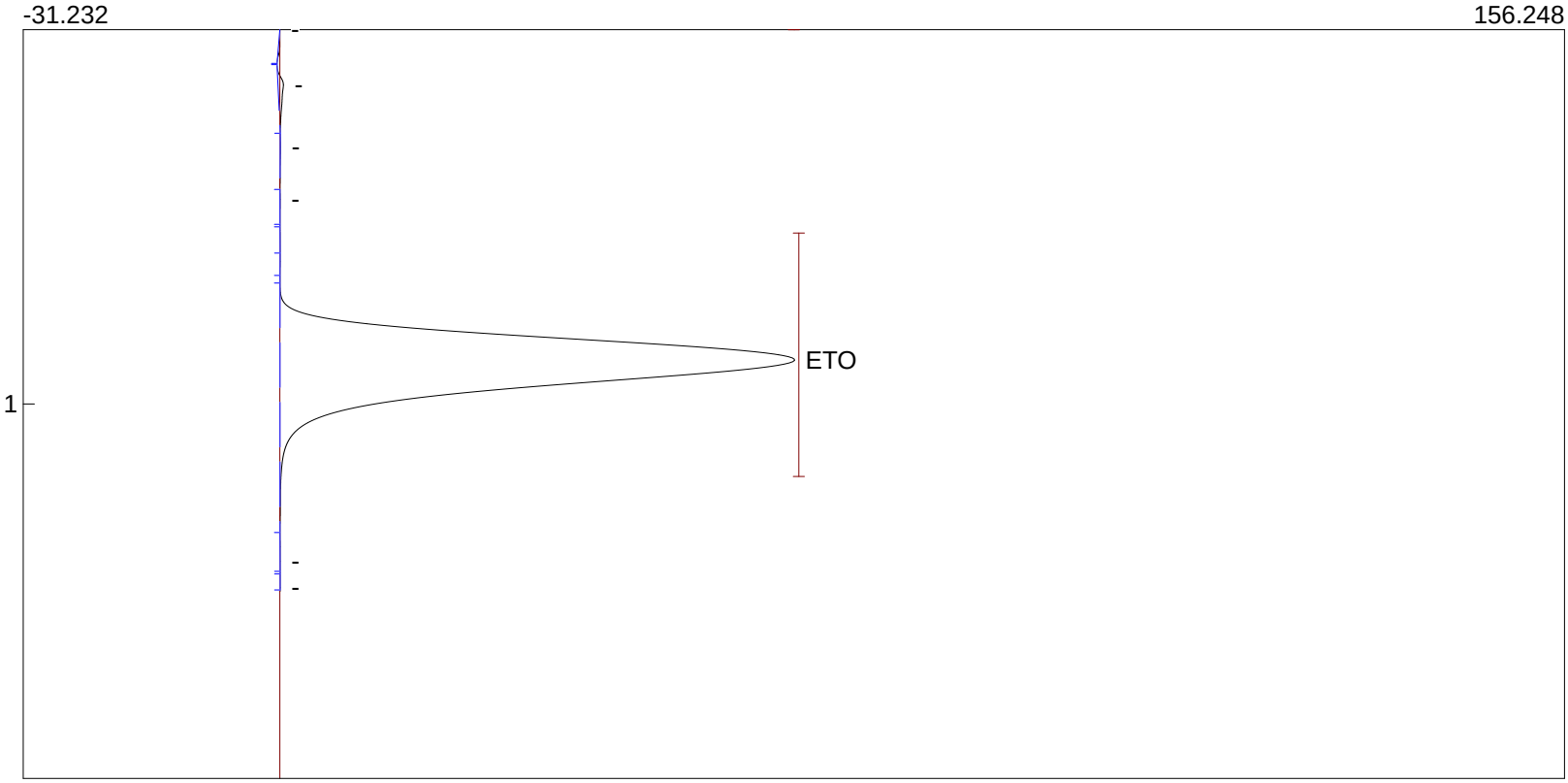
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	308.1706
1			308.1706

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:22:01
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_905. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 100ppm Cal Gas



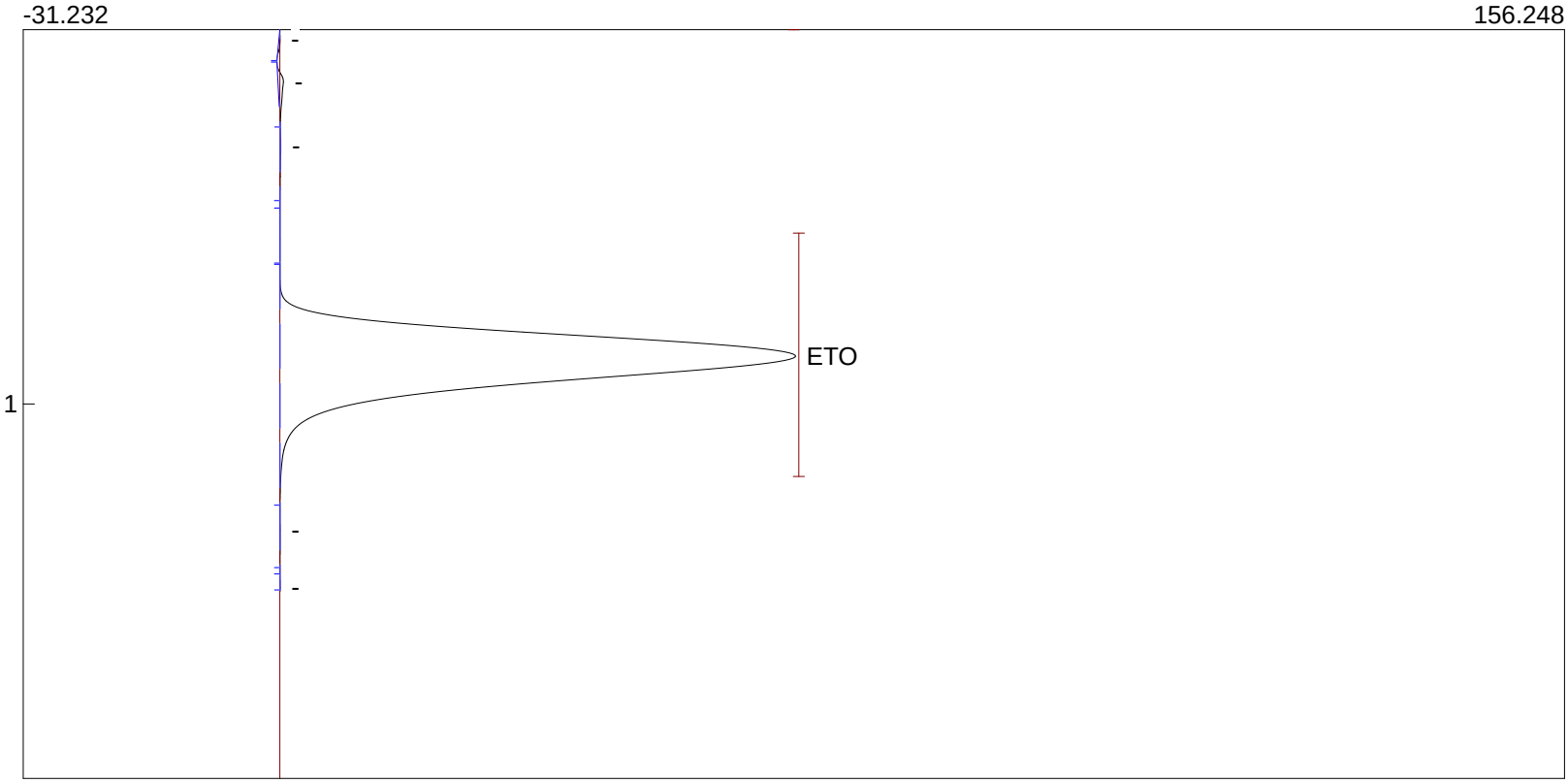
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	542.2717
1			542.2717

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:23:43
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_906. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 100ppm Cal Gas



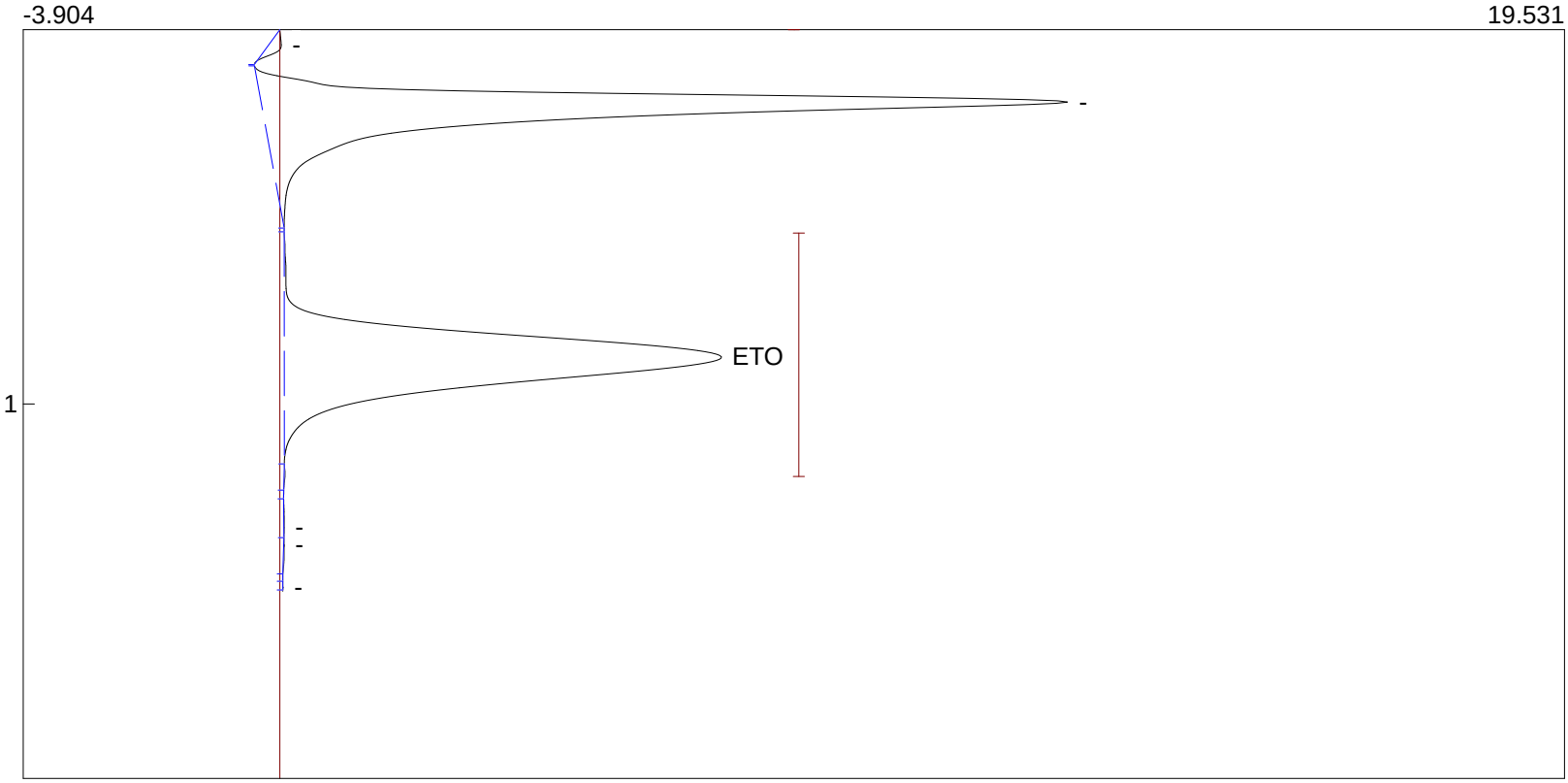
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.883	542.0292
1			542.0292

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:25:20
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_907. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 100ppm Cal Gas



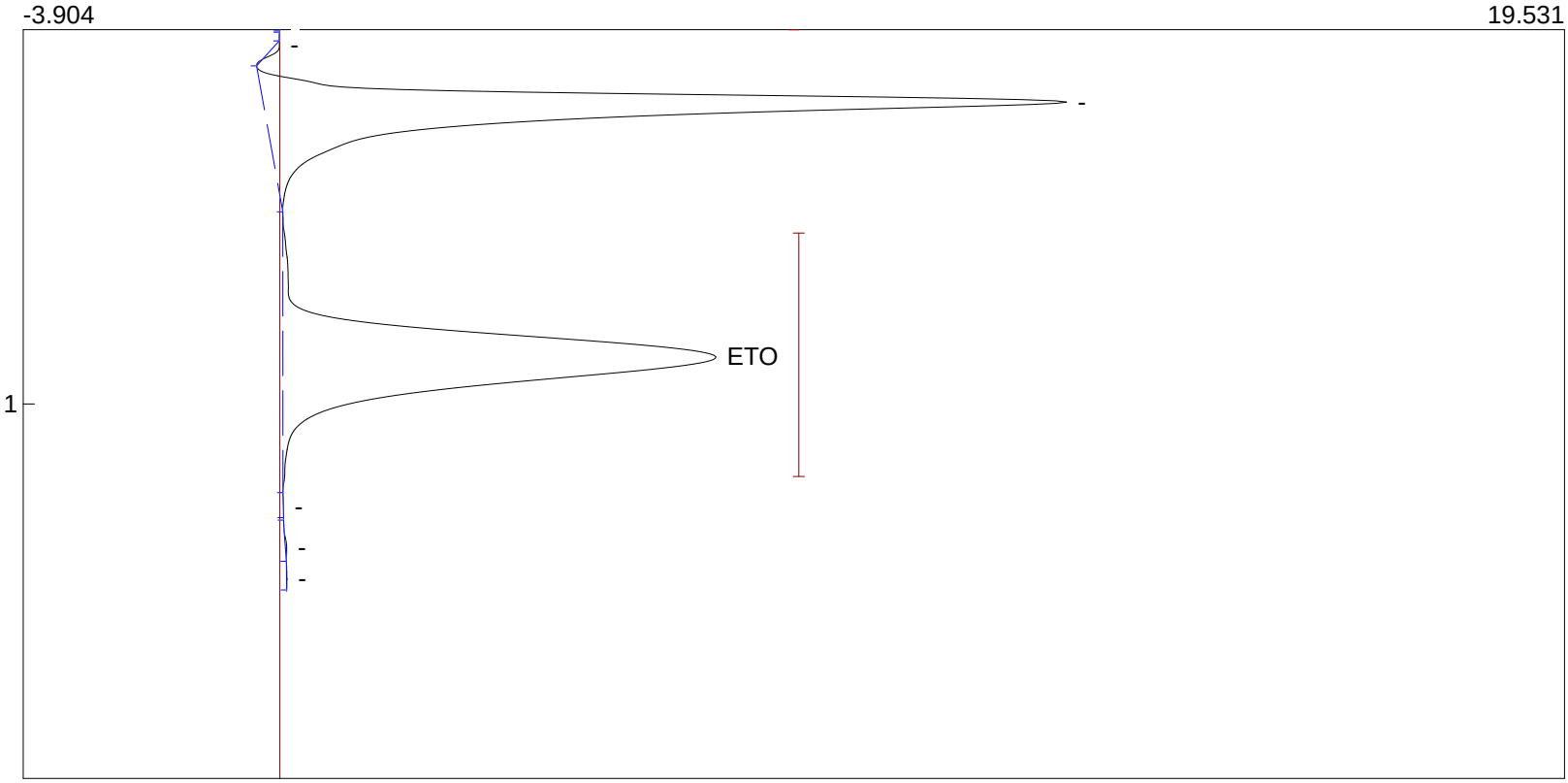
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	542.7906
1			542.7906

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:39:30
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_914. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10ppm Cal Gas



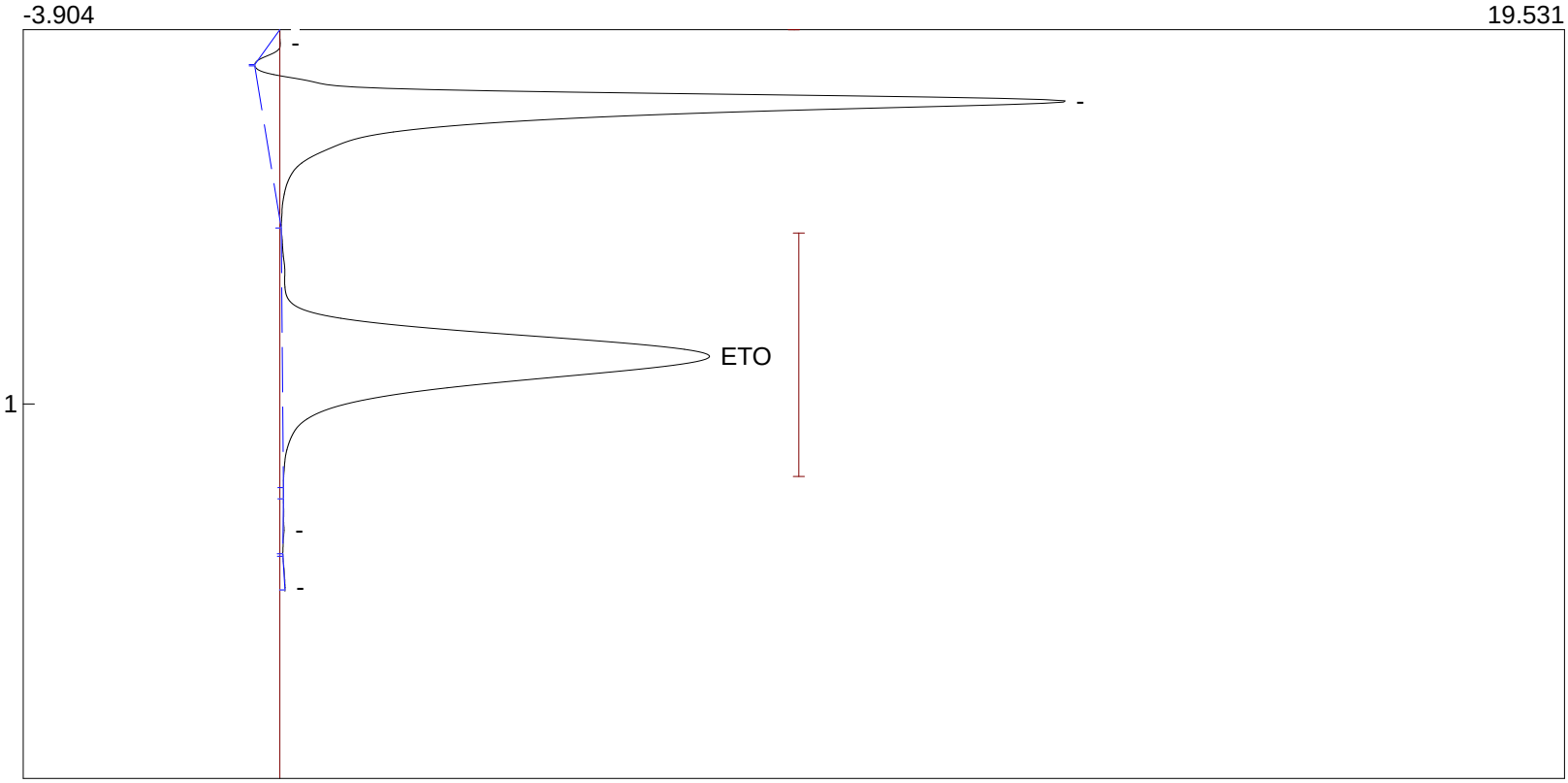
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	57.1820
1			57.1820

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:41:22
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_915. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10ppm Cal Gas



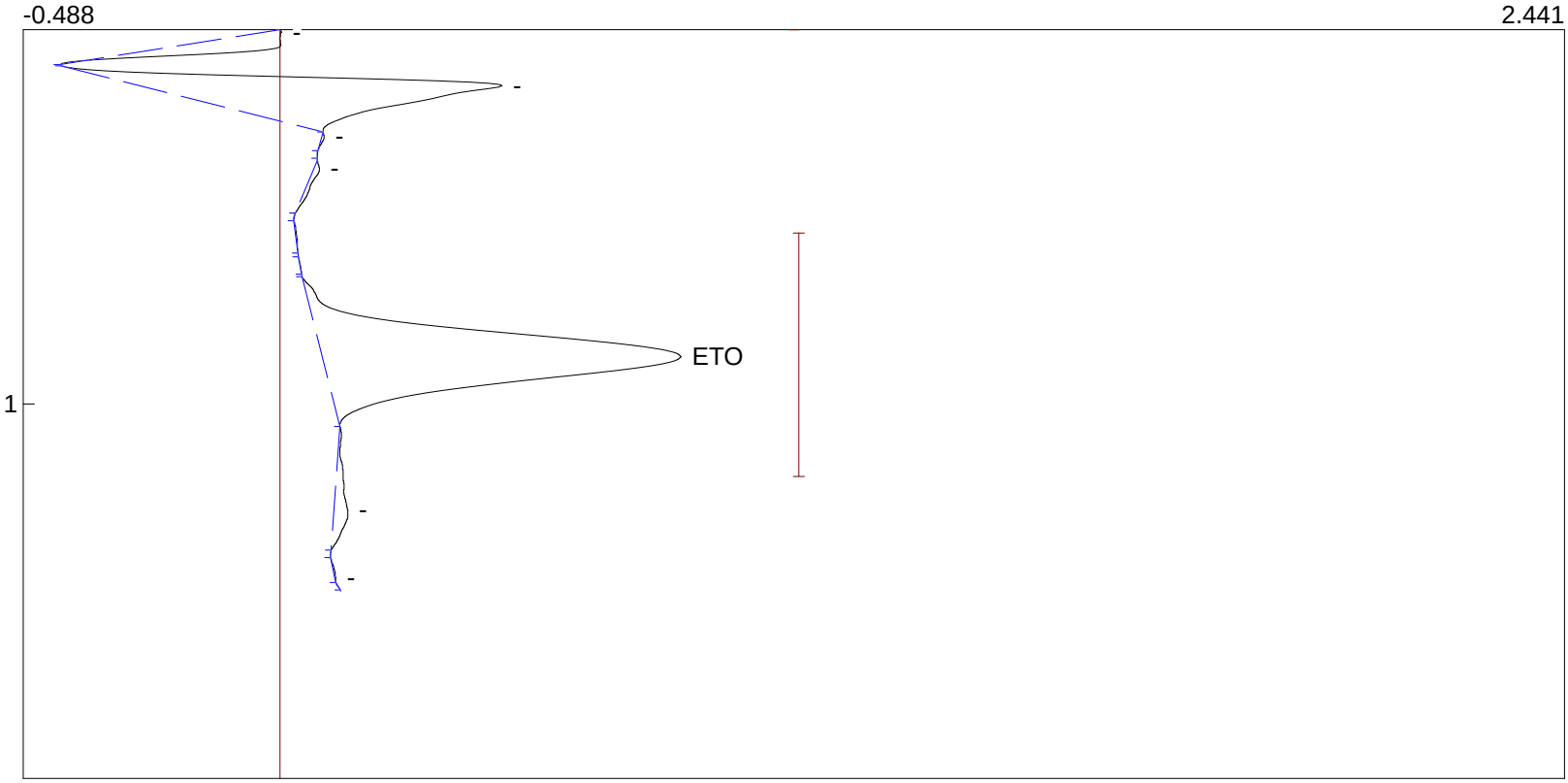
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	57.6427
1			57.6427

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:43:04
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_916. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10ppm Cal Gas



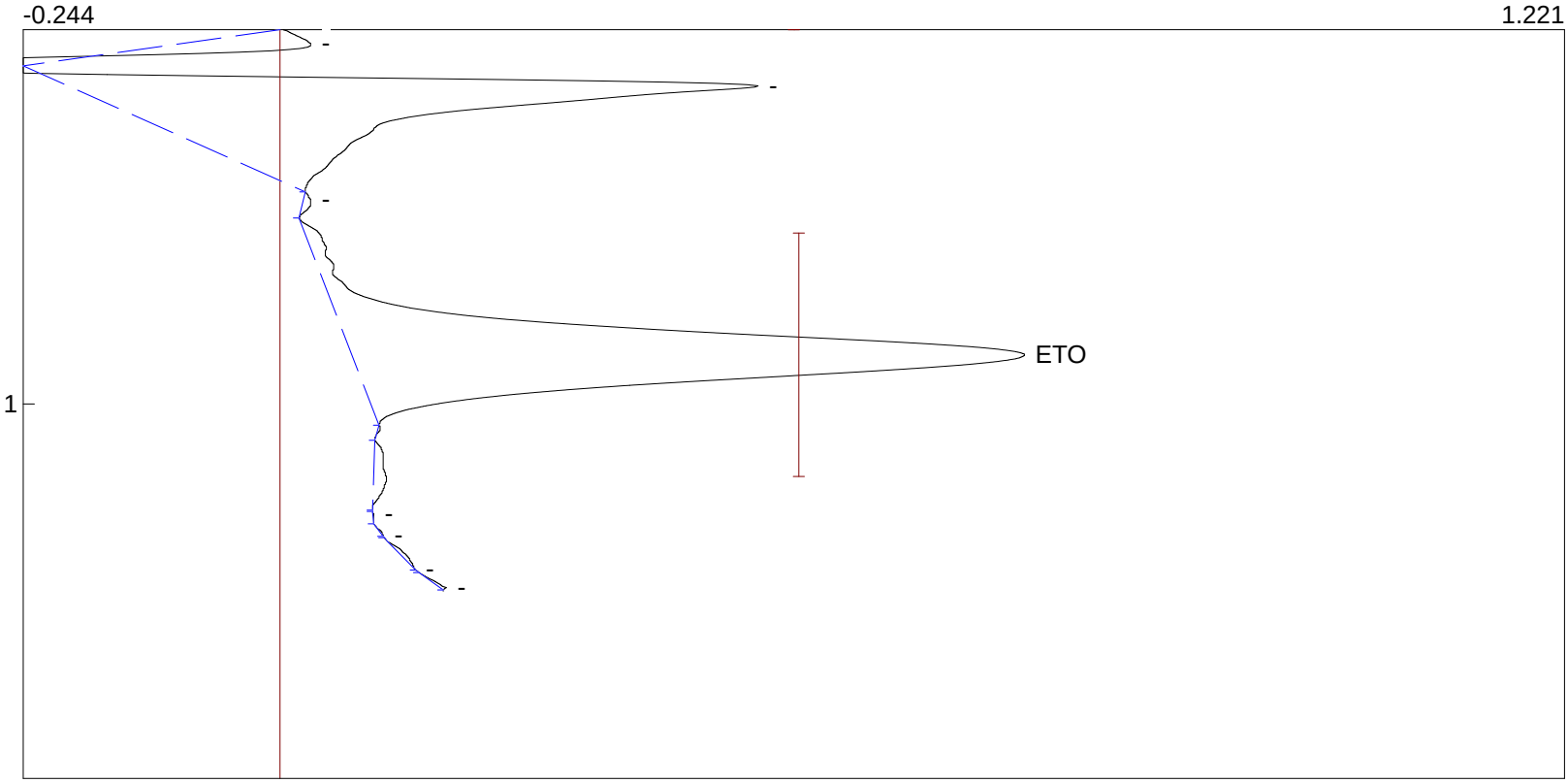
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	56.6848
1			56.6848

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:52:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_919. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 1ppm Cal Gas



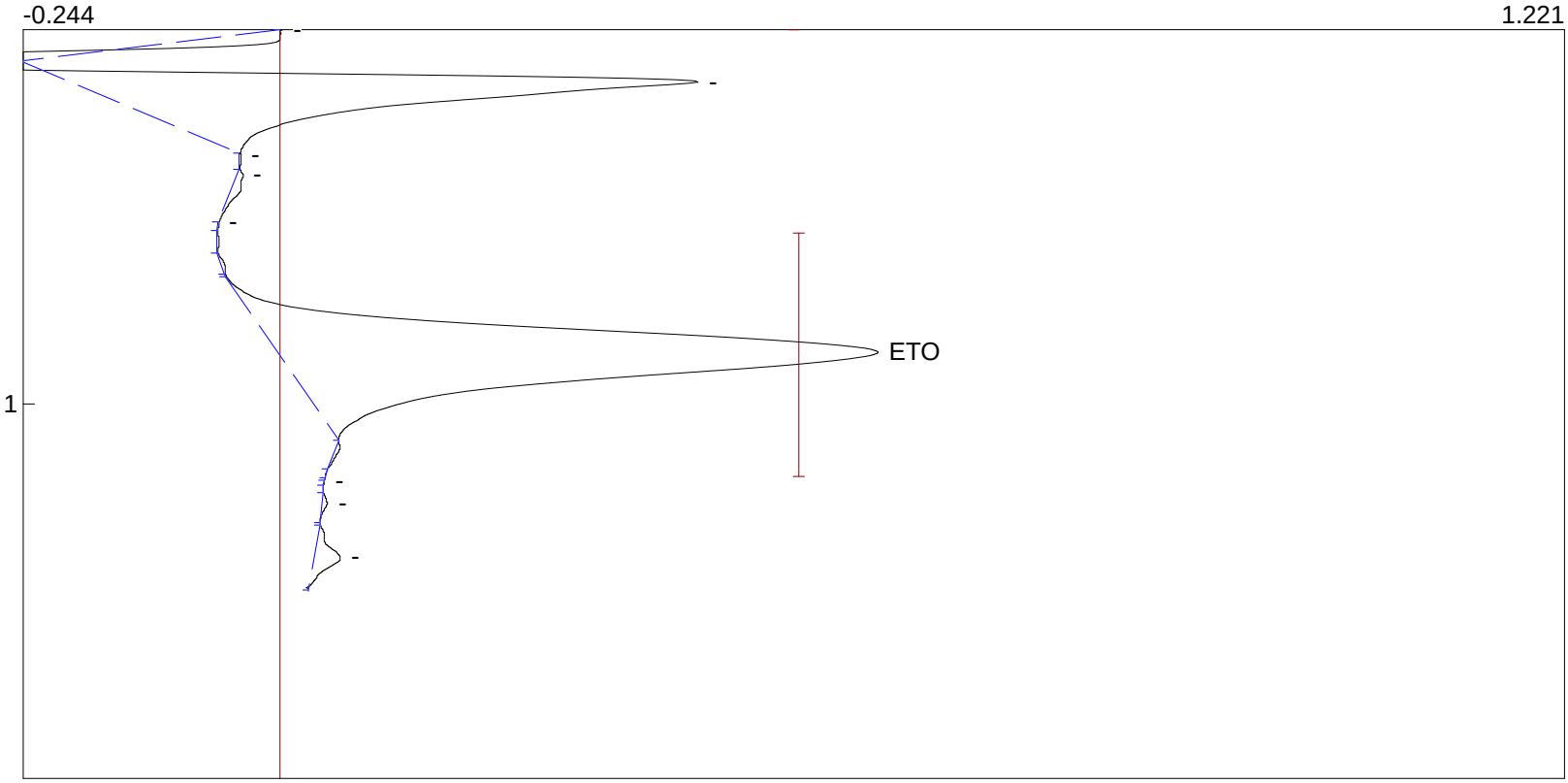
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	5.8788
1			5.8788

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:54:06
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_920. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 1ppm Cal Gas



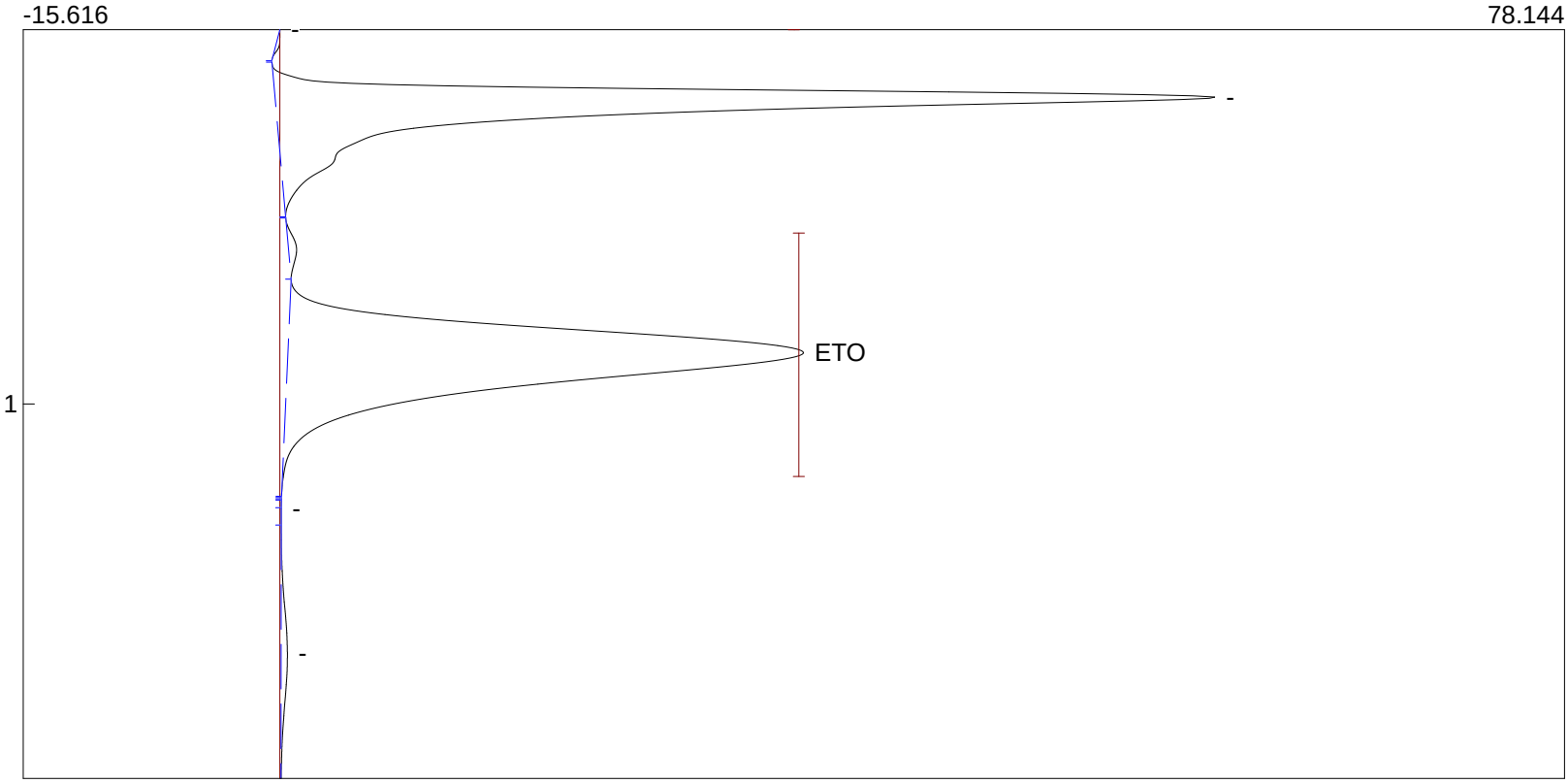
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.866	5.7524
1			5.7524

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 17:55:41
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_921. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 1ppm Cal Gas



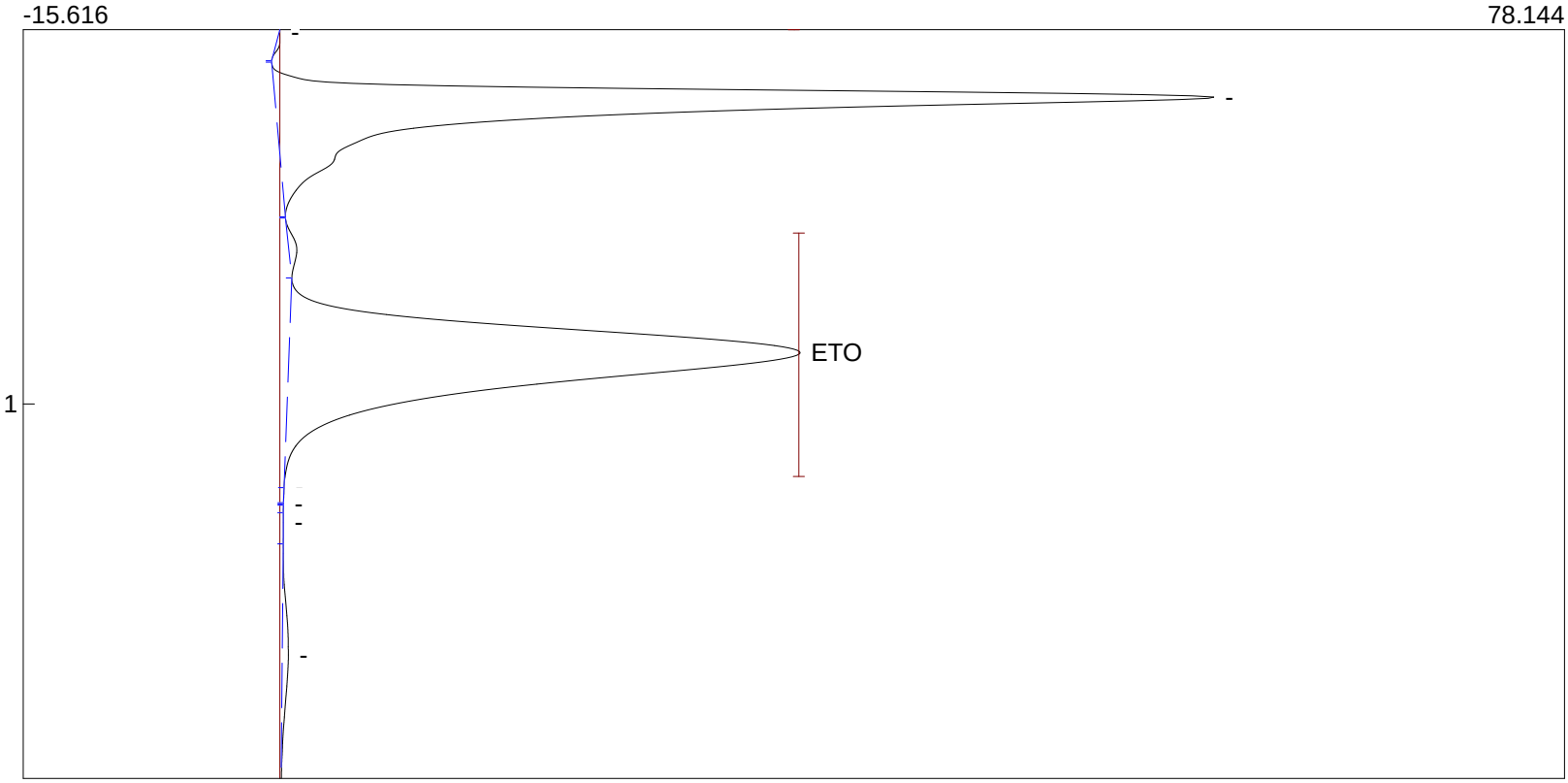
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.860	5.8756
1			5.8756

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 18:11:01
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_928. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Recovery Study Final



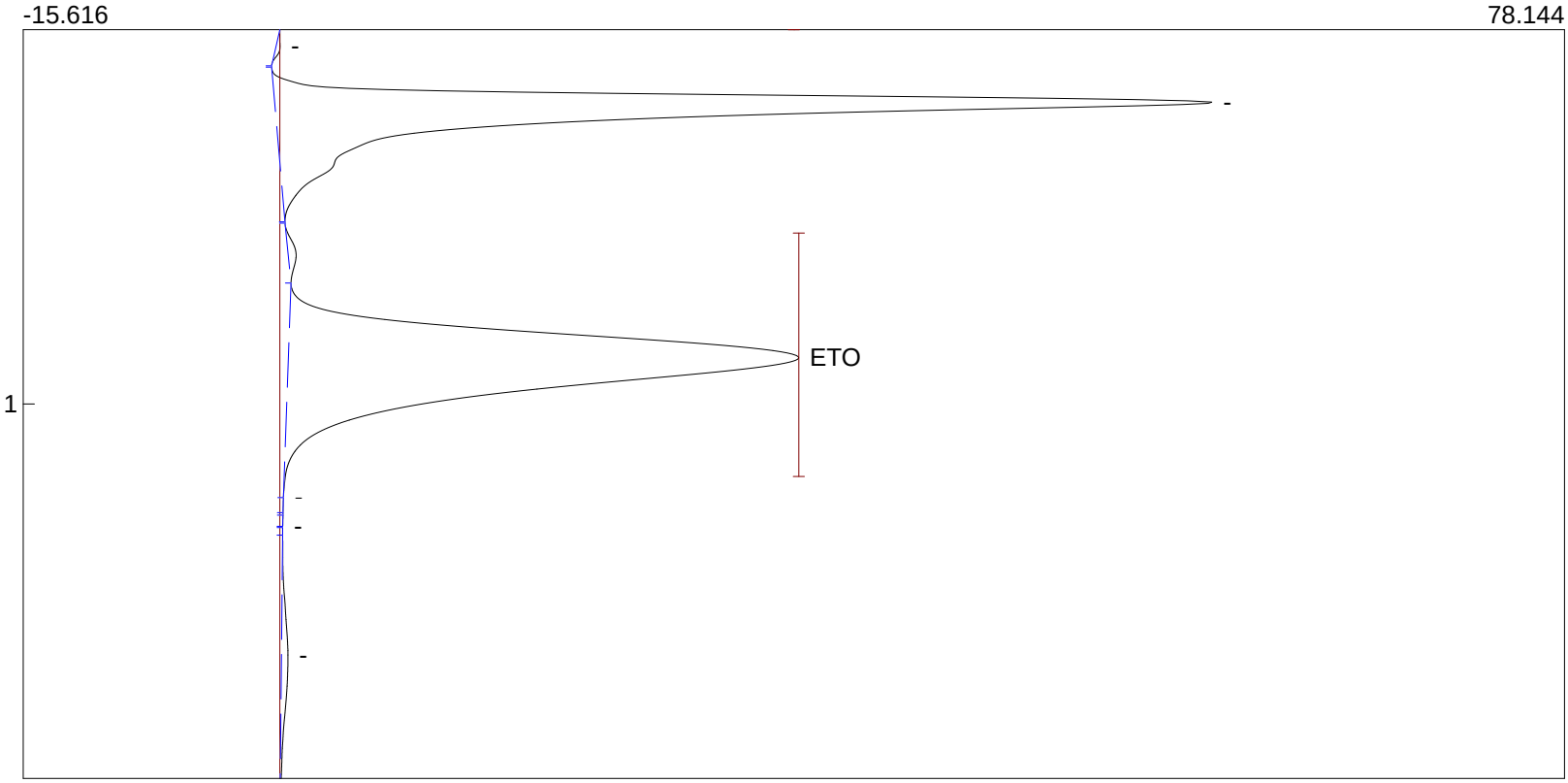
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	309.7882
1			309.7882

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 18:14:43
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_929. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Recovery Study Final



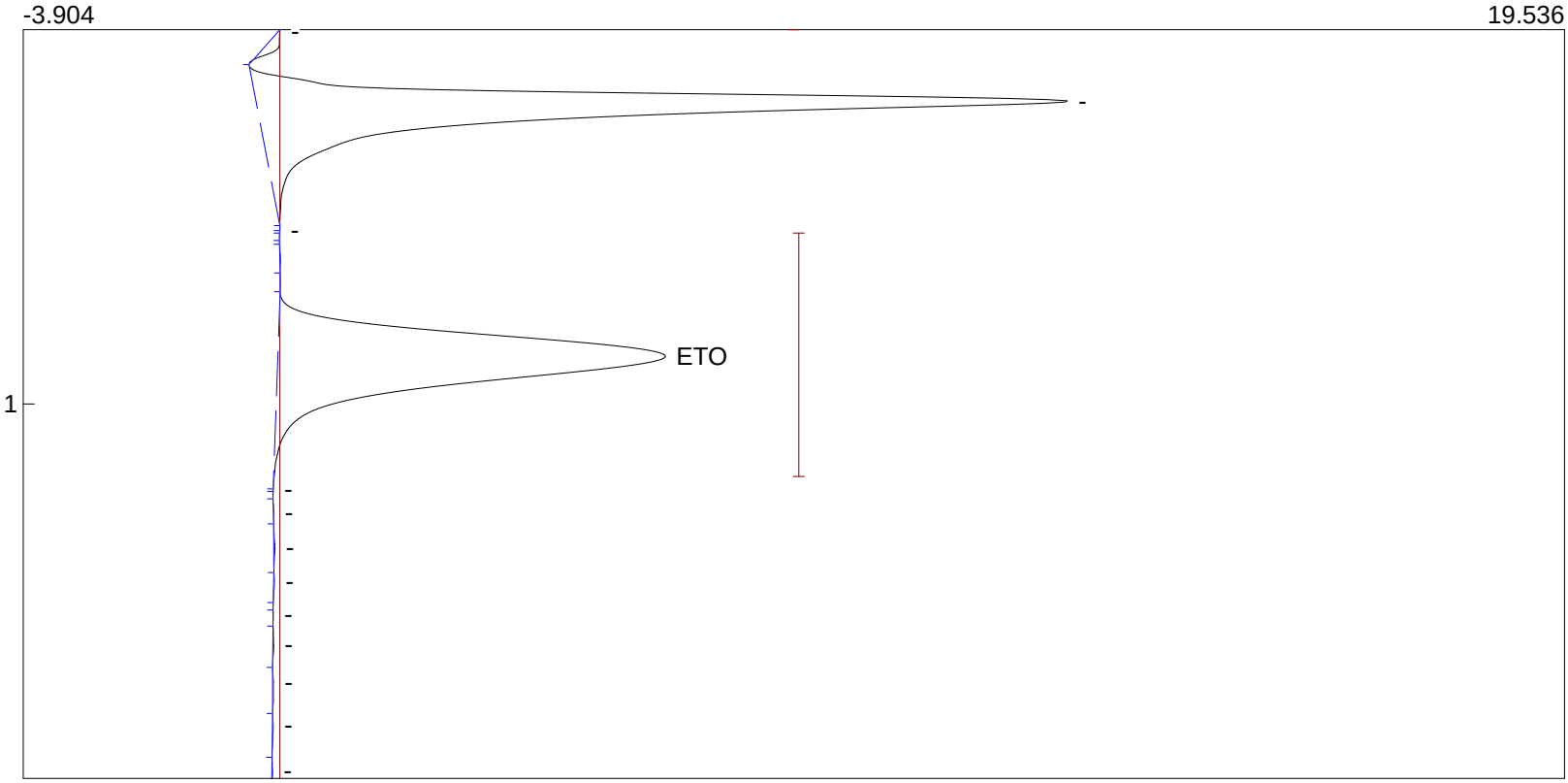
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	307.3648
1			307.3648

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 18:18:26
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_930. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Recovery Study Final



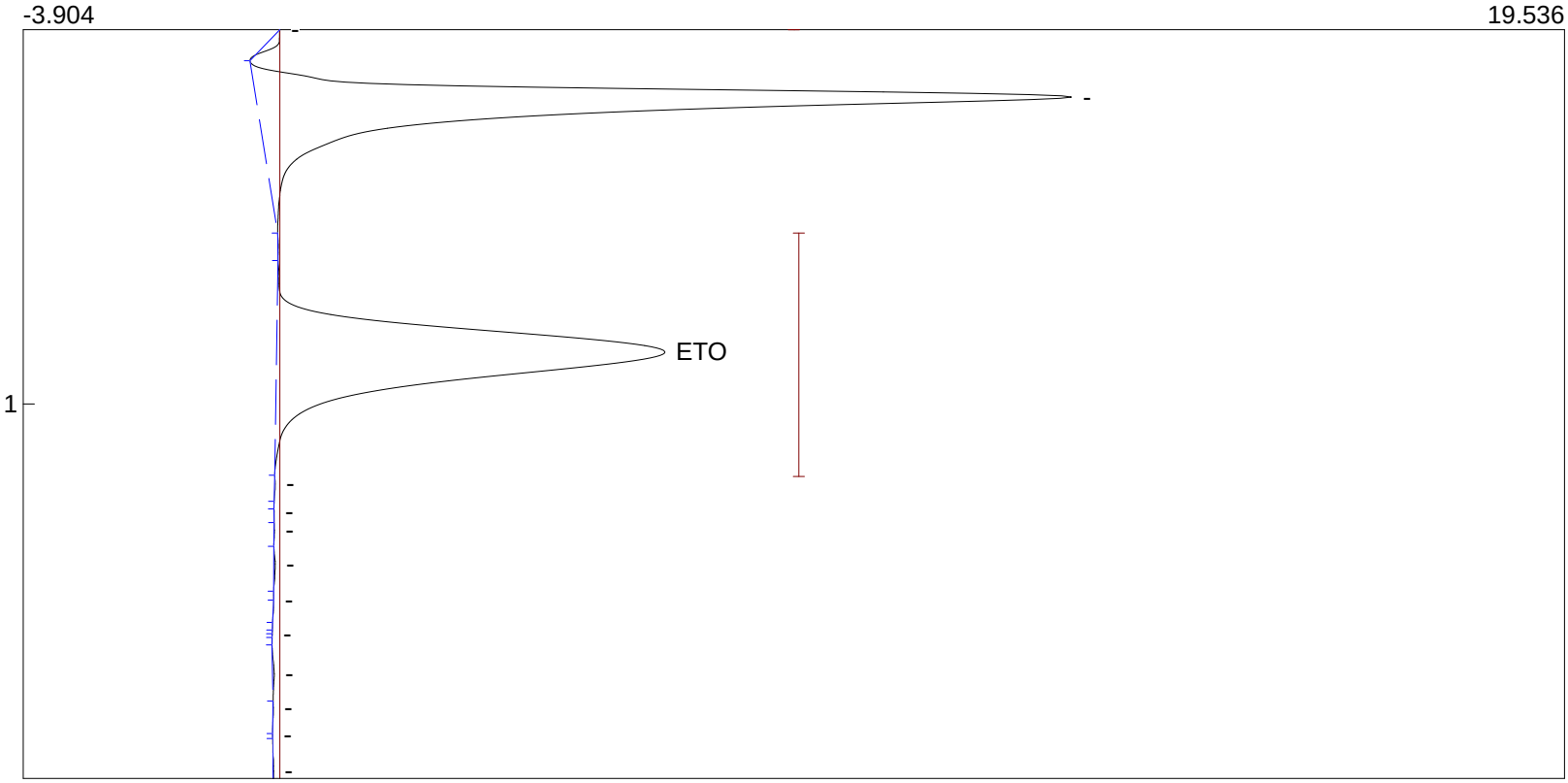
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.876	307.0918
1			307.0918

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 18:39:43
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_936. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Direct Interface Recovery Study



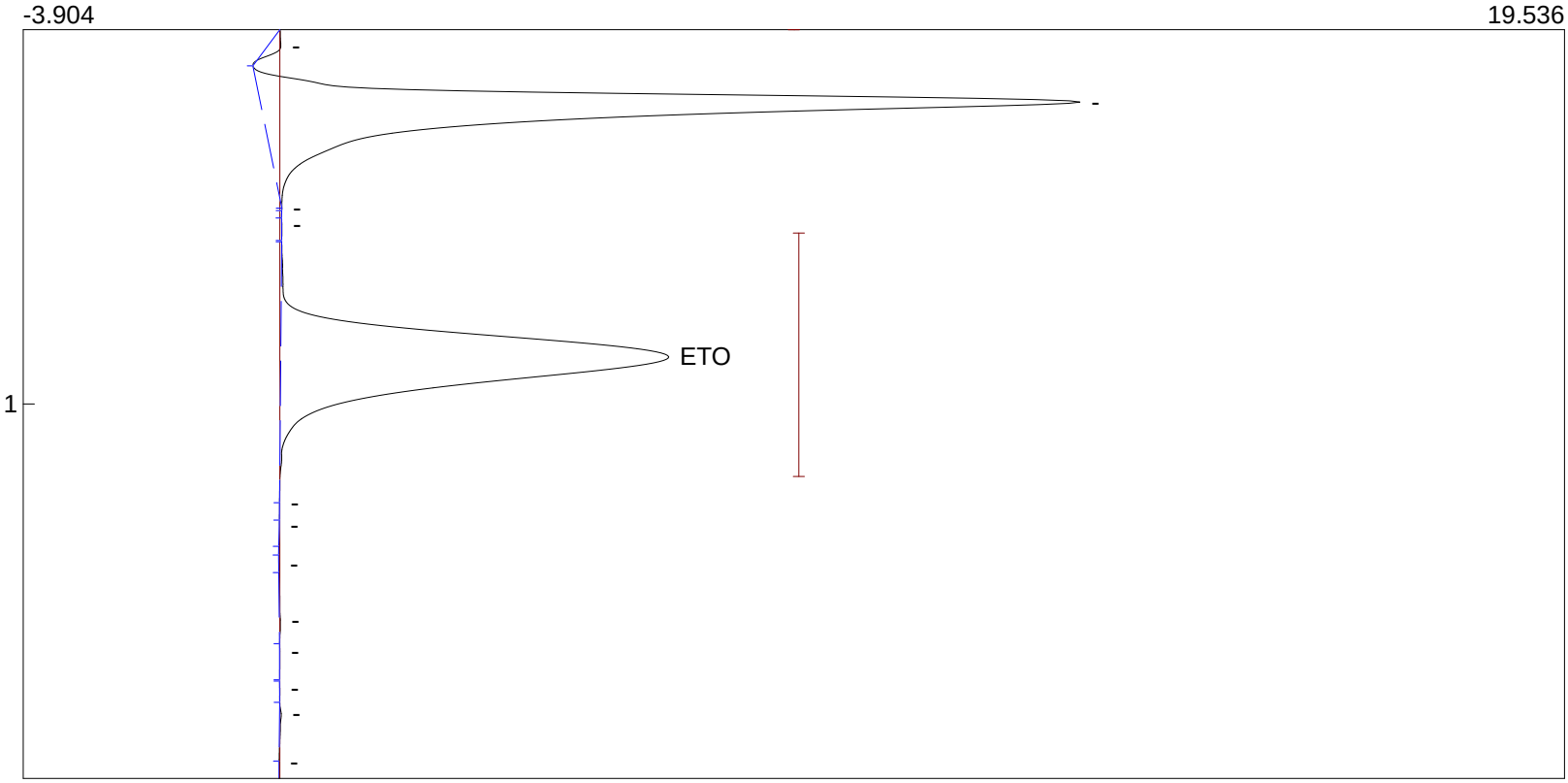
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	56.7228
1			56.7228

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 18:42:57
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_937. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Direct Interface Recovery Study



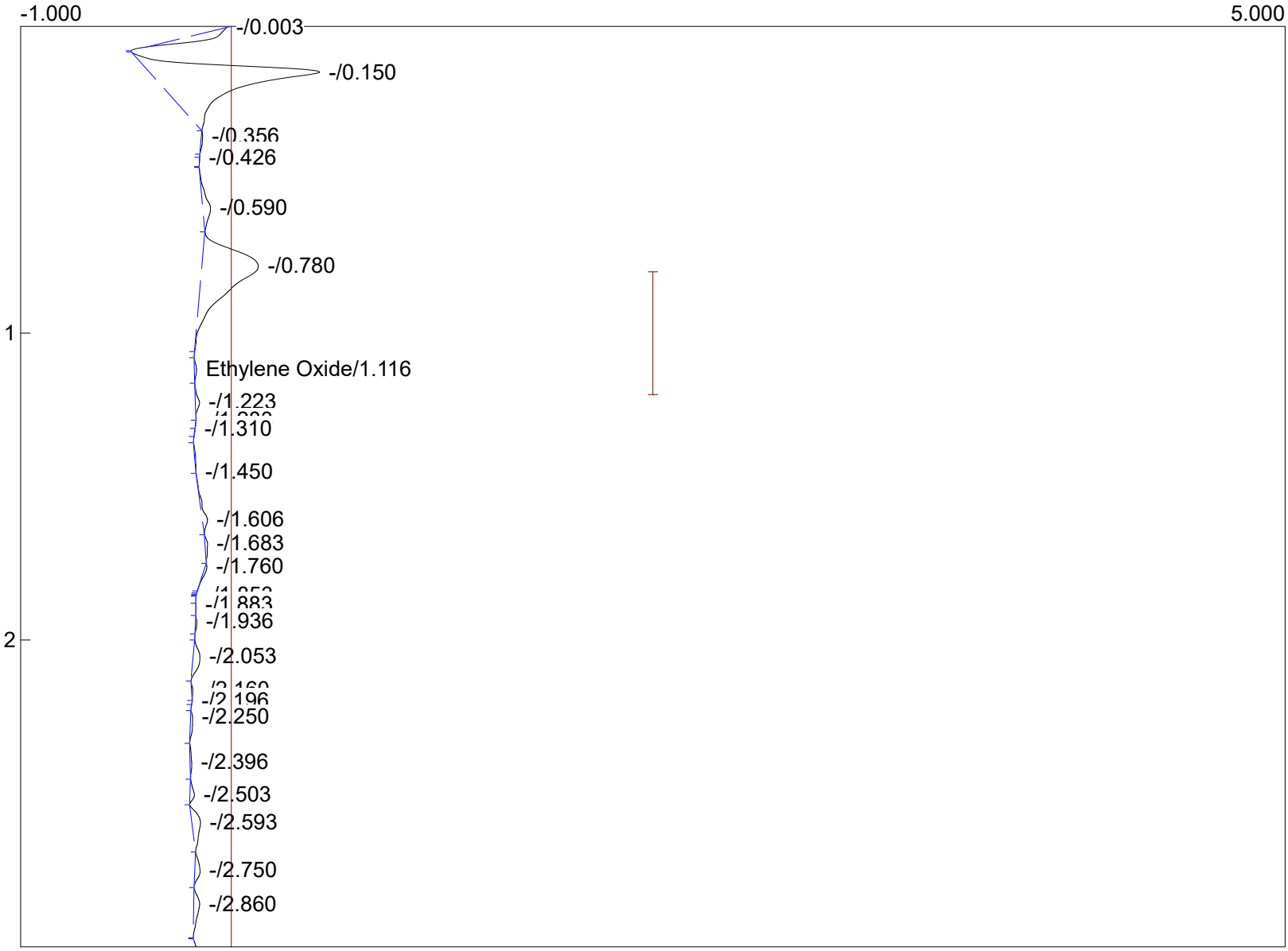
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.860	57.9918
1			57.9918

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 12/31/2019 18:46:00
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_938. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Direct Interface Recovery Study



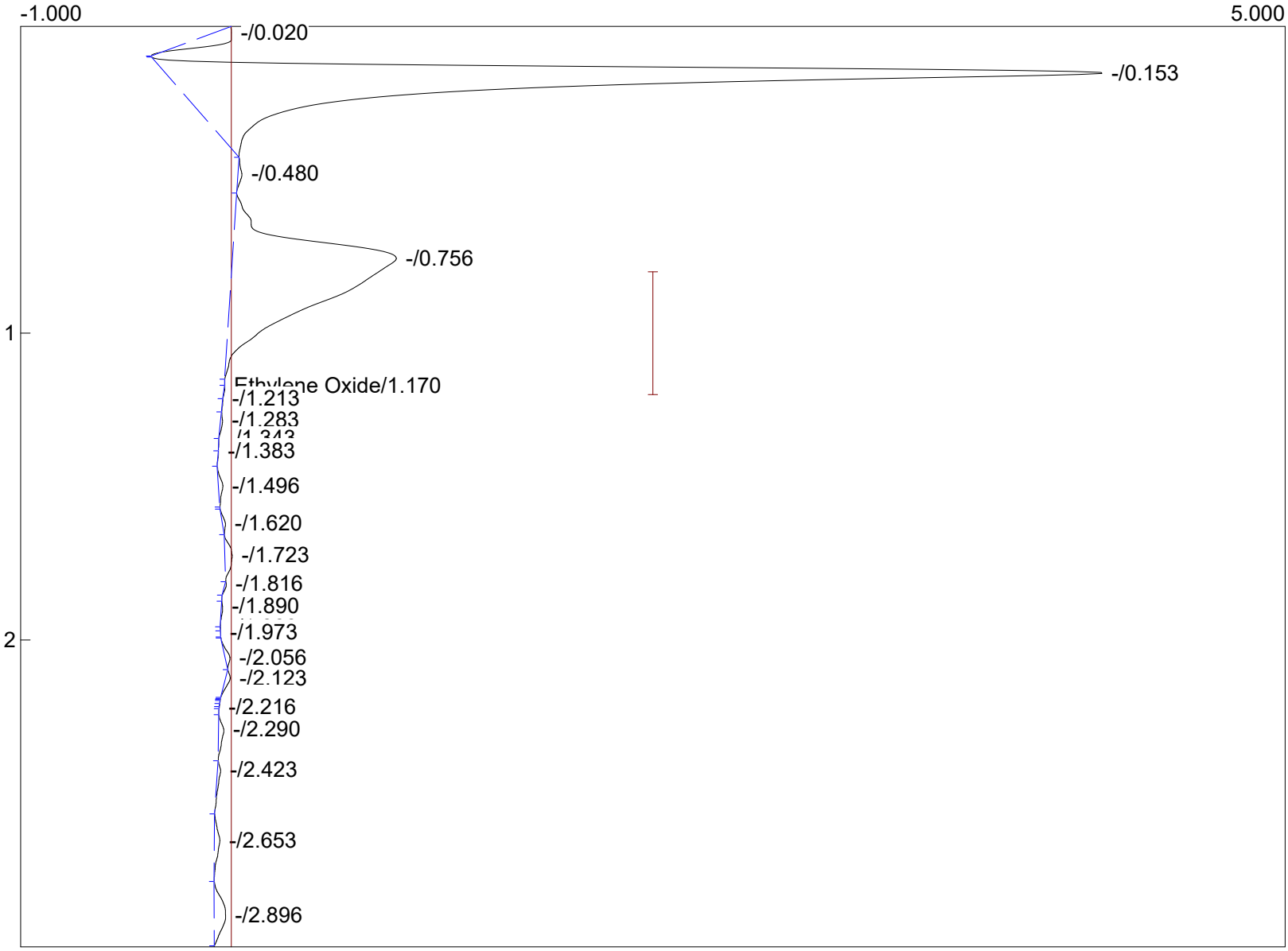
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.873	57.6547
1			57.6547

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:03:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_943..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



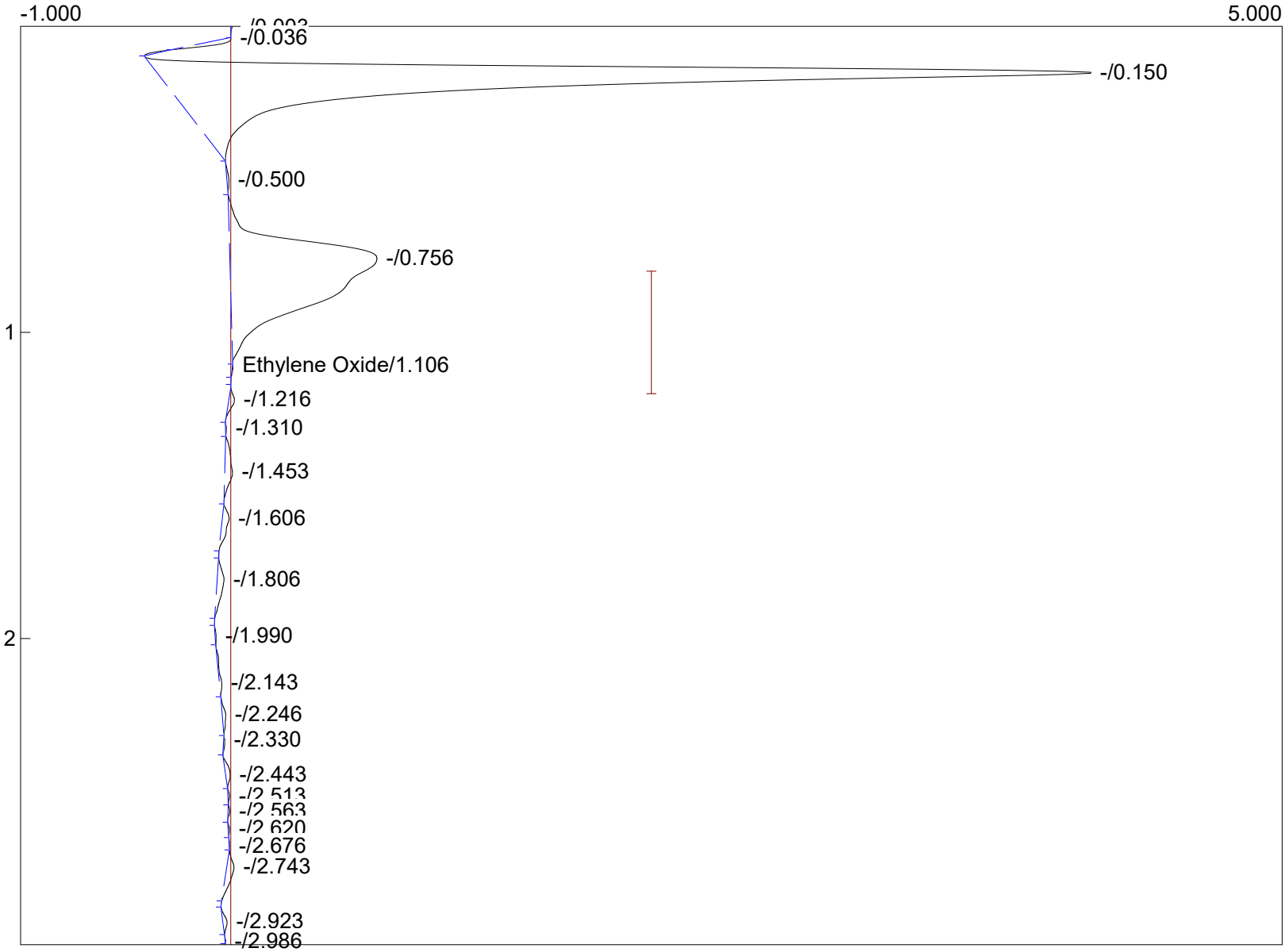
Component	Retention	Area
Ethylene Oxide	1.116	0.0245
		0.0245

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:07:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_944..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



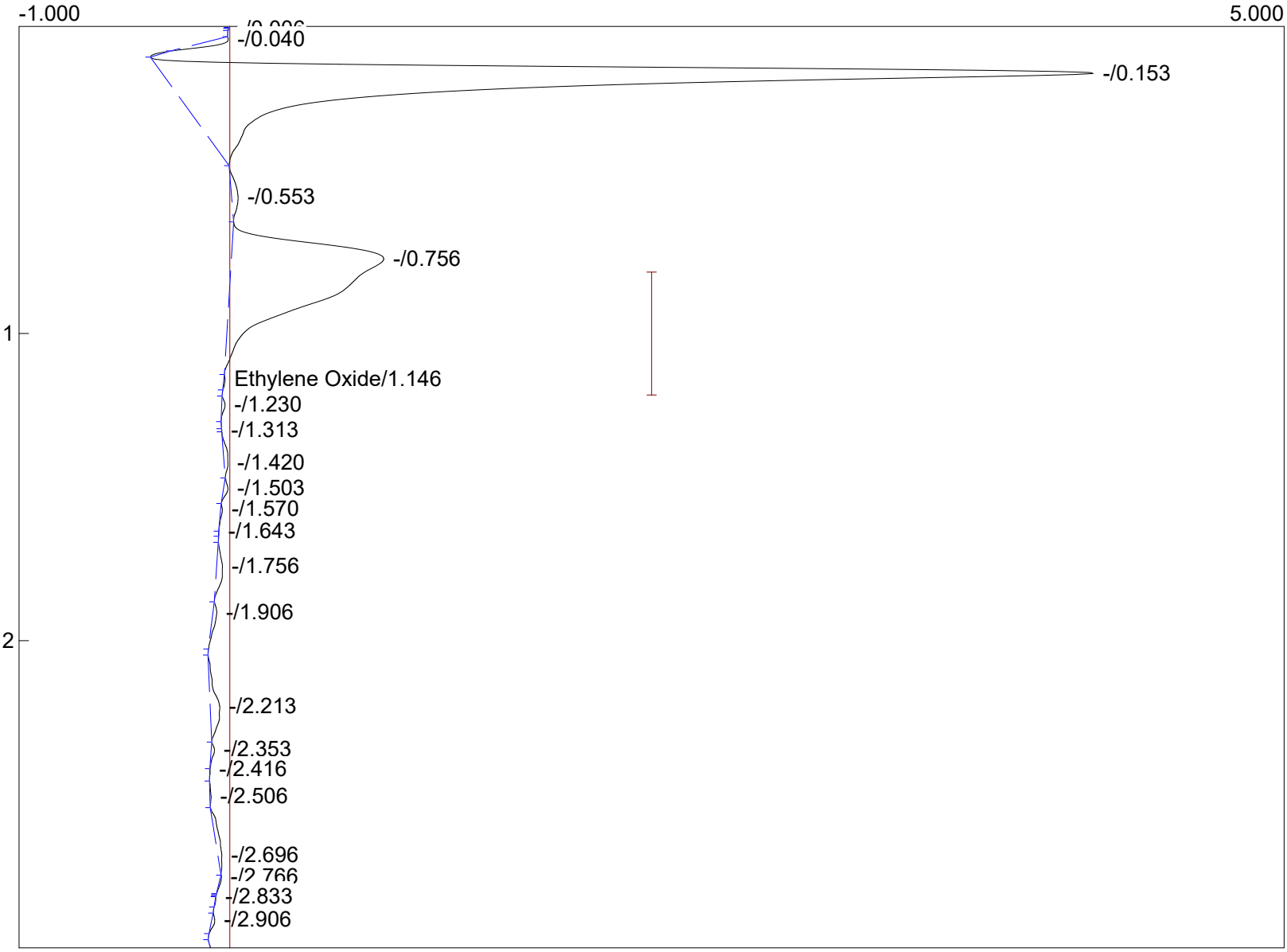
Component	Retention	Area
Ethylene Oxide	1.170	0.0045
		0.0045

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:11:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_945..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



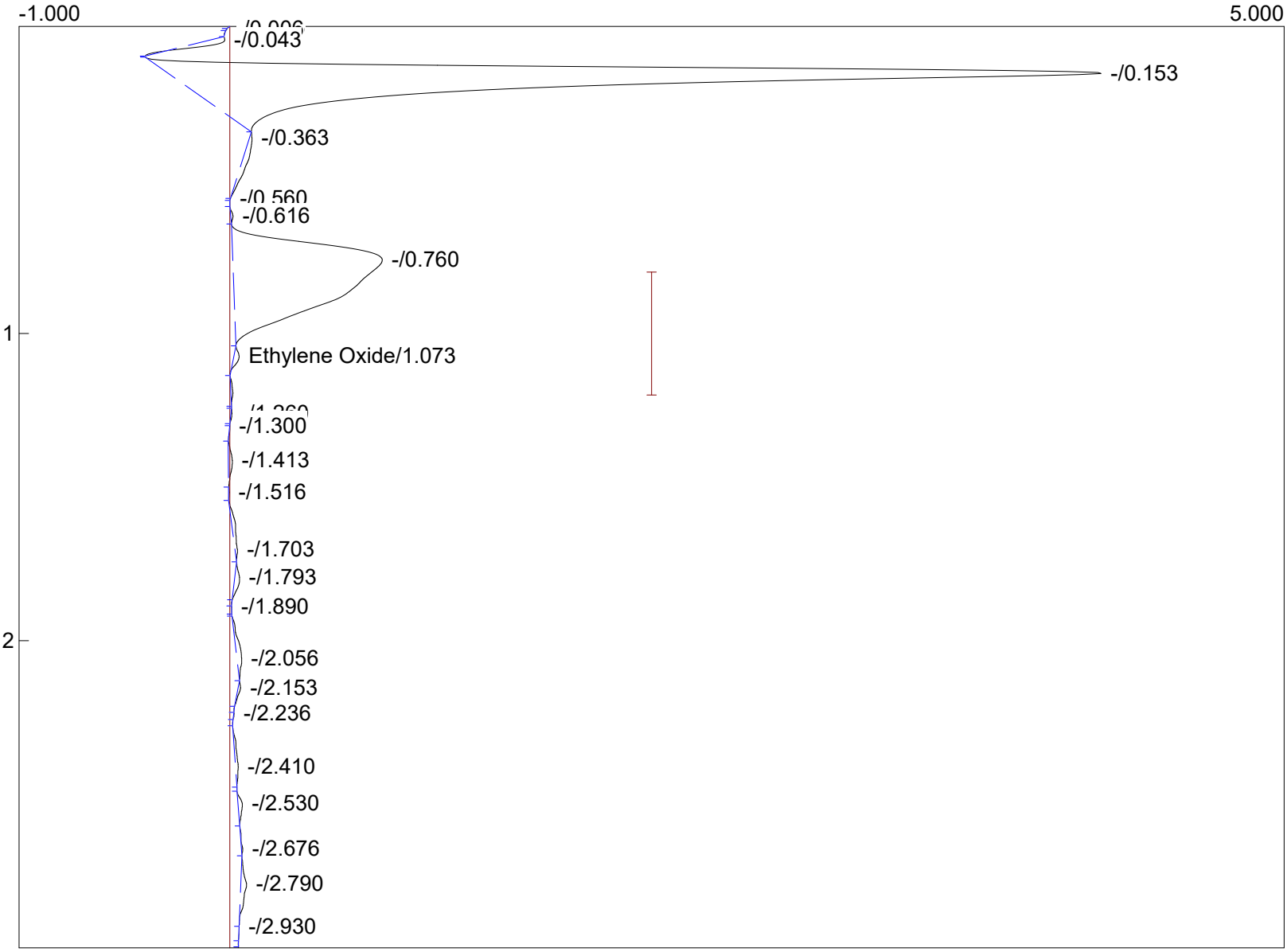
Component	Retention	Area
Ethylene Oxide	1.106	0.0057
		0.0057

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:15:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_946..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



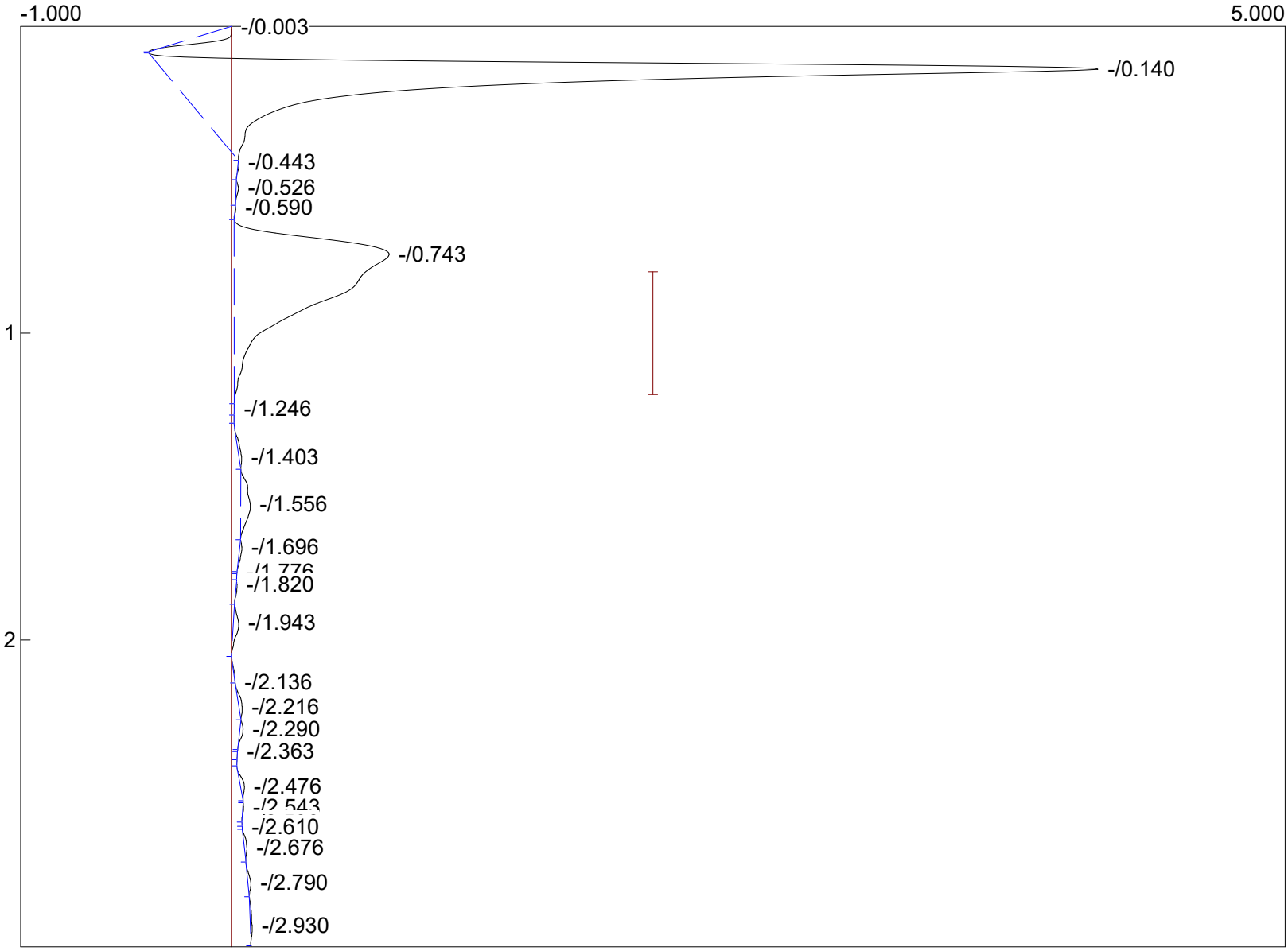
Component	Retention	Area
Ethylene Oxide	1.146	0.0108
		0.0108

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:19:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_947..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



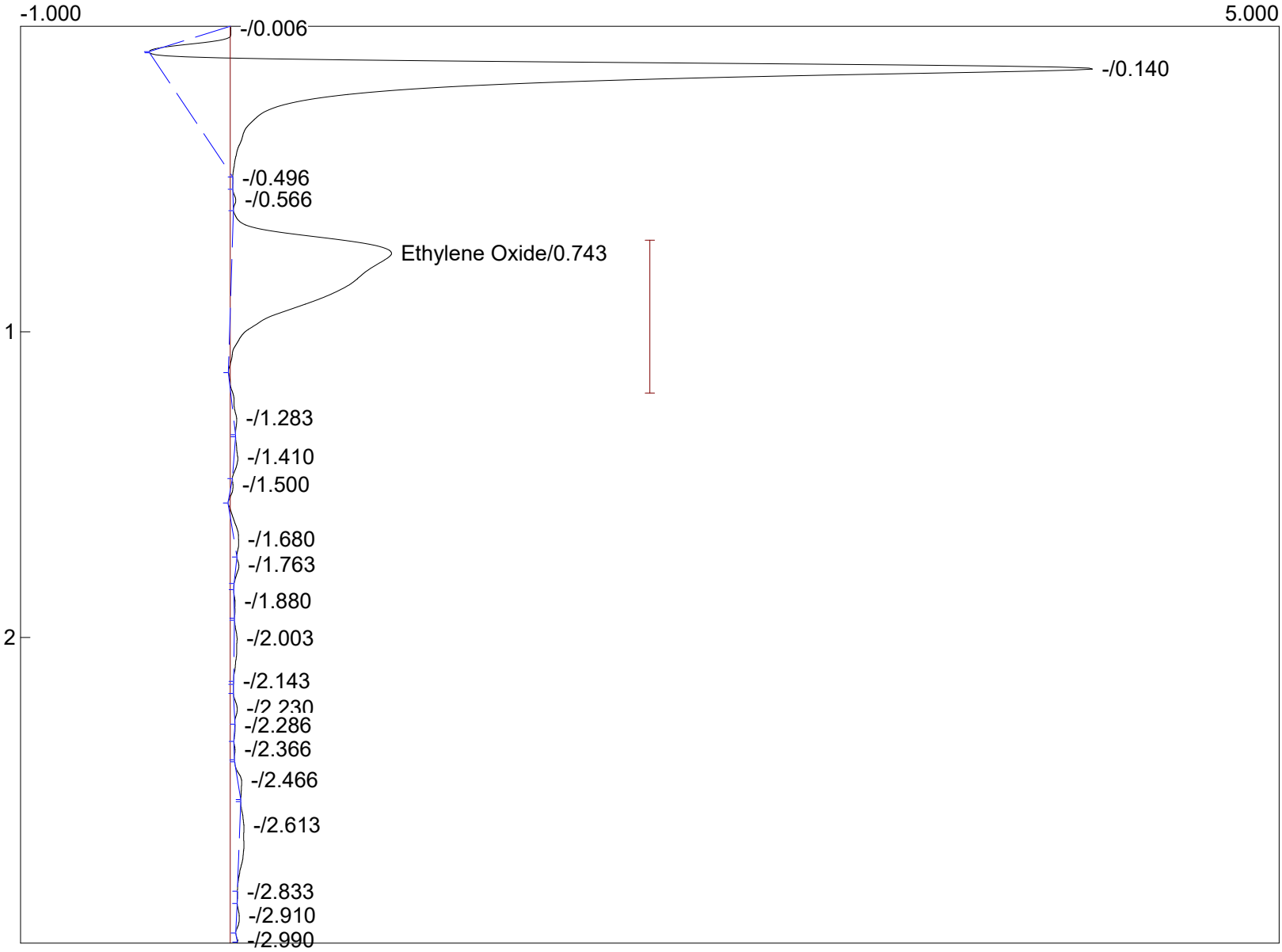
Component	Retention	Area
Ethylene Oxide	1.073	0.0710
		0.0710

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:23:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_948..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



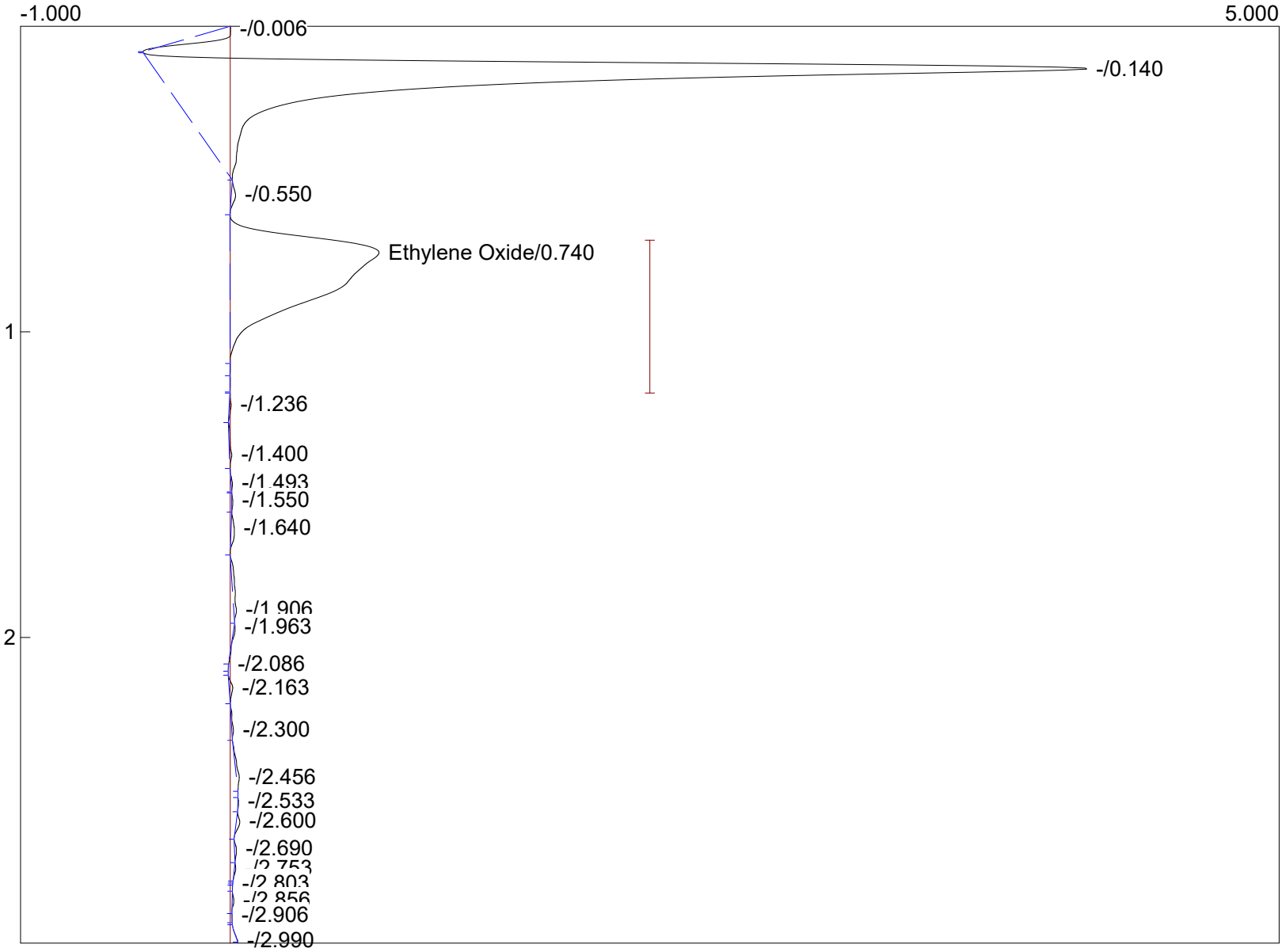
Component	Retention	Area
		0.0000

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:31:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_950..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



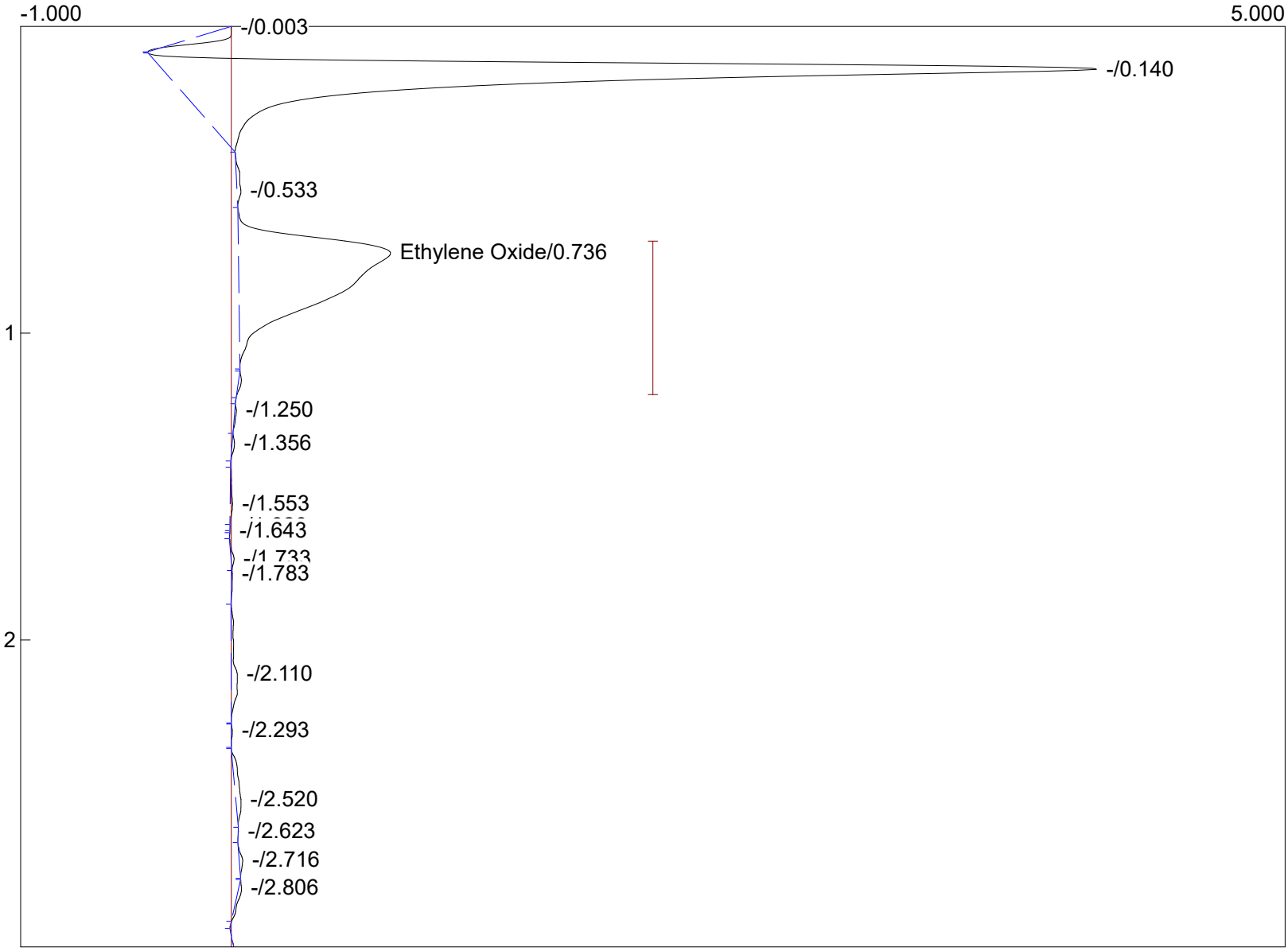
Component	Retention	Area
Ethylene Oxide	0.743	4.7220
		4.7220

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:35:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_951..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



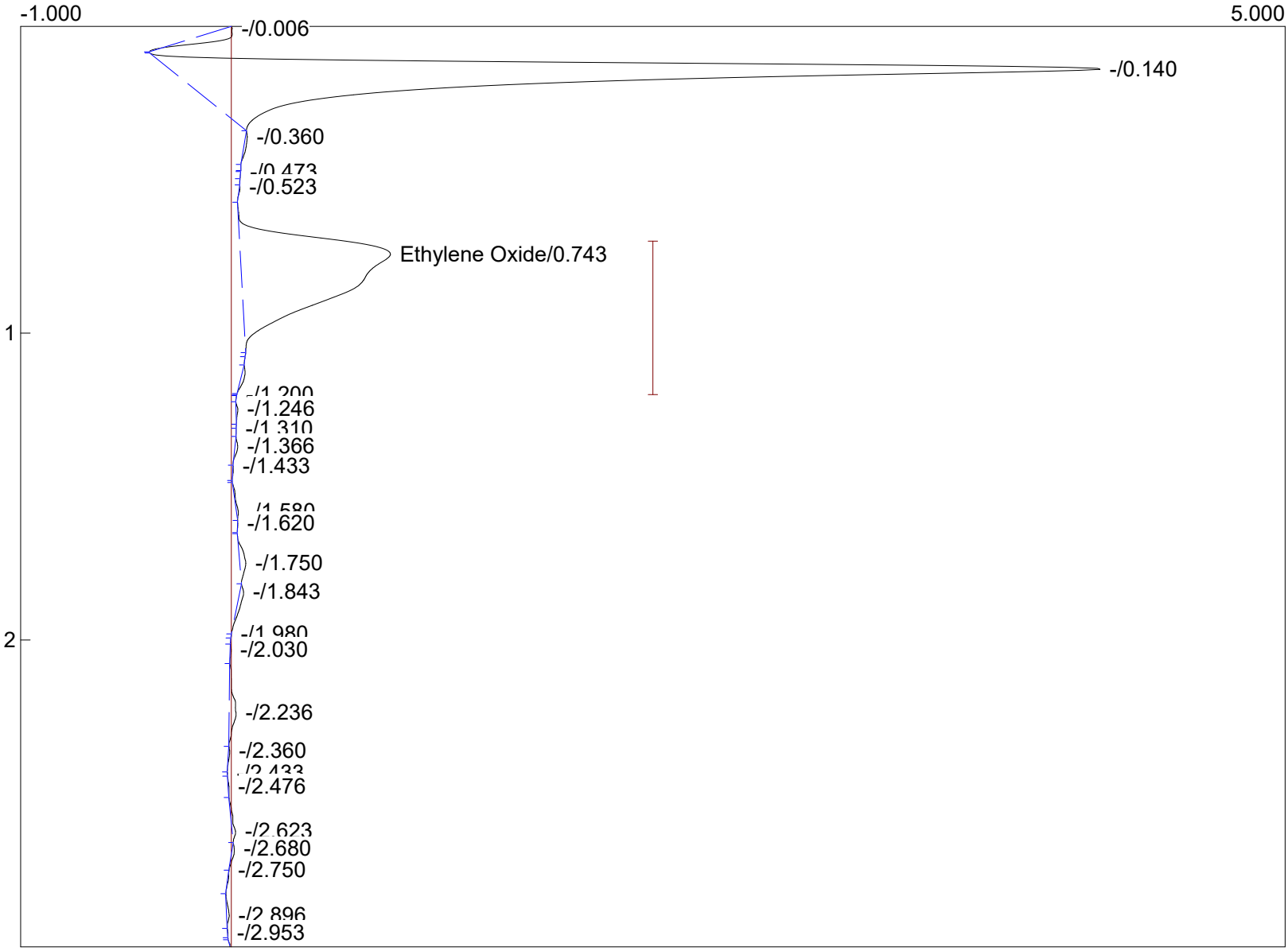
Component	Retention	Area
Ethylene Oxide	0.740	4.0366
		4.0366

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:39:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_952..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



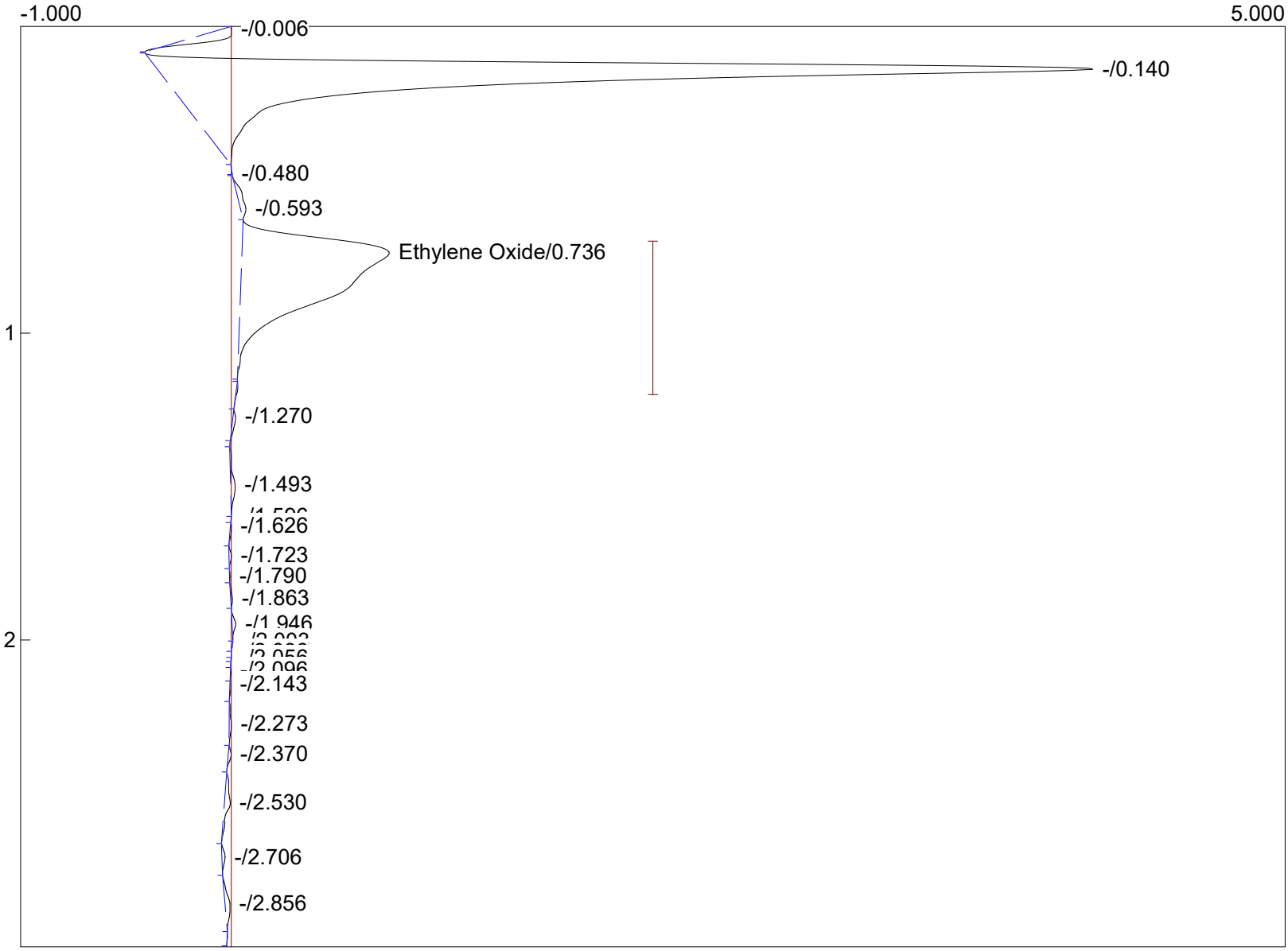
Component	Retention	Area
Ethylene Oxide	0.736	4.2074
		4.2074

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:43:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_953..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



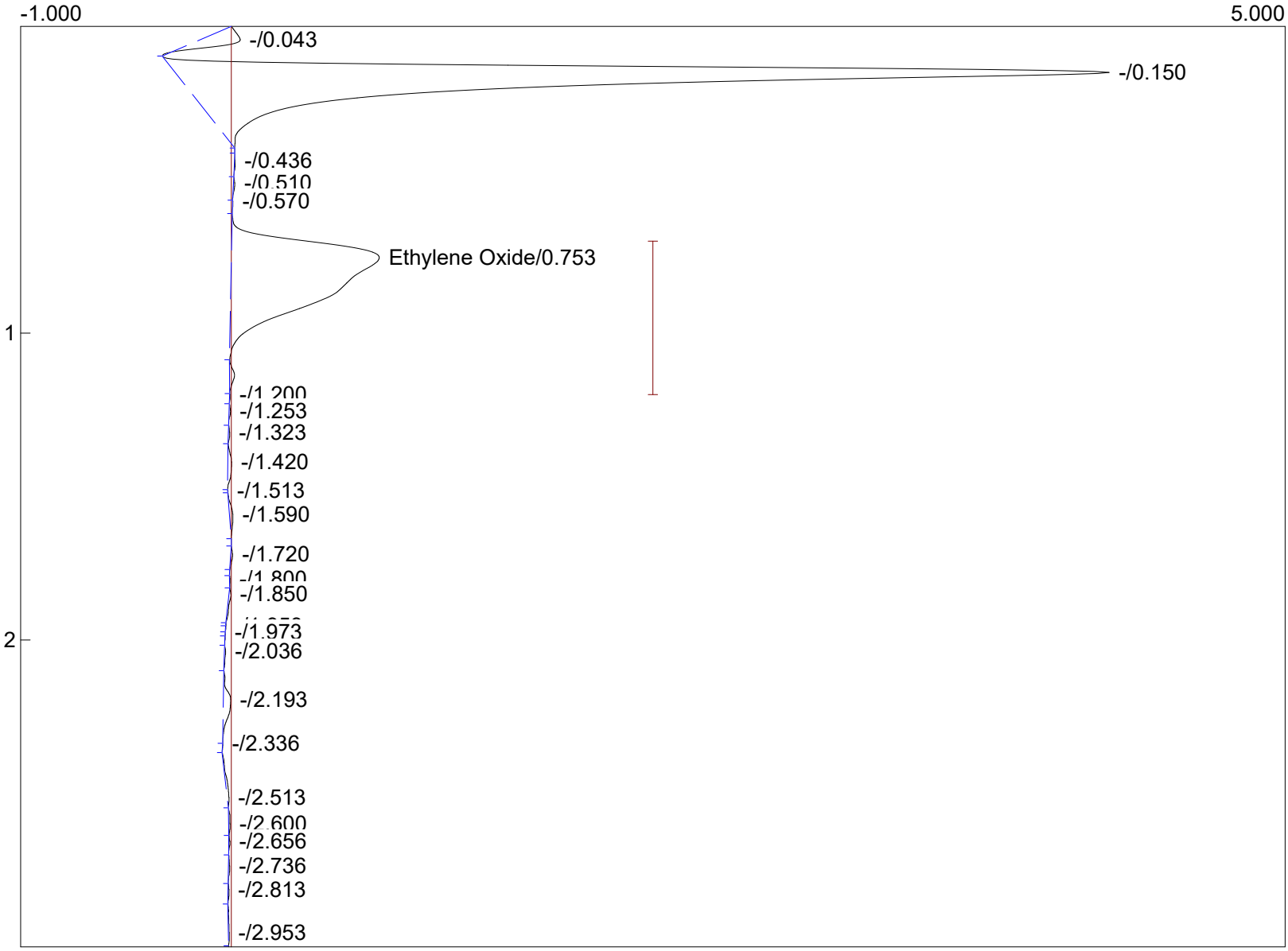
Component	Retention	Area
Ethylene Oxide	0.743	3.9635
		3.9635

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:47:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_954..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



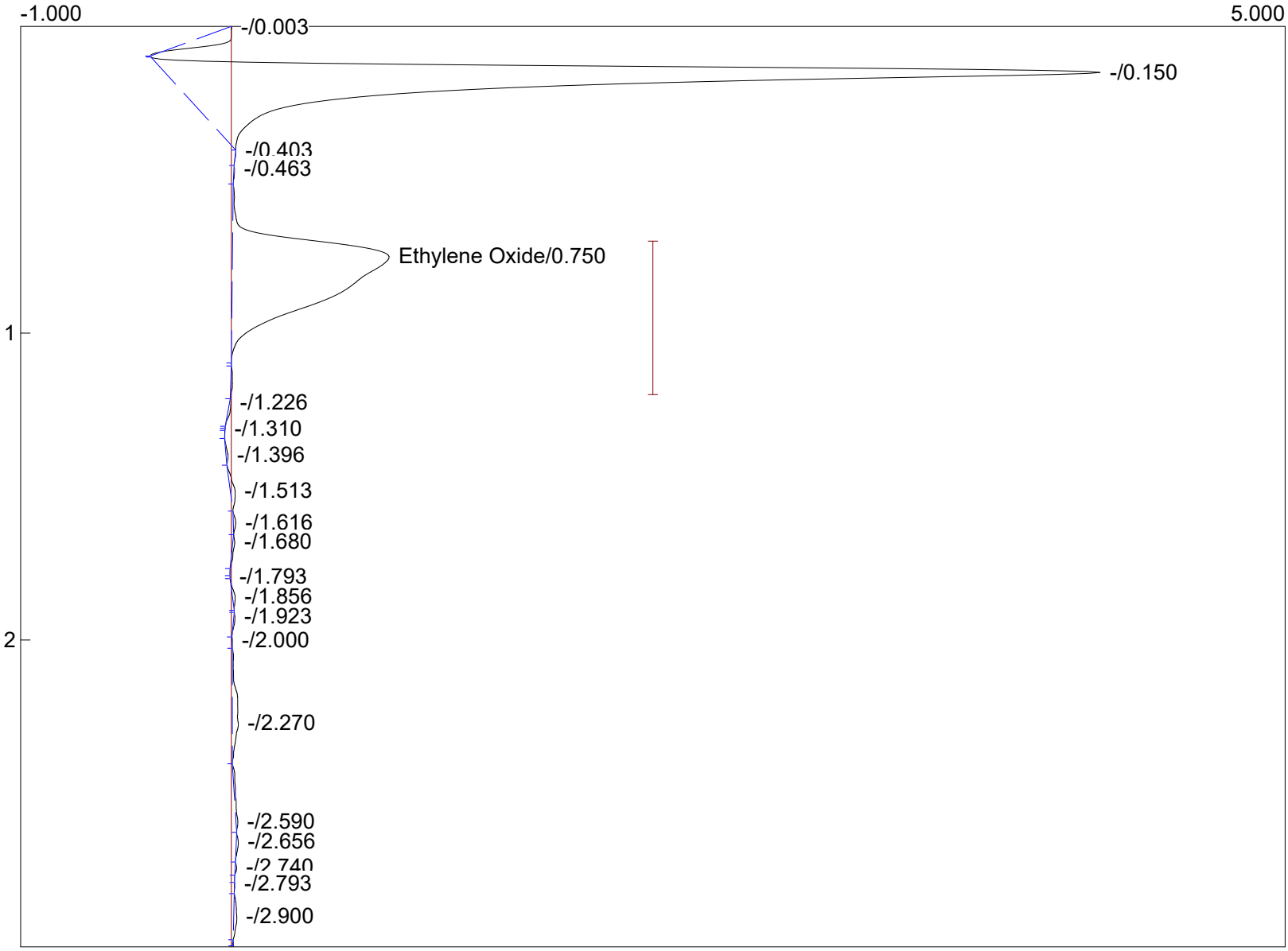
Component	Retention	Area
Ethylene Oxide	0.736	3.8808
		3.8808

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 21:59:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_957..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



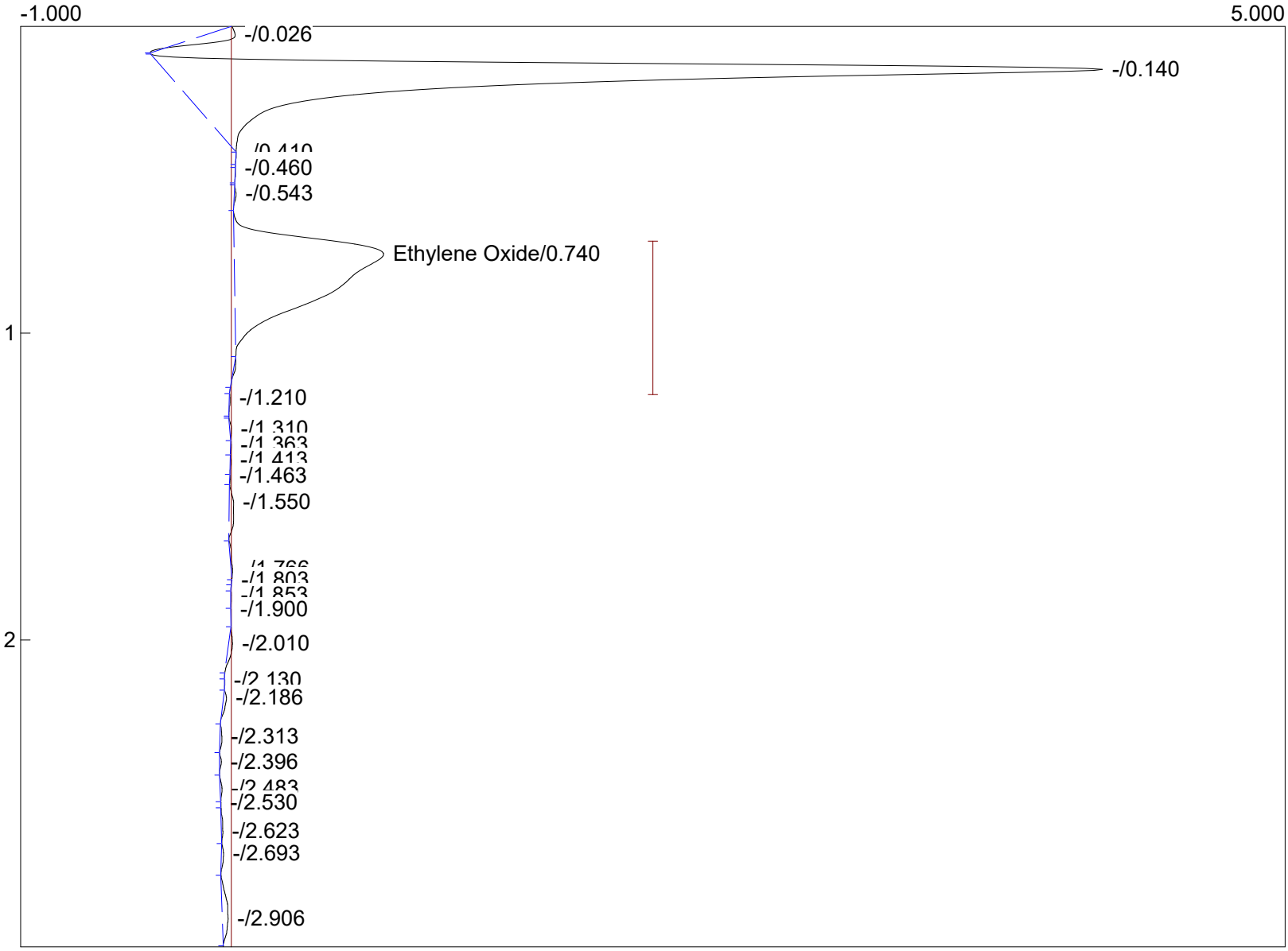
Component	Retention	Area
Ethylene Oxide	0.753	3.7207
		3.7207

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:03:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_958..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 1



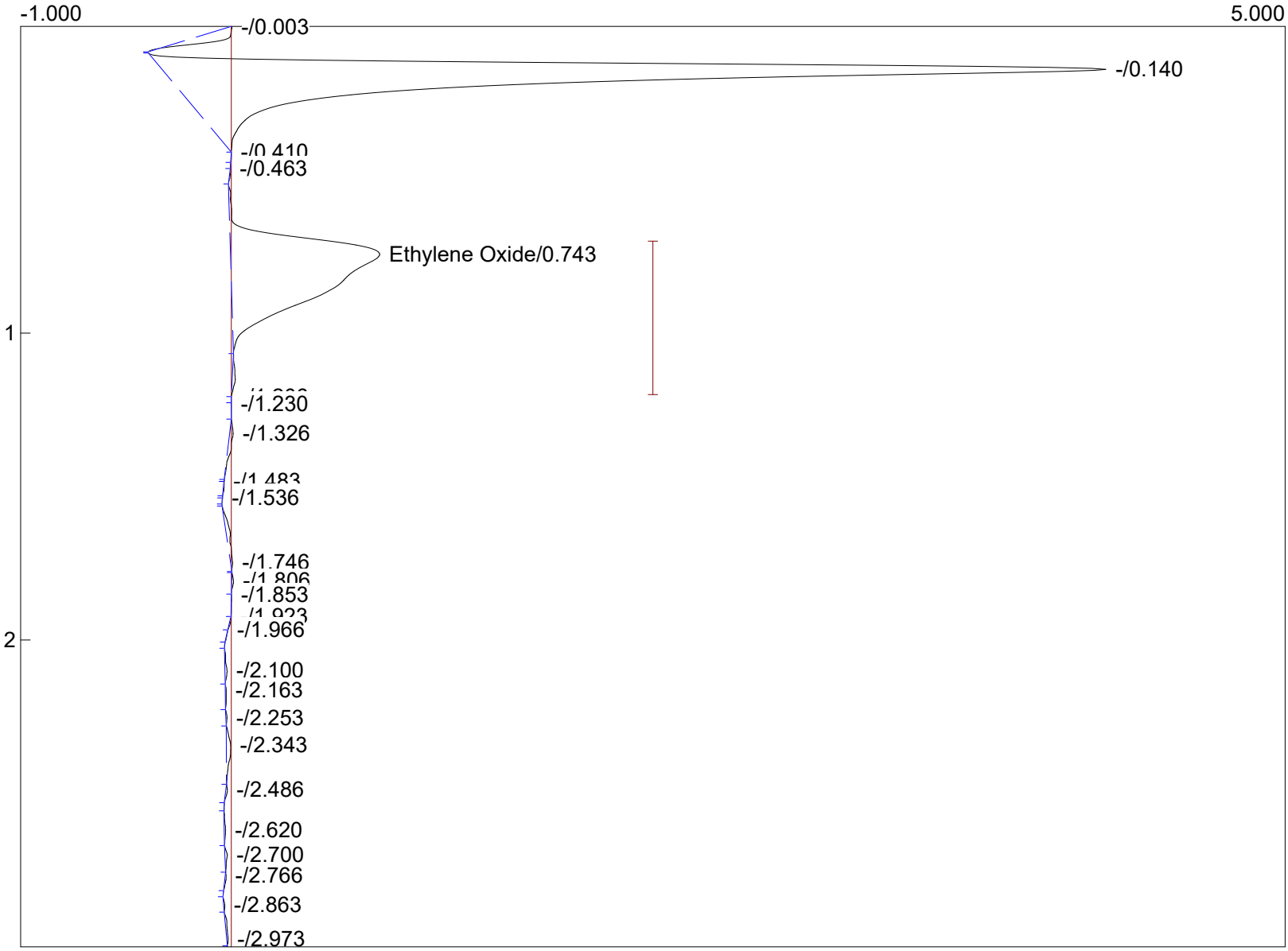
Component	Retention	Area
Ethylene Oxide	0.750	4.2847
		4.2847

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:07:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_959..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



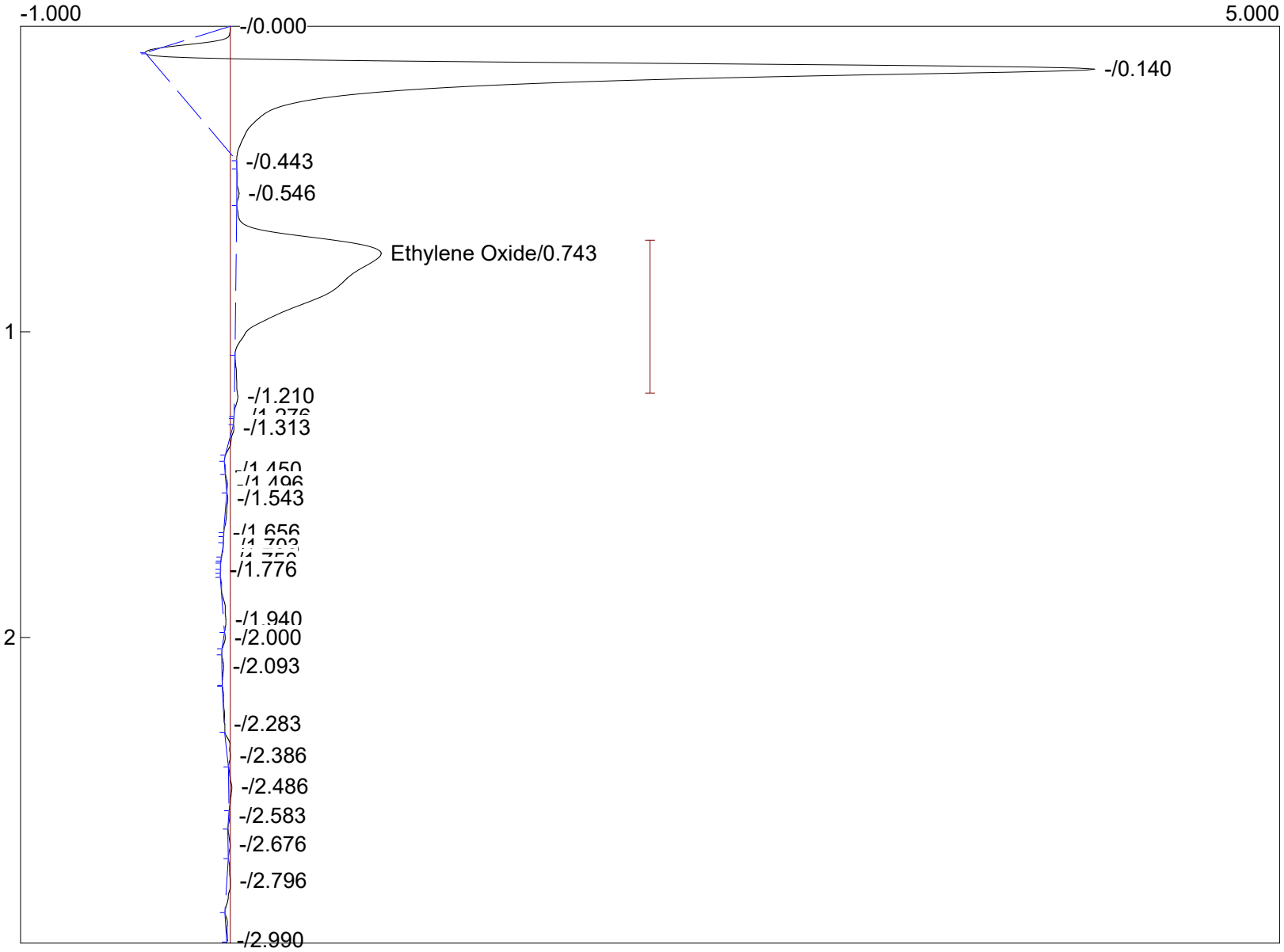
Component	Retention	Area
Ethylene Oxide	0.740	3.6765
		3.6765

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:11:34
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_960..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



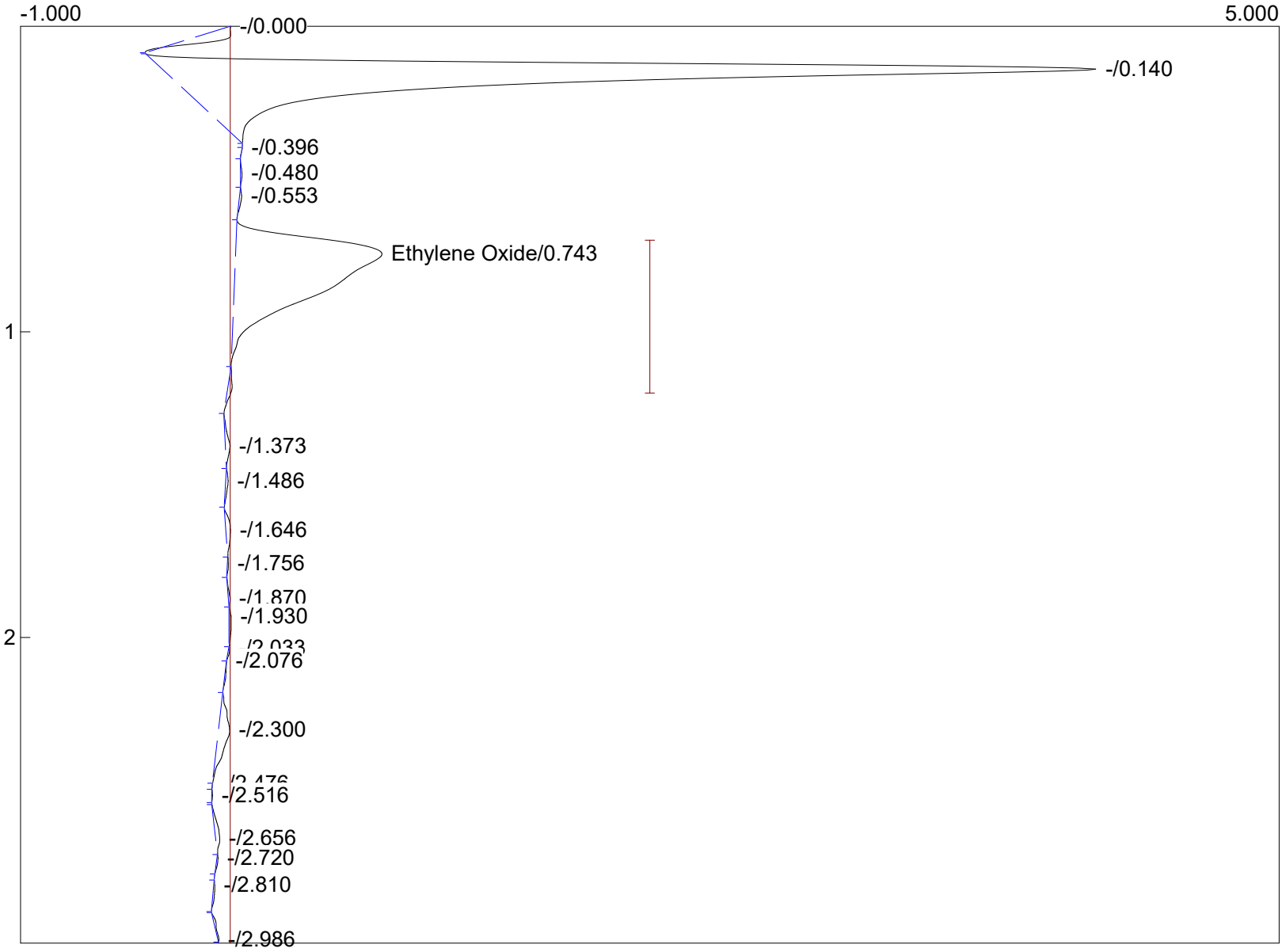
Component	Retention	Area
Ethylene Oxide	0.743	3.5402
		3.5402

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:15:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_961..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



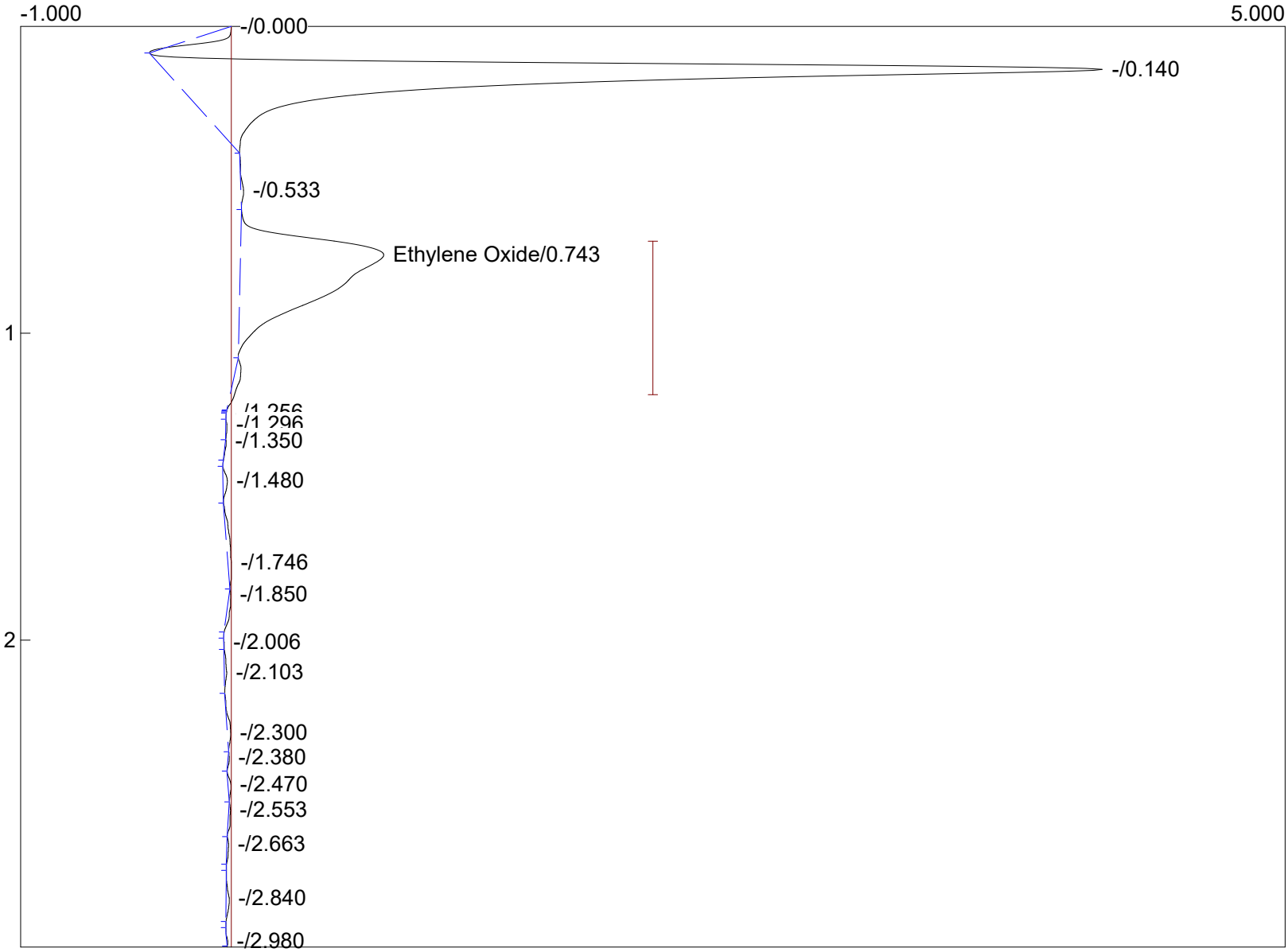
Component	Retention	Area
Ethylene Oxide	0.743	3.5765
		3.5765

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:19:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_962..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



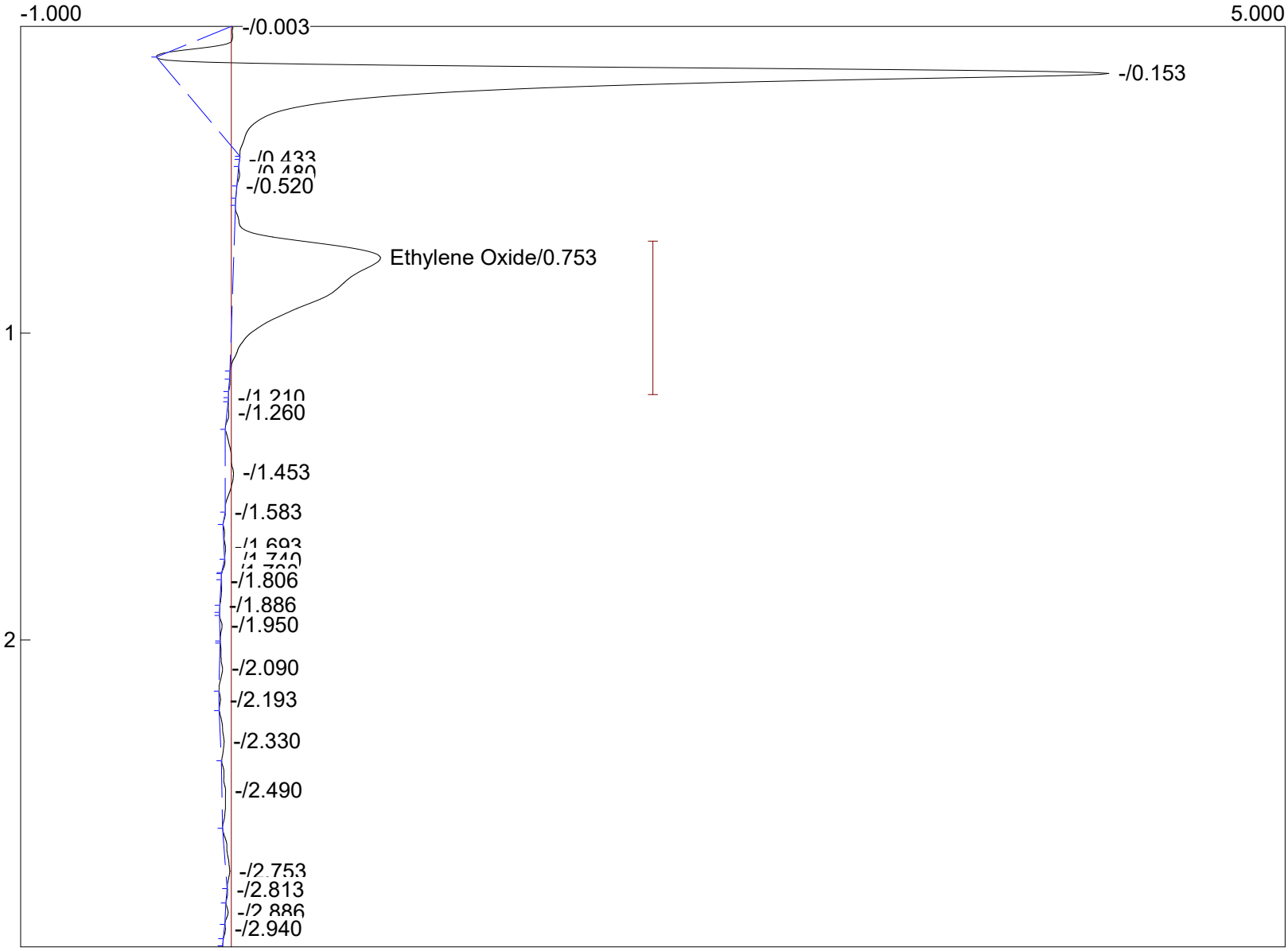
Component	Retention	Area
Ethylene Oxide	0.743	3.3196
		3.3196

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:27:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_964..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



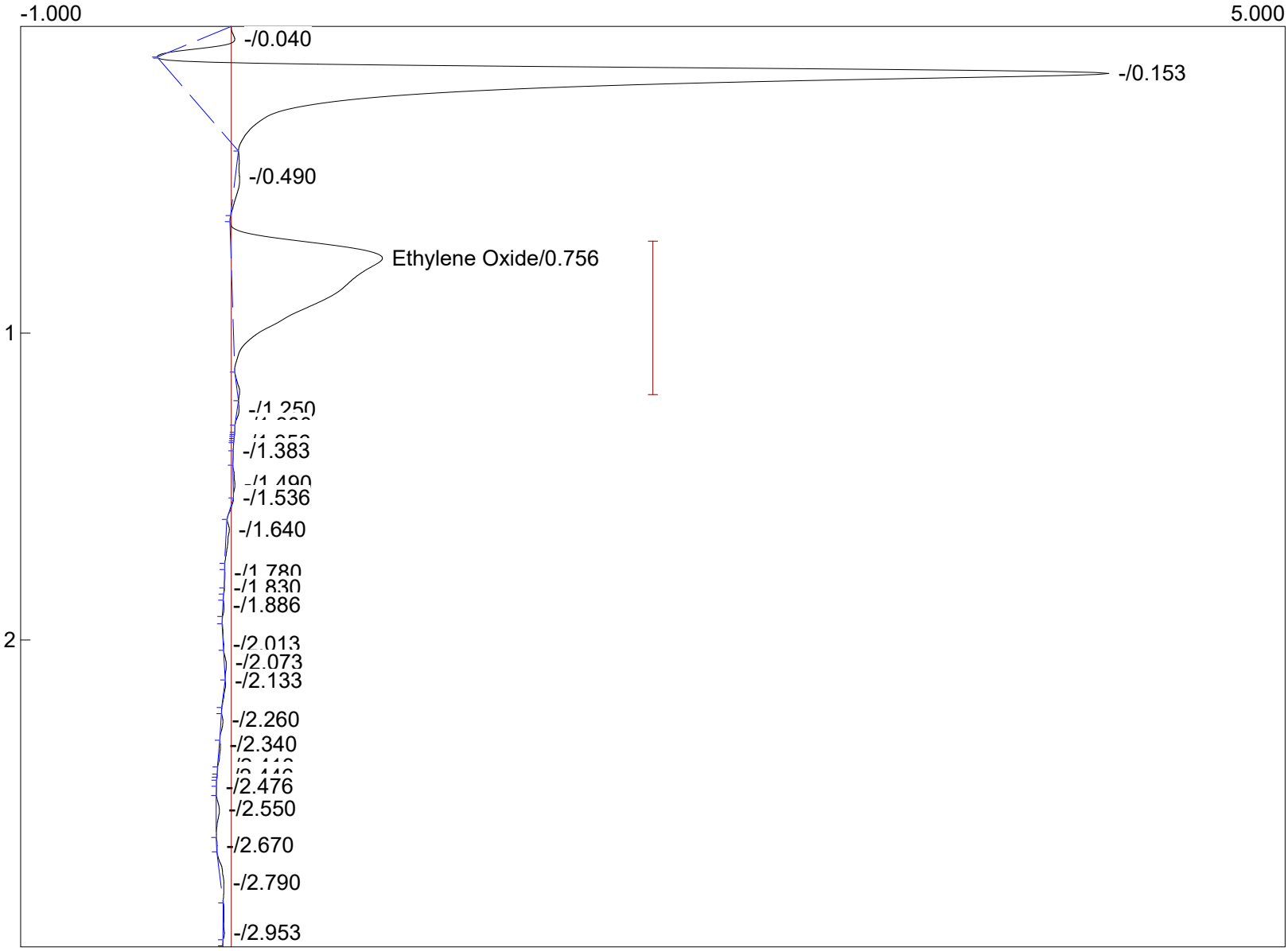
Component	Retention	Area
Ethylene Oxide	0.743	3.2937
		3.2937

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:31:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_965..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



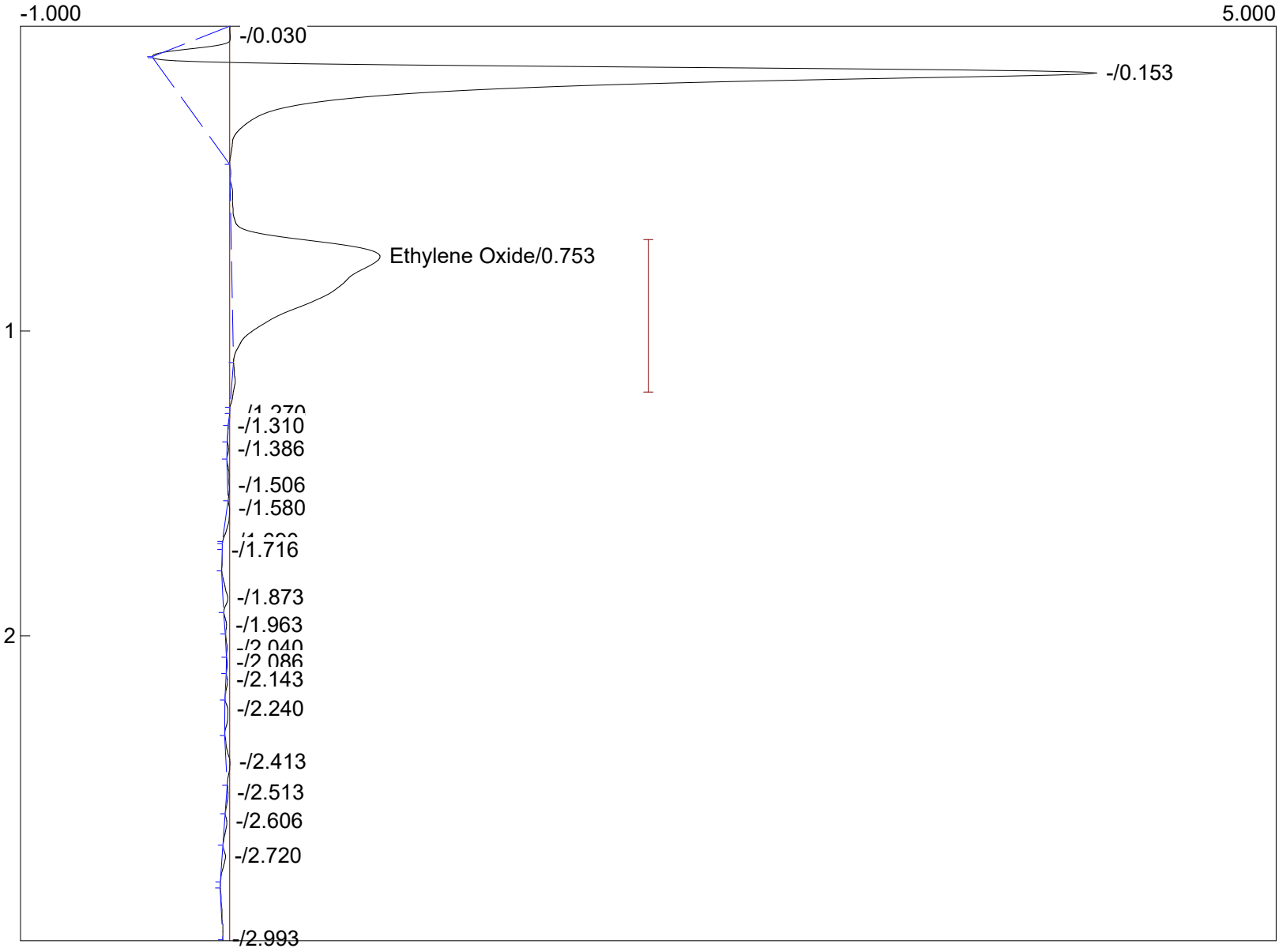
Component	Retention	Area
Ethylene Oxide	0.753	3.6320
		3.6320

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:35:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_966..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



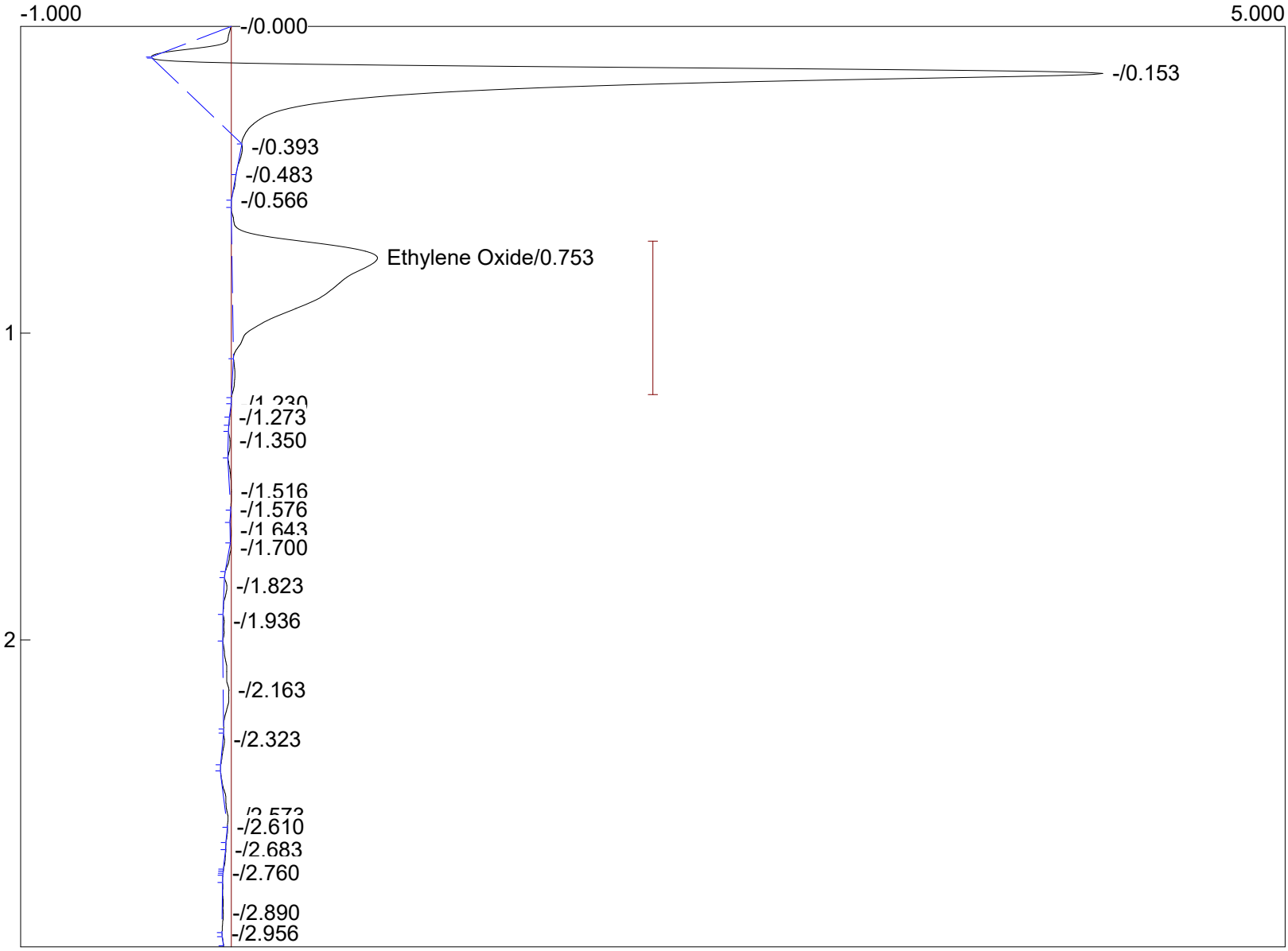
Component	Retention	Area
Ethylene Oxide	0.756	4.0763
		4.0763

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:39:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_967..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



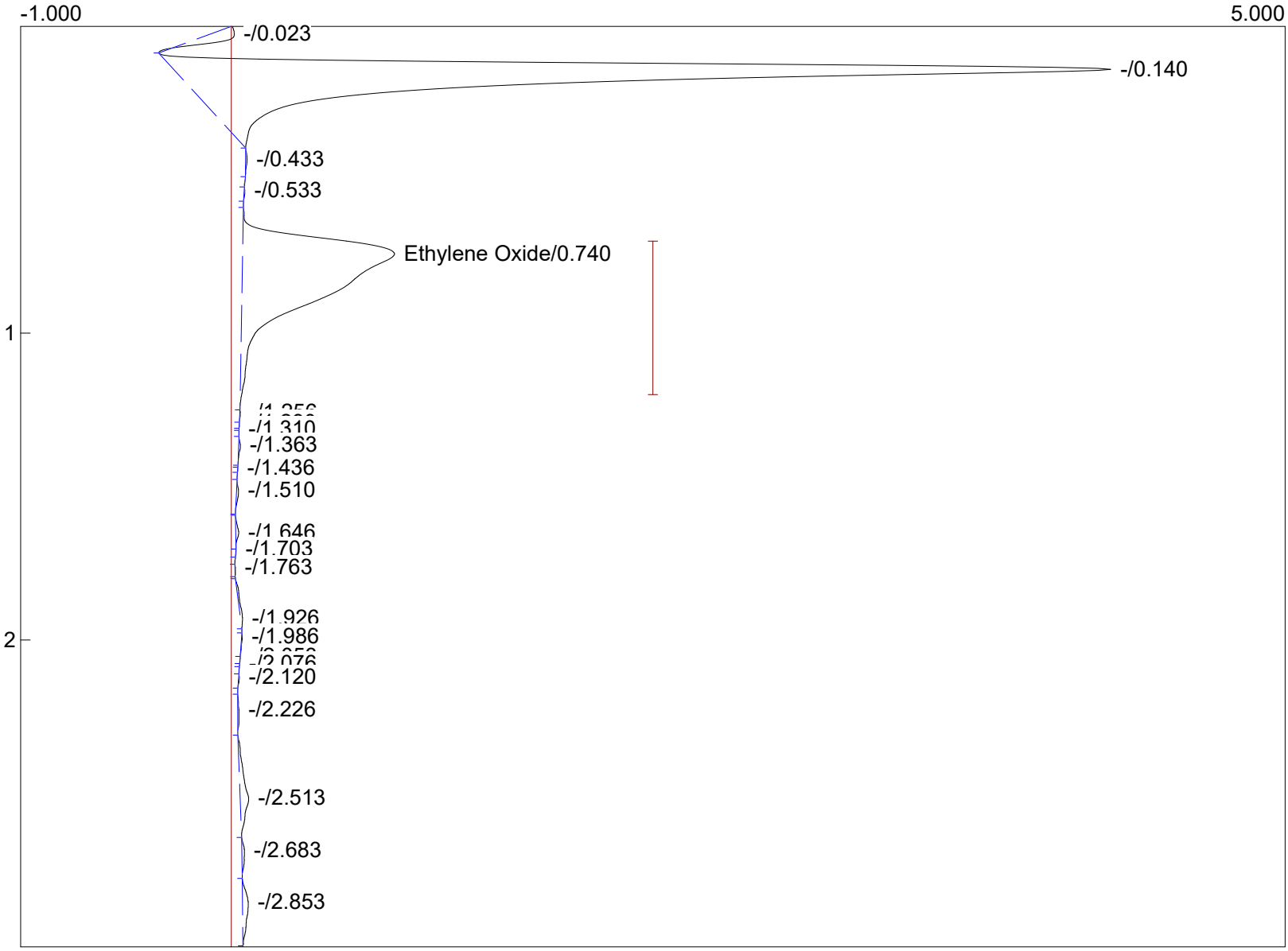
Component	Retention	Area
Ethylene Oxide	0.753	3.9118
		3.9118

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:43:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_968..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



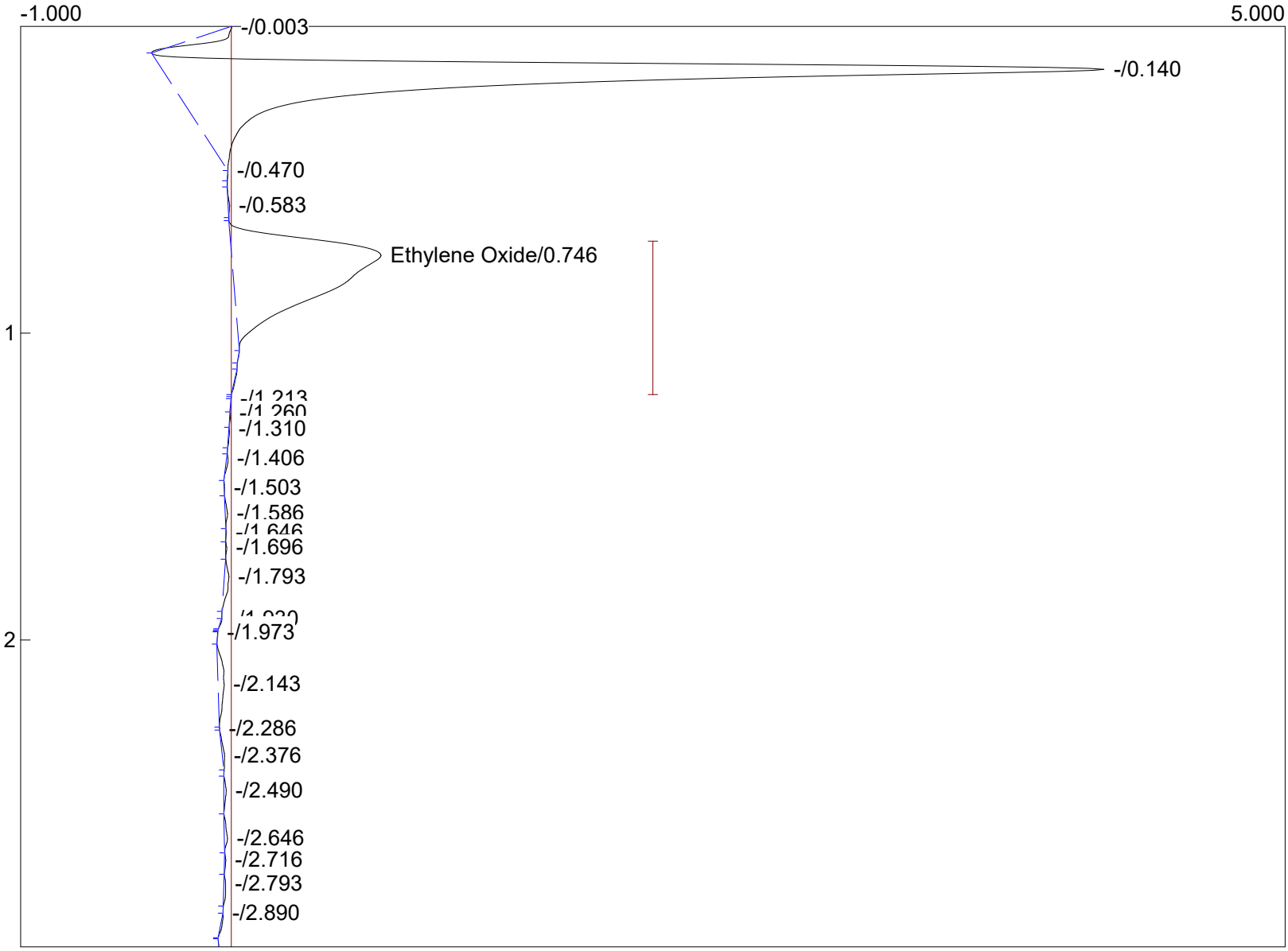
Component	Retention	Area
Ethylene Oxide	0.753	3.2680
		3.2680

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:47:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_969..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



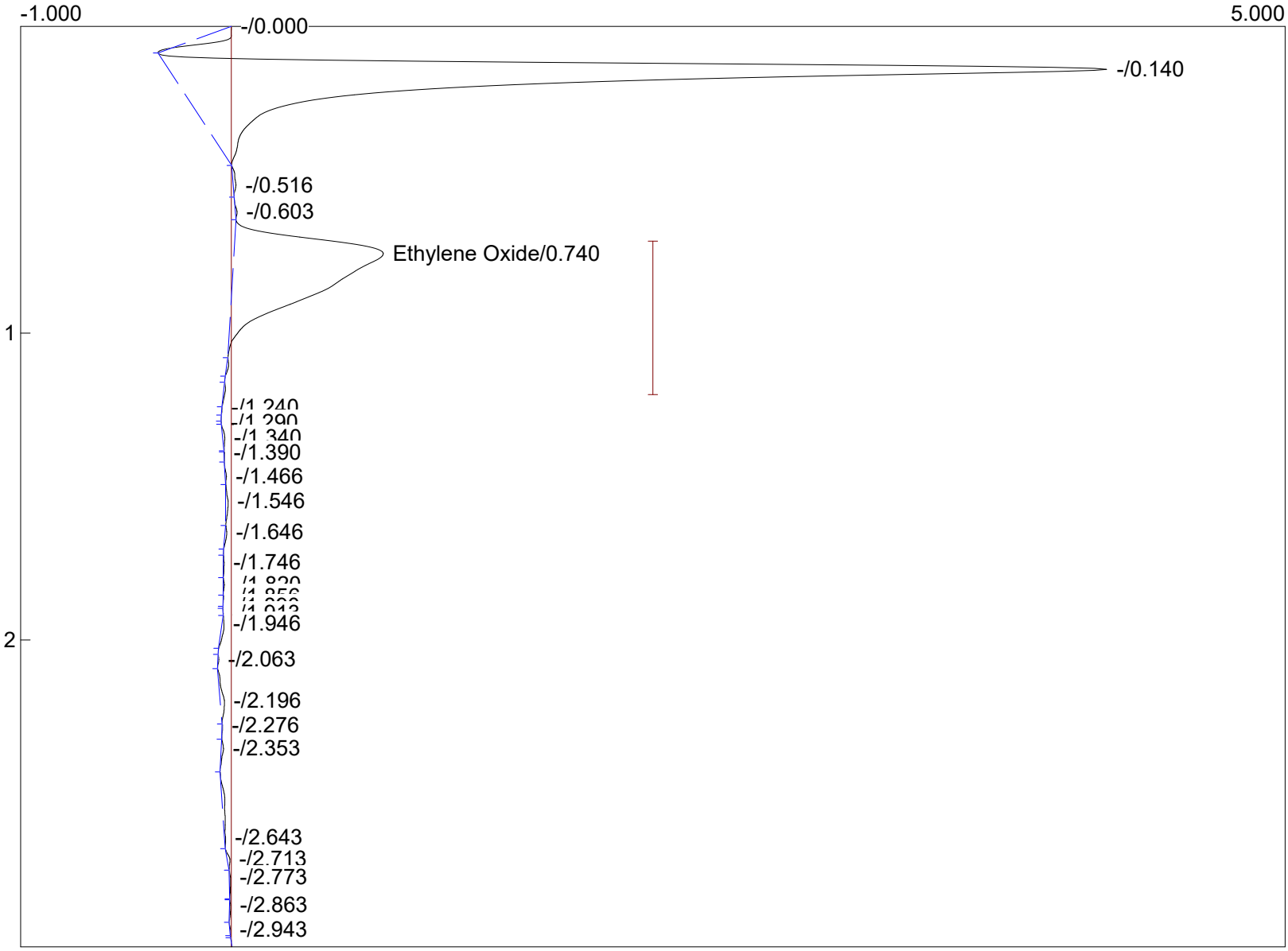
Component	Retention	Area
Ethylene Oxide	0.740	3.8742
		3.8742

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:51:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_970..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



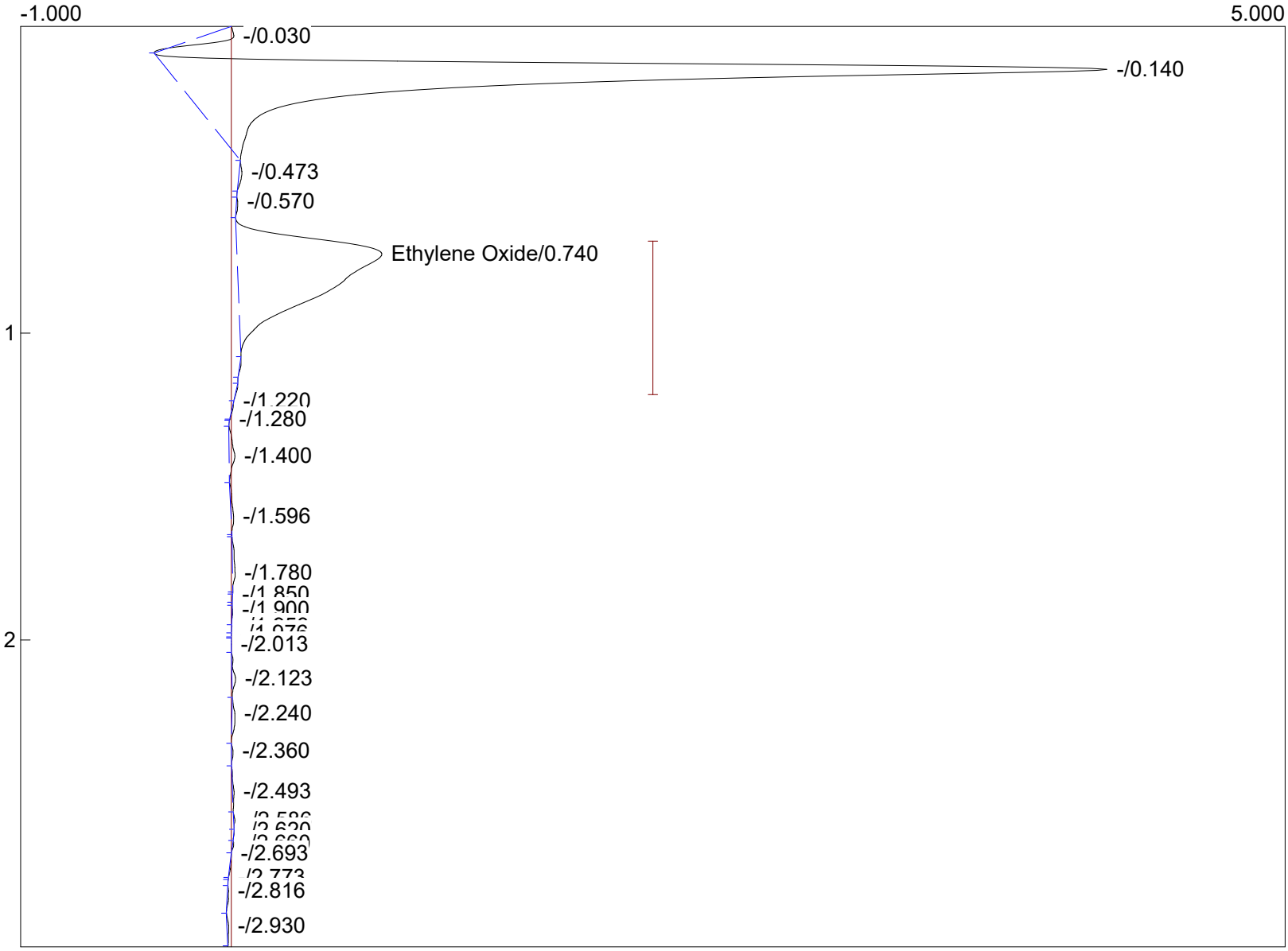
Component	Retention	Area
Ethylene Oxide	0.746	3.3550
		3.3550

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:55:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_971..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



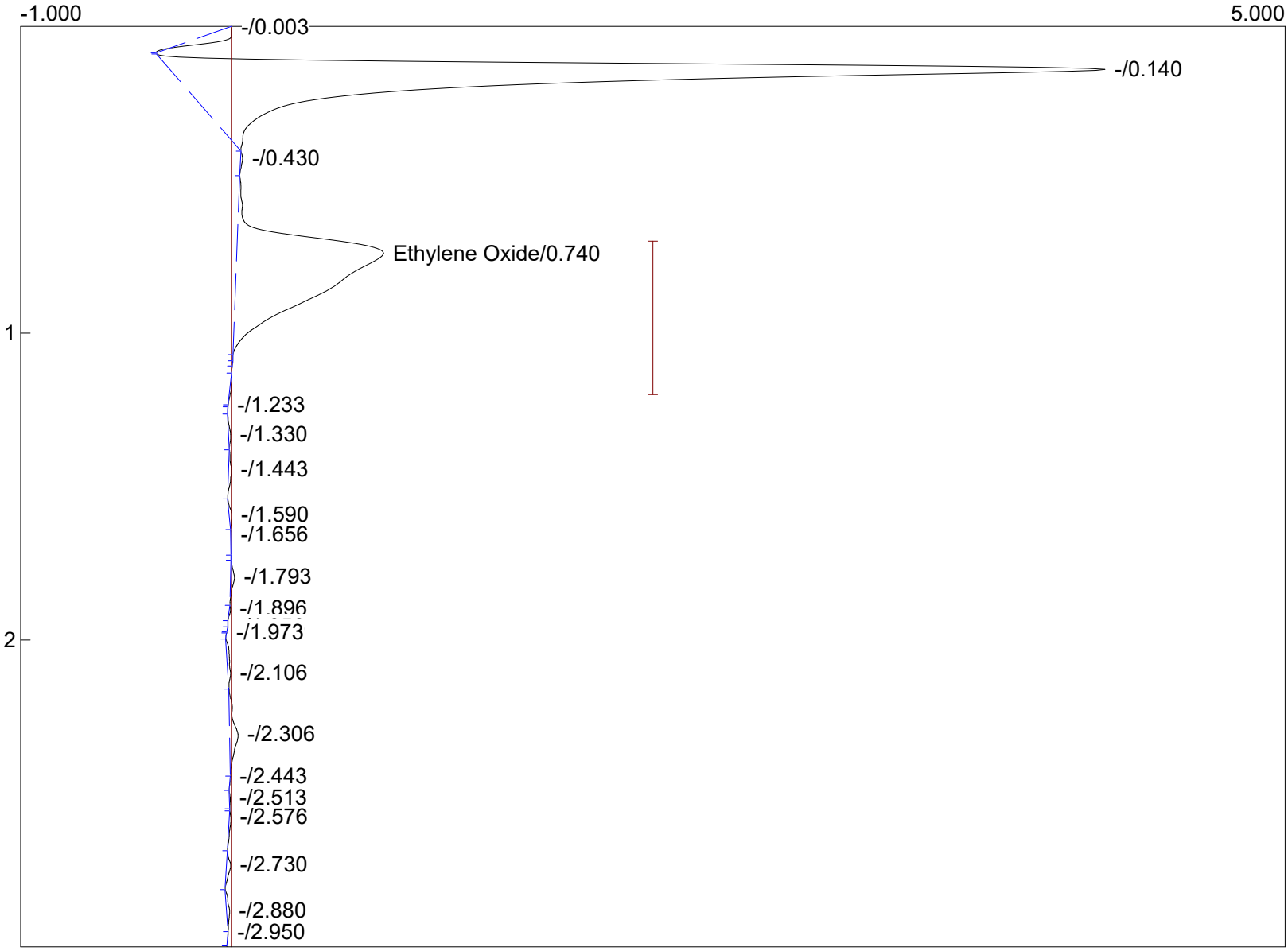
Component	Retention	Area
Ethylene Oxide	0.740	3.1113
		3.1113

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 22:59:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_972..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



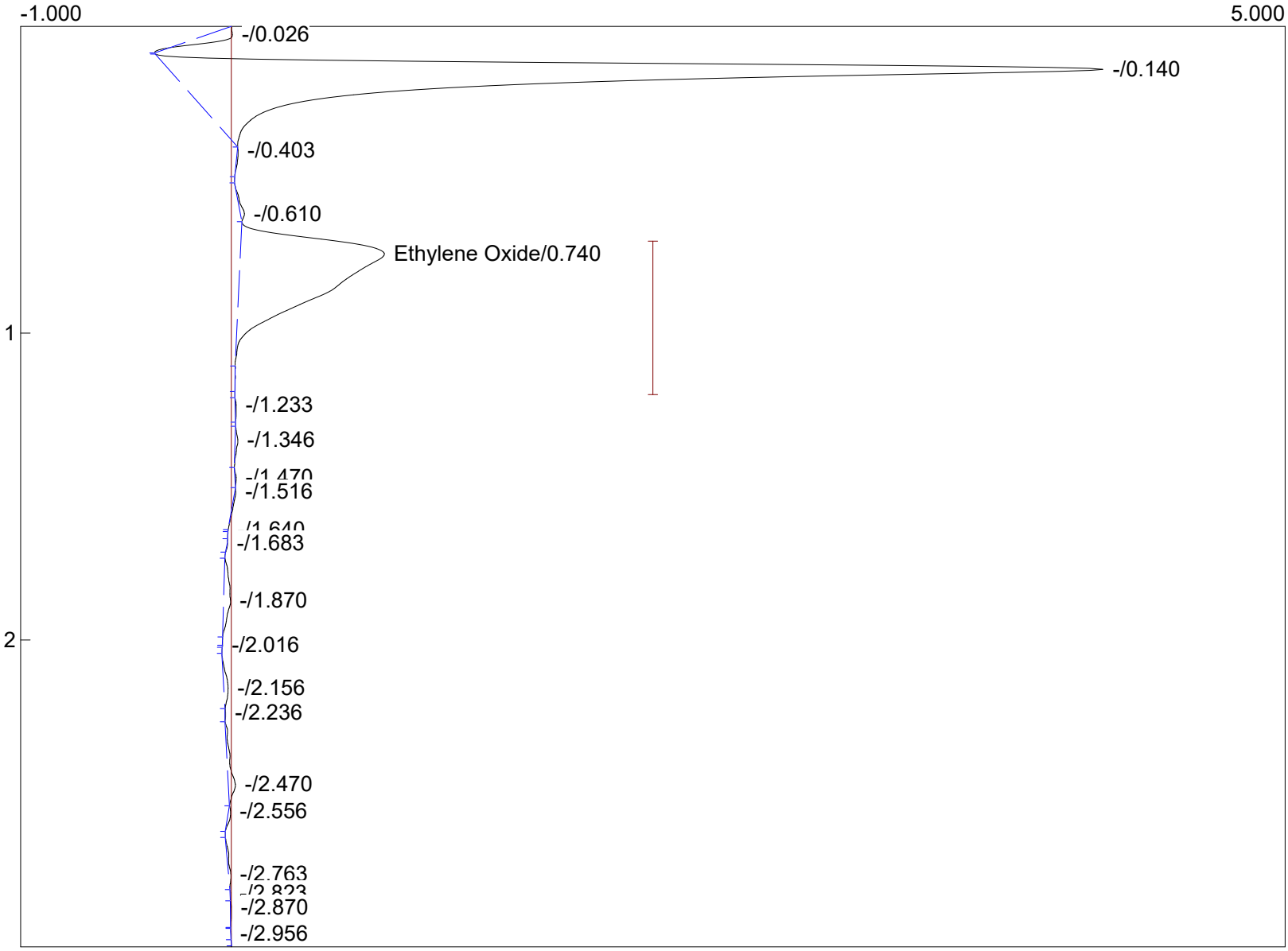
Component	Retention	Area
Ethylene Oxide	0.740	3.0844
		3.0844

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:03:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_973..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



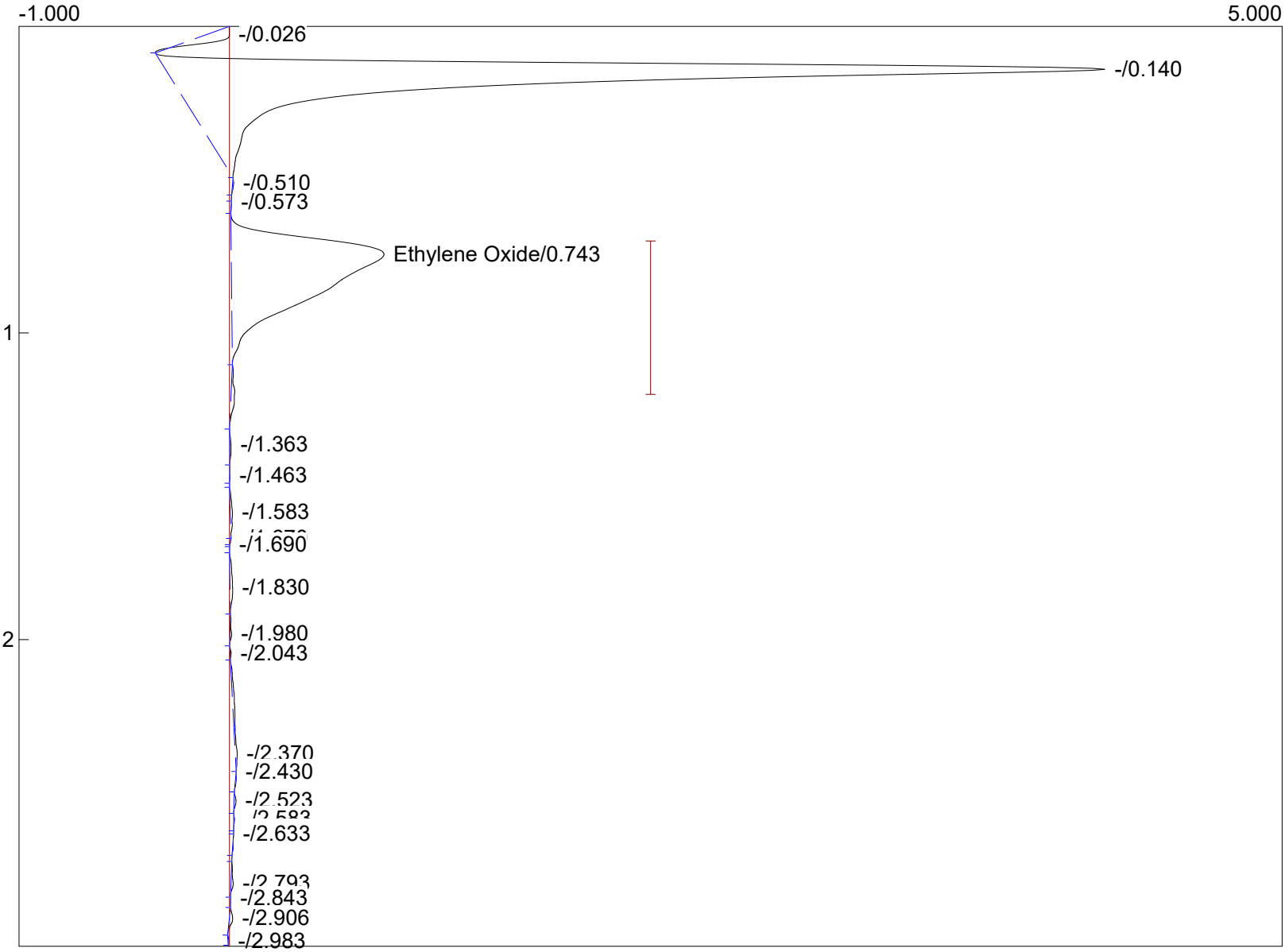
Component	Retention	Area
Ethylene Oxide	0.740	3.5334
		3.5334

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:07:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_974..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 2



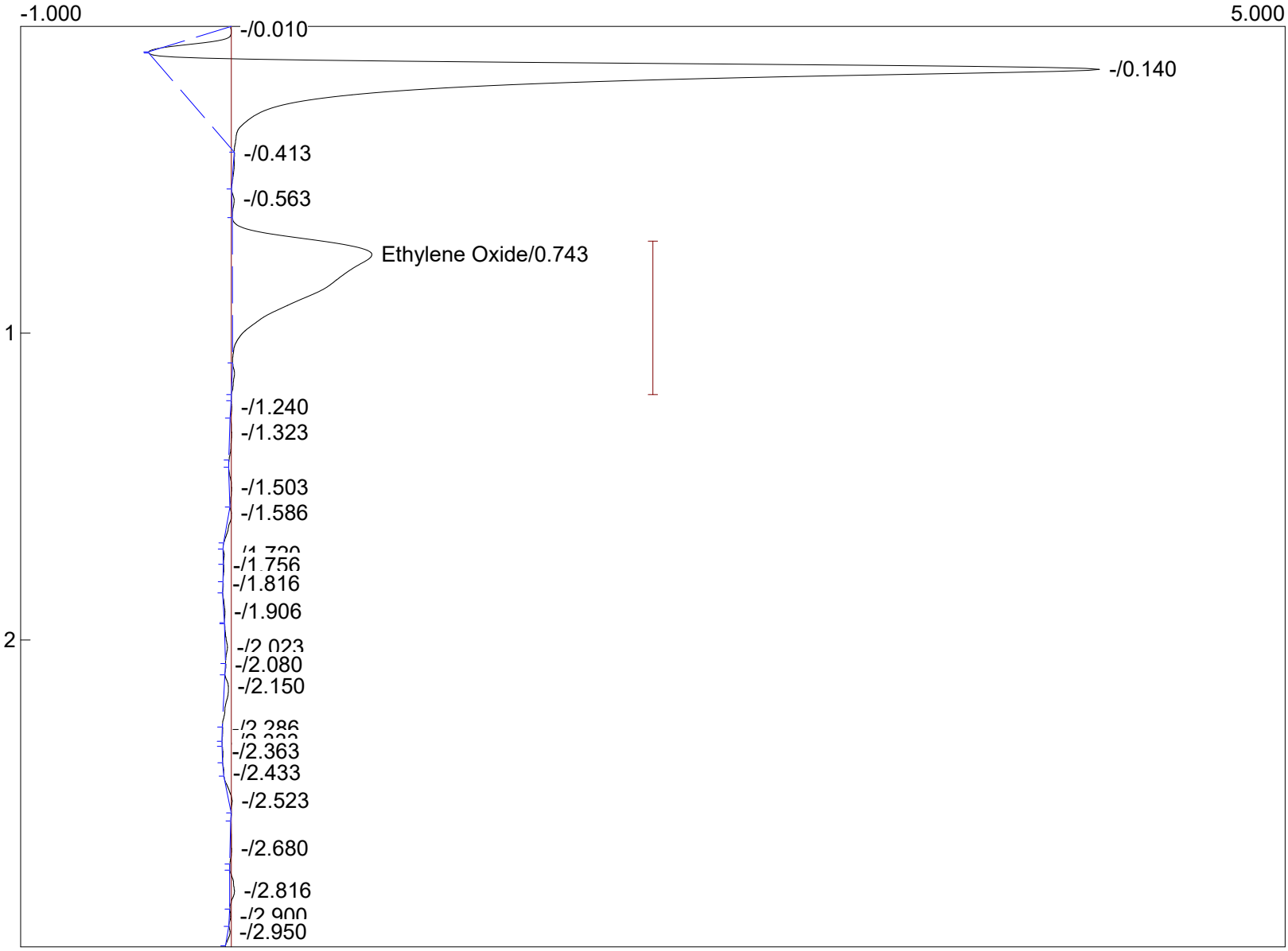
Component	Retention	Area
Ethylene Oxide	0.740	3.0760
		3.0760

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:11:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_975..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



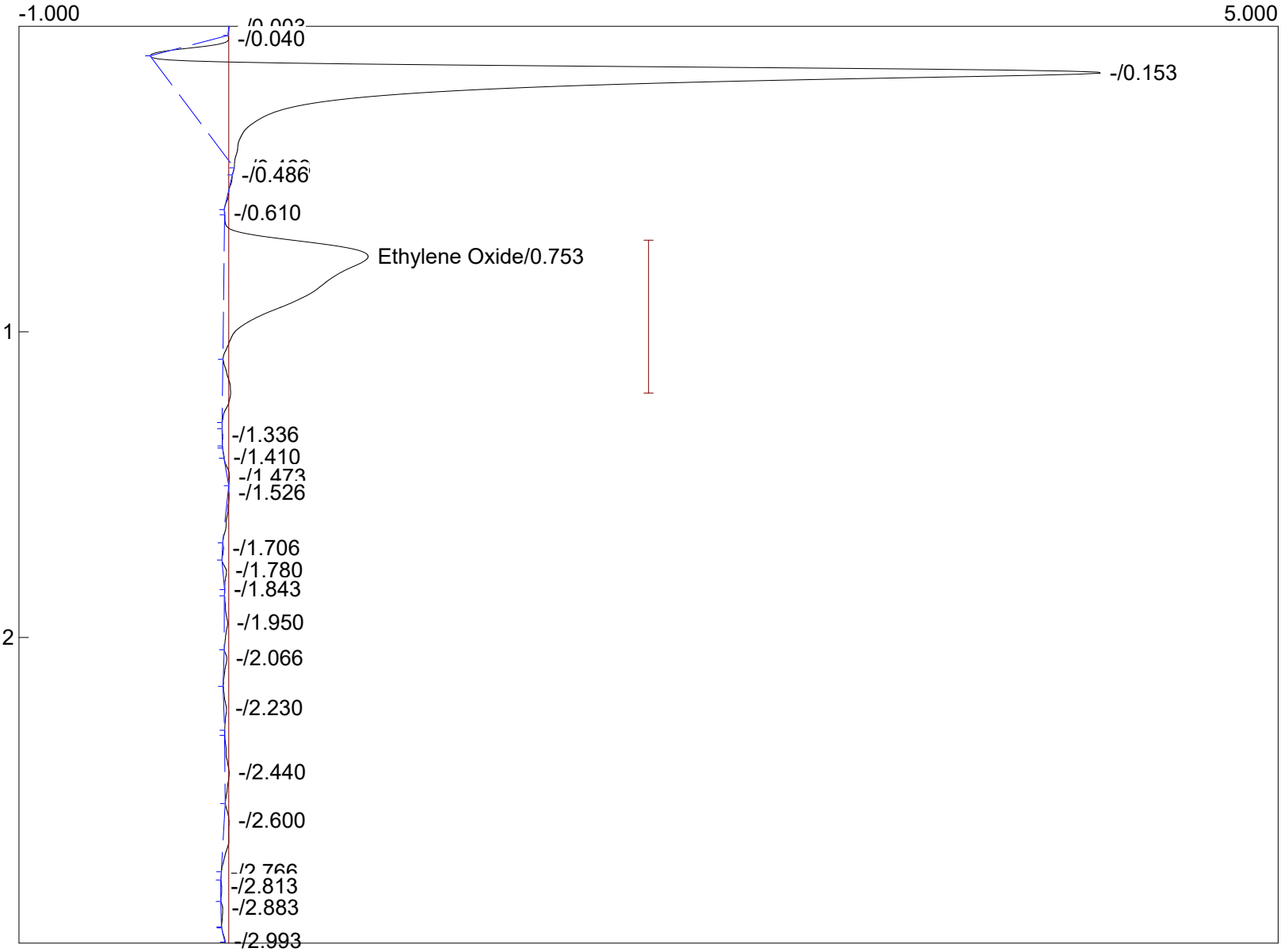
Component	Retention	Area
Ethylene Oxide	0.743	3.7324
		3.7324

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:15:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_976..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



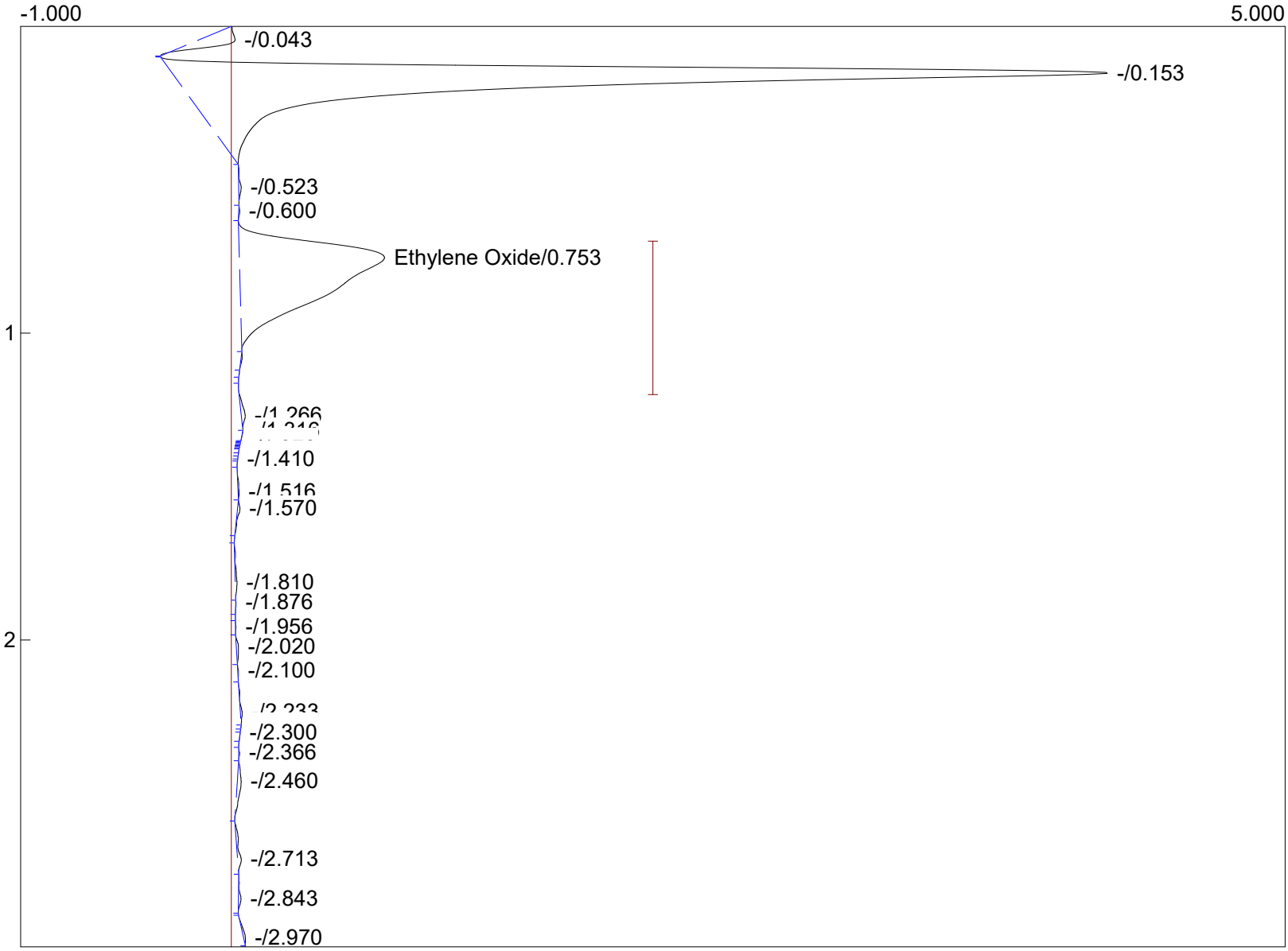
Component	Retention	Area
Ethylene Oxide	0.743	2.7842
		2.7842

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:19:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_977..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



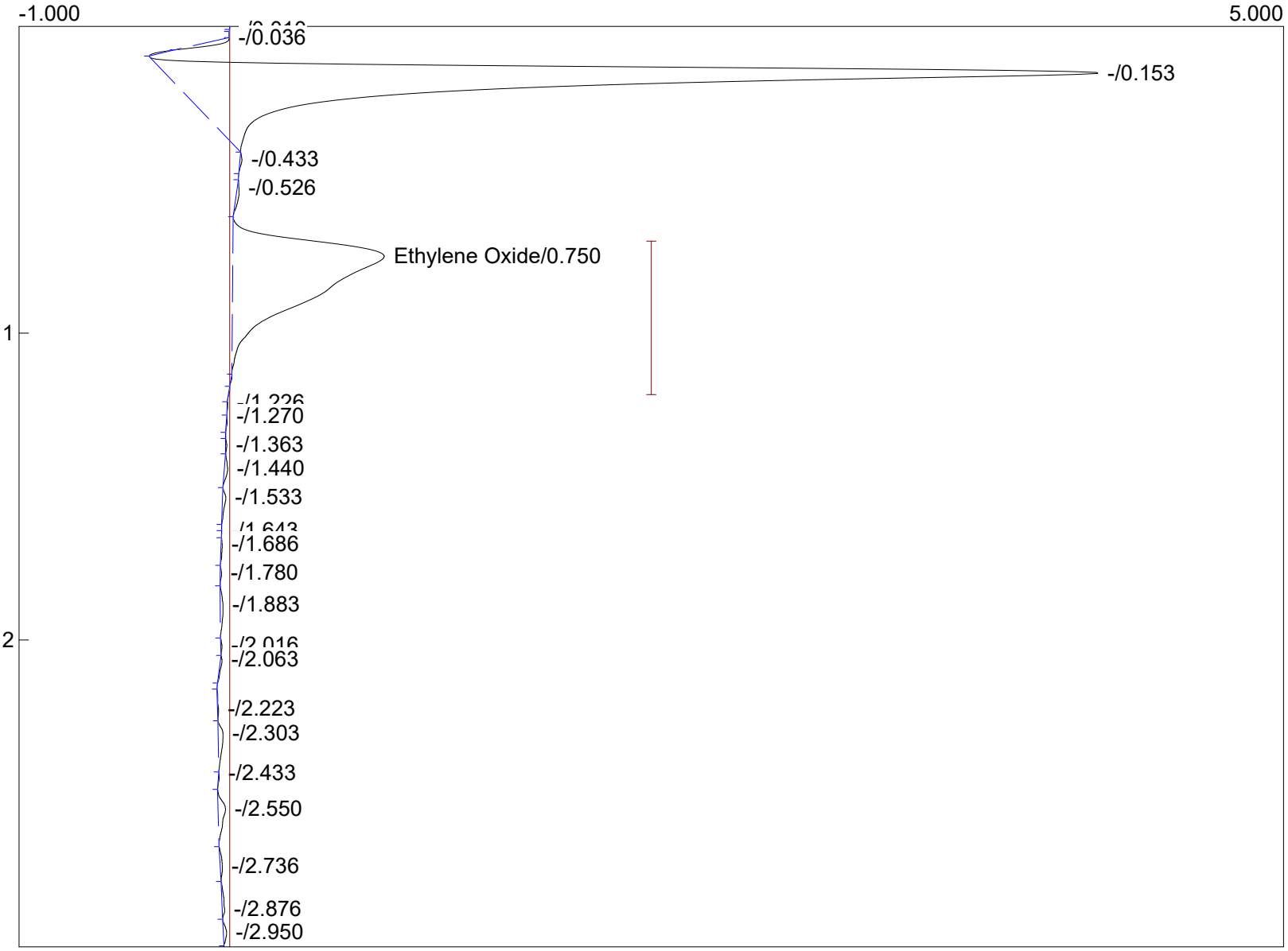
Component	Retention	Area
Ethylene Oxide	0.753	2.9044
		2.9044

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:23:35
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_978..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



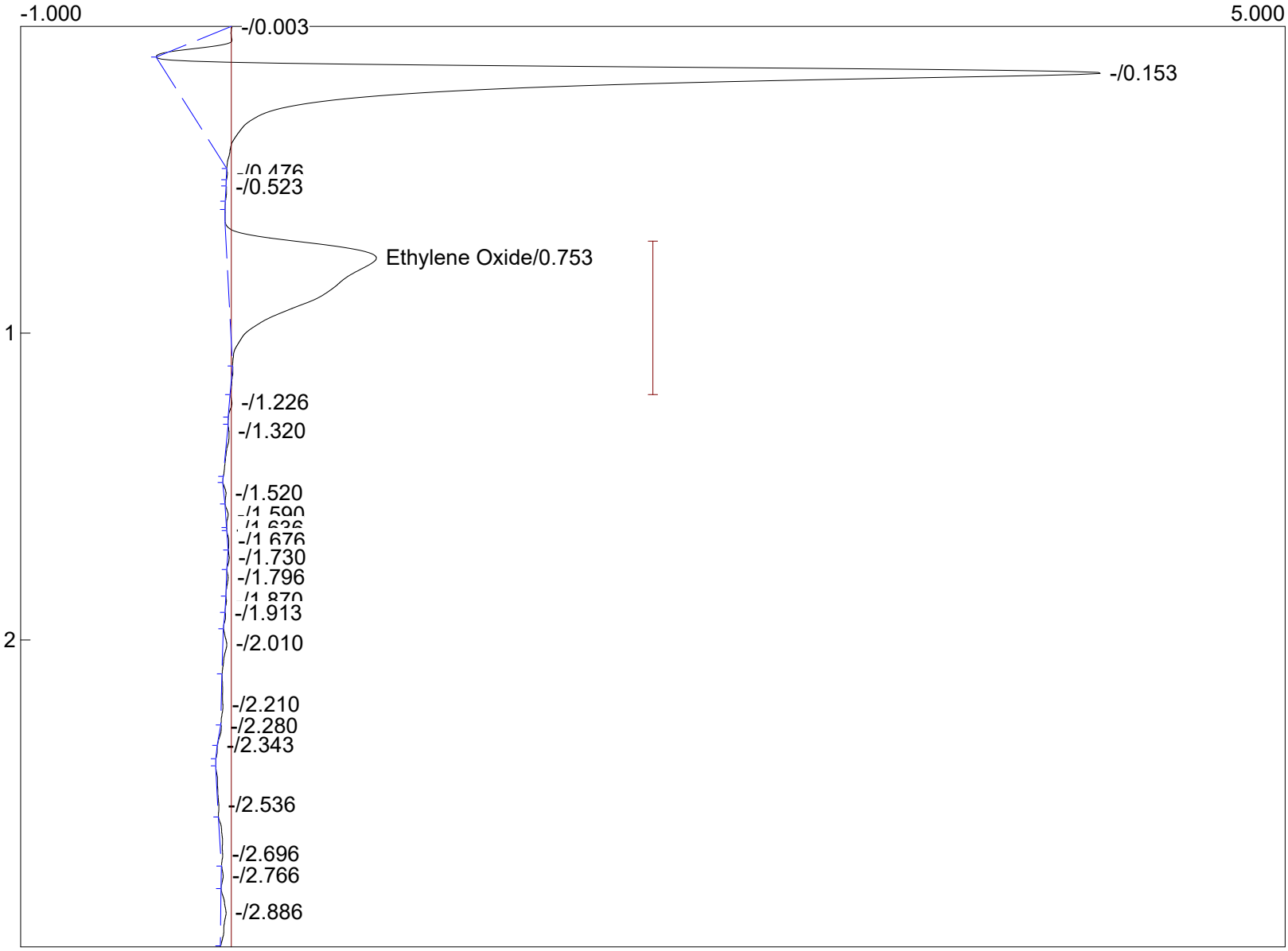
Component	Retention	Area
Ethylene Oxide	0.753	2.8986
		2.8986

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:27:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_979..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



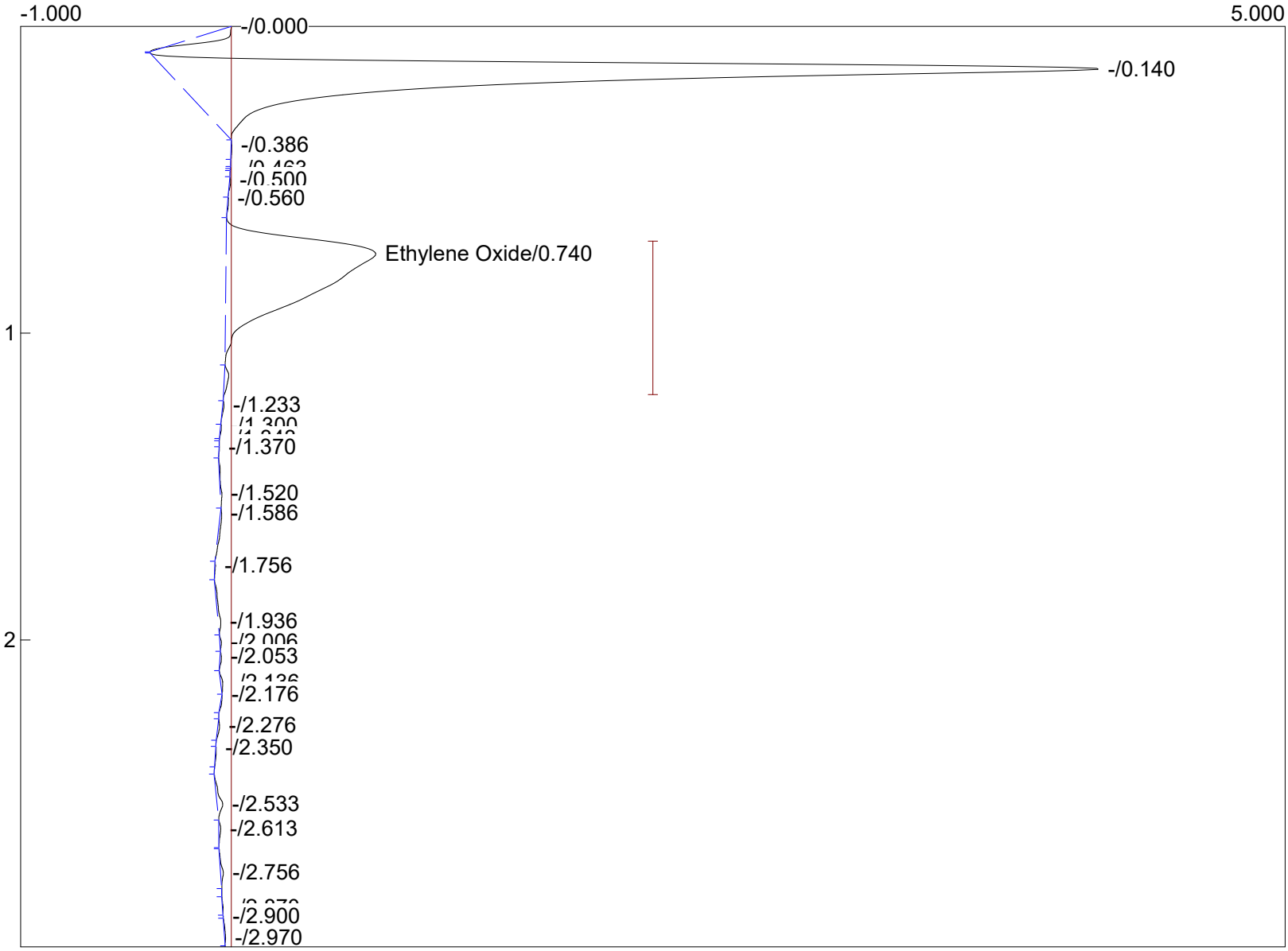
Component	Retention	Area
Ethylene Oxide	0.750	3.4024
		3.4024

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:31:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_980..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



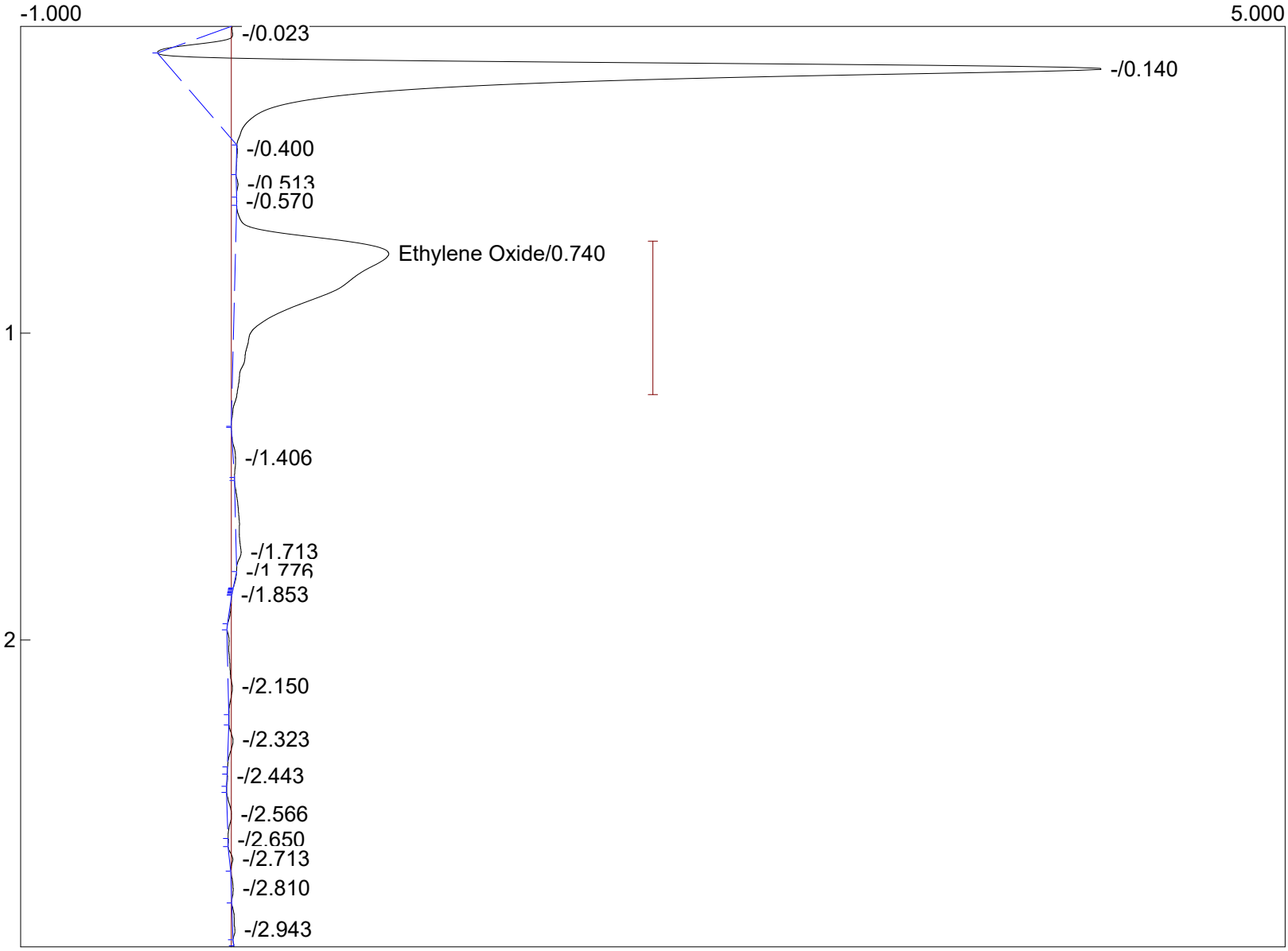
Component	Retention	Area
Ethylene Oxide	0.753	3.3888
		3.3888

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:35:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_981..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



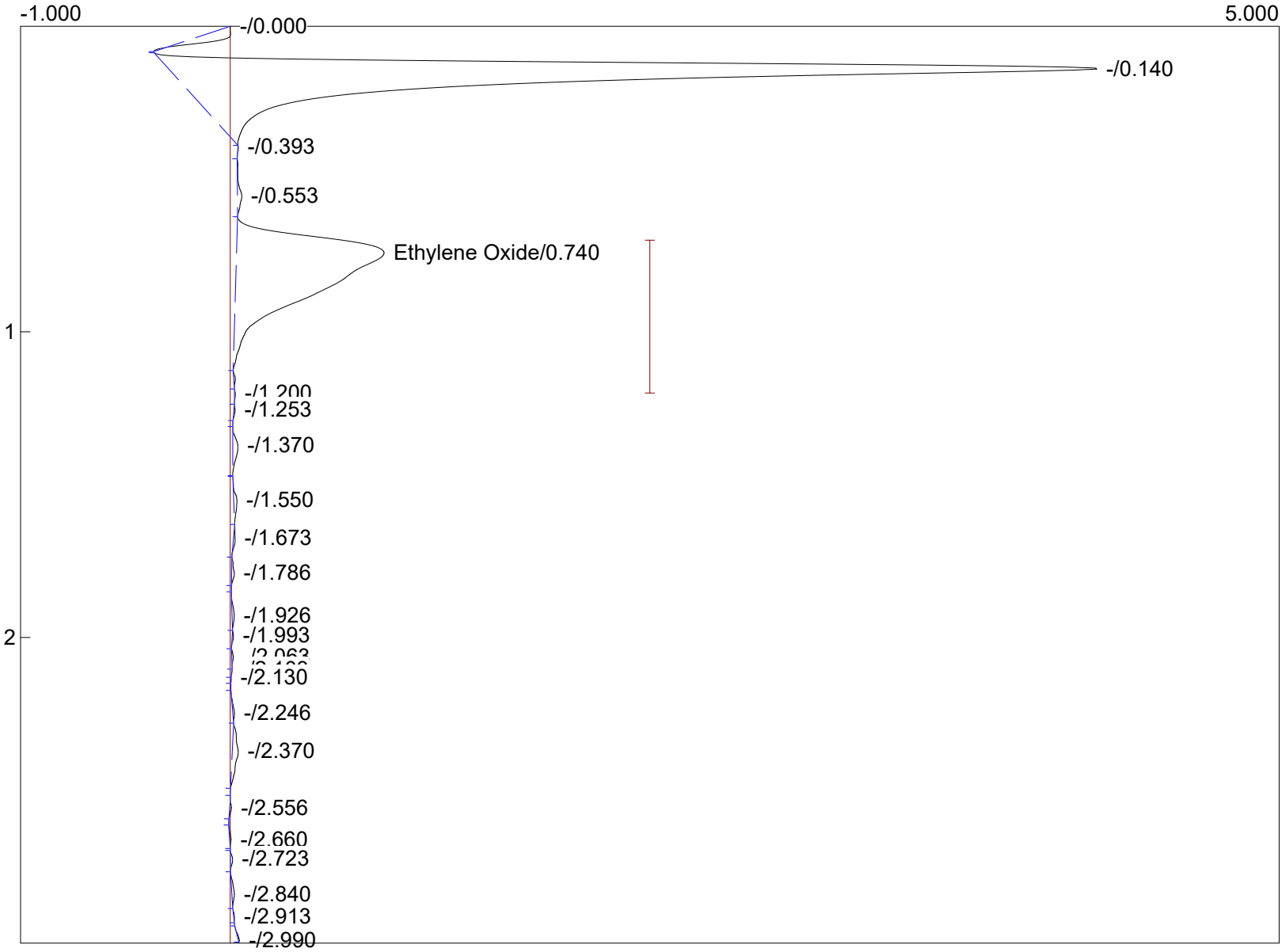
Component	Retention	Area
Ethylene Oxide	0.740	3.4320
		3.4320

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:39:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_982..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



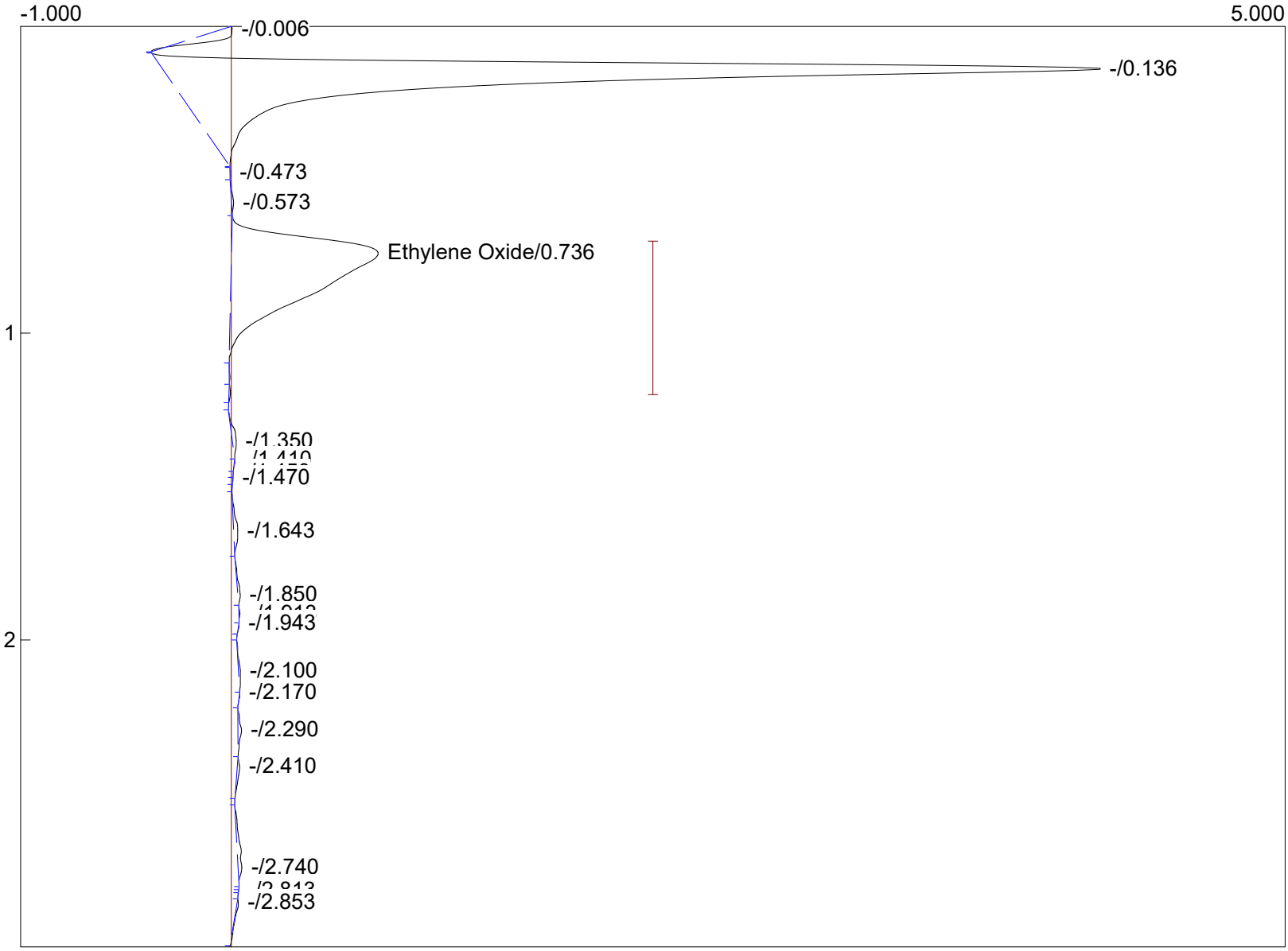
Component	Retention	Area
Ethylene Oxide	0.740	4.5250
		4.5250

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:43:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_983..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



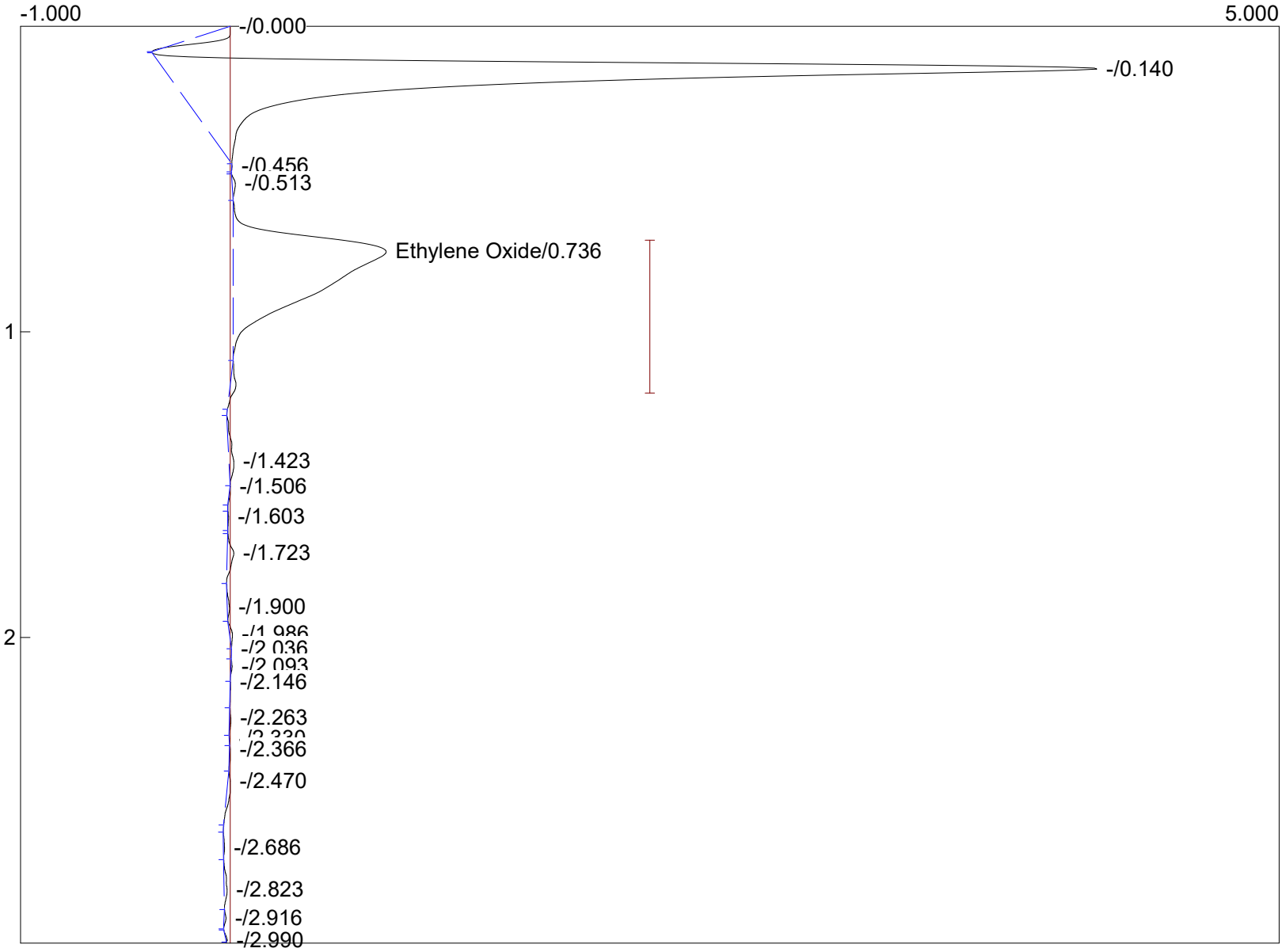
Component	Retention	Area
Ethylene Oxide	0.740	3.3899
		3.3899

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:47:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_984..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



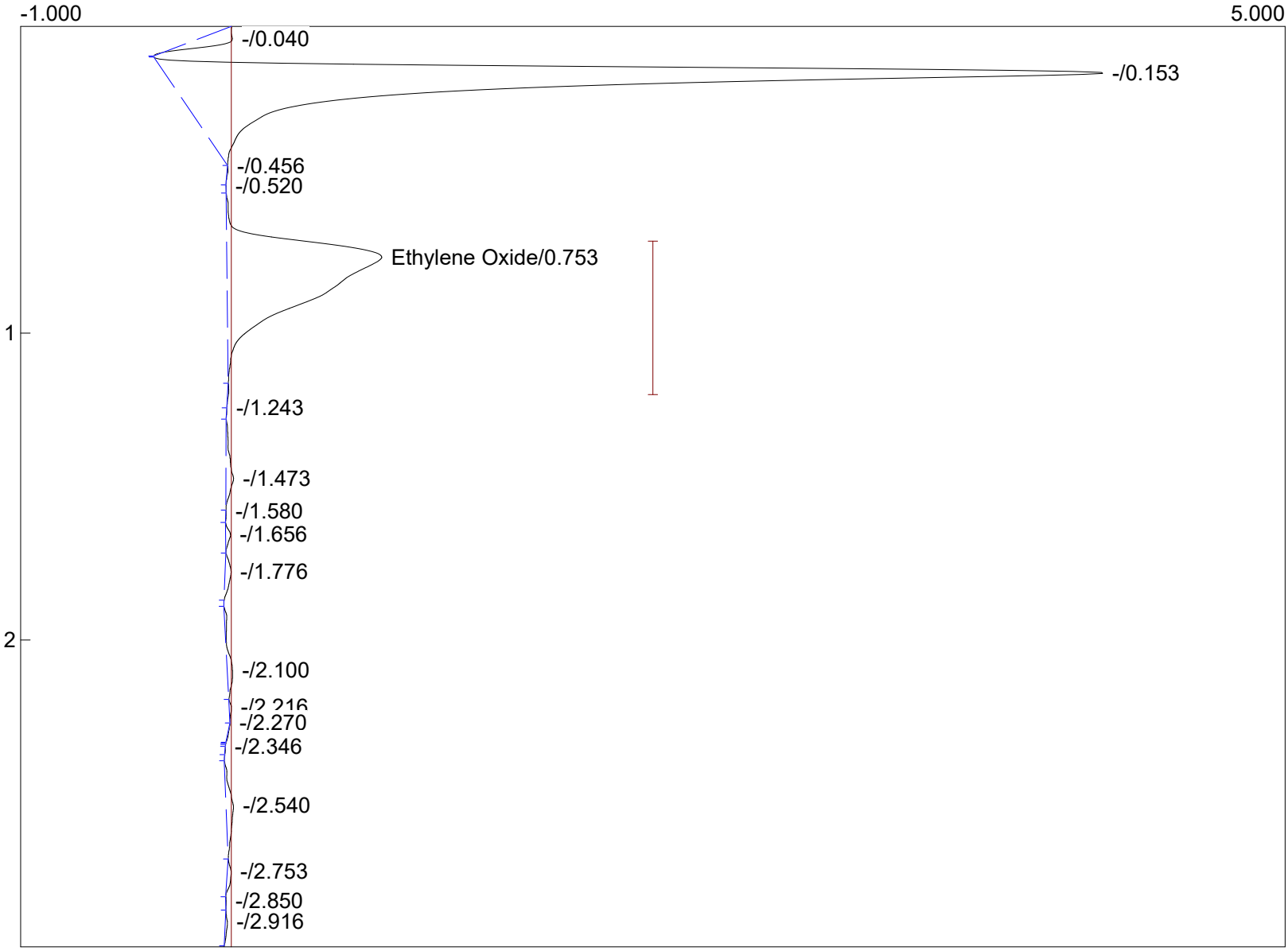
Component	Retention	Area
Ethylene Oxide	0.736	3.3160
		3.3160

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:51:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_985..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



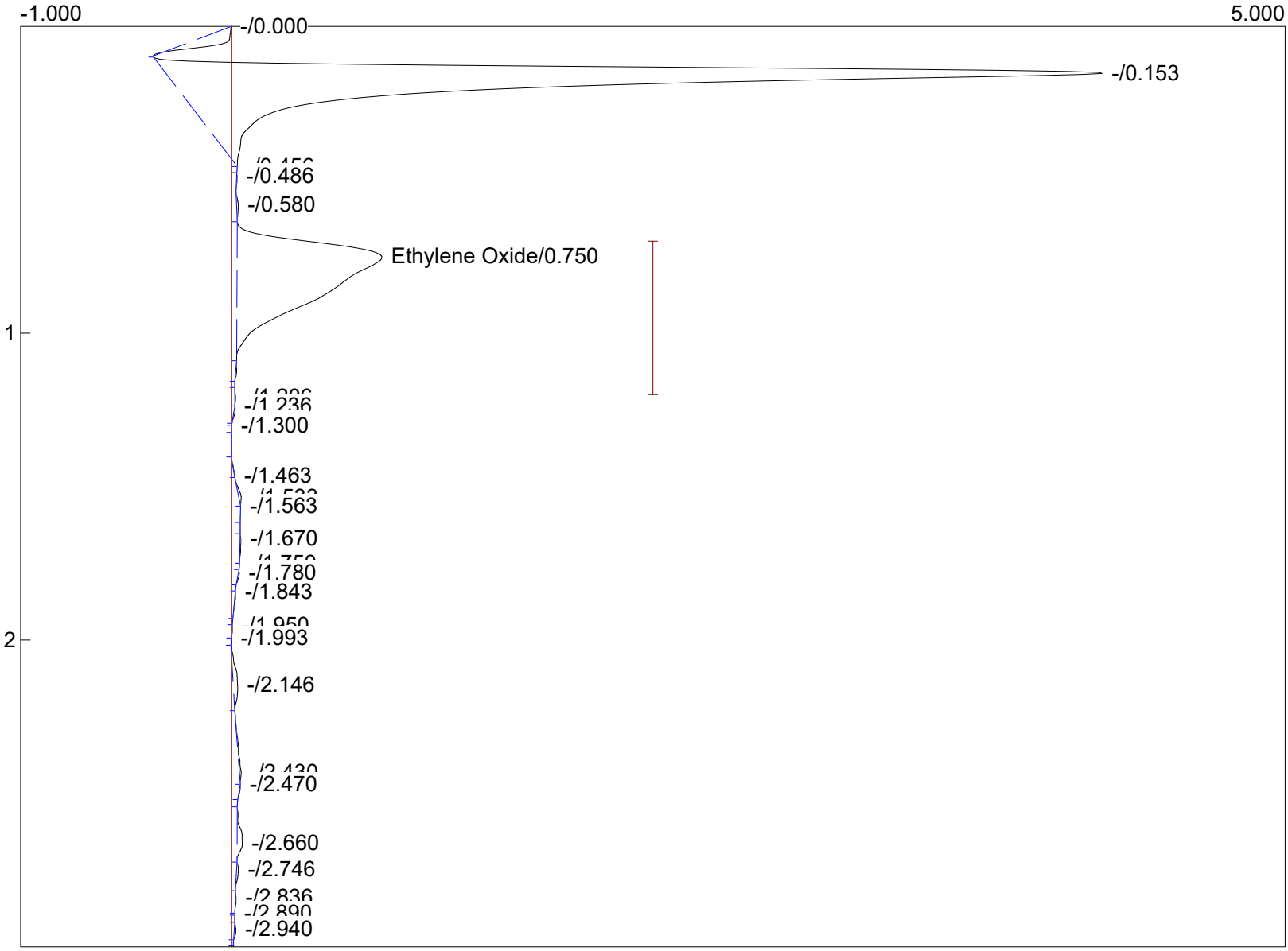
Component	Retention	Area
Ethylene Oxide	0.736	3.4900
		3.4900

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:55:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_986..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



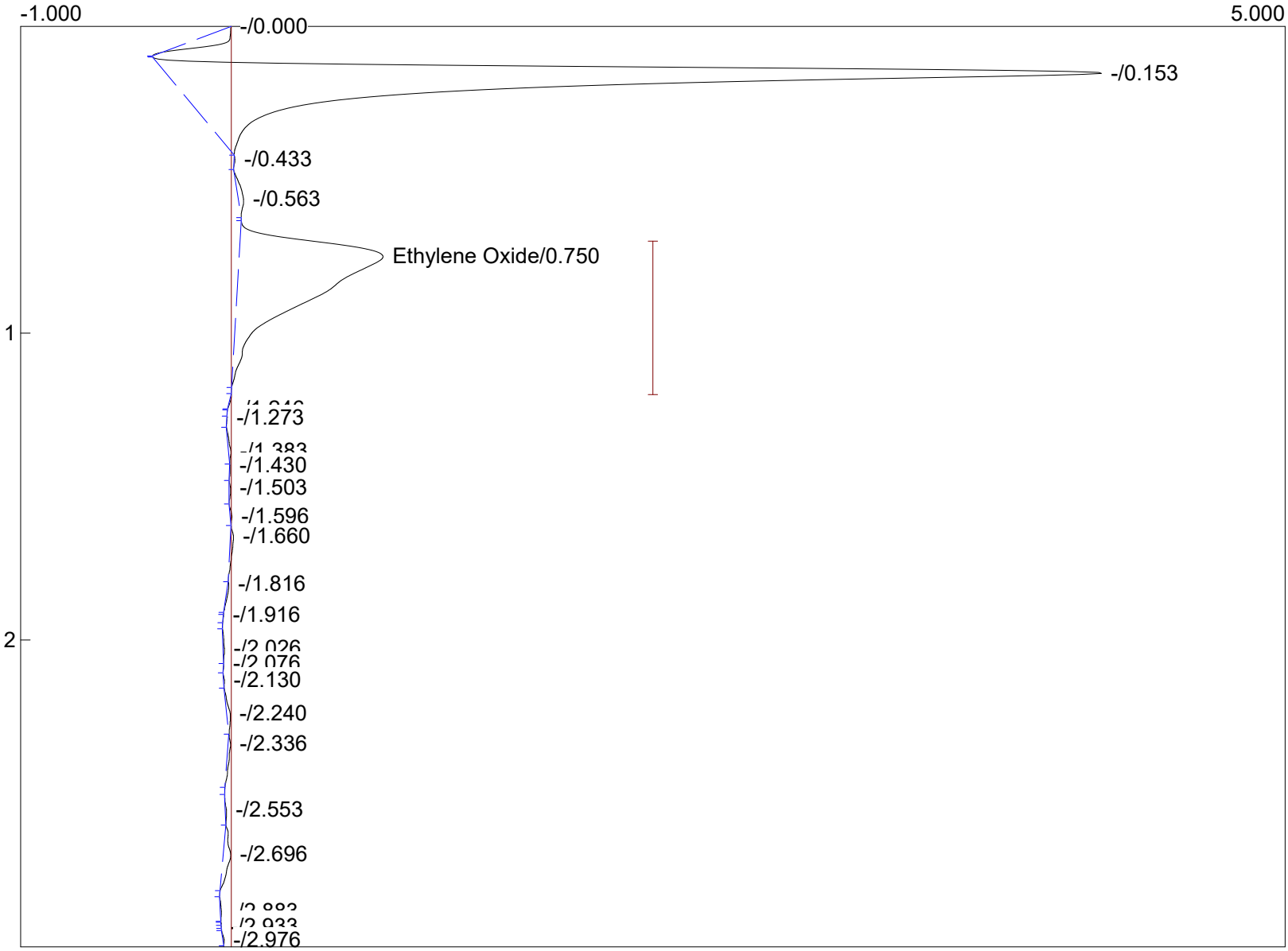
Component	Retention	Area
Ethylene Oxide	0.753	3.8158
		3.8158

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/09/2020 23:59:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_987..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



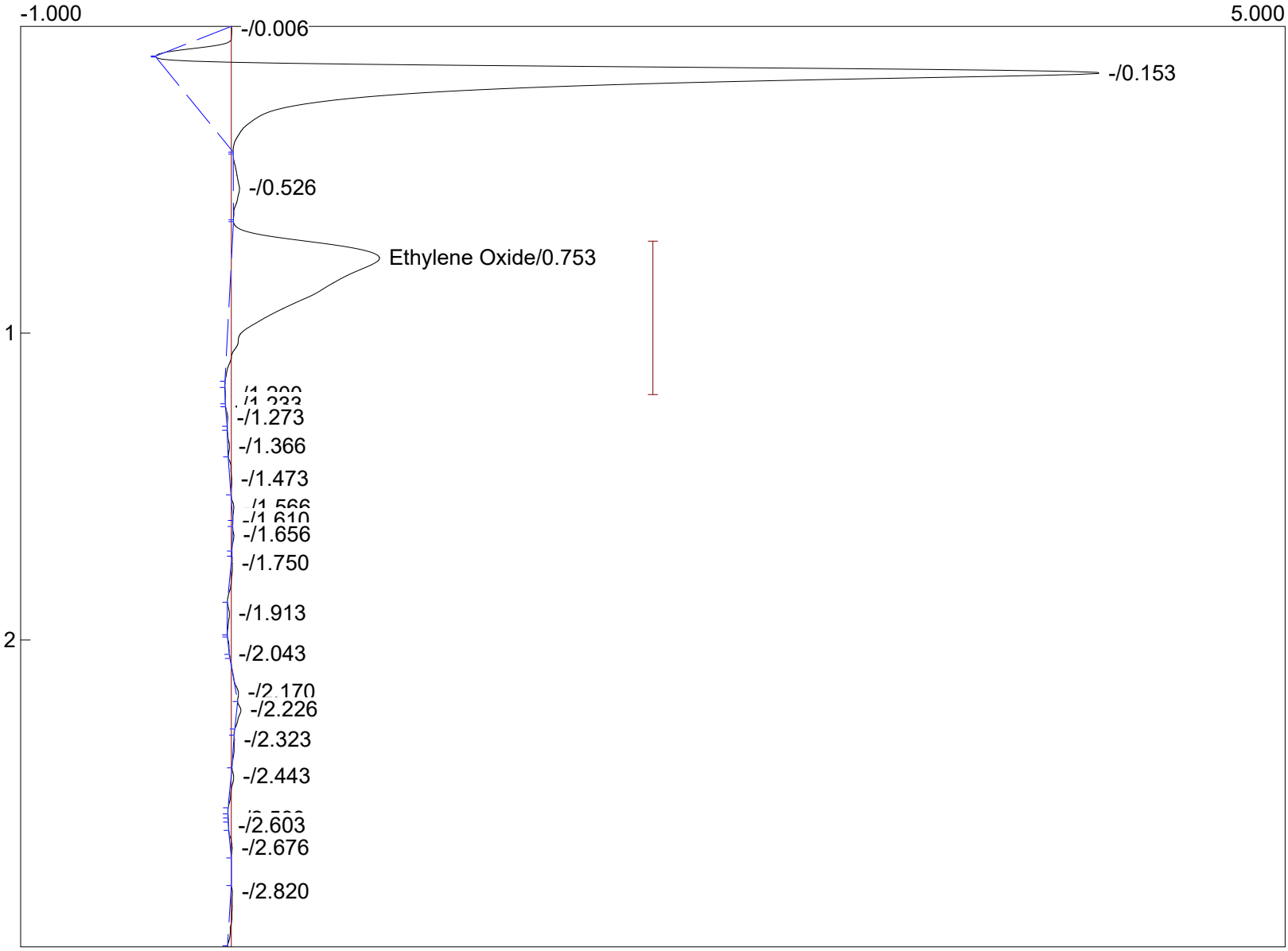
Component	Retention	Area
Ethylene Oxide	0.750	3.0318
		3.0318

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/10/2020 00:03:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_988..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



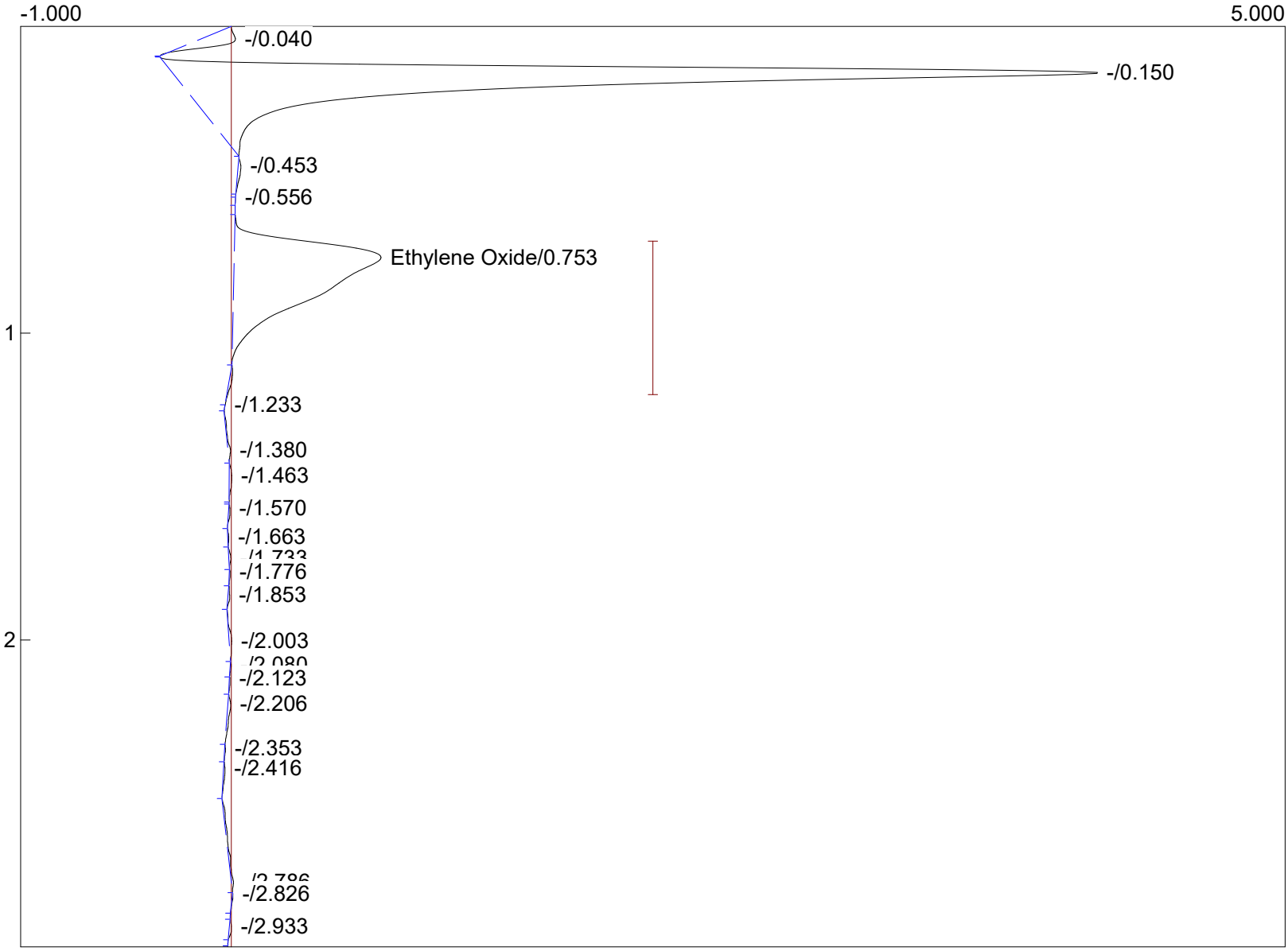
Component	Retention	Area
Ethylene Oxide	0.750	3.1634
		3.1634

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/10/2020 00:07:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_989..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



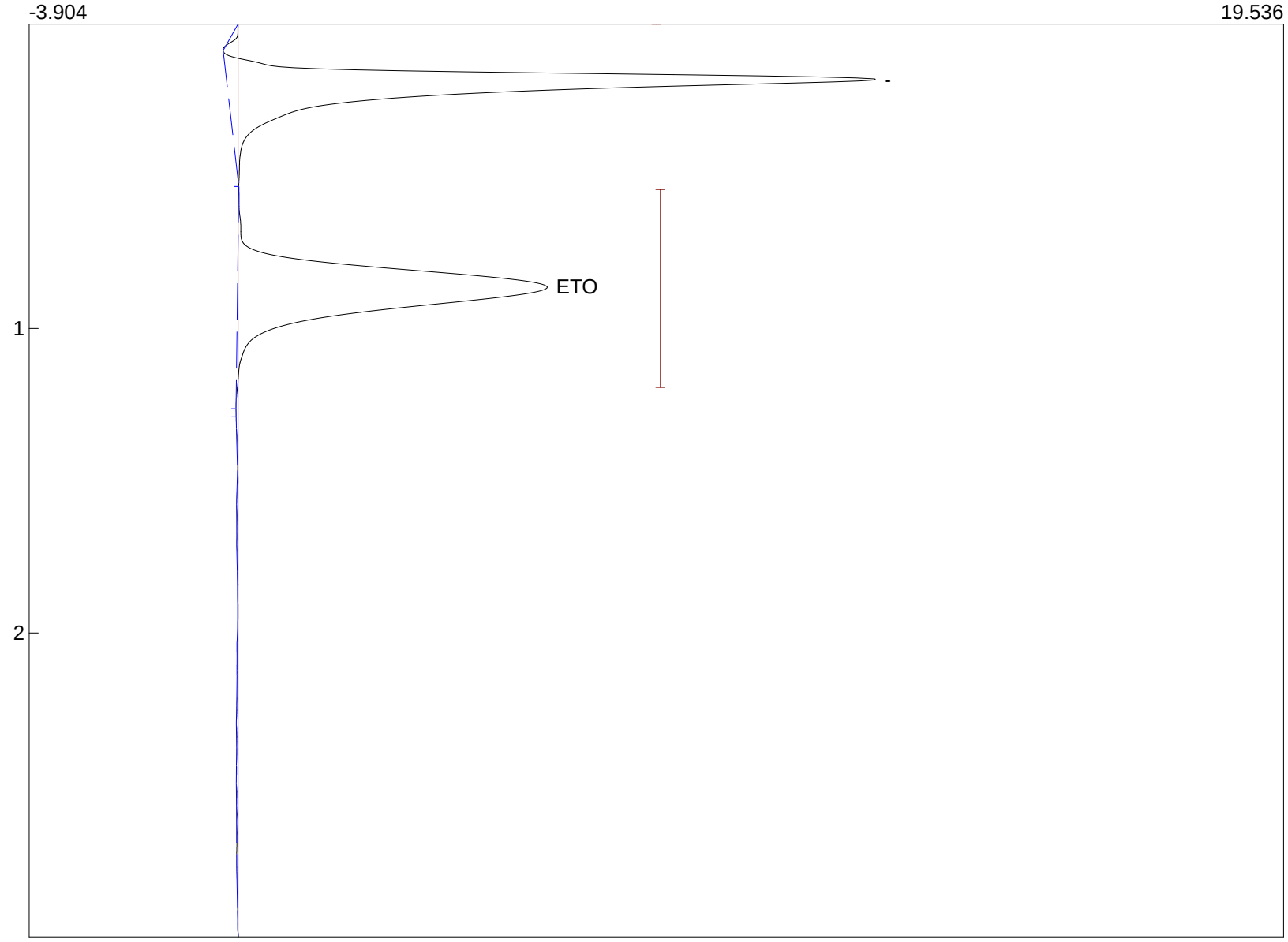
Component	Retention	Area
Ethylene Oxide	0.753	3.1552
		3.1552

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/10/2020 00:11:36
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_990..CHR ()
Sample: Sample
Operator: L Christopher Heilner
Comments: Aeration Room Vent Run 3



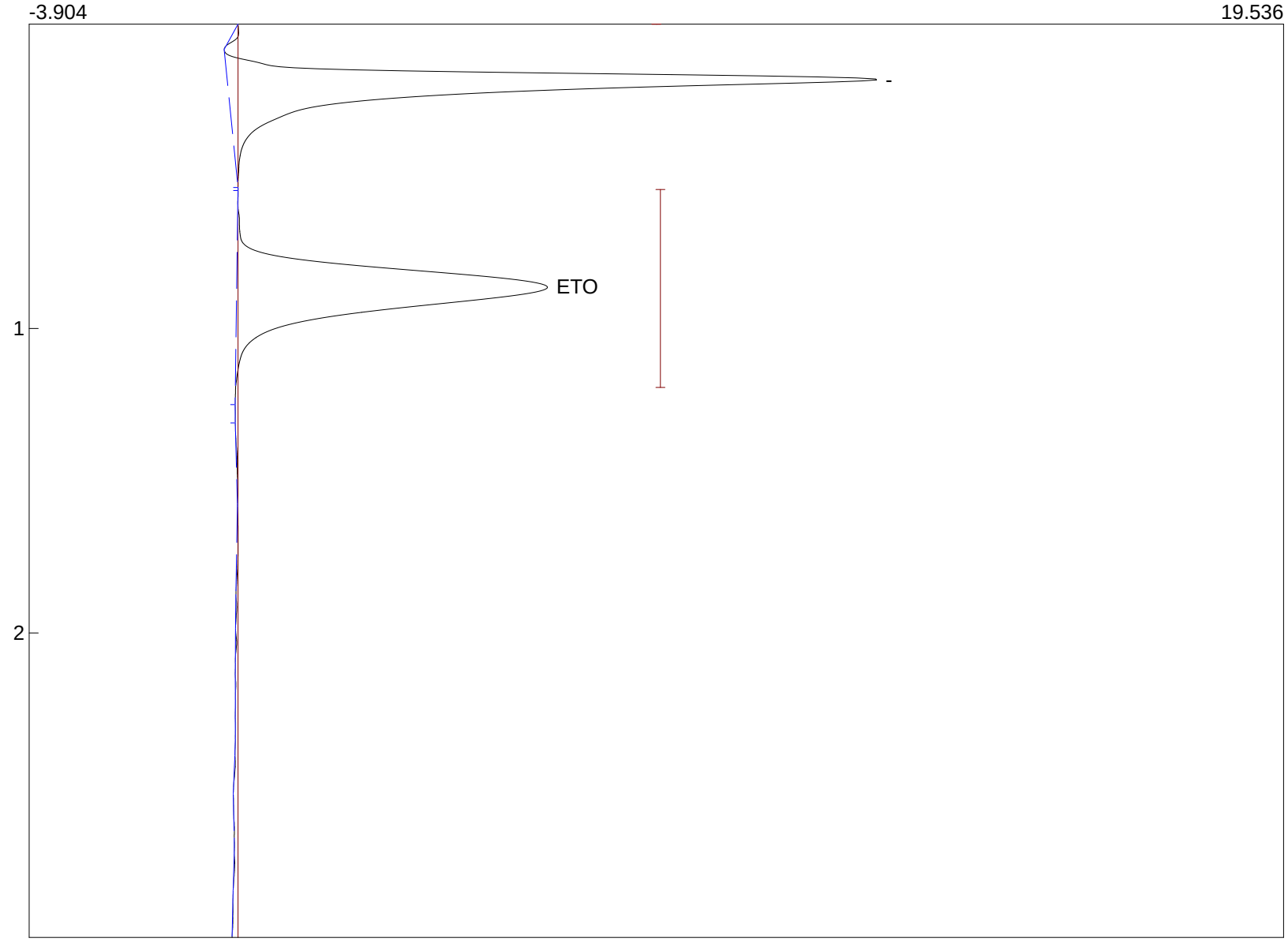
Component	Retention	Area
Ethylene Oxide	0.753	3.0843
		3.0843

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/10/2020 15:28:13
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_1220. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10 ppm Cal Gas Post Run Drift



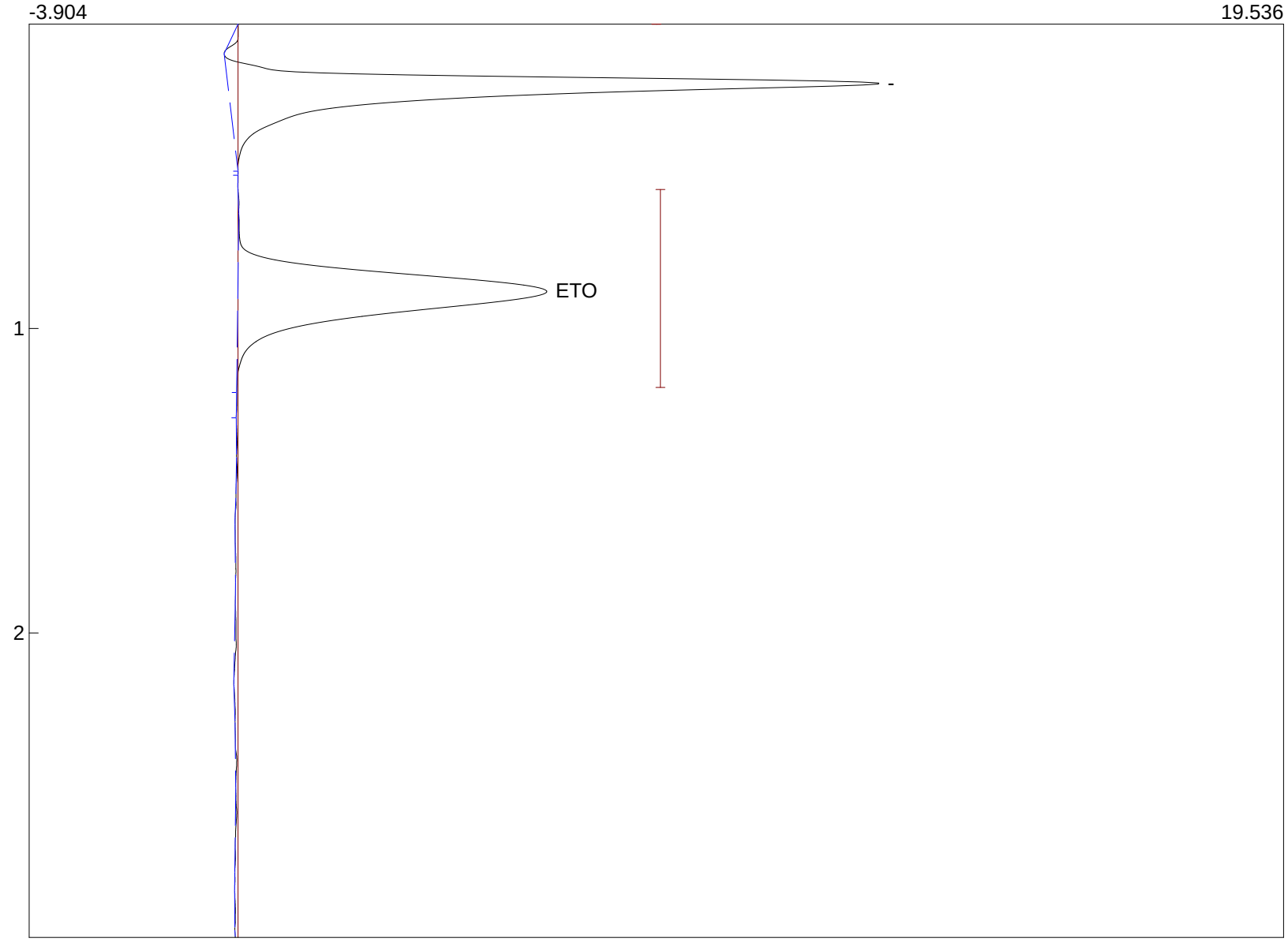
Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	56.3422
1			56.3422

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/10/2020 15:31:19
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_1221. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10 ppm Cal Gas Post Run Drift



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.863	56.7828
1			56.7828

Lab name: LCH Consulting Associates, LLC
Client: Customed, Inc.
Client ID: CI
Analysis date: 01/10/2020 15:34:25
Method: USEPA Method 18
Lab ID: PADEP 15-05860
Description: FID
Column: Haysep D
Carrier: UHP 99.99999% Helium AT 18 PSI
Data file: Customed2019_Q4_1222. ()
Sample: Sample
Operator: L Christopher Heilner
Comments: 10 ppm Cal Gas Post Run Drift



Number	Component	Retention	Area
0		0.000	0.0000
1	ETO	0.876	49.7302
1			49.7302

ATTACHMENT E

SUBPART O CALCULATIONS

Run 1	Thursday, January 9, 2020			Chamber Temperatures and Pressure with Units		
Chamber Number		units	1		1	
Run ID		Empty Chamber	Test	min	max	avg
Chamber Volume	V	cubic feet	1212.816			
Standard Molar Volume	SV	cubic feet	385.32			
Mol. Wt. EO	MWEO	# / #-mole	44.05			
Mol. Wt.H2O	MWH2O	# / #-mole	18			
Mol. Wt. N2	MWN2	# / #-mole	28			
Standard Temperature	Tstd	degree R	528			
Standard Barometric Pressure	Pstd	inch Hg	29.92			
Barometric Pressure	Pbar	inch Hg	30.0			
Conversion factor millibars to inches Hg			0.0295			
Conversion factor kg to pounds			2.2046	inch Hg		
Chamber pressure after nitrogen wash		mbar	237.2881356	7.0		
Chamber pressure after nitrogen wash		inch Hg	7.00	F	F	
Chamber temperature after nitrogen wash		degree C	54.4	132.0	128.0	130.0
Chamber temperature after nitrogen wash		degree R	590.0			
Volume nitrogen in chamber		cubic feet	316.22			
Pound moles nitrogen in chamber			0.91			
Mass nitrogen in chamber		pounds	25.61	inch Hg		
Chamber pressure after humidification	P	mbar	271.1864407	8.0		
Chamber pressure after humidification	P	inch Hg	8.00			
Pressure increase due to humidification	P	inch Hg	1.00	F	F	
Chamber temperature after humidification		degree C	53.3	128.0	128.0	128.0
Chamber temperature after humidification		degree R	588.0			
Volume H2O in chamber		cubic feet	45.02			
Pound Moles of H2O at chamber pressure			0.12			
Mass H2O at chamber pressure		pounds	2.10	lbs		
Mass EtO charged to chamber		kg	20	43.00		
Mass EtO charged to chamber	Wc	pounds	43.0	inch Hg		
Chamber pressure after EtO injection		mbar	661.0169492	19.5		
Chamber pressure after EtO injection		inch Hg	19.50	F	F	
Chamber Temperature after EtO injection		degree C	55.3	132.0	131.0	131.5
Chamber Temperature after EtO injection		degree R	591.5			
Chamber temperature after nitrogen blanket		degree R	591.5			
Total Moles N2 in chamber			0.91			
Total mass nitrogen in chamber		pounds	25.61			
Total volume gas in chamber		std. cubic feet	705.58			
Pound Moles EtO injected			0.98			
Weight % N2	WN2	%	36.22%			
Weight % water	WH2O	%	2.97%			
Weight % EtO	WEO	%	60.81%			
EtO mole fraction	%EOv	%	48.62%			
H2O mole fraction	%H2Ov	%	5.82%			
N2 mole fraction	%N2v	%	47.18%	inch Hg		
Chamber pressure after evacuation		mbar	237.2881356	7.0		
Chamber pressure after evacuation		inch Hg	7	F	F	
Chamber temperature after 1st evacuation		degree C	53.6	130.0	127.0	128.5
Chamber temperature after 1st evacuation		degree R	588.5			
Total volume gas in chamber		std. cubic feet	254.58			
Percent chamber gas evacuated		%	63.92%			
Residual Mass EtO remaining in chamber	Wr	pounds	15.51			
Mass EtO at Inlet to scrubber	Wi	pounds	27.49			
Concentration EtO in Scrubber Outlet	C	ppm	12.5			
Volume gas exiting scrubber	V	dscf	205.0			
Mass EtO exiting scrubber	Wb	pounds	0.00029			
Control Device Efficiency	% Eff	%	99.99894%			

Customed, Fajardo, Puerto Rico				
Run No.	One	Date	Thursday, January 9, 2020	
Barometric Pressure	30	in Hg	Moisture %	7.95%
Stack (Static) Pressure	0.15	in H2O	mol wt stack gas Md	30.00
Diameter of Stack	4	inch	mol wt stack gas Ms	29.05
Elapsed Time (Minutes)	Stack Differential Pressure ("H_2O)	Stack Gas Temperature (˚F)	Stack Gas Velocity (FPS)	Stack Gas Volumetric Flow (DSCF)
858	0.010	86.0	*6.70*	*31.30*
859	0.005	89.0	*4.75*	*22.07*
900	0.005	95.0	*4.78*	*21.95*
901	0.005	102.0	*4.81*	*21.81*
902	0.005	108.0	*4.83*	*21.70*
903	0.005	116.0	*4.86*	*21.55*
904	0.005	118.0	*4.87*	*21.51*
905	0.005	114.0	*4.86*	*21.58*
906	0.005	116.0	*4.86*	*21.55*
			Total	*205.02*
	Average	**107.3**		

Run 2	Thursday, January 9, 2020			Chamber Temperatures and Pressure with Units		
Chamber Number		units	1	1		
Run ID	SL20008		Test	min	max	avg
Chamber Volume	V	cubic feet	1212.816			
Standard Molar Volume	SV	cubic feet	385.32			
Mol. Wt. EO	MWEO	# / #-mole	44.05			
Mol. Wt.H2O	MWH2O	# / #-mole	18			
Mol. Wt. N2	MWN2	# / #-mole	28			
Standard Temperature	Tstd	degree R	528			
Standard Barometric Pressure	Pstd	inch Hg	29.92			
Barometric Pressure	Pbar	inch Hg	30.1			
Conversion factor millibars to inches Hg			0.0295			
Conversion factor kg to pounds			2.2046	inch Hg		
Chamber pressure after nitrogen wash		mbar	237.2881356	7.0		
Chamber pressure after nitrogen wash		inch Hg	7.00	F	F	
Chamber temperature after nitrogen wash		degree C	53.9	130.0	128.0	129.0
Chamber temperature after nitrogen wash		degree R	589.0			
Volume nitrogen in chamber		cubic feet	314.64			
Pound moles nitrogen in chamber			0.91			
Mass nitrogen in chamber		pounds	25.35	inch Hg		
Chamber pressure after humidification	P	mbar	271.1864407	8.0		
Chamber pressure after humidification	P	inch Hg	8.00			
Pressure increase due to humidification	P	inch Hg	1.00	F	F	
Chamber temperature after humidification		degree C	53.9	129.0	129.0	129.0
Chamber temperature after humidification		degree R	589.0			
Volume H2O in chamber		cubic feet	44.95			
Pound Moles of H2O at chamber pressure			0.12			
Mass H2O at chamber pressure		pounds	2.10	lbs		
Mass EtO charged to chamber		kg	27	60.40		
Mass EtO charged to chamber	Wc	pounds	60.4	inch Hg		
Chamber pressure after EtO injection		mbar	661.0169492	19.5		
Chamber pressure after EtO injection		inch Hg	19.50	F	F	
Chamber Temperature after EtO injection		degree C	55.0	131.0	131.0	131.0
Chamber Temperature after EtO injection		degree R	591.0			
Chamber temperature after nitrogen blanket		degree R	591.0			
Total Moles N2 in chamber			0.91			
Total mass nitrogen in chamber		pounds	25.35			
Total volume gas in chamber		std. cubic feet	706.18			
Pound Moles EtO injected			1.37			
Weight % N2	WN2	%	28.86%			
Weight % water	WH2O	%	2.39%			
Weight % EtO	WEO	%	68.75%			
EtO mole fraction	%EOv	%	57.29%			
H2O mole fraction	%H2Ov	%	4.87%			
N2 mole fraction	%N2v	%	38.96%	inch Hg		
Chamber pressure after evacuation		mbar	237.2881356	7.0		
Chamber pressure after evacuation		inch Hg	7	F	F	
Chamber temperature after 1st evacuation		degree C	53.9	130.0	128.0	129.0
Chamber temperature after 1st evacuation		degree R	589.0			
Total volume gas in chamber		std. cubic feet	254.36			
Percent chamber gas evacuated		%	63.98%			
Residual Mass EtO remaining in chamber	Wr	pounds	21.76			
Mass EtO at Inlet to scrubber	Wi	pounds	38.64			
Concentration EtO in Scrubber Outlet	C	ppm	16.2			
Volume gas exiting scrubber	V	dscf	240.6			
Mass EtO exiting scrubber	Wb	pounds	0.00044			
Control Device Efficiency	% Eff	%	99.99885%			

Customed, Inc. Fajardo, Puerto Rico				
Run No.	Two	Date	Thursday, January 9, 2020	
Barometric Pressure	30.00	in Hg	Moisture %	7.85%
Stack (Static) Pressure	0.15	in H2O	mol wt stack gas Md	30.00
Diameter of Stack	4	inch	mol wt stack gas Ms	29.06
Elapsed Time (Minutes)	Stack Differential Pressure ("H_2O)	Stack Gas Temperature (˚F)	Stack Gas Velocity (FPS)	Stack Gas Volumetric Flow (DSCF)
1801	0.010	82.0	*6.67*	*31.45*
1802	0.010	83.0	*6.68*	*31.42*
1803	0.005	87.0	*4.74*	*22.14*
1804	0.005	98.0	*4.79*	*21.92*
1805	0.005	105.0	*4.82*	*21.78*
1806	0.005	109.0	*4.84*	*21.70*
1807	0.005	109.0	*4.84*	*21.70*
1808	0.005	117.0	*4.87*	*21.55*
1809	0.005	120.0	*4.88*	*21.50*
1810	0.005	119.0	*4.88*	*21.51*
1810:11:00	0.005	119.0	*4.88*	*3.94*
			Total	*240.61*
	Average	**106.6**		

ATTACHMENT F

PROCESS RUN RECORDS

01/09/20 CUST.

		Ts	ΔP
Start	0	86	0.010
0858	1	89	0.005
	2	95	0.005
	3	102	0.005
	4	108	0.005
	5	116	0.005
	6	118	0.005
	7	114	0.005
0906	8	116	0.005
	9		
	10		
	11		
	12		
	13		
	14		
	15		

TANK 1
72.5"

TANK 2
~~17.5~~
16.5-17.0"

43 lbs EFO USED

Pbar 30.00
+0.15
Ps =

01/09/20 CUSTOMED SCRUBBER TEST #2

START	MINUTES	Δ P	TEMP	TANK 1	TANK 2
1801	0	0.010	82	72.2"	17.0"
	1	0.010	83		
	2	0.005	87		
	3	0.005	98	LBS ETO USED	
	4	0.005	105		
	5	0.005	109		
	6	0.005	109		
	7	0.005	117		
	8	0.005	120		
	9	0.005	119		
1810:11	10	0.005	119		
	11				
	12				

P_{bar} 30.00

P_s = 30.15

CUSTOMED It's all about healing

STERILIZATION PROCEDURE

FORM STP 002-02 Page 1of 1
Revision A 02-03-15
Effective Date ~~01-29-2015~~ 02-03-15

Issued by: _____ Title: Sterilization Manager Date: 01/29/15.

Approved by: _____ Title: QA Lead Date: 01-29-2015

TITLE: REGISTRO DE CONSUMO DE ETO

MONTH: December **YEAR:** 2019

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Cycle No.:	Cycle No.:	Cycle No.:	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): JI 01-03-2	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by Date:
Cycle No. 19340	Cycle No. 19343	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb): 62.5	Qty.EtO(lb): 61.0	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty. EtO.(lb):
Performed by: Date: 12-9-19	Performed by: Date: 12-10-19	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by; Date;
Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No:	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO.(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date: JI	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No:	Cycle No.	Cycle No.	Cycle No. 01-03-2	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO.(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:	Performed by: Date:

Week No.	1	2	3	4	5	Total Weight (lb)
Total Weight (lb.)	0	123.5	0	0	0	123.5

Verified by/Date: _____

CUSTOMED

STERILIZATION PROCEDURE

FORM STP 002-02 Page 1of 1
Revision A 02-03-15
Effective Date ~~01-29-2015~~ 02-03-15

Issued by: _____ Title: Sterilization Manager Date: 01/29/15.

Approved by: _____ Title: QA Lead Date: 01-29-2015

TITLE: REGISTRO DE CONSUMO DE ETO

MONTH: November (2019) **YEAR:** 2019

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Cycle No.:	Cycle No.:	Cycle No.:	Cycle No.	Cycle No. 19304	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): 60.5	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date:	Performed by: Date: 11-01-19	Performed by: Date:	Performed by: Date: 11-01-19	Performed by: Date: 11-04-19	Performed by Date:
Cycle No. 19305	Cycle No. 19308	Cycle No. 19309	Cycle No.	Cycle No. 19311	Cycle No.	Cycle No.
Qty.EtO(lb): 62.5	Qty.EtO(lb): 60.5	Qty.EtO(lb): 61.5	Qty.EtO(lb):	Qty.EtO(lb): 60.0	Qty.EtO(lb):	Qty. EtO.(lb):
Performed by: Date: 11-04-19	Performed by: Date: 11-05-19	Performed by: Date: 11-06-19	Performed by: Date: 11-08-19	Performed by: Date: 11-08-19	Performed by: Date: 11-11-19	Performed by; Date;
Cycle No.	Cycle No. 19315	Cycle No.	Cycle No. 19317	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb): 62.0	Qty.EtO(lb):	Qty.EtO(lb): 65.0	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date: 11-12-19	Performed by: Date: 11-12-19	Performed by: Date: 11-14-19	Performed by: Date: 11-14-19	Performed by: Date:	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No: 19322	Cycle No. 19323	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb): 58.5	Qty.EtO(lb): 60.0	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO.(lb):
Performed by: Date:	Performed by: Date: 11-19-19	Performed by: Date: 11-20-19	Performed by: Date:	Performed by: Date: 11-26-19	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No: 19329	Cycle No.	Cycle No.	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb): 60.5	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO.(lb):
Performed by: Date: 11-26-19	Performed by: Date: 11-26-19	Performed by: Date:	Performed by: Date:	Performed by: Date: 12-02-19	Performed by: Date:	Performed by: Date:

Week No.	1	2	3	4	5	Total Weight (lb)
Total Weight (lb.)	60.5	244.5	127.0	118.5	60.5	611

Verified by/Date: JD 12-02-19

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STERILIZATION PROCEDURE

FORM STP 002-02 Page 1of 1
Revision A 02-03-15
Effective Date ~~01-29-2015~~ 02-03-15

Issued by: _____ Title: Sterilization Manager Date: 01/29/15.

Approved by: _____ Title: QA Lead Date: 01-29-2015

TITLE: REGISTRO DE CONSUMO DE ETO

MONTH: October **YEAR:** 2019

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Cycle No.:	Cycle No.:	Cycle No.: 19274	Cycle No. 19275	Cycle No. 19276	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): 63.0	Qty.EtO(lb): 62.0	Qty.EtO(lb): 62.5	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date:	Performed by: Date: 10-02-19	Performed by: Date: 10-02-19	Performed by: Date: 10-03-19	Performed by: Date: 10-04-19	Performed by: Date: 10-07-19	Performed by Date:
Cycle No. 19277	Cycle No. 19280	Cycle No. 19281	Cycle No. 19282	Cycle No. 19283	Cycle No.	Cycle No.
Qty.EtO(lb): 63.0	Qty.EtO(lb): 62.0	Qty.EtO(lb): 60.0	Qty.EtO(lb): 63.5	Qty.EtO(lb): 62.5	Qty.EtO(lb):	Qty. EtO.(lb):
Performed by: Date: 10-07-19	Performed by: Date: 10-08-19	Performed by: Date: 10-09-19	Performed by: Date: 10-10-19	Performed by: Date: 10-11-19	Performed by: Date: 10-15-19	Performed by; Date;
Cycle No.	Cycle No.	Cycle No. 19288	Cycle No.	Cycle No. 19290	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): 59.5	Qty.EtO(lb):	Qty.EtO(lb): 61.0	Qty.EtO(lb):	Qty.EtO(lb):
Performed by: Date: 10-15-19	Performed by: Date:	Performed by: Date: 10-16-19	Performed by: Date: 10-18-19	Performed by: Date: 10-18-19	Performed by: Date: 10-21-19	Performed by: Date:
Cycle No.	Cycle No:	Cycle No.	Cycle No. 19296	Cycle No. 19297	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): 61.0	Qty.EtO(lb): 60.0	Qty.EtO(lb):	Qty.EtO.(lb):
Performed by: Date:	Performed by: Date: 10-24-19	Performed by: Date:	Performed by: Date: 10-24-19	Performed by: Date: 10-25-19	Performed by: Date:	Performed by: Date:
Cycle No.	Cycle No:	Cycle No. 19301	Cycle No. 19303	Cycle No.	Cycle No.	Cycle No.
Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO(lb): 62.0	Qty.EtO(lb): 63.5	Qty.EtO(lb):	Qty.EtO(lb):	Qty.EtO.(lb):
Performed by: Date: 10-30-19	Performed by: Date:	Performed by: Date: 10-30-19	Performed by: Date: 10-31-19	Performed by: Date:	Performed by: Date: 10-31-19	Performed by: Date:

Week No.	1	2	3	4	5	Total Weight (lb)
Total Weight (lb.)	187.5	311	120.5	121.0	125.5	865.5

Verified by/Date: TID 10-31-19

From: **Juan C. Pacheco** jpacheco@prhospital.com
Subject: PH
Date: January 9, 2020 at 12:40 PM
To: Ruben Martinez Vargas ruben.martinez@prhospital.com
Cc: Jose Becerril jose.becerril@prhospital.com

Saludos,
El PH inicial fue de .44 a .45 PH.
Luego de anadil 40 gal de Ácido Sulfúrico y anadil agua es de .44 PH.

Juan C. Pacheco
Tel. (787) 622-5151 Ext. 7110
cel. (787) 435-7723
Email: *jpacheco@prhospital.com*
Customed Inc.

==========

EQUIPMENT INFORMATION

Equipment Description

1. Manufacturer Vacudyne Company
   Address: 375 E. Joe Orr Road
   Chicago Heights, Illinois 60411

   Phone: (708) 754-5200 Fax (708) 754-4180

2. Contract Number J02 - 38
3. Serial Number J02-38
4. Location Calle Igualdad #7, Fajardo, P.R.
5. Asset Number
6. Vessel Dimensions 8'H X 4'7"1/8 W X 33'D (Cubic Meter = 35.3147 cu. ft = Size = 35.8 cubic meters

Manufacturer's Specifications

1. Copy Available Chamber Blueprint
2. Location CONTROL ROOM

3. Verify that all labelling and tagging is complete. Record ASME N.B. numbers and dates.

   Chamber: Max WP full vacuum to 15 PSI Max Temp 200 °F
   Jacket: Nat'l BD No
   Comments: Year Built 2002

Materials of Construction (Product Contact)

Component	Material	Contact
CHAMBER	Black Iron coated with 304 SS	Y__N X
PIPING-EO CONTACT LINES	304-3/16 SS (stainless Steel)	Y__N X
VALVES	304 SS	Y__N X
STEAM PIPING	Black Iron with SS and Brass valves	Y__N X
PNEUMATIC LINES	Copper	Y__N X

Comment: No Comments.

Researched/Reviewed By J. Pa[illegible] Date 12/13/04

Copyright By Consulting And Technical Services, Inc.
October 3, 2004 Protocol # 04107015

@E
DATE 01/09/20 Thu CYCLE 125 PROGRAM VERSION 4E-2 CHECK VALUE 13180
RUN ID # SL20008 OPERATOR A.Alicea

Customed Inc.

PROCESS PARAMETERS

CHAMBER TEMP	130 F, LO TOL 10 F, HI TOL 10 F, ABORT 165 F
INITIAL EVACUATION A	7.0 INHGA, 2.01 INHG/MIN
HUMIDITY INJECTION A	1.0 INHG
NITROGEN BLANKET A	25.0 INHGA, 1.00 INHG/MIN
NITROGEN DILUTION	2 CYCLES, RH 0:30 HH:MM, 55 % RH, UPPER 25.0 INHGA, LOWER 22.0 INHGA
INITIAL EVACUATION B	7.0 INHGA, 2.01 INHG/MIN
HUMIDITY INJECTION B	1.0 INHG
HUMIDITY DWELL	1:05 HH:MM, 8.0 INHGA, LO 7.5 INHGA, HI 8.5 INHGA, MAX 9.0 INHGA
STERILANT INJECTION	19.5 INHGA, 0.71 INHG/MIN
EXPOSURE	3:05 HH:MM, 19.5 INHGA, LO 19.0 INHGA, HI 20.0 INHGA, ABORT 21.5 INHGA LO 5 F, HI 5 F, ABORT 145 F, MAKEUPS: STERILANT
STERILANT REMOVAL	EXHAUST 0.0 SKIP, EVACUATION 7.0 INHGA, 2.01 INHG/MIN
NITROGEN WASH	3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHGA, LOWER 7.0 INHGA
AIR WASH A	3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHGA, LOWER 7.0 INHGA
FINAL AIRBREAK	27.0 INHGA, 2.01 INHG/MIN

E	TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
			INITIAL EVACUATION A PHASE				
E	11:48	124 F	30.1 INHGA	31 %	104 F		
E	11:50	124 F	26.0 INHGA	33 %	105 F		
E	11:52	124 F	22.0 INHGA	35 %	105 F		
E	11:54	124 F	18.0 INHGA	36 %	105 F		
E	11:56	124 F	14.2 INHGA	36 %	105 F		
E	11:58	125 F	11.0 INHGA	36 %	106 F		
E	11:58	125 F	10.8 INHGA	36 %	106 F	SLOW INCREMENT	
E	12:00	125 F	8.6 INHGA	36 %	106 F		
E	12:02	125 F	7.0 INHGA	36 %	106 F		

MAX:	125 F	-23.1 INHG	36 %	PHASE	0:13	PHASE ELAPSED	0:13
MIN:	124 F	(CHANGE)	31 %			CYCLE	0:13

			HUMIDITY INJECTION A (PRESS) PHASE				
E	12:02	125 F	7.0 INHGA	36 %	106 F		
E	12:02	126 F	8.0 INHGA	50 %	110 F		

MAX:	126 F	1.0 INHG	50 %	PHASE	0:00	PHASE ELAPSED	0:00
MIN:	125 F	(CHANGE)	36 %			CYCLE	0:14

			NITROGEN BLANKET A PHASE				
E	12:02	126 F	8.0 INHGA	56 %	114 F		
E	12:04	127 F	10.2 INHGA	100 %	107 F		
E	12:06	128 F	12.2 INHGA	88 %	110 F		
E	12:08	128 F	14.2 INHGA	75 %	112 F		

1

E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN	
E 12:10	128 F	16.2 INHGA	70 %	114 F			
E 12:12	128 F	18.3 INHGA	66 %	116 F			
E 12:14	128 F	20.3 INHGA	65 %	117 F			
E 12:16	128 F	22.3 INHGA	63 %	117 F			
E 12:18	129 F	24.3 INHGA	62 %	118 F			
E 12:19	128 F	25.0 INHGA	62 %	118 F			

MAX: 129 F 17.0 INHG 100 % PHASE 0:16 PHASE ELAPSED 0:16
MIN: 126 F (CHANGE) 50 % CYCLE 0:30

NITROGEN DILUTION (WASH) PHASE

E 12:19	128 F	25.0 INHGA	62 %	118 F			
E 12:19	128 F	25.0 INHGA	62 %	118 F		BEGIN RH	1
E 12:21	128 F	25.2 INHGA	61 %	117 F			
E 12:23	128 F	25.2 INHGA	63 %	116 F			
E 12:25	128 F	25.2 INHGA	65 %	115 F			
E 12:27	128 F	25.3 INHGA	67 %	114 F			
E 12:29	128 F	25.3 INHGA	68 %	114 F			
E 12:31	128 F	25.3 INHGA	69 %	113 F			
E 12:33	128 F	25.3 INHGA	70 %	113 F			
E 12:35	128 F	25.3 INHGA	70 %	112 F			
E 12:37	129 F	25.3 INHGA	71 %	112 F			
E 12:39	129 F	25.3 INHGA	72 %	111 F			
E 12:41	129 F	25.3 INHGA	72 %	111 F			
E 12:43	129 F	25.4 INHGA	72 %	111 F			
E 12:45	129 F	25.4 INHGA	73 %	110 F			
E 12:47	129 F	25.4 INHGA	73 %	110 F			
E 12:49	129 F	25.4 INHGA	73 %	110 F			
E 12:49	129 F	25.4 INHGA	73 %	110 F		BEGIN NITROGEN	1
E 12:49	129 F	25.4 INHGA	73 %	110 F		BEGIN EVACUATION	1
E 12:50	129 F	22.0 INHGA	68 %	110 F		BEGIN RH	2
E 12:51	129 F	21.9 INHGA	66 %	110 F			
E 12:53	129 F	22.0 INHGA	69 %	110 F			
E 12:55	129 F	22.0 INHGA	70 %	110 F			
E 12:57	129 F	22.0 INHGA	71 %	110 F			
E 12:59	129 F	22.1 INHGA	72 %	109 F			
E 13:01	129 F	22.1 INHGA	72 %	109 F			
E 13:03	130 F	22.1 INHGA	73 %	109 F			
E 13:05	130 F	22.1 INHGA	73 %	109 F			
E 13:07	130 F	22.1 INHGA	73 %	109 F			
E 13:09	130 F	22.2 INHGA	73 %	109 F			
E 13:11	130 F	22.2 INHGA	73 %	109 F			
E 13:13	130 F	22.2 INHGA	74 %	109 F			
E 13:15	130 F	22.2 INHGA	74 %	109 F			
E 13:17	130 F	22.2 INHGA	74 %	109 F			
E 13:19	130 F	22.2 INHGA	74 %	109 F			
E 13:20	130 F	22.2 INHGA	74 %	109 F		BEGIN NITROGEN	2
E 13:21	130 F	23.4 INHGA	75 %	111 F			
E 13:23	130 F	25.0 INHGA	73 %	114 F		BEGIN EVACUATION	2
E 13:23	130 F	25.1 INHGA	73 %	115 F			

E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 13:24	130 F	22.0 INHGA	65 %	114 F		
MAX:	130 F	-3.0 INHG	75 %		PHASE 1:05	PHASE ELAPSED 1:05
MIN:	128 F	(CHANGE)	61 %			CYCLE 1:35

INITIAL EVACUATION B PHASE

E 13:24	130 F	21.9 INHGA	64 %	114 F	
E 13:26	129 F	17.8 INHGA	58 %	112 F	
E 13:28	129 F	14.1 INHGA	55 %	112 F	
E 13:29	129 F	12.2 INHGA	53 %	112 F	SLOW INCREMENT
E 13:30	128 F	10.9 INHGA	52 %	112 F	
E 13:32	129 F	8.6 INHGA	50 %	112 F	
E 13:34	129 F	7.0 INHGA	49 %	112 F	
MAX:	130 F	-15.0 INHG	64 %		PHASE 0:09 PHASE ELAPSED 0:09
MIN:	128 F	(CHANGE)	49 %		CYCLE 1:45

HUMIDITY INJECTION B (PRESS) PHASE

E 13:34	129 F	7.0 INHGA	49 %	112 F	
E 13:34	129 F	8.0 INHGA	62 %	117 F	
MAX:	129 F	1.0 INHG	62 %		PHASE 0:00 PHASE ELAPSED 0:00
MIN:	129 F	(CHANGE)	49 %		CYCLE 1:46

HUMIDITY DWELL (PRESS) PHASE

E 13:34	129 F	8.0 INHGA	62 %	121 F
E 13:36	130 F	8.1 INHGA	100 %	127 F
E 13:38	130 F	8.0 INHGA	100 %	124 F
E 13:40	131 F	7.9 INHGA	95 %	121 F
E 13:42	131 F	7.9 INHGA	92 %	120 F
E 13:44	131 F	7.9 INHGA	90 %	119 F
E 13:46	131 F	7.9 INHGA	89 %	118 F
E 13:48	131 F	8.0 INHGA	88 %	117 F
E 13:50	131 F	8.0 INHGA	87 %	116 F
E 13:52	131 F	8.0 INHGA	87 %	115 F
E 13:54	131 F	8.0 INHGA	86 %	114 F
E 13:56	131 F	8.0 INHGA	86 %	114 F
E 13:58	131 F	8.0 INHGA	85 %	113 F
E 14:00	131 F	8.0 INHGA	85 %	113 F
E 14:02	131 F	8.0 INHGA	85 %	112 F
E 14:04	131 F	8.0 INHGA	84 %	112 F
E 14:06	131 F	8.0 INHGA	84 %	112 F
E 14:08	131 F	8.0 INHGA	84 %	111 F
E 14:10	131 F	8.0 INHGA	84 %	111 F
E 14:12	131 F	8.0 INHGA	84 %	111 F
E 14:14	131 F	8.0 INHGA	83 %	111 F
E 14:16	131 F	8.0 INHGA	83 %	110 F

E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 14:18	131 F	8.0 INHGA	83 %	110 F		
E 14:20	131 F	8.0 INHGA	83 %	110 F		
E 14:22	131 F	8.0 INHGA	83 %	110 F		
E 14:24	131 F	8.1 INHGA	83 %	110 F		
E 14:26	131 F	8.1 INHGA	83 %	110 F		
E 14:28	131 F	8.1 INHGA	82 %	110 F		
E 14:30	131 F	8.1 INHGA	82 %	110 F		
E 14:32	131 F	8.1 INHGA	82 %	110 F		
E 14:34	131 F	8.1 INHGA	82 %	110 F		
E 14:36	131 F	8.1 INHGA	82 %	110 F		
E 14:38	131 F	8.1 INHGA	82 %	110 F		
E 14:39	131 F	8.1 INHGA	81 %	110 F		

MAX: 131 F 0.0 INHG 100 % PHASE 1:05 PHASE ELAPSED 1:05
MIN: 129 F (CHANGE) 62 % CYCLE 2:51

STERILANT INJECTION PHASE

E 14:39	131 F	8.1 INHGA	81 %	110 F		
E 14:41	131 F	9.6 INHGA	91 %	111 F		
E 14:43	131 F	11.0 INHGA	88 %	114 F		
E 14:45	131 F	12.4 INHGA	83 %	116 F		
E 14:47	131 F	13.9 INHGA	81 %	118 F		
E 14:49	131 F	15.3 INHGA	78 %	118 F		
E 14:51	131 F	16.7 INHGA	76 %	120 F		
E 14:53	131 F	18.1 INHGA	72 %	121 F		
E 14:55	131 F	19.5 INHGA	71 %	122 F		

MAX: 131 F 11.4 INHG 91 % PHASE 0:15 PHASE ELAPSED 0:15
MIN: 131 F (CHANGE) 71 % CYCLE 3:07
STERILANT USED THIS PHASE: 54.6 LB, CYCLE TOTAL: 54.6 LB

EXPOSURE PHASE

E 14:56	131 F	19.5 INHGA	71 %	122 F		
E 14:58	130 F	19.4 INHGA	68 %	119 F		
E 15:00	130 F	19.4 INHGA	70 %	118 F		
E 15:02	130 F	19.3 INHGA	71 %	118 F		
E 15:04	130 F	19.3 INHGA	72 %	117 F		
E 15:06	130 F	19.3 INHGA	73 %	116 F		
E 15:08	131 F	19.3 INHGA	74 %	116 F		
E 15:10	131 F	19.2 INHGA	75 %	115 F		
E 15:12	131 F	19.2 INHGA	76 %	115 F		
E 15:12	131 F	19.5 INHGA	76 %	116 F	GAS ADDITION 1 COMPLETE	
E 15:14	131 F	19.6 INHGA	76 %	116 F		
E 15:16	131 F	19.6 INHGA	76 %	114 F		
E 15:18	131 F	19.5 INHGA	77 %	114 F		
E 15:20	131 F	19.5 INHGA	77 %	113 F		
E 15:22	131 F	19.5 INHGA	78 %	113 F		
E 15:24	131 F	19.5 INHGA	78 %	113 F		
E 15:26	130 F	19.5 INHGA	78 %	112 F		
E 15:28	130 F	19.4 INHGA	79 %	112 F		

E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 15:30	130 F	19.4 INHGA	79 %	112 F		
E 15:32	131 F	19.4 INHGA	79 %	112 F		
E 15:34	131 F	19.4 INHGA	80 %	112 F		
E 15:36	131 F	19.4 INHGA	80 %	111 F		
E 15:38	131 F	19.4 INHGA	80 %	111 F		
E 15:40	131 F	19.4 INHGA	80 %	111 F		
E 15:42	131 F	19.3 INHGA	80 %	111 F		
E 15:44	131 F	19.3 INHGA	81 %	111 F		
E 15:46	131 F	19.3 INHGA	81 %	111 F		
E 15:48	131 F	19.3 INHGA	81 %	111 F		
E 15:50	131 F	19.3 INHGA	81 %	111 F		
E 15:52	131 F	19.3 INHGA	81 %	111 F		
E 15:54	131 F	19.3 INHGA	81 %	111 F		
E 15:56	131 F	19.3 INHGA	81 %	111 F		
E 15:58	131 F	19.3 INHGA	81 %	111 F		
E 16:00	131 F	19.3 INHGA	82 %	110 F		
E 16:02	131 F	19.2 INHGA	82 %	110 F		
E 16:04	131 F	19.2 INHGA	82 %	110 F		
E 16:06	131 F	19.2 INHGA	82 %	110 F		
E 16:08	131 F	19.2 INHGA	82 %	110 F		
E 16:10	131 F	19.2 INHGA	82 %	110 F		
E 16:12	131 F	19.2 INHGA	82 %	110 F		
E 16:13	131 F	19.5 INHGA	82 %	110 F	GAS ADDITION 2 COMPLETE	
E 16:14	131 F	19.6 INHGA	83 %	113 F		
E 16:16	131 F	19.6 INHGA	81 %	111 F		
E 16:18	131 F	19.6 INHGA	82 %	110 F		
E 16:20	131 F	19.6 INHGA	82 %	110 F		
E 16:22	131 F	19.5 INHGA	82 %	110 F		
E 16:24	131 F	19.5 INHGA	82 %	110 F		
E 16:26	131 F	19.5 INHGA	82 %	110 F		
E 16:28	131 F	19.5 INHGA	82 %	110 F		
E 16:30	131 F	19.5 INHGA	82 %	110 F		
E 16:32	130 F	19.5 INHGA	83 %	110 F		
E 16:34	130 F	19.5 INHGA	83 %	110 F		
E 16:36	130 F	19.5 INHGA	83 %	110 F		
E 16:38	130 F	19.5 INHGA	83 %	110 F		
E 16:40	130 F	19.5 INHGA	83 %	110 F		
E 16:42	130 F	19.4 INHGA	83 %	110 F		
E 16:44	130 F	19.4 INHGA	83 %	110 F		
E 16:46	130 F	19.4 INHGA	83 %	110 F		
E 16:48	130 F	19.4 INHGA	83 %	110 F		
E 16:50	130 F	19.4 INHGA	83 %	110 F		
E 16:52	130 F	19.4 INHGA	83 %	110 F		
E 16:54	130 F	19.4 INHGA	83 %	110 F		
E 16:56	130 F	19.4 INHGA	83 %	110 F		
E 16:58	130 F	19.4 INHGA	83 %	110 F		
E 17:00	130 F	19.4 INHGA	83 %	110 F		
E 17:02	130 F	19.4 INHGA	83 %	110 F		
E 17:04	130 F	19.4 INHGA	83 %	110 F		
E 17:06	130 F	19.3 INHGA	83 %	110 F		
E 17:08	130 F	19.3 INHGA	84 %	110 F		
E 17:10	130 F	19.3 INHGA	84 %	110 F		
E 17:12	130 F	19.3 INHGA	84 %	110 F		
E 17:14	130 F	19.3 INHGA	84 %	110 F		
E 17:16	130 F	19.3 INHGA	84 %	110 F		
E 17:18	130 F	19.3 INHGA	84 %	110 F		

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E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 17:20	130 F	19.3 INHGA	84 %	110 F		
E 17:22	130 F	19.3 INHGA	84 %	110 F		
E 17:24	130 F	19.3 INHGA	84 %	110 F		
E 17:26	130 F	19.3 INHGA	84 %	110 F		
E 17:28	130 F	19.3 INHGA	84 %	110 F		
E 17:30	130 F	19.3 INHGA	84 %	110 F		
E 17:32	130 F	19.3 INHGA	84 %	110 F		
E 17:34	130 F	19.3 INHGA	84 %	110 F		
E 17:36	130 F	19.3 INHGA	84 %	110 F		
E 17:38	130 F	19.3 INHGA	84 %	110 F		
E 17:40	130 F	19.2 INHGA	84 %	110 F		
E 17:42	130 F	19.2 INHGA	84 %	110 F		
E 17:44	130 F	19.2 INHGA	84 %	110 F		
E 17:46	130 F	19.2 INHGA	85 %	110 F		
E 17:48	130 F	19.2 INHGA	85 %	110 F		
E 17:50	130 F	19.2 INHGA	85 %	110 F		
E 17:52	130 F	19.2 INHGA	85 %	110 F		
E 17:54	130 F	19.2 INHGA	85 %	110 F		
E 17:56	130 F	19.2 INHGA	85 %	110 F		
E 17:56	130 F	19.5 INHGA	85 %	107 F	GAS ADDITION 3 COMPLETE	
E 17:58	130 F	19.6 INHGA	85 %	111 F		
E 18:00	130 F	19.6 INHGA	84 %	109 F		
E 18:01	130 F	19.6 INHGA	84 %	109 F		

MAX: 131 F 0.1 INHG 85 % PHASE 3:05 PHASE ELAPSED 3:05
MIN: 130 F (CHANGE) 68 % CYCLE 6:12
STERILANT USED THIS PHASE: 5.8 LB, CYCLE TOTAL: 60.4 LB

STERILANT REMOVAL PHASE

E 18:01	130 F	19.6 INHGA	84 %	109 F		
E 18:01	130 F	19.6 INHGA	84 %	109 F		BEGIN EVACUATION
E 18:03	130 F	15.7 INHGA	76 %	109 F		
E 18:05	129 F	12.4 INHGA	70 %	109 F		
E 18:05	129 F	12.3 INHGA	70 %	109 F	SLOW INCREMENT	
E 18:07	129 F	10.0 INHGA	66 %	109 F		
E 18:09	129 F	8.1 INHGA	63 %	109 F		
E 18:10	128 F	7.0 INHGA	61 %	109 F		

MAX: 130 F -12.6 INHG 84 % PHASE 0:09 PHASE ELAPSED 0:09
MIN: 128 F (CHANGE) 61 % CYCLE 6:22

NITROGEN WASH (WASH) PHASE

E 18:10	128 F	7.0 INHGA	61 %	109 F		
E 18:10	128 F	7.0 INHGA	61 %	109 F		BEGIN NITROGEN 1
E 18:12	129 F	9.2 INHGA	52 %	108 F		
E 18:14	129 F	11.2 INHGA	49 %	109 F		
E 18:16	129 F	13.2 INHGA	48 %	111 F		
E 18:18	129 F	15.2 INHGA	49 %	114 F		
E 18:20	129 F	17.2 INHGA	49 %	115 F		
E 18:22	129 F	19.2 INHGA	50 %	116 F		

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E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN	
E 18:23	129 F	20.0 INHGA	49 %	116 F		BEGIN EVACUATION	1
E 18:24	129 F	16.8 INHGA	45 %	116 F			
E 18:26	128 F	13.1 INHGA	44 %	115 F			
E 18:27	128 F	12.3 INHGA	43 %	115 F	SLOW INCREMENT		
E 18:28	128 F	10.2 INHGA	43 %	114 F			
E 18:30	128 F	8.1 INHGA	43 %	114 F			
E 18:32	128 F	7.0 INHGA	43 %	113 F		BEGIN NITROGEN	2
E 18:32	129 F	8.2 INHGA	44 %	109 F			
E 18:34	129 F	10.2 INHGA	43 %	109 F			
E 18:36	129 F	12.2 INHGA	42 %	111 F			
E 18:38	129 F	14.2 INHGA	42 %	114 F			
E 18:40	129 F	16.2 INHGA	42 %	115 F			
E 18:42	129 F	18.2 INHGA	41 %	117 F			
E 18:44	129 F	20.0 INHGA	41 %	118 F		BEGIN EVACUATION	2
E 18:44	129 F	19.5 INHGA	41 %	118 F			
E 18:46	129 F	15.4 INHGA	37 %	117 F			
E 18:48	128 F	11.8 INHGA	37 %	116 F			
E 18:49	128 F	10.7 INHGA	37 %	116 F	SLOW INCREMENT		
E 18:50	128 F	9.2 INHGA	38 %	115 F			
E 18:52	128 F	7.2 INHGA	38 %	115 F			
E 18:53	128 F	7.0 INHGA	38 %	114 F		BEGIN NITROGEN	3
E 18:54	129 F	9.2 INHGA	42 %	111 F			
E 18:56	129 F	11.2 INHGA	39 %	111 F			
E 18:58	129 F	13.2 INHGA	38 %	113 F			
E 19:00	129 F	15.2 INHGA	37 %	116 F			
E 19:02	130 F	17.2 INHGA	37 %	117 F			
E 19:04	130 F	19.2 INHGA	37 %	118 F			
E 19:05	130 F	20.0 INHGA	37 %	118 F		BEGIN EVACUATION	3
E 19:06	129 F	17.4 INHGA	33 %	118 F			
E 19:08	128 F	13.5 INHGA	33 %	117 F			
E 19:10	128 F	10.7 INHGA	34 %	116 F	SLOW INCREMENT		
E 19:10	128 F	10.4 INHGA	34 %	116 F			
E 19:12	128 F	8.1 INHGA	36 %	115 F			
E 19:14	128 F	7.0 INHGA	36 %	115 F			

MAX: 130 F 0.0 INHG 61 % PHASE 1:03 PHASE ELAPSED 1:03
MIN: 128 F (CHANGE) 33 % CYCLE 7:25

AIR WASH A (WASH) PHASE

E 19:14	128 F	7.0 INHGA	36 %	115 F			
E 19:14	128 F	7.0 INHGA	36 %	115 F		BEGIN INBLEED	1
E 19:16	130 F	11.5 INHGA	36 %	114 F			
E 19:18	130 F	15.5 INHGA	35 %	114 F			
E 19:20	130 F	19.5 INHGA	36 %	113 F			
E 19:20	130 F	20.0 INHGA	35 %	113 F		BEGIN EVACUATION	1
E 19:22	129 F	16.2 INHGA	32 %	113 F			
E 19:24	128 F	12.7 INHGA	34 %	112 F			
E 19:25	128 F	10.7 INHGA	34 %	112 F	SLOW INCREMENT		
E 19:26	128 F	9.7 INHGA	34 %	112 F			
E 19:28	128 F	7.6 INHGA	34 %	112 F			
E 19:28	128 F	7.0 INHGA	35 %	112 F		BEGIN INBLEED	2
E 19:30	129 F	11.1 INHGA	34 %	111 F			
E 19:32	130 F	15.0 INHGA	33 %	111 F			

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E01/09/20 Thu CYCLE 125 RUN ID # SL20008

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN	
E 19:34	130 F	18.9 INHGA	32 %	111 F			
E 19:34	130 F	20.1 INHGA	33 %	111 F		BEGIN EVACUATION	2
E 19:36	129 F	17.9 INHGA	31 %	111 F			
E 19:38	128 F	14.0 INHGA	31 %	111 F			
E 19:40	128 F	10.8 INHGA	32 %	111 F	SLOW INCREMENT		
E 19:40	128 F	10.8 INHGA	32 %	111 F			
E 19:42	128 F	8.4 INHGA	32 %	110 F			
E 19:43	128 F	7.0 INHGA	33 %	110 F		BEGIN INBLEED	3
E 19:44	129 F	9.6 INHGA	37 %	110 F			
E 19:46	130 F	13.6 INHGA	32 %	110 F			
E 19:48	130 F	17.6 INHGA	32 %	110 F			
E 19:49	130 F	20.1 INHGA	32 %	110 F		BEGIN EVACUATION	3
E 19:50	130 F	19.9 INHGA	32 %	110 F			
E 19:52	129 F	15.5 INHGA	29 %	110 F			
E 19:54	128 F	11.8 INHGA	30 %	110 F			
E 19:54	128 F	10.7 INHGA	30 %	110 F	SLOW INCREMENT		
E 19:56	128 F	9.1 INHGA	30 %	110 F			
E 19:58	128 F	7.1 INHGA	31 %	110 F			
E 19:58	128 F	7.0 INHGA	31 %	110 F			

MAX: 130 F 0.0 INHG 37 % PHASE 0:44 PHASE ELAPSED 0:44
MIN: 128 F (CHANGE) 29 % CYCLE 8:09

FINAL AIRBREAK PHASE

E 19:58	128 F	7.0 INHGA	31 %	110 F			
E 20:00	130 F	11.5 INHGA	30 %	110 F			
E 20:02	130 F	15.5 INHGA	30 %	110 F			
E 20:04	130 F	19.4 INHGA	31 %	109 F			
E 20:06	130 F	23.4 INHGA	32 %	109 F			
E 20:07	130 F	27.0 INHGA	32 %	109 F			

MAX: 130 F 20.0 INHG 32 % PHASE 0:09 PHASE ELAPSED 0:09
MIN: 128 F (CHANGE) 30 % CYCLE 8:19

END OF CYCLE PHASE

20:07 TOTAL CYCLE 8:18 CYCLE ELAPSED 8:19

OPERATOR A.J. 01-09-20

ACCEPT ✓ NON CONFORMANCE _____

_Q.A. _____ DATE _____
_SUPERVISOR

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CUSTOMED

Form STP-002-01 Page 1 of 3
Revision K
Effective Date: 06-24-19

STERILIZATION PROCEDURE (STP)

Issued by:	Title: QA/Doc. Control	Date: 06-06-19
Approved by:	Title: QA Director	Date: 06-17-19

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

PARA USO DEL DEPARTAMENTO DE CALIDAD
Num. de **Lote de Carga SL #** 20008

Para Productos: Ver Forma STP 002-03
Procedimiento Etapa de Pre-acondicionamiento: STP 003
Procedimiento Proceso de Esterilización: STP 002 , STP 010
Procedimiento Etapa de Aireación: STP 004

[✓] Full Cycle (Soft Cycle 125)
[ ] Ciclo contiene productos a ser re-esterilizados (Soft Cycle 125)
[ ] Validation Half Cycle (Soft Cycle 126)

BI's Lot # 0259 , expiration date: 07-25-20

Cantidad de BI's Utilizados: 32 + (Control positivo: 1 BI) = 33 Total:

Documento Completado y BI's Ubicados por/Fecha: 01-08-20

Verificado por/Fecha: 01-08-20

Etapa de Pre – Acondicionamiento

Comienzo de Etapa de Pre Acondicionamiento
Realizado por/Fecha: 01-08-20 Hora: 05:57 ☐AM ☑PM

Verificado por/Fecha: 01-08-20

Finalización de Etapa de Pre Acondicionamiento
Verifique y marque con marca de cotejo (Si o No) que los parámetros de temperatura y humedad relativa y tiempo de exposición son aceptables:
Parámetros de ciclo 125 (Soft cycle): Temperatura: **115° F ± 9°F**, Humedad: **65%RH ± 15%RH**;
Tiempo exposición mínimo a parámetros de temperatura / humedad: **12 horas**.
Parámetros aceptables: **SI** ☑ **NO** ☐

Hora de transferencia de la 1ra paleta fuera del cuarto: 11:38 ☑AM ☑PM

Realizado por/Fecha: 01-09-20 Verificado por/Fecha: 01-09-20

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

Ciclo de Esterilización:

☑ **Full Cycle (Soft Cycle 125)** ☐ **Half Cycle (Soft Cycle 126) Seleccionado por/Fecha:** S.Sin 01-09-20

Verificado por/Fecha: J.V 01-09-20

Verificación de Utilidades:

Utilidades	Parámetro	A	R	N/A	Realizado por / Fecha	Verificado por / Fecha
Nivel de agua en radiador bomba de vacío (BOC EDWARDS)	En el cuello del radiador	✓			S.Sin 01-09-20	J.V 01-09-20
Presión de agua en la Cámara	15 psi ± 5	✓			S.Sin 01-09-20	J.V 01-09-20
Agua caliente en la cámara"Jacket Temperatura"	130 F ± 3	✓			S.Sin 01-09-20	J.V 01-09-20
Sistema de "LEL's "	Alarmas no activadas	✓			S.Sin 01-09-20	J.V 01-09-20
Sistema de "Scrubber"	"OK To Run"	✓			S.Sin 01-09-20	J.V 01-09-20
Agua de enfriamiento	(47 – 54) F	✓			S.Sin 01-09-20	J.V 01-09-20
Vapor de Agua	75 psi – 10	✓			S.Sin ① 01-20 01-09-20	J.V 01-09-20
Aire Comprimido	**100** psi - 30	✓			S.Sin 01-09-20	J.V 01-09-20
Papel en la Impresora	Papel alineado en la parte superior	✓			S.Sin 01-09-20	J.V 01-09-20
Bomba (TRAVAINI)	**Verificar nivel de Aceite**			✓	S.Sin 01-09-20	J.V 01-09-20
Tanque de ETO a Tierra	Cable de tierra conectado al tanque	✓			S.Sin 01-09-20	J.V 01-09-20
Cantidad de ETO	Sobre 80 lb.	✓			S.Sin 01-09-20	J.V 01-09-20
Válvulas de ETO	Deben estar abiertas	✓			S.Sin 01-09-20	J.V 01-09-20
Temperatura "volitilizador"	180 F ± 10	✓			S.Sin 01-09-20	J.V 01-09-20

A= Cumplimiento de parámetro establecido. R= No se cumple con el parámetro establecido.

TANQUE DE ETO A		TANQUE DE ETO B	
A. Num. Tanque:	E004567	**A.** Num. Tanque:	E000519
B. Fecha de Llenado:	09-11-19	**B.** Fecha de Llenado:	10-14-19
C. Fecha de Expiración:	01-09-20	**C.** Fecha de Expiración:	02-11-20

D. Fecha de Vencimiento Calibración Balanza de ETO	11 / 20 Mes/Año	Realizado por/ Fecha: S.Sin 01-09-20	Verificado por/ Fecha: J.V 01-09-20
E. Peso de Comienzo	982.5 lbs.	Realizado por/ Fecha: S.Sin 01-09-20	Verificado por/ Fecha: J.V 01-09-20
F. Peso de Terminación	922.0 lbs.	Realizado por/ Fecha: S.Sin 01-09-20	Verificado por/ Fecha: [illegible] 01-09-20
G. Dosis de Gas (D-E)	60.5 lbs.	Realizado por/ Fecha: S.Sin 01-09-20	Verificado por/ Fecha: [illegible] 01-09-20

Tanques Utilizados:		**TANQUE DE ETO A**	✓	**TANQUE DE ETO B**

H. Verificado por QA/Fecha:

① Fecha Incorrecta S.Sin 01-09-20

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

Ciclo de Esterilización

~Cámara Cargada: Realizado por/Fecha: JM 01-09-20

Puerta de Carga Cerrada (Hora): 11:46 ☒ AM ☐ PM

Realizado por/Fecha: JM 01-09-20 Verificado por/Fecha: A. Sin 01-09-20

~Comienzo de ciclo (Hora): 11:48 ☑ AM ☐ PM

Realizado por/Fecha: A. Sin 01-09-20 Verificado por/Fecha: JM 01-09-20

~Puerta de esterilizadora abierta 6" por un mínimo 30 minutos (Hora): 08:08 ☐ AM ☑ PM

(Hora) Remoción de ciclo: 08:46 ☐ AM ☑ PM

Realizado por/Fecha: A. Sin 01-09-20 Verificado por/Fecha: JM 01-09-20

Etapa De Aireación

Puerta de cámara de aireación abierta (Hora): 08:13 ☐ AM ☑ PM
(Luego de abrir la puerta del cuarto de aereación, esperar no menos de 10 minutos para entrar al mismo.)

Realizado por/Fecha: A. Sin 01-09-20 Verificado por/Fecha: JM 01-09-20

Comienzo de Etapa de Aireación y Remoción de Indicadores Biológicos
(Nota: Remover Indicadores Biológicos mientras mueve paletas a cuarto de aireación.)

Realizado por/Fecha: A. Sin 01-09-20 Hora: 08:57 ☐ AM ☑ PM

Verificado por/Fecha: JM 01-09-20

Finalización de Etapa

Verifique los parámetros, gráfica y tiempo de exposición son aceptables: Temperatura: 125° F +/-10
Tiempo de exposición mínimo para los productos es de: 24 horas

SI ☐ NO ☐ - Hora de transferido de la 1ra paleta fuera del cuarto: _____ ☐ AM ☐ PM

Realizado por/Fecha: _____ Verificado por fecha: _____

Auditado por/Fecha: _____

Aprobado por (QA)/Fecha: _____

Empty ~~cy~~ Cycle with ETO 01-09-2020

@E
DATE 01/09/20 Thu CYCLE 125 PROGRAM VERSION 4E-2 CHECK VALUE 13180
RUN ID # Empty Chamber OPERATOR A.Alicea

Customed Inc.
W/ETO

COPY

PROCESS PARAMETERS

CHAMBER TEMP	130 F, LO TOL 10 F, HI TOL 10 F, ABORT 165 F
INITIAL EVACUATION A	7.0 INHGA, 2.01 INHG/MIN
HUMIDITY INJECTION A	1.0 INHG
NITROGEN BLANKET A	25.0 INHGA, 1.00 INHG/MIN
NITROGEN DILUTION	2 CYCLES, RH 0:30 HH:MM, 55 % RH, UPPER 25.0 INHGA, LOWER 22.0 INHGA
INITIAL EVACUATION B	7.0 INHGA, 2.01 INHG/MIN
HUMIDITY INJECTION B	1.0 INHG
HUMIDITY DWELL	1:05 HH:MM, 8.0 INHGA, LO 7.5 INHGA, HI 8.5 INHGA, MAX 9.0 INHGA
STERILANT INJECTION	19.5 INHGA, 0.71 INHG/MIN
EXPOSURE	3:05 HH:MM, 19.5 INHGA, LO 19.0 INHGA, HI 20.0 INHGA, ABORT 21.5 INHGA LO 5 F, HI 5 F, ABORT 145 F, MAKEUPS: STERILANT
STERILANT REMOVAL	EXHAUST 0.0 SKIP, EVACUATION 7.0 INHGA, 2.01 INHG/MIN
NITROGEN WASH	3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHGA, LOWER 7.0 INHGA
AIR WASH A	3 CYCLES, EVAC DWELL 0:00 HH:MM, UPPER 20.0 INHGA, LOWER 7.0 INHGA
FINAL AIRBREAK	27.0 INHGA, 2.01 INHG/MIN

E	TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
			INITIAL EVACUATION A PHASE				
E	05:16	134 F	29.8 INHGA	18 %	103 F		
E	05:18	132 F	25.8 INHGA	16 %	103 F		
E	05:20	130 F	21.7 INHGA	14 %	103 F		
E	05:22	129 F	17.7 INHGA	12 %	104 F		
E	05:24	129 F	13.9 INHGA	10 %	104 F		
E	05:26	129 F	10.6 INHGA	7 %	104 F		
E	05:26	129 F	10.5 INHGA	7 %	104 F	SLOW INCREMENT	
E	05:28	129 F	8.2 INHGA	6 %	104 F		
E	05:29	129 F	7.0 INHGA	5 %	104 F		

MAX: 134 F -22.8 INHG 18 % PHASE 0:13 PHASE ELAPSED 0:13
MIN: 129 F (CHANGE) 5 % CYCLE 0:13

			HUMIDITY INJECTION A (PRESS) PHASE				
E	05:29	129 F	7.0 INHGA	5 %	104 F		
E	05:29	129 F	8.0 INHGA	9 %	106 F		

MAX: 129 F 1.0 INHG 9 % PHASE 0:00 PHASE ELAPSED 0:00
MIN: 129 F (CHANGE) 5 % CYCLE 0:13

1

E01/09/20 Thu CYCLE 125 RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN

NITROGEN BLANKET A PHASE

E 05:29	129 F	8.1 INHGA	9 %	106 F		
E 05:31	132 F	10.2 INHGA	42 %	107 F		
E 05:33	134 F	12.2 INHGA	43 %	109 F		
E 05:35	134 F	14.2 INHGA	44 %	112 F		
E 05:37	135 F	16.2 INHGA	44 %	114 F		
E 05:39	135 F	18.2 INHGA	45 %	115 F		
E 05:41	135 F	20.2 INHGA	45 %	116 F		
E 05:43	135 F	22.2 INHGA	45 %	117 F		
E 05:45	135 F	24.2 INHGA	45 %	118 F		
E 05:45	135 F	25.0 INHGA	45 %	118 F		

MAX: 135 F 17.0 INHG 45 % PHASE 0:16 PHASE ELAPSED 0:16
MIN: 129 F (CHANGE) 9 % CYCLE 0:29

COPY

NITROGEN DILUTION (WASH) PHASE

E 05:45	135 F	25.0 INHGA	45 %	118 F		
E 05:45	135 F	25.0 INHGA	45 %	118 F	BEGIN RH	1
E 05:47	135 F	27.0 INHGA	73 %	116 F		
E 05:49	135 F	26.8 INHGA	81 %	115 F		
E 05:51	134 F	26.8 INHGA	83 %	114 F		
E 05:53	134 F	26.8 INHGA	85 %	113 F		
E 05:55	134 F	26.8 INHGA	87 %	113 F		
E 05:57	134 F	26.8 INHGA	88 %	112 F		
E 05:59	133 F	26.8 INHGA	89 %	112 F		
E 06:01	133 F	26.8 INHGA	90 %	112 F		
E 06:03	133 F	26.8 INHGA	91 %	111 F		
E 06:05	133 F	26.8 INHGA	91 %	111 F		
E 06:07	133 F	26.8 INHGA	92 %	111 F		
E 06:09	133 F	26.8 INHGA	93 %	111 F		
E 06:11	133 F	26.8 INHGA	94 %	110 F		
E 06:13	133 F	26.8 INHGA	94 %	110 F		
E 06:15	133 F	26.8 INHGA	95 %	110 F		
E 06:15	133 F	26.8 INHGA	95 %	110 F	BEGIN NITROGEN	1
E 06:15	133 F	26.8 INHGA	95 %	110 F	BEGIN EVACUATION	1
E 06:17	131 F	22.8 INHGA	85 %	111 F		
E 06:18	131 F	22.0 INHGA	85 %	111 F	BEGIN RH	2
E 06:19	131 F	22.2 INHGA	85 %	110 F		
E 06:21	132 F	22.2 INHGA	85 %	110 F		
E 06:23	132 F	22.2 INHGA	85 %	110 F		
E 06:25	132 F	22.3 INHGA	86 %	109 F		
E 06:27	132 F	22.3 INHGA	86 %	109 F		
E 06:29	132 F	22.3 INHGA	86 %	109 F		
E 06:31	132 F	22.3 INHGA	87 %	109 F		
E 06:33	132 F	22.4 INHGA	87 %	109 F		
E 06:35	132 F	22.4 INHGA	88 %	109 F		
E 06:37	132 F	22.4 INHGA	88 %	109 F		
E 06:39	132 F	22.4 INHGA	89 %	109 F		
E 06:41	132 F	22.4 INHGA	89 %	109 F		
E 06:43	132 F	22.4 INHGA	89 %	109 F		
E 06:45	132 F	22.4 INHGA	90 %	109 F		
E 06:47	132 F	22.4 INHGA	90 %	109 F		

2

E01/09/20 Thu CYCLE 125 RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 06:48	132 F	22.4 INHGA	90 %	109 F		BEGIN NITROGEN 2
E 06:49	133 F	24.7 INHGA	91 %	112 F		
E 06:50	133 F	25.0 INHGA	91 %	112 F		BEGIN EVACUATION 2
E 06:51	132 F	22.0 INHGA	83 %	111 F		
E 06:51	132 F	22.0 INHGA	83 %	111 F		

MAX: 135 F -3.0 INHG 95 % PHASE 1:06 PHASE ELAPSED 1:06
MIN: 131 F (CHANGE) 45 % CYCLE 1:36

INITIAL EVACUATION B PHASE

COPY

E 06:52	132 F	21.9 INHGA	83 %	111 F	
E 06:54	130 F	17.9 INHGA	71 %	110 F	
E 06:56	128 F	14.0 INHGA	60 %	110 F	
E 06:58	128 F	10.8 INHGA	49 %	109 F	
E 06:58	128 F	10.7 INHGA	49 %	109 F	SLOW INCREMENT
E 07:00	128 F	8.3 INHGA	41 %	109 F	
E 07:01	128 F	7.0 INHGA	36 %	109 F	

MAX: 132 F -15.0 INHG 83 % PHASE 0:09 PHASE ELAPSED 0:09
MIN: 128 F (CHANGE) 36 % CYCLE 1:45

HUMIDITY INJECTION B (PRESS) PHASE

E 07:01	128 F	7.0 INHGA	36 %	109 F
E 07:01	128 F	8.0 INHGA	39 %	111 F

MAX: 128 F 1.0 INHG 39 % PHASE 0:00 PHASE ELAPSED 0:00
MIN: 128 F (CHANGE) 36 % CYCLE 1:45

HUMIDITY DWELL (PRESS) PHASE

E 07:01	128 F	8.1 INHGA	39 %	111 F	
E 07:02	129 F	8.5 INHGA	50 %	121 F	HI HUMIDITY
E 07:03	131 F	8.6 INHGA	71 %	122 F	
E 07:05	131 F	8.7 INHGA	72 %	119 F	
E 07:07	131 F	8.7 INHGA	74 %	117 F	
E 07:09	131 F	8.8 INHGA	75 %	116 F	
E 07:11	132 F	8.8 INHGA	76 %	115 F	
E 07:13	132 F	8.8 INHGA	77 %	114 F	
E 07:15	132 F	8.9 INHGA	78 %	113 F	
E 07:17	132 F	8.9 INHGA	78 %	112 F	
E 07:19	132 F	8.9 INHGA	79 %	112 F	
E 07:21	132 F	9.0 INHGA	80 %	111 F	
E 07:23	131 F	9.0 INHGA	80 %	111 F	MAXIMUM HUMIDITY
E 07:23	131 F	9.0 INHGA	80 %	111 F	
E 07:25	131 F	9.0 INHGA	81 %	110 F	
E 07:27	131 F	9.0 INHGA	81 %	110 F	
E 07:29	131 F	9.1 INHGA	82 %	109 F	
E 07:31	131 F	9.1 INHGA	82 %	109 F	

E01/09/20 Thu CYCLE 125 RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 07:33	131 F	9.1 INHGA	83 %	109 F		
E 07:35	131 F	9.1 INHGA	83 %	109 F		
E 07:37	131 F	9.1 INHGA	84 %	108 F		
E 07:39	131 F	9.1 INHGA	84 %	109 F		
E 07:41	131 F	9.1 INHGA	84 %	108 F		
E 07:43	131 F	9.2 INHGA	85 %	108 F		
E 07:45	131 F	9.2 INHGA	85 %	108 F		
E 07:47	131 F	9.2 INHGA	85 %	108 F		
E 07:49	131 F	9.2 INHGA	86 %	108 F		
E 07:51	131 F	9.2 INHGA	86 %	108 F		
E 07:53	131 F	9.2 INHGA	86 %	108 F		
E 07:55	131 F	9.2 INHGA	87 %	108 F		
E 07:57	131 F	9.2 INHGA	87 %	108 F		
E 07:59	131 F	9.2 INHGA	87 %	108 F		
E 08:01	131 F	9.2 INHGA	88 %	108 F		
E 08:03	131 F	9.2 INHGA	88 %	108 F		
E 08:05	131 F	9.3 INHGA	88 %	108 F		
E 08:06	131 F	9.3 INHGA	88 %	108 F		

COPY

MAX: 132 F 1.2 INHG 88 % PHASE 1:05 PHASE ELAPSED 1:05
MIN: 128 F (CHANGE) 39 % CYCLE 2:50

STERILANT INJECTION PHASE

E 08:06	131 F	9.3 INHGA	88 %	108 F		
E 08:08	131 F	10.8 INHGA	96 %	113 F		
E 08:10	132 F	11.8 INHGA	97 %	116 F		
E 08:11	132 F	11.9 INHGA	94 %	115 F	SLOW INCREMENT	

EGROSS =1011.1 LB
, USING DRUM A

CYCLE STOP

EGROSS =1011.1 LB
, USING DRUM B
EXIT SCALE COMMAND

E 08:12	131 F	12.0 INHGA	90 %	114 F		
E 08:13	131 F	12.0 INHGA	88 %	114 F		CYCLE CONTINUED
E 08:14	131 F	13.7 INHGA	92 %	113 F		
E 08:16	132 F	15.1 INHGA	95 %	114 F		
E 08:18	132 F	16.5 INHGA	96 %	115 F		
E 08:20	132 F	17.9 INHGA	97 %	116 F		
E 08:22	132 F	19.3 INHGA	96 %	117 F		
E 08:23	132 F	19.5 INHGA	96 %	117 F		

MAX: 132 F 10.2 INHG 97 % PHASE 0:16 PHASE ELAPSED 0:16
MIN: 131 F (CHANGE) 88 % CYCLE 3:07
STERILANT USED THIS PHASE: 43.0 LB, CYCLE TOTAL: 43.0 LB

E01/09/20 Thu CYCLE 125 RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
		EXPOSURE PHASE				
E 08:23	132 F	19.7 INHGA	96 %	118 F		
E 08:25	132 F	19.6 INHGA	90 %	115 F		
E 08:27	131 F	19.6 INHGA	90 %	114 F		
E 08:29	131 F	19.6 INHGA	91 %	114 F		
E 08:31	130 F	19.6 INHGA	92 %	113 F		
E 08:33	130 F	19.6 INHGA	92 %	113 F		
E 08:35	130 F	19.6 INHGA	92 %	112 F		
E 08:37	130 F	19.6 INHGA	93 %	112 F		
E 08:39	130 F	19.7 INHGA	93 %	111 F		
E 08:41	130 F	19.7 INHGA	93 %	111 F		
E 08:43	130 F	19.7 INHGA	94 %	111 F		
E 08:45	130 F	19.7 INHGA	94 %	111 F		
E 08:47	130 F	19.7 INHGA	94 %	110 F		
E 08:49	130 F	19.7 INHGA	94 %	110 F		
E 08:51	130 F	19.7 INHGA	95 %	110 F		
E 08:53	130 F	19.7 INHGA	95 %	110 F		
E 08:55	130 F	19.7 INHGA	95 %	110 F		
E 08:57	130 F	19.7 INHGA	95 %	110 F		
E 08:58	130 F	19.7 INHGA	95 %	110 F		OPERATOR CYCLE ABORT
E 08:58	130 F	19.7 INHGA	95 %	110 F	SHORT EXPOSURE	
E 08:58	130 F	19.7 INHGA	95 %	110 F		

MAX: 132 F 0.0 INHG 96 % PHASE 0:34 PHASE ELAPSED 0:34
MIN: 130 F (CHANGE) 90 % CYCLE 3:42

COPY

		STERILANT REMOVAL PHASE				
E 08:58	130 F	19.7 INHGA	95 %	110 F		
E 08:58	130 F	19.7 INHGA	95 %	110 F		BEGIN EVACUATION
E 09:00	129 F	15.6 INHGA	85 %	110 F		
E 09:02	127 F	12.1 INHGA	72 %	110 F		
E 09:03	127 F	10.5 INHGA	65 %	109 F	SLOW INCREMENT	
E 09:04	127 F	9.3 INHGA	60 %	109 F		
E 09:06	127 F	7.2 INHGA	50 %	108 F		
E 09:06	127 F	7.0 INHGA	49 %	108 F		

MAX: 130 F -12.7 INHG 95 % PHASE 0:08 PHASE ELAPSED 0:08
MIN: 127 F (CHANGE) 49 % CYCLE 3:50

		NITROGEN WASH (WASH) PHASE				
E 09:06	127 F	7.0 INHGA	49 %	108 F		
E 09:06	127 F	7.0 INHGA	49 %	108 F		BEGIN NITROGEN 1
E 09:08	129 F	9.1 INHGA	49 %	107 F		
E 09:10	130 F	11.1 INHGA	48 %	108 F		
E 09:12	131 F	13.1 INHGA	47 %	110 F		
E 09:14	132 F	15.1 INHGA	47 %	113 F		
E 09:16	132 F	17.1 INHGA	47 %	114 F		
E 09:18	132 F	19.1 INHGA	47 %	115 F		
E 09:18	132 F	20.0 INHGA	47 %	115 F		BEGIN EVACUATION 1

E01/09/20 Thu CYCLE 125 RUN ID # Empty Chamber

COPY

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN	
E 09:20	130 F	16.8 INHGA	42 %	115 F			
E 09:22	128 F	13.1 INHGA	36 %	114 F			
E 09:23	127 F	10.7 INHGA	31 %	113 F	SLOW INCREMENT		
E 09:24	127 F	10.0 INHGA	30 %	113 F			
E 09:26	127 F	7.7 INHGA	25 %	112 F			
E 09:27	127 F	7.0 INHGA	23 %	112 F		BEGIN NITROGEN	2
E 09:28	128 F	8.6 INHGA	23 %	110 F			
E 09:30	130 F	10.6 INHGA	22 %	110 F			
E 09:32	131 F	12.6 INHGA	22 %	111 F			
E 09:34	132 F	14.6 INHGA	22 %	113 F			
E 09:36	132 F	16.6 INHGA	21 %	115 F			
E 09:38	132 F	18.6 INHGA	21 %	116 F			
E 09:39	132 F	20.0 INHGA	21 %	116 F		BEGIN EVACUATION	2
E 09:40	132 F	17.8 INHGA	20 %	117 F			
E 09:42	129 F	14.3 INHGA	17 %	115 F			
E 09:44	127 F	10.9 INHGA	14 %	115 F			
E 09:44	127 F	10.6 INHGA	14 %	115 F	SLOW INCREMENT		
E 09:46	127 F	8.4 INHGA	11 %	114 F			
E 09:47	127 F	7.0 INHGA	10 %	114 F		BEGIN NITROGEN	3
E 09:48	128 F	8.2 INHGA	10 %	110 F			
E 09:50	130 F	10.2 INHGA	10 %	109 F			
E 09:52	131 F	12.2 INHGA	9 %	110 F			
E 09:54	131 F	14.2 INHGA	9 %	113 F			
E 09:56	132 F	16.2 INHGA	9 %	115 F			
E 09:58	132 F	18.3 INHGA	9 %	116 F			
E 10:00	132 F	20.0 INHGA	9 %	117 F		BEGIN EVACUATION	3
E 10:00	132 F	19.7 INHGA	9 %	117 F			
E 10:02	130 F	15.7 INHGA	7 %	117 F			
E 10:04	128 F	11.9 INHGA	6 %	116 F			
E 10:05	127 F	10.6 INHGA	6 %	115 F	SLOW INCREMENT		
E 10:06	127 F	9.1 INHGA	5 %	115 F			
E 10:08	127 F	7.0 INHGA	4 %	114 F			

MAX: 132 F 0.0 INHG 49 % PHASE 1:01 PHASE ELAPSED 1:01
MIN: 127 F (CHANGE) 4 % CYCLE 4:52

AIR WASH A (WASH) PHASE

E 10:08	127 F	7.0 INHGA	4 %	114 F			
E 10:08	127 F	7.0 INHGA	4 %	114 F		BEGIN INBLEED	1
E 10:10	131 F	11.4 INHGA	6 %	114 F			
E 10:12	133 F	15.4 INHGA	8 %	113 F			
E 10:14	133 F	19.3 INHGA	10 %	113 F			
E 10:14	133 F	20.1 INHGA	10 %	113 F		BEGIN EVACUATION	1
E 10:16	131 F	16.2 INHGA	9 %	112 F			
E 10:18	128 F	12.7 INHGA	8 %	112 F			
E 10:19	128 F	10.7 INHGA	7 %	112 F	SLOW INCREMENT		
E 10:20	127 F	9.7 INHGA	6 %	112 F			
E 10:22	127 F	7.5 INHGA	5 %	111 F			
E 10:22	127 F	7.0 INHGA	4 %	111 F		BEGIN INBLEED	2
E 10:24	130 F	11.7 INHGA	6 %	111 F			
E 10:26	132 F	15.7 INHGA	8 %	111 F			
E 10:28	133 F	19.6 INHGA	10 %	110 F			
E 10:29	134 F	20.1 INHGA	11 %	110 F		BEGIN EVACUATION	2

E01/09/20 Thu CYCLE 125 RUN ID # Empty Chamber

TIME	TEMP	PRESSURE	RH	GAS INJ	ALARMS & MESSAGES	ACTION TAKEN
E 10:30	132 F	17.7 INHGA	10 %	110 F		
E 10:32	129 F	13.7 INHGA	9 %	110 F		
E 10:34	128 F	10.7 INHGA	7 %	110 F	SLOW INCREMENT	
E 10:34	128 F	10.5 INHGA	7 %	110 F		
E 10:36	127 F	8.1 INHGA	5 %	110 F		
E 10:37	127 F	7.0 INHGA	5 %	110 F		BEGIN INBLEED 3
E 10:38	129 F	9.5 INHGA	6 %	110 F		
E 10:40	133 F	13.4 INHGA	8 %	110 F		
E 10:42	133 F	17.4 INHGA	10 %	110 F		
E 10:43	133 F	20.1 INHGA	11 %	110 F		BEGIN EVACUATION 3
E 10:44	133 F	18.4 INHGA	11 %	110 F		
E 10:46	130 F	14.7 INHGA	9 %	110 F		
E 10:48	128 F	11.3 INHGA	7 %	110 F		
E 10:48	128 F	10.7 INHGA	7 %	110 F	SLOW INCREMENT	
E 10:50	127 F	8.6 INHGA	6 %	110 F		
E 10:51	127 F	7.0 INHGA	5 %	110 F		

MAX: 134 F 0.0 INHG 11 % PHASE 0:43 PHASE ELAPSED 0:43
MIN: 127 F (CHANGE) 4 % CYCLE 5:35

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FINAL AIRBREAK PHASE

E 10:51	127 F	7.0 INHGA	5 %	110 F	
E 10:53	131 F	11.4 INHGA	7 %	109 F	
E 10:55	133 F	15.3 INHGA	9 %	109 F	
E 10:57	134 F	19.3 INHGA	11 %	110 F	
E 10:59	134 F	23.2 INHGA	13 %	110 F	
E 11:01	134 F	27.0 INHGA	15 %	109 F	

MAX: 134 F 20.0 INHG 15 % PHASE 0:09 PHASE ELAPSED 0:09
MIN: 127 F (CHANGE) 5 % CYCLE 5:45

END OF CYCLE PHASE

11:01 TOTAL CYCLE 5:44 CYCLE ELAPSED 5:45

OPERATOR_____

ACCEPT_____ NON CONFORMANCE_____

_Q.A._____ DATE_____
_SUPERVISOR

Empty Chamber with ETO
01-09-2020
Samples taken for SCV Testing

CUSTOMED

STERILIZATION PROCEDURE (STP)

Issued by: [signature]	Title: QA/Doc. Control	Date: 06-06-19
Approved by: [signature]	Title: QA Director	Date: 06-14-19

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

PARA USO DEL DEPARTAMENTO DE CALIDAD
Num. de **Lote de Carga SL #** Empty cycle WITH ETO 01/09/2020

Para Productos: Ver Forma STP 002-03
Procedimiento Etapa de Pre-acondicionamiento: STP 003
Procedimiento Proceso de Esterilización: STP 002 , STP 010
Procedimiento Etapa de Aireación: STP 004

COPY

[ ] Full Cycle (Soft Cycle 125)
[ ] Ciclo contiene productos a ser re-esterilizados (Soft Cycle 125)
[ ] Validation Half Cycle (Soft Cycle 126)

BI's Lot # _____ , expiration date: _____

Cantidad de BI's Utilizados: _____ + (Control positivo: 1 BI) = _____ Total:

Documento Completado y BI's Ubicados por/Fecha: _____

Verificado por/Fecha: _____

Etapa de Pre – Acondicionamiento

Comienzo de Etapa de Pre Acondicionamiento
Realizado por/Fecha: _____ Hora: _____ ☐AM ☐PM

Verificado por/Fecha: _____ IA 01-09-20

Finalización de Etapa de Pre Acondicionamiento
Verifique y marque con marca de cotejo (Si o No) que los parámetros de temperatura y humedad relativa y tiempo de exposición son aceptables:
Parámetros de ciclo 125 (Soft cycle): Temperatura: **115° F ± 9°F**, Humedad: **65%RH ± 15%RH**, Tiempo exposición mínimo a parámetros de temperatura/ humedad: **12 horas**.
Parámetros aceptables: **SI** ☐ **NO** ☐ N

Hora de transferencia de la 1ra paleta fuera del cuarto: _____ ☐AM ☐PM

Realizado por/Fecha: _____ Verificado por/Fecha: _____

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

Ciclo de Esterilización:

☒ **Full Cycle (Soft Cycle 125)** ☐ **Half Cycle (Soft Cycle 126) Seleccionado por/Fecha:** S. Sin 01-09-20

Verificado por/Fecha: JIA 01-09-20

Verificación de Utilidades:

Utilidades	Parámetro	A	R	N/A	Realizado por / Fecha	Verificado por / Fecha
Nivel de agua en radiador bomba de vacío (BOC EDWARDS)	En el cuello del radiador	✓			S. Sin 01-09-20	JIA 01-09-20
Presión de agua en la Cámara	15 psi ± 5	✓			S. Sin 01-09-20	JIA 01-09-20
Agua caliente en la cámara"Jacket Temperatura"	130 F ± 3	✓			S. Sin 01-09-20	JIA 01-09-20
Sistema de "LEL's "	Alarmas no activadas	✓			S. Sin 01-09-20	JIA 01-09-20
Sistema de "Scrubber"	"OK To Run"	✓			S. Sin 01-09-20	JIA 01-09-20
Agua de enfriamiento	(47 – 54) F	✓			S. Sin 01-09-20	JIA 01-09-20
Vapor de Agua	75 psi – 10	✓			S. Sin 01-09-20	JIA 01-09-20
Aire Comprimido	**100** psi - 30	✓			S. Sin 01-09-20	JIA 01-09-20
Papel en la Impresora	Papel alineado en la parte superior	✓			S. Sin 01-09-20	JIA 01-09-20
Bomba (TRAVAINI)	**Verificar nivel de Aceite**			✓	S. Sin 01-09-20	JIA 01-09-20
Tanque de ETO a Tierra	Cable de tierra conectado al tanque	✓			S. Sin 01-09-20	JIA 01-09-20
Cantidad de ETO	Sobre 80 lb.	✓			S. Sin 01-09-20	JIA 01-09-20
Válvulas de ETO	Deben estar abiertas	✓			S. Sin 01-09-20	JIA 01-09-20
Temperatura "volitilizador"	180 F ± 10	✓			S. Sin 01-09-20	JIA 01-09-20

A= Cumplimiento de parámetro establecido. R= No se cumple con el parámetro establecido.

TANQUE DE ETO A		TANQUE DE ETO B	
A. Num. Tanque:	E004567	**A.** Num. Tanque:	E000519
B. Fecha de Llenado:	09-11-19	**B.** Fecha de Llenado:	10-14-19
C. Fecha de Expiración:	01-09-20	**C.** Fecha de Expiración:	02-11-20

D. Fecha de Vencimiento Calibración Balanza de ETO	11/20 Mes/Año	Realizado por/ Fecha: S. Sin 01-09-20	Verificado por/ Fecha: JIA 01-09-20
E. Peso de Comienzo	4,025.5 lbs.	Realizado por/ Fecha: S. Sin 01-09-20	Verificado por/ Fecha: JIA 01-09-20
F. Peso de Terminación	982.5 lbs.	Realizado por/ Fecha: S. Sin 01-09-20	Verificado por/ Fecha:
G. Dosis de Gas (D-E)	43.0 lbs.	Realizado por/ Fecha: S. Sin 01-09-20	Verificado por/ Fecha:

Tanques Utilizados:	✓	**TANQUE DE ETO A**	✓ **TANQUE DE ETO B**

H. Verificado por QA/Fecha:

COPY

TITLE: FORMA PARA REGISTRO PARA CICLO DE ESTERILIZACION

Ciclo de Esterilización

~Cámara Cargada: Realizado por/Fecha: _____

Puerta de Carga Cerrada (Hora): _____ ☐ AM ☐ PM

Realizado por/Fecha: _____ Verificado por/Fecha: _____

~Comienzo de ciclo (Hora): _____ ☐ AM ☐ PM

Realizado por/Fecha: _____ Verificado por/Fecha: _____

~Puerta de esterilizadora abierta 6" por un mínimo 30 minutos (Hora): ① 11:02 ☐ AM ☑ PM

(Hora) Remoción de ciclo: _____ ☐ AM ☐ PM

Realizado por/Fecha: A.A. 01-09-20 Verificado por/Fecha: _____

Etapa De Aireación ① Puerta cerrada a las 11:35 A.M. A.A. 01-09-20

Puerta de cámara de aireación abierta (Hora): _____ ☐ AM ☐ PM
(Luego de abrir la puerta del cuarto de aereación, esperar no menos de 10 minutos para entrar al mismo.)

Realizado por/Fecha: _____ Verificado por/Fecha: _____

Comienzo de Etapa de Aireación y Remoción de Indicadores Biológicos
(Nota: Remover Indicadores Biológicos mientras mueve paletas a cuarto de aireación.)

Realizado por/Fecha: _____ Hora: _____ ☐ AM ☐ PM

Verificado por/Fecha: _____

Finalización de Etapa

Verifique los parámetros, gráfica y tiempo de exposición son aceptables: Temperatura: 125° F +/-10
Tiempo de exposición mínimo para los productos es de: 24 horas

SI ☐ NO ☐ - Hora de transferido de la 1ra paleta fuera del cuarto: _____ ☐ AM ☐ PM

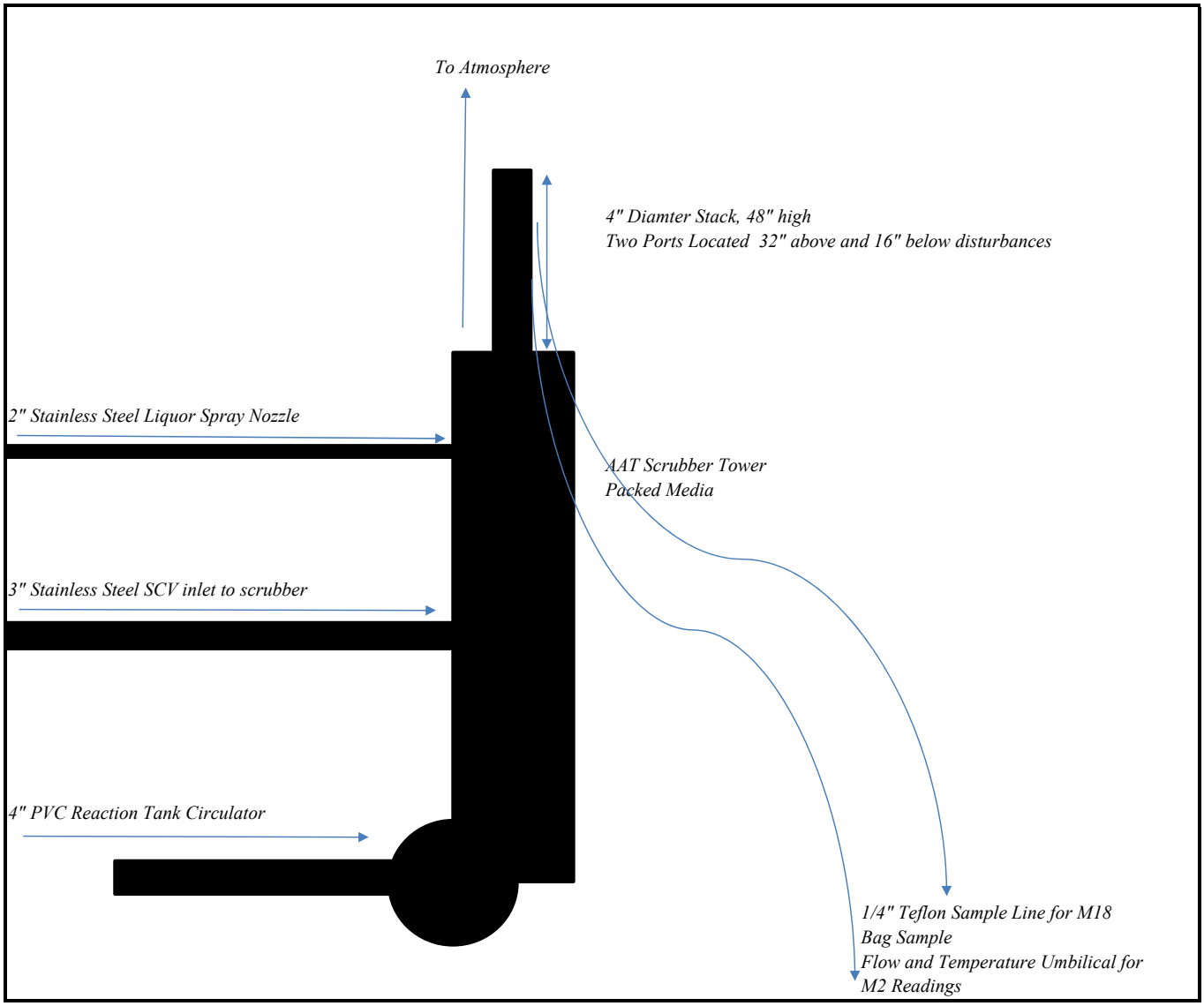
Realizado por/Fecha: _____ Verificado por fecha: _____

Auditado por/Fecha: _____

Aprobado por (QA)/Fecha: _____

ATTACHMENT G

SCRUBBER SKETCH


To Atmosphere
4" Diamter Stack, 48" high
Two Ports Located 32" above and 16" below disturbances
2" Stainless Steel Liquor Spray Nozzle
AAT Scrubber Tower
Packed Media
3" Stainless Steel SCV inlet to scrubber
4" PVC Reaction Tank Circulator
1/4" Teflon Sample Line for M18
Bag Sample
Flow and Temperature Umbilical for
M2 Readings

ATTACHMENT H

CALIBRATION RECORDS

GLOBAL CALIBRATION GASES LLC
ISO/IEC 17025:2017

Certificate of Analysis

Certified Standard

Customer:	Keen	Reference#:	120819SY-J
CGA:	180	Certification Date:	12/10/2019
Customer PO#:	79633	Expiration Date:	12/10/2020
Cylinder #:	CK1551770	Pressure, psig:	1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	5ppm	4.8ppm	± 10%
Nitrogen	Balance	Balance	

This report states accurately the results of the investigation made upon the material submitted to the analytical laboratory. Every effort has been made to determine objectively the information requested. However, in connection with this report, Global Calibration Gases LLC shall have no liability in excess of the established charge for this service.

Produced by:

Global Calibration Gases LLC.
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Kurtis Wilson
Date: 12/10/2019

Principal Reviewer: Jenna Pittman
Date: 12/10/2019

GLOBAL CALIBRATION GASES LLC
ISO/IEC 17025:2017

Certificate of Analysis

Certified Standard

Customer:	Keen	Reference#:	120819SY-G
CGA:	180	Certification Date:	12/10/2019
Customer PO#:	79633	Expiration Date:	12/10/2020
Cylinder #:	CK1551640	Pressure, psig:	1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	1.0ppm	1.0ppm	± 10%
Nitrogen	Balance	Balance	-

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Produced by:

Global Calibration Gases LLC.
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Keith Walker
Date: 12/10/2019

Principal Reviewer: Jeanette Homey
Date: 12/10/2019

GLOBAL CALIBRATION GASES LLC
ISO/IEC 17025:2017

Certificate of Analysis

Certified Standard

Customer:	Keen	Reference#:	120819SY-H
CGA:	180	Certification Date:	12/10/2019
Customer PO#:	79633	Expiration Date:	12/10/2020
Cylinder #:	CK1551650	Pressure, psig:	1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	0.5ppm	0.5ppm	± 20%
Nitrogen	Balance	Balance	-

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Produced by:

Global Calibration Gases LLC.
1090 Commerce Blvd N.
Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Kurtis Walker
Date: 12/10/2019

Principal Reviewer: Jennifer Homey
Date: 12/10/2019

GLOBAL CALIBRATION GASES LLC
ISO/IEC 17025:2017

Certificate of Analysis

Certified Standard

Customer:	Keen	Reference#:	120819SY-I
CGA:	180	Certification Date:	12/10/2019
Customer PO#:	79633	Expiration Date:	12/10/2020
Cylinder #:	CK1551725	Pressure, psig:	1800

Components	Requested Concentration	Certified Concentration	Analytical Accuracy
Ethylene Oxide	2.5ppm	2.4ppm	± 10%
Nitrogen	Balance	Balance	-

This report states accurately the results of the investigation made upon the material submitted to the analytical laboratory. Every effort has been made to determine objectively the information requested. However, in connection with this report, Global Calibration Gases LLC shall have no liability in excess of the established charge for this service.

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Sarasota, Florida 34243 USA
PGVP Vendor ID.: N22019

Principal Analyst: Keith Walker
Date: 12/10/2019

Principal Reviewer: Jenna Honey
Date: 12/10/2019

GASCO AFFILIATES, LLC.

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Oldsmar, FL 34677
(800) 910-0051
fax: (866) 755-8920
www.gascogas.com

CERTIFICATE OF ANALYSIS

Date: January 10, 2020
Order Number: PO092519
Lot Number: BCA-X02NI99CA9800B3-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 10%)	Analytical Result (+/- 2%)
Ethylene Oxide	1 PPM	1 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

The calibration gas prepared by Gasco is considered a certified standard. It is prepared by gravimetic, or partial pressure techniques. The calibration standard provided is certified against Gasco's G.M.I.S. (Gas Manufacturer's Intermediate Standard) which is either prepared by weights traceable to the National Institute of Standards and Technology (NIST) or by using NIST Standard Reference Materials where available.

TECHNICAL RECOMMENDATIONS
For best results, use the following procedure when using Reactive Gas Mixtures and always use the shortest length possible of Teflon Tubing between the Cylinder Regulator Hose Barb and the Gas Detection Instrument. Turn the regulator on before connection is made with the cylinder, allowing any trapped air to be purged from the regulator. Be sure to turn the regulator off as soon as the regulator is fully connected. Always ensure delivery tubing is compatible with the Gas. Do not store this cylinder with the regulator installed due to possible leakage or long-term reaction with internal components of the regulator. Follow instrument manufacturer's instruction manual.

Analyst:

Afton Eakins
Afton Eakins

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CERTIFICATE OF ANALYSIS

Date: January 10, 2020
Order Number: PO092519
Lot Number: BCA-X02NI99CA9800A6-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 10%)	Analytical Result (+/- 2%)
Ethylene Oxide	5 PPM	5.1 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

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CERTIFICATE OF ANALYSIS

Date: January 10, 2020
Order Number: PO092519
Lot Number: BCA-X02NI99CA9800A7-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 10%)	Analytical Result (+/- 2%)
Ethylene Oxide	10 PPM	10.1 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

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CERTIFICATE OF ANALYSIS

Date: January 10, 2020
Order Number: PO092519
Lot Number: BCA-X02NI99CA9800A9-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 5%)	Analytical Result (+/- 2%)
Ethylene Oxide	100 PPM	100.2 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

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Date: January 10, 2020
Order Number: PO092519
Lot Number: BCA-X02NI99CA9800B1-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 5%)	Analytical Result (+/- 2%)
Ethylene Oxide	1000 PPM	990 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

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CERTIFICATE OF ANALYSIS

Date: January 10, 2020
Order Number: PO092519
Lot Number: BCA-X02NI99CA9800B2-1

Customer: LGH Consulting Services LLC

Use Before: 01/10/2021

Component	Specification (+/- 5%)	Analytical Result (+/- 2%)
Ethylene Oxide	5000 PPM	5000 PPM
Nitrogen	BALANCE	BALANCE

Cylinder Size: 4.0 Cu. Ft.
Contents: 110 Liter

Valve: CGA 180
Pressure: 1500 psig

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