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 material such as viruses (H1N1, Norovirus, etc.), bacteria, fungi, somatic cells, biofilms, etc. that may be present in the indoor environment within K-12 schools and classrooms. The K-12 school and classroom 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, 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 before and after cleaning associated with the K-12 school and classroom indoor environmental on 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: educational environments, including classrooms, classroom contents, food service areas and common areas and surfaces within the K-12 school and classroom indoor environment.

The Bio-reveal® bio-contamination detection 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 – “high touch points” (desks, cafeteria tables, restroom stalls and stall doors, sink fixtures and sink surroundings, related, etc.)
   b. Interior building surfaces (floors, drinking fountains, door handles, doors, gym equipment such as mats, and student chairs.)
   c. Furnishings (hard surface and porous)
   d. Interior items not related to the building materials (ie: electronics, personal effects, phones, keyboards, 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 K-12 CLASSROOM / SCHOOL**  
**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: “high touch points” (desks, cafeteria tables, restroom stalls and stall doors, sink fixtures and sink surroundings, floors, drinking fountains, door handles, doors, gym equipment such as mats, and student chairs, etc.)*

<table>
<thead>
<tr>
<th>Sampled Surface</th>
<th>Highly Effective Cleaning (RLU)*</th>
<th>Effective Cleaning/May Need Improvement (RLU)*</th>
<th>Ineffective Cleaning (RLU)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classroom Desks</td>
<td>≤ 3</td>
<td>4 - 9</td>
<td>≥ 10</td>
</tr>
<tr>
<td>Cafeteria Tables</td>
<td>≤ 9</td>
<td>10 - 18</td>
<td>≥ 19</td>
</tr>
<tr>
<td>Restroom Stall Doors</td>
<td>≤ 1</td>
<td>2 - 6</td>
<td>≥ 7</td>
</tr>
<tr>
<td>Sink Surroundings</td>
<td>≤ 1</td>
<td>2 - 4</td>
<td>≥ 5</td>
</tr>
</tbody>
</table>

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

**References:**

- ISSA Standard for Measuring the Effectiveness of Cleaning in K-12 Schools - Under Development by CIRI and ISSA with the Support of the Clean Standard Development and Stakeholder Committees – DRAFT July 2013

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:
Phone number: 866-989-5567, ext 2, Cell number: 320-309-5448
email at info@bio-reveal.com

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