



- FOOD CONTACT SURFACE HYGIENE GUIDELINE

PROTOCOL FOR BIO-REVEAL SAMPLING OF FOOD CONTACT 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 contamination for viable biological matter, such as bacteria, fungi, somatic cells, biofilms, etc. that may be present on potentially contaminated food contact surfaces. The use of the Bio-reveal® testing system will allow quality assurance professionals, sanitarians, facility maintenance staff, microbiologists and related professionals in the food safety consulting and testing industry the real-time ability to quantify the relative level of bio-contamination on food contact surfaces associated with food residues that may be present during manufacturing, packaging, preparing or serving of food related items. Additionally, the Bio-reveal® testing system can provide quality assurance to the cleaning of decontamination of food contact surfaces.

The Bio-reveal® bio-contamination detection system is designed to evaluate the level of surface cleanliness and sanitized 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, unhygienic or where direct impaction of food, food residues or potentially pathogenic organisms exist.

Methodology – Surface Sampling

Steps

- 1) Identify the target surface to sample for determining the level of biocontamination present:
 - a. Food Contact Surface Materials (general – non-porous or semi-porous)
- 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 FOOD CONTACT SURFACE TESTING

Guideline for Surface Sampling of Food Contact Materials
Includes Initial Assessments, Pre - Cleaning & Post Cleaning Verification Testing
of Food Contact Materials
(Surface samples are collected using the Bio-reveal Ultrasnap swab from food contact surface materials)

Sampled Surface Condition (Biological Contamination)	Bio-reveal Surface Sampling Result (RLU)*	Interpretation Result
Relatively Clean Food Contact Materials	≤ 10	PASS (ACCEPTABLE)
Moderately Soiled or Potentially Contaminated Food Contact Materials	≥ 11 and < 30	CAUTION (PASSING BUT DIRTY)
Heavily Soiled or Contaminated Food Contact Materials	≥ 30	FAIL (NOT ACCEPTABLE)

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

This food contact surface testing guideline was developed by Hygiene, LLC.

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 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:

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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