

- BIOHAZARD HYGIENE GUIDELINE -

PROTOCOL FOR BIO-REVEAL SAMPLING OF BIOHAZARD IMPACTED MATERIALS -GENERAL

Statement of Use

The Bio-reveal® Ultrasnap ATP swabs and the Bio-reveal® Systemsure Plus luminometer will be used to determine the level of surface hygiene on materials potentially contaminated with biohazards and viable biological matter, such as blood, body fluids, tissues, somatic cells, etc. that may be present. The use of the Bio-reveal® testing system will allow biohazard restoration cleaners, police or EMT professionals, facility maintenance staff, restoration professionals, restoration contractors and the Indoor Environmental Professional (IEP) the real-time ability to quantify the relative level of bio-contamination associated with biohazards. Additionally, the Bio-reveal® testing system can provide quality assurance to the cleaning of biohazard impacted materials or restoration process as well as post restoration verification testing for surface decontamination.

The Bio-reveal® bio-contamination detection system is designed to evaluate the level of surface cleanliness and overall hygiene of biohazard impacted materials. This system will not detect specific strains of bacterial, viral or other micro-organisms, rather will measure and document the total surface hygiene conditions that may harbor these types of organisms as a result of dirty, unhygienic or where direct impaction of biohazards and viable biological matter, such as blood, body fluids, tissues, somatic cells, etc. have occurred.

Methodology - Surface Sampling

Steps

- 1) Identify the target surface to sample for determining the level of biocontamination present:
 - a. Flooring materials or substrates (remaining in building)
 - b. Wall materials or substrates (remaining in building)
 - c. Ceiling materials or substrates (remaining in building)
 - d. Concrete materials
 - e. Exterior concrete, asphalt, etc.
 - Tile materials (ceramic or vinyl type)
 - g. Wood building materials or substrates (remaining in building)
 - h. Furnishings or substrates (remaining in building)
 - i. Interior items not related to the building materials (ie: personal effects, etc.)
 - j. Restoration equipment and remediation devices
 - Other not mentioned above that may be site specific or specifically affected by the biohazard contaminants
- 2) Use aseptic techniques for all sample collection. Remove the plastic cover or tube from the Bio-reveal® Ultrasnap ATP swab. This will expose the collection end or swab bud, which is pre-moistened to assist in sample collection. Ensure to <u>NOT</u> directly touch the swab bud or swab shaft with your fingers or hand or it will become contaminated.
- 3) Thoroughly swab the desired sample surface over a 2" X 2" sampling area (4 inches square) using approximately 10 strokes vertical and 10 strokes horizontal over the sample area while rotating the swab over the surface. Allow the swab bud to "clean" the sampled surface in order to accurately reflect the sampled surface contamination potential.
- 4) After swabbing place the plastic tube back over the swab bud and insert the open end back into the collar of the entire device.
- 5) Grasp the bulb end of the sampling device and the small plastic stem inside the bulb. Then break the snap valve by bending this plastic stem forward and backward until the stem breaks off. Hold the device upright during this step.
- 6) Squeeze the bulb twice to expel the reagent in the bulk down into the collection tube covering the swab bud tip.
- 7) Gently shake the device to thoroughly mix the liquid contents in the base of the device for approximately 5 seconds. This ensures the swab bud is properly washed or bathed in the reagent solution.
- 8) Insert the entire sampling device into top of the Bio-reveal® Systemsure Plus luminometer. Be sure to insert the device completely into the open port hole before closing the lid of the luminometer. The sample device should be inserted into the luminometer and read within 60 seconds after breaking the valve stem and activating the reagent as outlined in Step 5), for the most accurate results.
- 9) Close the lid of the Bio-reveal® luminometer.
- 10) Press the "OK" button to read the sample results. This process will take 15 seconds from the time you press the "OK" button. Be sure to hold the instrument up and down (vertical position) to obtain the best results.

Interpretation of Bio-reveal Sampling Results

BIO-REVEAL INTERPRETATION FOR BIOHAZARD CONTAMINATION TESTING

Guideline for Surface Sampling of Biohazard Impacted Materials
(Building and Non-Building), Contents, Etc.

ncludes Initial Assessments, Cleaning & Post Restoration Verification Tes

Includes Initial Assessments, Cleaning & Post Restoration Verification Testing of Biohazard Impacted Materials (Building and Non-Building)

(Surface samples are collected using the Bio-reveal Ultrasnap swab from Biohazard Impacted materials)

| Sampled Surface Condition (Biological Contamination) | Bio-reveal Surface Sampling Result (RLU)* | Interpretation Result |
|--|---|--------------------------------|
| Ideally Clean or | <u><</u> 15 | PASS |
| Decontaminated Surfaces / Materials | | (ACCEPTABLE) |
| Moderately Contaminated | ≥ 16 and < 50 | CAUTION |
| Surfaces / Materials | | (PASSING BUT RECLEANING MAY |
| | | BE NECESSARY) |
| Biohazard | <u>≥</u> 50 | FAIL |
| Contaminated | | (NOT ACCEPTABLE) |
| Surfaces / Materials | | |

RLU – Relative light unit or unit of measure for bioluminescent measurements

Considerations when using the Bio-reveal sampling system

- Avoid collecting large amounts of sample debris on the swab bud. Too much sampled material may reduce signal strength of test and provide inaccurate readings or false negatives.
- b. Damaged or accidental activations of the sampling swab device should not be used and should be disposed of.
- c. Disposal of the sampling swab device can be in general waste. No special precautions are required for disposal.
- d. Hold the Bio-reveal® Systemsure II upright during Step 10).
- e. Hold the Bio-reveal® Ultrasnap ATP swab device upright when activating in Step 5).
- f. The Bio-reveal® Ultrasnap ATP swabs will tolerate room temperature storage for up to two months but all unused sampling devices should be stored in the refrigerator, where they will remain viable for up to 12 months.

For Technical Questions or Customer Service, please contact Slade Smith at: Phone number: 866-989-5567, ext 2.

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Or

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ALTERNATIVE INTERPRETATION GUIDELINE SETTINGS

Recommended Threshold Setting Procedure

- Step 1) Identify the sample points or critical control points.
- Step 2) Clean the sample point surfaces thoroughly. This procedure may be repeated 2 or more times to achieve the best possible cleanliness.
- Step 3) Conduct ATP sampling at each location identified and cleaned, using 10 test replicates.
- Step 4) Calculate the average RLU. This will be considered the *PASS* level.
- Step 5) FAIL limits are determined by multiplying the PASS level by a factor of 2.
- Step 6) Caution is the region between the PASS and FAIL calculated limits.
- Step 7) Monitor results and assess the trends. Recalculation of the PASS and FAIL limits may be warranted to optimize the results and improve the quality standards.

Alternative Threshold Setting Procedure

- Step 1) Identify the sample points or critical control points.
- Step 2) Clean the sample point surfaces thoroughly. This procedure may be repeated 2 or more times to achieve the best possible cleanliness.
- Step 3) Conduct ATP sampling at each location identified and cleaned several times and over several days, using a minimum of 50 test replicates.
- Step 4) Calculate the average and standard deviation for the documented RLUs.
- Step 5) Set limits as follows:

Pass <= Mean RLU

Caution >= Mean RLU < Mean + 3 standard deviations

Fail >= Mean RLU + 3 standard deviations