Checking reprocessed surgical instruments for contamination is a tricky business because there are often unseen contaminants such as proteins and blood still clinging to the surface. To detect these unseen hazards, staff in hospital sterile services departments (SSDs), currently rely on visual inspection plus a simple colourimetric test. This involves swabbing the instrument and then testing the swab with a protein detection test. Many of the gold standard methods of protein detection rely on chemical reactions with the free amino groups within the proteins to show a colour change for protein contamination. This practice of swabbing means that the protein being tested for is the amount that is transferred onto the swab and this type of test has been shown to be relatively insensitive, allowing large amounts of protein contamination to remain undetected on surgical instruments. Therefore, these tests do not give a true indication of whether surgical instruments have had all their protein removed after washing or where the contamination actually lies on the instrument.

The inability to determine where proteins still remain means that it is difficult for SSDs to put in place corrective action with the decontamination process to ensure proteins on the critical tip of an instrument for use in critical neurological surgery for example, are removed. The inherent failure of these tests to monitor levels of protein contamination on surgical instruments creates the possibility that highly dangerous and robust biological agents (such as prions) may remain infectious and undetected, even after standard cleaning and sterilisation procedures.

In the past few years in the UK, a number of hospitals (for example, Hillingdon Hospital in August 2010) have had to close for a period of time due to the poor cleanliness of surgical instruments. Worse than this, in 2011, 38 patients in Wales were informed that they may have been put at risk of contracting Creutzfeldt-Jakob Disease (CJD) through contaminated surgical instruments. With hospital acquired infections (HAI) running at nine percent in the UK, thorough decontamination and accurate methods of validating decontamination of surgical instruments are now viewed by The Department of Health as critical public health issues.

This led to the release in 2012 of new CFPP-01-01 guidelines for decontamination of surgical instruments. The guidelines state that an OPA/NAC (o-phthaldialdehyde/N-acetyl cysteine) fluorescence-based digital image capture system provides increased sensitivity and quantification of residual protein on reprocessed instruments.

This fluorescence-based technology, which has been jointly developed over four years by Queen Mary University of London (QMUL) and Synoptics Health has been commercialised as a test for use in SSDs and is known as ProReveal. The test utilises a spray that SSD operatives mist over a reprocessed surgical instrument. In the presence of protein and/or amino acids, the spray reacts to produce a stable fluorophore, which emits fluorescence. The fluorescence ranges from 425 to 460 nm and is detected under UV light in a 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 viewer’s built-in software indicates via an on-screen green tick or red cross if this is a pass or fail of the decontamination process. This simple test, takes less than five minutes, enabling users in SSDs to perform sensitive in-situ detection of proteins on whole reprocessed surgical instruments.

To date, results show that the ProReveal test can detect as little as 50ng of protein, which is over one hundred times more sensitive than current protein tests and the prototype of the test has been shown to perform effectively in studies at SSDs in UK Hospitals, Great Ormond Street Hospital (GOSH) and University College London Hospital (UCLH).

Commenting on the new test,
Sylvia Martin, Decontamination and Sterile Services Manager at UCLH stated: “I found the OPA fluorescence method enlightening as it is a visible way of seeing what’s really on surgical instruments. When you see the results with the OPA test you can’t dispute how sensitive it is. This method if it becomes more widely trialled could represent a quality enhancement that will improve patient care.”

Margaret Hollis, Head of Decontamination at GOSH added: “OPA fluorescence detection has been known for some years but the commercial development of the ProReveal system is a whole new approach. I believe when this technology is more widely statistically tested, it could potentially become a new standard for testing the cleanliness of surgical instruments.”

For further information or to arrange a demonstration, please go to www.synopticshealth.com or email matthew@peskettsolutions.com

References
2. Operations suspended after flesh contamination. Available at: http://www.hsj.co.uk/acute-care/operations-suspended-after-flesh-contamination/5018531.article#3

DISTRIBUTION PARTNER

Synoptics Health is delighted to announce the appointment of Peskett Solutions Ltd. as its exclusive UK and Ireland distribution partner for ProReveal. Under the terms of the agreements, Peskett Solutions will market and support The brand new ProReveal Test.

The test consists of a ProReveal Protein Detection Test Kit, which conforms to BS EN ISO 15883-1 and a ProReveal Viewer, which when used in combination will detect nanogram amounts of fluorescent proteins on surgical instruments.

Matthew Peskett, Managing Director of Peskett Solutions explained: “We saw the ProReveal technology being developed by Synoptics Health in collaboration with Queen Mary University of London and were amazed by how easily it could detect where protein contamination is located on a surgical instrument. Current protein tests don’t really tell you where the protein is on an instrument and in an SSD, knowing where the protein is, can help you pin-point if and where, the issues lie with your decontamination process, and this is where ProReveal will provide a major benefit.”

Matthew added: “We were also impressed that the ProReveal Protein Detection Test Kit combined sensitivity and affordability. We believe that ProReveal will be a real advance for decontamination testing and this is why we’re very excited to be chosen as UK distributors of this innovative technology.”

Paul Ellwood, CEO of Synoptics Health commented: “We are delighted to be partnering with such a well-respected decontamination company to help us support our ProReveal Test. Peskett Solutions has an extensive network of professionals with SSD expertise and this will make it quicker and easier for decontamination professionals to implement the ProReveal technology into their facility, confident that they will have expert guidance in their transition to a more sensitive and cost-effective protein decontamination testing method.”

Web: peskettsolutions.com