MicroBioTest Protocol

Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

Testing Facility
MicroBioTest
Division of Microbac Laboratories, Inc.
105 Carpenter Drive
Sterling, VA 20164

Prepared for
Luminore, Inc.
6060 Corte del Cedro
Carlsbad, CA 92011

June 16, 2014

MicroBioTest Protocol: LUM.3a.06.16.14

MicroBioTest Project: 872 - 108

OBJECTIVE:

This test is designed to substantiate effectiveness claims for a substance containing copper with sanitizing claims intended to be registered with the Environmental Protection Agency as an inanimate hard surface other than those that come in contact with food or beverages. The test is consistent with the EPA Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces.

TESTING CONDITIONS:

Initial sets of test and control surfaces (four replicates each per microorganism) representing new surfaces will be inoculated with *Staphylococcus aureus* and *Enterobacter aerogenes*, held for the stipulated contact time, transferred to a neutralizing solution and mixed. Dilutions of the neutralizer will be plated, incubated and observed for growth. The initial percent reduction of the new surfaces will be calculated. Three lots of a copper enhanced hard surface will be evaluated.

Additional sets of test and control surfaces (four replicates each per microorganism) will be subjected to multiple wet and dry wears and reinoculation cycles. Following the multiple insults, the carriers will be inoculated with the challenge microorganisms, dried and held for the stipulated contact time, transferred to a neutralizing solution and mixed. Dilutions of the neutralizer will be plated, incubated and observed for growth. The percent reduction of the worn/insulted surfaces will be calculated to demonstrate the effectiveness of the surface as a sanitizer during normal use in between surface cleanings. Three lots of a copper enhanced hard surface will be evaluated.

MATERIALS:

A. Test and control surfaces supplied by the sponsor: (see last page for details).

Test and control carriers: 1" x 1" coupons, also referred to as carriers

- The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or reference surfaces shall be determined for each batch and shall be documented by the sponsor before its use in a study. Methods of synthesis, fabrication, or derivation of the test, control, or reference surfaces shall be documented and retained by the sponsor.

- When relevant to the conduct of the study the solubility of each test, control, or reference agent shall be determined by the sponsor before the experimental start date. The stability of the test, control, or reference agent shall be determined by the sponsor before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

The test and control surfaces will be tested as supplied by the sponsor unless directed otherwise. All operations performed on the surfaces such as dilution or specialized storage conditions must be specified by the sponsor before initiation of testing.

The sponsor assures MicroBioTest, Division of Microbac Laboratories, Inc. (MicroBioTest) testing facility management that the test surface has been appropriately tested for identity, strength, purity, stability, and uniformity as applicable.

MicroBioTest will retain all unused test and control surfaces after completion of the test, and then only discard them with client permission in a manner that meets the approval of the safety officer.

B. Materials supplied by MicroBioTest including but not limited to:

1. Challenge microorganisms, required by EPA and the sponsor:
   a. *Staphylococcus aureus*, ATCC 6538
   b. *Enterobacter aerogenes*, ATCC 13048

2. Media and reagents:
   a. Tryptic Soy Broth (TSB)
   b. Neutralizer: 2X Letheen Broth
   c. Tryptic Soy Agar (TSA)
   d. Heat-inactivated Fetal Bovine Serum (FBS)
   e. Triton X-100 solution (1% solution)
   f. Sterile deionized water
   g. 70-85% Isopropyl alcohol

3. Miscellaneous laboratory equipment and supplies, including:
   a. Gardco Washability and Wear Tester – Paul N. Gardner Co., Inc., Model #D10V, Catalog # WA-2153
   b. Abrasion Boat and Weights for Washability and Wear Tester – Paul N. Gardner Co., Inc., Catalog #'s WA-2225, WA-2227, and WA2210/P01
   c. Polyurethane Foam Liner – Foam Wipe wiper, VWR Catalog # TW-TX704
   d. Cotton Cloth – TexWipe Clean Cotton Wipers, VWR Catalog # TW-TX309
   e. Preval sprayer (or equivalent)
   f. Control coupons, 1" x 1" (substrate material containing no active)

TEST SYSTEM IDENTIFICATION:

All test and control tube racks will be labeled with microorganism, test agent (if applicable) and project number prior to initiation of the study and during incubation. Petri dishes will be labeled with microorganism prior to initiation of the study and microorganism and project number during incubation.

EXPERIMENTAL DESIGN:

A. Inocula preparation:

For *Staphylococcus aureus*: Bacteria from stock cultures will be transferred into TSB and incubated at 35-37°C for 24±2 hours. Daily transfers will be made for at least three consecutive days (but no more than 10 days). For each transfer, tubes containing 10 mL of TSB will be inoculated using two loopfuls (4-mm inside diameter) of inoculum for each tube.

For *Enterobacter aerogenes*: Bacteria from stock cultures will be transferred into TSB and incubated at 25-30°C for 24±2 hours. Daily transfers will be made for at least three consecutive days (but no more than 10 days). For each transfer, tubes containing 10 mL of TSB will be inoculated using two loopfuls (4-mm inside diameter) of inoculum for each tube.

For both cultures: transfers more than 15 days away from the stock cultures will not be used for the inocula for the test.

For the initial and final sanitizer tests inoculum:

For each challenge microorganism, a 48-54 hour culture will be mixed on a vortex and allowed to stand for 15±1 minutes.

Addition of organic load: a 0.25 mL aliquot of FBS plus 0.05 mL1% Triton X-100 solution to 4.70 mL of bacteria suspension to yield a 5% FBS and 0.01% Triton X-100 soil load.

The upper two-thirds of each culture will be aspirated and used as the inoculum.

For the inoculation/reinoculations of the carriers used in the simulated wears tests:

For each challenge microorganism, an 18-24 hour culture will be mixed on a vortex and allowed to stand for 15±1 minutes. The upper two-thirds of each culture will be aspirated and used as the inoculum. Two 1:100 dilutions of the culture will be made using sterile deionized water (two 0.1 mL to 9.9 mL serial dilutions) and one final dilution of 5.0 mL of the diluted suspension to 5.0 mL of sterile deionized water.

Addition of organic load: a 0.25 mL aliquot of FBS plus 0.05 mL1% Triton X-100 solution to 4.70 mL of bacteria suspension to yield a 5% FBS and 0.01% Triton X-100 soil load.

Note: No culture will be allowed to stand with organic load longer than eight hours.

B. Test and Control Carrier preparation:

The test and control surfaces (carriers) will be cleaned by submersion in 70-85% in Isopropyl alcohol, rinsed with sterile deionized water, and allowed to air dry. After drying completely, the carriers may be steam sterilized for 15 minutes at 121°C, or sterilized in a method approved by the sponsor. The carriers will be allowed to cool and held at ambient room temperature until use. Prior to use, each carrier will be aseptically transferred into plastic Petri dishes (one dish for each carrier) matted with two pieces of filter paper using sterile forceps.

For each lot of the test material, per microorganism, two sets of with four replicate carriers per set will be prepared along with two sets per microorganism of the control material with four replicate carriers each for the primary aspects of the test. Additional surfaces will be prepared as required for remaining controls (see Table 1).

Table 1: Test and Control Carrier Description and Count

Method	Lot	Test and Primary Controls				Miscellaneous Controls				Grand Total
		Reps	Organisms	Contact Time or Runs	TOTAL	NE	Viab	Sterility	TOTAL	
Residual	1	4	2	2	16	2	0	1	3	19
	2	4	2	2	16	2	0	1	3	19
	3	4	2	2	16	2	0	1	3	19
	Control	4	2	2	16	2	2	1	5	21

C. Initial Sanitizer Evaluation Test:

For each lot of the test surface, per microorganism, four carriers and four control surface carriers (per microorganism) will be inoculated at staggered intervals with 10 µL (0.01 mL) of the prepared initial sanitizer inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8" of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C, at a 38-42% relative humidity (RH).

Immediately after drying, the contact time selected by the sponsor (exposure period) will begin at ambient temperature.

At the conclusion the contact time selected by the sponsor, each carrier will be transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar will be sonicated for 20±2 seconds. The samples will then be mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilutions will be prepared using sterile deionized water as required. Duplicate 1.0 mL aliquots from each jar/dilution ($10^0 - 10^{-2}$) for the test carriers will be plated using TSA pour plates. Duplicate 1.0 mL aliquots from each jar/dilution ($10^2 - 10^{-4}$) for the control carriers will be plated using TSA pour plates.

Note: All dilutions and plating for each replicate carrier will be performed within one hour of

the transfer into the neutralizer.

For *Staphylococcus aureus*: Plates will be incubated for 48±4 hours at 35-37°C, colonies will be counted and CFU/carrier calculated.

For *Enterobacter aerogenes*: Plates will be incubated for 48±4 hours at 25-30°C, colonies will be counted and CFU/carrier calculated.

D. Simulated Wear and Reinoculation:

Prior to inoculation, the abrasion tester will be set to a speed of 2.25 – 2.50 for a total surface contact time of approximately 4-5 seconds for one complete cycle. The speed will be measured with a calibrated stopwatch. The machine's cycle will be calibrated by adjusting the number counter to 1, 5, 10, and 20 and verifying cycle time. It will be set so that one pass on the abrasion tester with the surfaces is equal to a contact time of approximately 2-seconds.

A wear cycle will equal one pass to the left and a return pass to the right on the Gardner scrubber with an abrasion boat fitted with a foam liner and dry cotton cloth. The fully-assembled abrasion boat will consist of two weights, a foam liner and a cotton cloth. It will be assembled in an aseptic manner. The weight of the fully-assembled weight boat will be verified to weigh 1084 ±1g prior to use.

For each lot of the test surface, per microorganism, four carriers will be inoculated at staggered intervals with 10 µL (0.01 mL) of the prepared simulated wears inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8" of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. These inoculation and drying procedures will be designated as "reinoculated and drying".

To initiate the wear cycles, each carrier will be subjected to a dry wear cycle using the Gardco Washability and Wear Tester and the fully-assembled weight boat.

At least 15 minutes after the initial wear cycle; each carrier will be reinoculated and dried at ambient temperature.

Each carrier will then be subjected to a wet wear cycle using the Gardco Washability and Wear Tester and the fully-assembled weight boat. The fully-assembled weight boat is sprayed for one second with sterile deionized water using a Preval sprayer (or equivalent) from a distance of 75±1 cm for not more than one

second.

At least 15 minutes after this secondary wear cycles, each carrier will be reinoculated and dried, and subjected to alternating dry and wet wears until a total of 11 reinoculations and 12 wear cycles have been performed in accordance with the procedures and timeline outlined in Table 1 on the following page.

Note: The surface holder on the Gardner apparatus will be decontaminated with 70% IPA between each set of surface wears to prevent carryover contamination. The IPA will be allowed to completely evaporate before proceeding. The foam liner and the cotton cloth will be replaced between each set of surface wears.

Table 1: Wear and Reinoculation Procedure
1. Initial inoculation and drying
2. Wear cycle with dry cloth (wear #1)
3. Reinoculation and drying
4. Wear cycle with moist cloth (wear #2)
5. Reinoculation and drying
6. Wear cycle with dry cloth (wear #3)
7. Reinoculation and drying
End of first day
8. Wear cycle with moist cloth (wear #4)
9. Reinoculation and drying
10. Wear cycle with dry cloth (wear #5)
11. Reinoculation and drying
12. Wear cycle with moist cloth (wear #6)
13. Reinoculation and drying
14. Wear cycle with dry cloth (wear #7)
15. Reinoculation and drying
16. Wear cycle with moist cloth (wear #8)
17. Reinoculation and drying
18. Wear cycle with dry cloth (wear #9)
19. Reinoculation and drying
20. Wear cycle with moist cloth (wear #10)
21. Reinoculation and drying

22. Wear cycle with dry cloth (wear #11)
23. Reinoculation and drying
24. Wear cycle with moist cloth (wear #12)
Final Sanitizer Evaluation is performed after the 12th wear cycle and two days after the initial inoculation

E. Final Sanitizer Evaluation: (Performed at least two days after the initial inoculation to the Simulated Wear and Reinoculation procedures)

For each lot of the test surface, per microorganism, four carriers and four control surface carriers (per microorganism) will be inoculated at staggered intervals with 10 µL (0.01 mL) of the prepared final sanitizer inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8" of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C, at a 38-42% relative humidity (RH).

Immediately after drying, the contact time selected by the sponsor (exposure period) will begin at ambient temperature.

At the conclusion the contact time, each carrier will be transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar will be sonicated for 20±2 seconds. The samples will then be mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilutions will be prepared using sterile deionized water as required. Duplicate 1.0 mL aliquots from each jar/dilution ($10^0 – 10^{-2}$) for the test carriers will be plated using TSA pour plates. Duplicate 1.0 mL aliquots from each jar/dilution ($10^2 – 10^{-4}$) for the control carriers will be plated using TSA pour plates.

Note: All dilutions and plating for each replicate carrier will be performed within one hour of the transfer into the neutralizer.

For *Staphylococcus aureus*: Plates will be incubated for 48±4 hours at 35-37°C, colonies will be counted and CFU/carrier calculated.

For *Enterobacter aerogenes*: Plates will be incubated for 48±4 hours at 25-30°C, colonies will be counted and CFU/carrier calculated.

F. Controls:

1. Culture purity control:

   Each prepared culture will be streaked for isolation using TSA (initial and final sanitizer inocula preparations as well as each Simulated Wear and Reinoculation inocula (two, one for each day of the two day regimen)). All plates will be incubated appropriately in the same manner as the test plates as applicable for each challenge microorganism. The isolated cultures will be observed for purity.

2. Organic soil sterility control:

   Duplicate 1.0 mL aliquots of the prepared organic soil will be plated in TSA pour plates. This will be performed on each of the following days of the assay: the initial and final sanitizer days as each of the two day Simulated Wear and Reinoculation procedures. The plates will be incubated for 48±4 hours at 35-37°C and observed for growth or no growth.

3. Inoculum confirmation counts control:

   Each prepared inoculum will be serially diluted using sterile deionized water and selected dilutions will be plated in duplicate using TSA pour plates. This will be performed on each of the following days of the assay: the initial and final sanitizer days and each of the two day Simulated Wear and Reinoculation procedures. All plates will be incubated appropriately in the same manner as the test plates as applicable for each challenge microorganism.

4. Neutralizer sterility control:

   A single jar of containing the neutralizer will be incubated for 48±4 hours at 35-37°C. The neutralizer will be observed for growth or no growth.

5. Carrier sterility control:

   An uninoculated test (per lot) and control carrier will be subcultured into independent jars containing the neutralizer and incubated for 48±4 hours at 35-37°C. The neutralizer will be observed for growth or no growth.

6. Carrier viability control:

For each challenge microorganism, a single inoculated control carrier will be subcultured into a jar containing the neutralizer and incubated in the same manner as the test plates as applicable for each challenge microorganism (this control will be done for both the initial and final sanitizer test days). The neutralizer jars will be observed for growth or no growth.

7. Neutralizer effectiveness control:

The neutralization efficacy will be evaluated for each challenge microorganism concurrently with the testing. Using sterile forceps, sterile carriers (one replicate for each of the three test lots and one replicate of the control surface) will be transferred into jars containing 30 mL of neutralizer. At time intervals after each surface addition, an aliquot of the bacterial suspension (to yield approximately 1,000 CFU) will be added and the jars will be mixed. At 5±1 minutes, a 1.0 mL aliquot will be removed from each jar and plated using TSA pour plates.

These procedures will be repeated using additional dilutions (to yield approximately 500 CFU and 250 CFU).

All plates will be incubated appropriately in the same manner as the test plates as applicable for each challenge microorganism (on the initial sanitizer test day).

8. Microorganism confirmation procedures:

A randomly selected colony from the carrier quantitation control plates, and if applicable, a randomly selected colony from a test plate will be confirmed by colony morphology and Gram stain according to extant SOPs. The same procedures will be performed using the culture purity control plates and the result regarding purity will be documented as well.

TEST ACCEPTANCE CRITERIA:

The test will be acceptable for evaluation of the test results if the neutralizer is effective and non-toxic. The study director may consider other causes that may affect test reliability and acceptance. There are no proposed statistical methods for this test.

- The average recovery for the control surfaces must be at least 2.0×10^4 CFU/carrier for both the Initial and Final Sanitizer Test evaluations.

- The CFU recovered for the test surfaces and the control surfaces for the neutralizer effectiveness controls (per concentration of inoculum evaluated) should be within 1.0 $\log_{10}$.
- The carrier sterility controls must exhibit no growth.
- The carrier viability controls must exhibit growth.
- The purity controls must demonstrate pure cultures.
- The organic soil sterility controls must exhibit no growth.
- The neutralizer sterility controls must exhibit no growth.

PRODUCT EVALUATION CRITERIA:

According to EPA guidelines, the test agent meets effectiveness requirements, if the test results exhibit a bacterial reduction of at least 99.9% over the Carrier Quantitation Control for both the Initial and Final Sanitizer evaluations.

DATA PRESENTATION:

The final report will include the following information in tabular form:

- The average colony-forming units (CFU)/carrier and percent reduction for each evaluation.
- The results for all the controls.

PERSONNEL AND TESTING FACILITIES:

A study director will be assigned before initiation of the test. Resumes for technical personnel are maintained and are available on request. This study will be conducted at MicroBioTest, 105 Carpenter Drive, Sterling, VA 20164.

CONFIDENTIALITY:

All data generated at MicroBioTest are held in strictest confidence and are available only to the sponsor and the sponsor designated authorities (if applicable). In turn, no reference to MicroBioTest's promotion of the evaluated test articles may be made public by the sponsor.

REPORT FORMAT:

MicroBioTest employs a standard report format for each test design. Each final report provides the following information:

- Sponsor identification and test agent identification

- Type of test and project number
- Dates of study initiation and completion
- Interpretation of results and conclusions
- Test results
- Methods and evaluation criteria
- Signed Quality Assurance and Compliance Statements (for GLP studies, if provided by the sponsor)

REGULATORY COMPLIANCE AND QUALITY ASSURANCE (applicable to GLP studies only)

This study will be performed in compliance with the US Environmental Protection Agency's Good Laboratory Practices regulations, 40 CFR 160. Note: information on the identity, strength, purity, stability, uniformity, and dose solution analysis of the test agent resides with the sponsor of the study unless otherwise stated.

The Quality Assurance Unit of MicroBioTest will inspect the conduct of the study for GLP compliance. The dates of the inspections and the dates that findings are reported to the study management and study director will be included in the final report.

RECORDS TO BE MAINTAINED:

All raw data, protocol, protocol modifications, test agent records, final report, and correspondence between MicroBioTest and the sponsor will be stored in the archives at MicroBioTest, 105 Carpenter Drive, Sterling, Virginia 20164 or in a controlled facility off site.

All changes or revisions to this approved protocol will be documented, signed by the study director, dated and maintained with this protocol. The sponsor will be notified of any change, resolution, and impact on the study as soon as practical.

The proposed experimental start and termination dates; additional information about the test agent; challenge microorganism used; media and reagent identification; and the type of neutralizers employed in the test will be addressed in a project sheet issued separately for each study. The date the study director signs the protocol will be the initiation date. All project sheets will be forwarded to the study sponsor.

MISCELLANEOUS INFORMATION:

The following information is to be completed by sponsor before initiation of study:

A. Name and address: Luminore, Inc.
6060 Corte del Cedro
Carlsbad, CA 92011

B. Test surface information:

Test surface name	Luminore Copper-Nickel		
Lot No.	Lot 1	Lot 2	Lot 3
	092314A	092414A	092414B
- Manufacture Date	09/23/2014	09/24/2014	09/24/2014
- Expiration Date	NA	NA	NA
Active ingredient	Copper/Nickel		
Substrate	aluminum magnesium (the sponsor will provide coupons that are not treated with the active ingredient for use as the control carriers as applicable)		

Note: All three lots will be tested (therefore supplied) at or below the Lower Certified Limit (LCL)

C. Test conditions:

Contact time: 2 (must be ≤ 2 hours)

Note: the same contact time will be used for the Initial and Final Sanitizer evaluations

Exposure temperature: Ambient room temperature (20±1C)

D. Organic load – serum added to achieve 5% in the inoculum: ■ yes ☐ no

E. Precautions/storage – MSDS or certificate of analysis provided: ☒ yes ☐ no

MISCELLANEOUS INFORMATION: (continued)

REPORT HANDLING: The sponsor intends to submit this information to: US EPA

STUDY CONDUCT: GLP

PROTOCOL APPROVAL:

Sponsor:
LuminOre, Inc.
A California Corporation

By: Thomas J Valente
Thomas J. Valente

Date: OCT 8, 2014

Title: President

Study Director Signature: _____
Angela L. Hollingsworth

Date: 11/8/14

Date Issued: 11/08/14	Project Sheet No. 1	Page No. 1	Laboratory Project Identification No. 872-108

STUDY TITLE: Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces	**STUDY DIRECTOR:** Angela L. Hollingsworth Signature 11/8/14 Date

TEST AND CONTROL ARTICLES:	**LOT NO:**	**DATE RECEIVED:**	**DS NO:**
LuminOre Copper/Nickel	092314A	10/17/14	E529
LuminOre Copper/Nickel	092414A	10/17/14	E530
LuminOre Copper/Nickel	092414B	10/17/14	E531
Non Treated Coupons	Not applicable	10/17/14	E532

PERFORMING DEPARTMENT: Applied Microbiology Laboratory	**STORAGE CONDITIONS:** Location: K4 ■ Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator ☐ Other:

PROTECTIVE PRECAUTION REQUIRED: MSDS ☐ Yes / ■ No (Certificate of Analysis was provided)

PHYSICAL DESCRIPTION: ■ Solid ☐ Liquid ☐ Aerosol ☐ Other:

PURPOSE: See attached protocol. **AUTHORIZATION:** See client signature.

PROPOSED EXPERIMENTAL START DATE: 11/09/14 **TERMINATION DATE:** 11/13/14

CONDUCT OF STUDY: ☐ FDA ■ EPA ☐ R&D ■ GLP ☐ GCP ☐ Other:

SPONSOR:	Luminore, Inc. 6060 Corte del Cedro Carlsbad, CA 92011	**CONTACT PERSON:** Phone: E-mail:	Thomas J. Valente (760) 431-7705 ext: 101 tom@luminore.com

TEST CONDITIONS:

Challenge organism(s):	*Staphylococcus aureus*, ATCC 6538 *Enterobacter aerogenes*, ATCC 13048		
Active ingredient(s):	Copper/Nickel		
Neutralizer(s):	Letheen Broth – 2X		
Contact Time(s):	2 hours (Initial and Final Sanitizer Evaluations)		
Contact Temperature(s):	Ambient (20±1ºC)	Dilution(s):	Ready to Use
Organic Load:	■ Yes / ☐ No (Per the protocol to achieve 5% in the inoculum)		
Incubation Time(s):	48±4 hours		
Incubation Temperature(s):	35-37ºC (*Staphylococcus aureus*), 25-30ºC (*Enterobacter aerogenes*)		
Comments:	The sponsor provided aluminum magnesium coupons that are not treated with the active ingredient for use as the control carriers (Non Treated Coupons).		

Date Issued: 11/08/14 Project Sheet No. 2 Page No. 1 Laboratory Project Identification No. 872-108

STUDY TITLE: Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces	**STUDY DIRECTOR:** Angela L. Hollingsworth Signature 11/8/14 Date

TEST AND CONTROL ARTICLES:	**LOT NO:**	**DATE RECEIVED:**	**DS NO:**
LuminOre Copper/Nickel	092314A	10/17/14	E529
LuminOre Copper/Nickel	092414A	10/17/14	E530
LuminOre Copper/Nickel	092414B	10/17/14	E531
Non Treated Coupons	Not applicable	10/17/14	E532

PERFORMING DEPARTMENT: Applied Microbiology Laboratory	**STORAGE CONDITIONS:** Location: K4 ■ Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator ☐ Other:

CONDUCT OF STUDY: ☐ FDA ■ EPA ☐ R&D ■ GLP ☐ GCP ☐ Other:

SPONSOR: Luminore, Inc. 6060 Corte del Cedro Carlsbad, CA 92011	**CONTACT PERSON:** Thomas J. Valente Phone: (760) 431-7705 ext: 101 E-mail: tom@luminore.com

EXPLANATION:

Protocol Amendment(s):

1. In reference to the Miscellaneous Information section of the protocol. The sponsor inadvertently did not indicate the units of measurement for the contact time. The contact time will be 2 hours. This amendment serves to clarify an omission in the protocol.

Date Issued: 01/26/15	Project Sheet No. 3	Page No. 1	Laboratory Project Identification No. 872-108

STUDY TITLE: Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces	**STUDY DIRECTOR:** Angela L. Hollingsworth Signature FOR ALH FEB 04 2015 Date		
TEST AND CONTROL ARTICLES:	**LOT NO:**	**DATE RECEIVED:**	**DS NO:**
LuminOre Copper/Nickel	092314A	10/17/14	E529
LuminOre Copper/Nickel	092414A	10/17/14	E530
LuminOre Copper/Nickel	092414B	10/17/14	E531
Non Treated Coupons	Not applicable	10/17/14	E532
PERFORMING DEPARTMENT: Applied Microbiology Laboratory	**STORAGE CONDITIONS:** Location: K4 ■ Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator ☐ Other:		

CONDUCT OF STUDY: ☐ FDA ■ EPA ☐ R&D ■ GLP ☐ GCP ☐ Other:

SPONSOR:	Luminore, Inc. 6060 Corte del Cedro Carlsbad, CA 92011	**CONTACT PERSON:** Phone: E-mail:	Thomas J. Valente (760) 431-7705 ext: 101 tom@luminore.com

EXPLANATION:

Protocol Amendment(s):

2. The protocol inadvertently did not include the Carrier Quantitation Control; for clarification, the following procedures were performed: For each challenge microorganism, a parallel control will be run using the control carriers (surfaces) in the same manner as the test (including the contact time). All plates will be incubated appropriately in the same manner as the test plates as applicable for each challenge microorganism.
3. Page 15 of the protocol did not specify the percent of copper in each test surface. Per the sponsor, the percentage of copper in each test surface is as follows:
   - Lot No. 092314A: 60.1% copper
   - Lot No. 092414A: 60.7% copper
   - Lot No. 092414B: 60.4% copper

LuminOre®
visualize | realize | metalize

6060 Corte Del Cedro
Carlsbad, CA 92011
Phone: 760-431-7705
Fax: 760-431-7706

Certificate of Analysis

Material: Copper/Nickel
Batch No.: 092314A

Parameter	Actual	Acceptable
Temperature	82°F	No less than 70°F
Humidity	36%	Less than or equal to 40%
Cross link	Pass	Pass
Mil thickness	Pass	No less than 12 mils

Passes all quality control standards for the LuminOre product.

APPROVED BY: Joe Logan **Date:** 10-16-14

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Carlsbad, CA 92011
Phone: 760-431-7705
Fax: 760-431-7706

Certificate of Analysis

Material: Copper/Nickel
Batch No.: 092414A

Parameter	Actual	Acceptable
Temperature	81°F	No less than 70°F
Humidity	29%	Less than or equal to 40%
Cross link	Pass	Pass
Mil thickness	Pass	No less than 12 mils

Passes all quality control standards for the LuminOre product.

APPROVED BY: Jon Bergen **Date:** 10-16-14

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6060 Corte Del Cedro
Carlsbad, CA 92011
Phone: 760-431-7705
Fax: 760-431-7706

Certificate of Analysis

Material: Copper/Nickel
Batch No.: 092414B

Parameter	Actual	Acceptable
Temperature	82°F	No less than 70°F
Humidity	31%	Less than or equal to 40%
Cross link	Pass	Pass
Mil thickness	Pass	No less than 12 mils

Passes all quality control standards for the LuminOre product.

APPROVED BY: Date: 10-16-14