



INDOOR ENVIRONMENTAL QUALITY HYGIENE GUIDELINE

PROTOCOL FOR BIO-REVEAL SAMPLING OF INDOOR ENVIRONMENTAL SURFACES 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 bio-contamination that could harbor potentially infectious disease as well as measure the conditions that lead to the presence of viable biological matter such as viruses (H1N1, Norovirus, etc.), bacteria, fungi, somatic cells, biofilms, etc. that may be present in the indoor environment. The indoor environment may be potentially contaminated due to poor hygiene cleaning practices, occupant activities, cross-contamination from occupants that may be ill or carrying infectious disease, water damage, etc. The use of the Bio-reveal® testing system will allow the user the real-time ability to quantify the relative level of bio-contamination associated with indoor environmental surfaces and contents. Additionally, the Bio-reveal® testing system can provide quality assurance to the cleaning of the interior of the indoor environment including but not limited to: office environments, residential environments, educational environments, healthcare environments, common public areas and surfaces, etc.

The Bio-reveal® bio-contamination detection system is designed to evaluate the level of surface cleanliness and overall hygiene within the indoor environment. 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 and unhygienic conditions.

Methodology – Surface Sampling

Steps

- 1) Identify the target surface to sample for determining the level of biocontamination present:
 - a. Interior surfaces (desks, hand contact surfaces, phones, keyboards, related, etc.)
 - b. Interior building surfaces (floors, walls, etc.)
 - c. Furnishings (hard surface and porous)
 - d. Interior items not related to the building materials (ie: electronics, personal effects, etc.)
 - e. Other not mentioned above that may be site specific or specifically affected by bio-contamination
- 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 NOT 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 INDOOR ENVIRONMENTAL SURFACE TESTING

**Guideline for Surface Sampling of Indoor Environmental Surfaces
Includes Initial Assessments, Pre-Cleaning & Post Cleaning Verification Testing
of Indoor Environment**

(Surface samples are collected using the Bio-reveal Ultrasnap swab from indoor environmental surfaces such as: office environments, residential environments, educational environments, healthcare environments, public areas/surface, etc.)

Sampled Surface Condition (Biological Contamination)	Bio-reveal Surface Sampling Result (RLU)*	Interpretation Result
Relatively Clean or Uncompromised Indoor Environmental Surfaces	≤ 30	PASS (ACCEPTABLE)
Moderately Soiled or Potentially Contaminated Indoor Environmental Surfaces	≥ 31 and < 100	CAUTION (PASSING BUT DIRTY)
Heavily Soiled or Likely Compromised Indoor Environmental Surfaces	≥ 100	FAIL (NOT ACCEPTABLE)

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

Considerations when using the Bio-reveal sampling system

- a. 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 luminometer 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:

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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 \leq Mean RLU
 - Caution \geq Mean RLU < Mean + 3 standard deviations
 - Fail \geq Mean RLU + 3 standard deviations