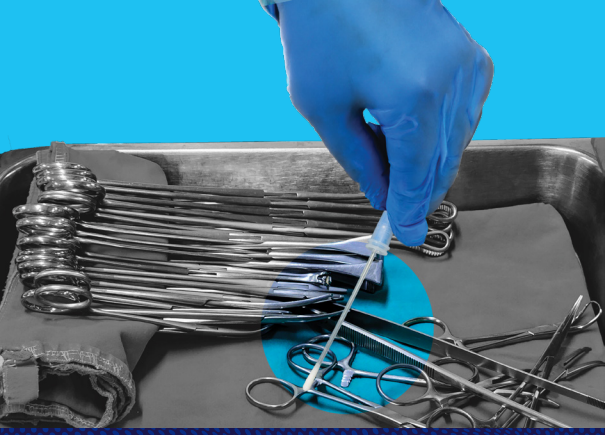

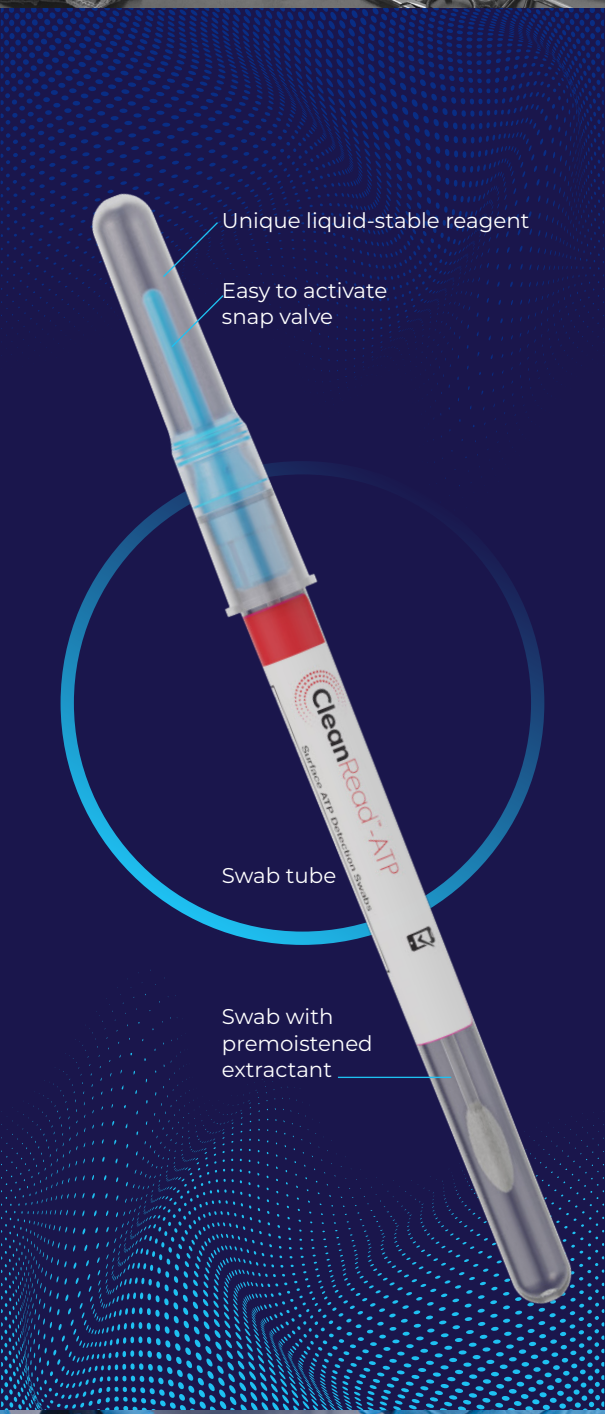

For use with all CleanRead™ Luminometers.

CleanRead™ Surface ATP Detection Swabs

Verify cleanliness and measure microbial contamination on any scope, cannulated instrument or surface in **15 seconds!**

CleanRead™ Surface ATP Detection Swab provides a rapid, simple and reliable way to verify cleanliness and measure microbial contamination on the surface of surgical instruments, scopes, washer-disinfectors, exam rooms, operating rooms, restrooms, waiting rooms – anywhere that can harbor possible contaminants.

Features

- All-in-one sampling device.
- 15-month shelf life (from date of mfg.) at refrigerated temperatures (36°F to 46°F) (2°C to 8°C).
- 4 week shelf life at room temperatures (70°F) (21°C).
- Unique liquid-stable reagent.
- Tolerant to temperature abuse and sanitizers.

Here's how it works

The CleanRead™ Contamination Monitoring System detects Adenosine Triphosphate (ATP), the universal energy molecule found in all animal, plant, bacterial, yeast, and mold cells. Microbial contamination contains ATP, but in smaller amounts. After cleaning, all sources of ATP should be significantly reduced.

When ATP is picked up by the tip of the Surface ATP Detection Swab and brought into contact with the unique, liquid stable luciferase/luciferin reagent in the Surface ATP Detection Swab, light is emitted in direct proportion to the amount of ATP present. The Surface ATP Detection Swab is then placed in the CleanRead™ Handheld unit where it measures the amount of Relative Light Units (RLU) generated and displays the level of contamination present in just 15 seconds. CleanRead™ Handheld unit will detect 1/100,000th dilution of blood, i.e. 0.2mg protein per swab. The handheld unit can then be synced to a PC where the reading is downloaded to an easy-to-use database management software for tracking the results. The software program can be used to run comparison charts and produce color trend analysis graphs and reports.

Empire Bio Diagnostics

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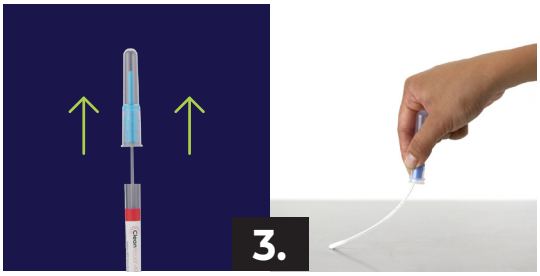

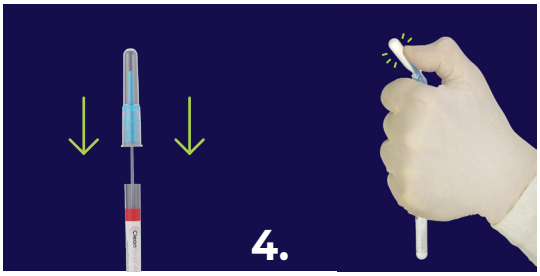

Instructions / Directions For Use

Testing should be done after cleaning, prior to high-level disinfection or sterilization.*

1. On the homescreen, tap on Dashboard and navigate to Test points.
2. Look up for the test group that needs to be tested either by scrolling down the list of available test groups OR by typing in the search bar OR use the barcode/RFID reader in the Dashboard. (Note: Barcodes and RFIDs need to be registered before use.) Select the desired test group, tap on the desired test point (red tag) and press 'Start'. Alternately you can switch to the List view to select the test points.
3. Take the Surface ATP Detection Swab out of the tube and swab a defined area (approximately 10 cm^2) using consistent downward pressure, in a standardized pattern (e.g., horizontal and vertical strokes) to cover the surface adequately. Twirl the Surface ATP Detection Swab during sampling to ensure adequate loading of organic residues.
4. Place the Surface ATP Detection Swab back into the tube. Hold the swab tube firmly and use the thumb to break the blue nib by applying pressure against the bulb wall—about half-way up--until the blue nib inside snaps.
5. Once the blue nib snaps squeeze and gently shake the bulb from side to side for 5 seconds to make sure that all the reagent is released and makes contact with the tip of the swab. Open the top of the CleanRead™ hand held unit and insert the Surface ATP Detection Swab tube, pushing it fully into the device.
6. **Close the lid** and press **"OK"**. In 15 seconds the unit will display the amount of contamination detected, and if the test passed or failed.
7. The CleanRead™ hand held device will automatically sync to the web portal --via WiFi--for tracking results.

***Please note**: Testing after HLD is an option for periodic testing of HLD processor maintenance. This would be up to the facility to determine procedure and frequency.

CleanRead™ uses AWS which enables covered entities and their business associates subject to the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) to use the secure AWS environment to process, maintain, and store protected health information.

If you have a test failure please contact the manufacturer of the device being tested for advice on the best cleaning practice and products available that will help produce better outcomes.

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