Protein testing: A quantitative approach
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The largest hospital in Wales is using ProReveal *in-situ* Protein Testing to optimise the decontamination process for neurosurgical instruments. By reviewing and making changes to its decontamination process, the hospital has been able to reduce its residual proteins from 3µg to 400ng in six months.

University Hospital of Wales (UHW) is a major 1000-bed hospital in Cardiff, Wales. The hospital is the largest hospital in Wales and the third largest University Hospital in the UK and is operated by Cardiff and Vale University Health Board.

The hospital is using ProReveal to detect proteins on surgical instruments and for routine monitoring and process improvement of surgical instrument decontamination protocols. This will help prevent inadvertent exposure to prion infections associated with conditions such as vCJD (Creutzfeldt Jakob Disease).

Available from Synoptics Health, a manufacturer of innovative digital imaging systems for healthcare applications, the HSDU Department at UHW is using the *in-situ* fluorescence detection system daily to precisely quantify how much protein remains on reprocessed surgical instruments and is the first in Wales to adopt the technology.

Additionally, it is being used as part of continuous process improvement research where staff are assessing a range of decontamination parameters, such as manual pre-washing and ultrasonic cleaning, as well as different types of washer/disinfectors and detergents to develop the optimum process for removing residual protein on neurosurgical instruments.

The patented protein detection test is an ultra-sensitive fluorescence technique for checking and detecting residual proteins that can remain on surgical instruments after the decontamination process. Used with its diagnostic tools, it also provides a monitor device to check the performance of the washer disinfecter process over time. This aids the detection of any changes in process parameters and helps to guide the user to optimise their process to achieve maximum performance from their facility.

The system is designed to test for protein detection as an alternative to the ‘swabbing techniques’ used in many SSDs. The new CFPP-01-01 guidelines on decontamination of reusable surgical instruments indicate that the sensitivity of fluorescence-based detection tests may be greater than that provided by existing tests.

In trials at two major London Hospitals, the system has been shown to detect as little as 50ng of protein on reprocessed surgical instruments, making this the most sensitive detection method currently available for a decontamination environment.

With the equipment test the whole instrument is checked for protein not just a small ‘swabbed’ area, and the results provide a visual display of the presence (or absence) of any protein. Additionally, it is possible to pre-set a defined level of detection limit when required.

The sensitivity of the test and the method used is designed to remove any doubt from the checking process. The test is simple and takes less than five minutes to perform and the test is both visual and quantifiable.

The technology can be implemented in SSDs, and when using the diagnostics tools, the SSD Manager has full control on how the process is working. It also has the ability to pinpoint parameter changes which may affect system performance levels.

**A quantitative approach to test cleaning efficiency**

A calibrated tag is a microscope slide size stainless steel test strip, onto which is bound a known amount of protein.

This calibrated tag is put through the washer disinfecter process during a normal load process. Tags are simply placed in any position in the washing machine. It is
suggested that the position and frequency of use is determined by the CSSD manager.

Once the washer cycle is complete, the tag is removed and a ProReveal test is conducted. The equipment test will indicate if all the protein has been washed off or if any is still adhering to the tag surface. The measured level of any residual protein will indicate if the washer disinfecter process needs any optimisation and the degree to which attention is required.

The calibrated tags are designed to be used alongside regular instrument checks as a way of quickly determining if the washing process is working to an optimum standard and if the ProReveal test system itself is performing correctly. ProReveal Tags are an aid to improve surgical instrument cleaning with a quantifiable result.

The protein detection test consists of a specially patented reagent based on an OPA fluorescent spray which reacts with any residual proteins remaining on an instrument after the wash process. Users apply ProReveal spray as a light mist over the whole instrument from the spray bottle in which it is supplied. They then place the instrument inside the viewer where specially configured lighting causes the spray to fluoresce where it has reacted to any protein. An image of the instrument is displayed on a small screen on the viewer. This image shows any fluorescence on the instrument, indicating any remaining protein.

Integral software within the device quantitatively assesses the fluorescence and hence the amount of protein remaining on the instrument. This shows whether the washing process has met the required standard, eliminating the need for subjective user decisions on how well the decontamination process has worked. The viewer can store a copy of each image together with the test data for later review, if required.

The ProReveal reporting system allows for data to be saved within the unit, exported to a memory stick, printed or when the test equipment is connected to a network, allows files to be saved to other computers.

When using the system in its diagnostics mode, users can input process data by entering bar codes or text and then monitor the performance over time of their washer disinfecter process. Data can include user ID, washing machine information, detergent, shelf/tray position, process temperature and process details which are then plotted as a graph showing, over a chosen period, how the wash cycle is performing. These visual trend plots clearly show any change in operating parameters and point towards the need for washer optimisation. This powerful diagnostic tool can be used to analyse stored data within the ProReveal and even data sets from other systems for comparison purposes.

Mark Campbell, decontamination service manager at UHW, said: “The HTM 01-01 is quite clear that instruments used in neurosurgery should be tested for proteins using in-situ methods rather than swabs because potentially they aren’t sensitive enough to detect low levels of proteins or indeed prion proteins.

“We have been trialling ProReveal since 2016 and decided that as this is currently the only in-situ test, we purchased a system in 2017 to ensure compliance to the updated WHTM and bring further safety factors for managing high risk sets.

“We now use it for routine testing and as a research improvement tool to help us reduce the amount of residual protein on neurosurgical instruments.

“By reviewing and making changes to our decontamination process, in just six months, we have been able to reduce our residual proteins from 3µg to 400ng and have set our ProReveal to detect nanogram rather than microgram levels as we were getting results of 0µg. It is now key to assuring us that we have done everything practically possible to reduce patients’ risk of exposure to prion related diseases.”

Guy Fiddian, of Synoptics Health, added: “We’re pleased that the largest hospital in Wales is also the first to be routinely using this system for in-situ detection of proteins on reprocessed surgical instruments. Their rigorous approach to continuous quality improvement has shown some very impressive results in reducing residual proteins on neurosurgical instruments and demonstrates that minimising patients’ exposure to prions is viewed very seriously by this hospital.”

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**Edited by:** CSJ

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**Suggested reads:**

- Suggested readings and further information can be found on the website of the Clinical Services Journal (www.clinicalservicesjournal.com) for more comprehensive coverage of the latest developments in surgical instrument cleaning and decontamination.