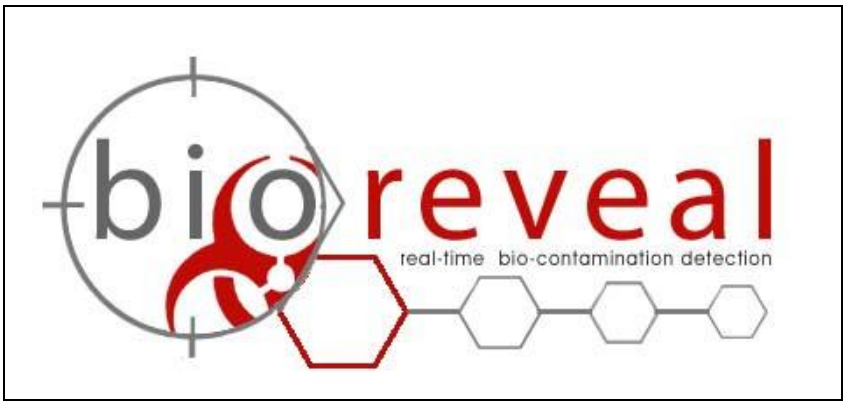

- HEALTHCARE, HOSPITALS & PATIENT CARE SETTING -

PROTOCOL FOR BIO-REVEAL SAMPLING IN THE HOSPITAL AND PATIENT ENVIRONMENT

Statement of Use

Infectious diseases in a hospital or clinic environment can be attributed to many factors. A significant source for biological pathogens, such as MRSA in a healthcare setting is the result of dirty or unhygienic surfaces. These surfaces become reservoirs for somatic cells, bioburden and biofilms that harbor the ideal environment for serious infections from MRSA and vancomycin resistant enterococcus (VRE). Eliminating or reducing the conditions that promote infectious agents in a healthcare setting is a high priority for facility Infection Control and Environmental Services personnel.

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, somatic cells, biofilms and microbial organisms. The purpose of the sampling is to determine the level of biological surface contamination of equipment, devices, and general surfaces within a methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin resistant enterococcus (VRE) patient room, procedure room, or high infection potential risk area within the facility. The Bio-reveal bio-contamination detection system is designed to evaluate the level of surface cleanliness and sanitized hygiene in the hospital and patient room environment. This system will not detect specific bacterial, viral or fungal organisms but will document the surface conditions where these organisms may be detected or harbored as a result of dirty or unhygienic situations.

Methodology

Steps

1) Identify the target surface to sample (ie; door-knobs to the bathroom and hallway, handles on sink spigots, bed handrail, computer keyboard & mouse, over-bed table, charts: MAR, order book, etc., bathroom and patient room tile for cleaning effectiveness, and other related surfaces within a patient room)

2) Use aseptic techniques for all sample collection. Remove the plastic cover or tube from the ATP swab sampling device. This will expose the swab bud, which is pre-moistened to assist in sample collection. Ensure to NOT directly touch the swab bud with your fingers or hand or it will become contaminated.

3) Thoroughly swab the desired sample surface over a 4" X 4" sampling area using approximately 10 strokes vertical and 10 strokes horizontal over the sample area while rotating the swab over the surface.

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 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 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 to obtain the best results.

Interpretation of Bio-reveal Sampling Results

Guideline for Healthcare and Hospitals Surface Contamination

(Healthcare Environmental Surfaces, Operating Rooms, Medical Equipment, Pharmacy, etc.)

Bio-reveal Surface Sampling Result (RLU)*	Interpretation Result
< 10	PASS
10 - 20	CAUTION
> 20	FAIL

* 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 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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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

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