How the ProReveal Test can help Optimize the Decontamination Process
Ensuring Surgical Instruments Are Safe to Reuse

Background

With the levels of vCJD (Creutzfeldt-Jakob Disease) now estimated at 1-2 in a million¹ in the US and 1 in 2000 in the UK², efficient removal of protein from surgical instruments is critical to preventing vCJD and other post-operative iatrogenic infections. Surgical instruments are generally decontaminated by washing and then by thermal disinfection. However, if the soil and protein have not been removed by the wash process cycles, the thermal disinfection cycle will bake the soil onto the surface of the instrument. It is therefore vital for staff in Sterile Processing Departments (SPDs) to be able to visualize contaminants on instruments or soil tests to check that these have been totally removed for proper cleaning and high-level disinfection.

Checking for contamination

Traditionally, staff in SPDs in many US hospitals have relied upon visual inspection to detect unacceptable levels of post-decontamination soiling. This method has poor sensitivity, is very subjective and can be influenced by the operative’s eye sight as well as the intensity and nature of the lighting in the SPD.

In recent years, staff in SPDs have been made aware that there are often unseen contaminants still clinging to the surface of instruments post processing and some now use tests such as detection of protein with the Ninhydrin, Biuret or ATP test. Many US SPDs take a different approach and instead of using tests to check their surgical instruments for contamination they check the efficacy of their cleaning equipment using blood soil tests such
as the Browne Washer-Disinfector Test Soil or the TOSI™ washer test. Many believe that the routine use of these types of soil test will help ensure that their decontamination equipment is performing at a consistent level and so continue to rely on routine visual inspection of their surgical instruments rather than swab tests as the final check for contamination.

Since removal of protein decontamination currently represents the ultimate challenge in cleaning efficacy, the inability to accurately determine where proteins still lurk means that it is difficult to check for total protein removal. This creates the possibility that highly dangerous, robust biological agents (such as prions) may remain infectious and undetected, even after standard cleaning and sterilization. Recently in Europe, a standard safe level of residual protein of 5µg protein per instrument\(^3\) has been proposed but there is no such limit in the US which has meant that SPDs have set their own acceptable residual protein standards, which have varied widely from hospital to hospital.

**The potential for vCJD infection**

Using this type of decontamination process and visual checking procedure, in the past three years alone, 31 patients in North Carolina\(^4\) and New Hampshire\(^5\) and an undisclosed number of patients traced over a three-month period at Washington Regional Medical Center\(^6\) have been put at risk of contracting vCJD via being operated on with contaminated surgical instruments. There is now such concern over the decontamination process in relation to vCJD that there is in depth research into producing detergents suitable for effective protein removal. However, without an accurate method of in-situ protein detection it is very difficult to prove the efficacy of any washer or cleaning protocol’s performance in relation to protein decontamination.

![Figure 2: An image of decontaminated surgical instrument produced using the ProReveal showing where the protein still remains](image-url)
Optimizing cleaning efficacy

To address this issue, the ProReveal, a fluorescence-based in-situ test was developed\(^7, 8\) and is ideal as a diagnostic for use by staff in SPDs as it also has been designed to test for proteins on surgical instruments or on soil tests for checking the cleaning efficacy of washing equipment.

The ProReveal test utilizes OPA/NAC (o-phthalaldehyde/Nacetyl cysteine) fluorescence (cited in a major European decontamination report as the most sensitive protein detection method\(^9\)) and is compliant with current Association for the Advancement of Medical Instrumentation (AAMI) ST79 guidelines\(^10\), which includes Annex D. Annex D states SPD personnel should use verification of cleaning processes such as measuring and evaluating residual contaminants after applying the established cleaning process. They should also establish benchmarks for the level of cleaning that can be achieved consistently and develop rapid, easy-to-perform test methods that reliably demonstrate the cleaning benchmarks have been achieved.

To use the ProReveal test, operatives apply an OPA/NAC spray over a reprocessed surgical instrument and if protein and/or amino acids are present, then the spray reacts to emit fluorescence.

The fluorescence is detected by UV light in the ProReveal viewer (Figure 1). The viewer automatically shows an image of contaminating proteins in-situ on the instrument (Figure 2) and measures the amount of residual fluorescent proteins.

The software in the ProReveal viewer includes Inspection and Control Mode, making it easier for SPD personnel to choose how to detect residual proteins. In Inspection Mode, users can see where any residual protein is left on an instrument, as well as produce an accurate protein measurement. In Control Mode, an acceptable residual protein level, set by the SPD staff is entered into the ProReveal and the viewer displays a simple tick or cross to pass or fail the instrument. This simple test takes less than five minutes and can detect as little as 50 nanogram of protein, a level of sensitivity that no other commercial protein detection method for SPD use can currently achieve.

Since the test provides a visual display of where contamination is, this aids appreciation of how the loading configuration and the types of detergents used may affect the cleaning process in a washer/disinfector. As the test also provides semi-quantitative data on residual
protein, SPD staff can assess how much protein their washers and detergents will remove and can use that as a benchmark to find ways to improve those processes. For example, they can use a barcode scanner to check which operator performed the test, which washer/disinfector was used, the carriage level that the instrument was cleaned in and the type of detergent used for cleaning. All of this information can be used to benchmark the cleaning process and to then determine which cleaning parameters can be optimized.

Case study – Florida Hospital Tampa

The ProReveal test has been successfully trialed at the Florida Hospital Tampa where the test was used over five months to check surgical instruments for protein after they were cleaned in a washer/disinfector. Staff there used random testing, with the goal of checking three surgical instruments per shift per day and optimizing their decontamination process. Using the ProReveal, the Florida Hospital Tampa SPD was able to achieve residual protein levels of 0-5 µg per instrument, which is within safe and acceptable decontamination guideline limits but has measured up to 25 µg of protein remaining on their instruments before they began the optimization process.

Prior to using the ProReveal, SPD staff at the hospital used a Brown soil test to check the cleaning efficacy of their washer-decontamination system and relied on visual inspection as the final check of cleaning efficacy.

Damon Denton, an SPD Manager at Florida Hospital Tampa commented: “The SPD staff found the ProReveal system easy to use and we saw it as an opportunity to set a base line for cleaning efficacy. The ProReveal has helped us to see where our cleaning processes were failing to reach areas in the surgical instruments as it highlighted all those places that protein was still sticking that we couldn’t see by eye. Unfortunately, bioburden often doesn’t have a color so even if a surgical instrument looks clean contaminating protein can often still be clinging there and you can’t detect it.”

Damon added: “Since we trialed the ProReveal, we have had a mock joint commission inspection and the ‘inspectors' were very impressed with our quality assurance because we have been able to optimize our decontamination process by using the ProReveal. This test really is a fabulous invention and any SPD that uses it for benchmarking and then optimizing their cleaning performance can’t go wrong. We have been so impressed by the ProReveal that our department has put in a capital request so that we can have one here permanently.”
Conclusion
Since the ProReveal utilizes sensitive, in-situ fluorescence imaging, the system can detect residual contamination on washer soil tests or where protein contamination is located on surgical instruments and can accurately quantify the amount of residual protein to nanogram levels. This offers SPDs, such as the Florida Hospital Tampa's SPD an opportunity to benchmark their cleaning processes for optimum protein decontamination, thus helping to protect patients from the misery of potentially fatal post-operative infections.

For further information or to arrange a demonstration, please go to: www.ultracleansystems.com or email: tom.overby@ultracleansystems.com

References
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