Implementing a test to detect residual proteins

Robbie Cormie, decontamination lead at University Hospitals Coventry & Warwick NHS Trust, explains why – and how – his department has adopted an *in situ* test for detecting proteins on surgical instruments.

University Hospitals Coventry & Warwick NHS Trust Sterile Services Department (SSD) employs 55 staff and currently reprocesses around 13,000 trays of surgical instruments per month. The types of instruments we decontaminate vary in complexity and are from a full range of surgical specialties, including cardiology, neurology, orthopaedics, trauma, ENT and ophthalmology.

To process our surgical instruments, we operate five Getinge 88 Turbo and one Medisafe Niagara washer-disinfectors, five Getinge H-66 Series sterilisers and a STERRAD 100NX gas plasma steriliser.

Like all accredited SSD departments we fully comply with HTM 01-01 and we are ISO 13485 (2016) accredited. Washers are checked daily, weekly, quarterly and annually as required by the HTM 01-01 and until October 2017, we were using a standard swabbing technique to test our surgical instruments for residual protein after cleaning.

In 2017, we received a letter from the Department of Health (DoH) which stated that the HTM 01-01 regulations on testing for residual proteins on surgical instruments were changing and all SSDs had to move to *in situ* testing for protein on surgical instruments likely to be in contact with tissue potentially harbouring prions that could cause infections such as Variant Creutzfeldt-Jakob disease (vCJD).

The DoH letter made it clear that swabbing could be ineffective, open to error or misinterpretation and that the DoH now required a quantitative process to check for proteins. We looked and listened to all the advice and arguments which were (and still are) underway with regards to contaminant scanning. As a high-risk Trust, we decided we had to implement *in situ* testing straight away. From a quality/regulatory compliance point of view, our belief was that it would be easier to comply rather than thinking up excuses as to why we had chosen not to.

**Assessing the technology**

When deciding which in situ testing technology to implement at Coventry & Warwick NHS Trust, I drew on previous experiences of the technology I had seen or used. I first came across in situ testing in 2012, when I used a Synoptics Health ProReveal system at Southport and Ormskirk Hospital NHS Trust, where I worked previously. At this Trust we had constant failures in the cleaning of one specific orthopaedic instrument. Whilst following the manufacturers’ reprocessing instructions to the letter, we would still have residual protein contamination within this item.

We used the ProReveal for in situ testing to measure the levels of the contamination on this surgical instrument after its first, second and third reprocessing until the contamination was gone. It took between three and four wash processes to achieve this and it was only possible to understand what level of cleaning this instrument required using in situ testing.

My second experience with in situ testing was in January 2017 when our SSD at the Coventry & Warwick NHS Trust chose to change from an alkaline detergent to a neutral one to ensure our department was compliant with most instrument manufacturers’ reprocessing instructions.

Our detergent manufacturer used a ProReveal for in situ testing to set up and validate the new detergent on all our machines as they said it was the most accurate method of checking for residual protein for this application.

Having had positive experiences using the ProReveal for in situ testing, we purchased our machine in September 2017 and after delivery and training went live with it in October 2017.

**Implementing *in situ* testing**

Implementing in situ testing has not changed the way we reprocess instruments, just the way we test them. This has involved writing a Standard Operating Procedure (SOP) and putting in place a regime of daily instrument testing.

Using the ProReveal our SSD now tests a minimum of 50 instruments per month per washer-disinfector and we test one instrument from each washer disinfector per day (Monday to Friday) and one instrument from our handwashing sink too as a comparison to see how manual cleaning compares with an automated validated process.

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We use a random daily sampling process (see Table 1), where we select instruments that are compatible with the ProReveal system. These are items made entirely of stainless steel as some plastics can fluoresce and this shows as a false positive result.

Currently, we are performing around 30 in situ tests per week and we always test any neurology instruments as a priority over other instrument types.

Fastrack items are not tested as they require re-washing afterwards and this takes time we often don’t have.

To use the ProReveal, we scan the staff ID badge, bottle of ProReveal spray and the tray ID barcode tag and select the instrument type from the menu. Then we select the washer and enter the cycle and wash cart level information and where the tray was positioned. We designate the top level as level 1 and level 5 is the bottom level from our washer-disinfectors.

We open the drawer of the ProReveal, insert black paper and place the instrument to be tested on top of the paper and then mist the ProReveal spray evenly over the instrument using five or six sprays. Finally, we close the drawer and the system gives us a reading of how many nanograms are on the instrument by measuring the amount of fluorescence visible which is binding to the proteins on the surface of the instrument under UV light (Figure 2). We set the ProReveal with a maximum limit of 5000ng (5µg) per instrument side and if instruments are above this they are a fail. If a fail occurs, we investigate to find out what is wrong with the washers, the water or the detergents we are using and the problem is rectified.

The results are documented on a ProReveal Daily Log Sheet that is given to SSD Management at the end of the day shift.

We are storing the numerical residual protein data we have obtained from our in situ testing in an Excel spreadsheet. As we have only a very basic knowledge of Excel and spreadsheets in our SSD, the most confusing part was the creation of the control chart as specified in HTM 01-01.

Fortunately, we have good IT support here at Coventry & Warwick NHS Trust and they were able to make up the control chart for us – otherwise we would have never achieved it without having to pay an external consultant. We believe the DoH should have produced the control chart as a downloadable template to ensure that all ProReveal users are logging the data in the same way. This would eliminate data collection variation across different Trusts.

We also believe the DoH should have written an SOP for the use of the ProReveal so that the method is the same across the different organisations using this device.

Process reassurance
We are now using in situ testing routinely in place of swabbing to confirm the cleanliness of our surgical instrument instruments. This is giving us the assurance that our cleaning equipment is continuing to work as we expect it to. Currently, most of the surgical instruments cleaned with the validated automated process

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have between 0 and 1µg of residual protein on them, well below the 5µg DoH requirement and the variation is due to the age and type of item. The hand washed instruments have between 0 and 3µg of residual protein on them, so in situ test is showing our SSD personnel the proven benefits of automated validated processing over handwashing as staff can see for themselves both the numerical data and images of the visible contamination on the surgical instrument using the ProReveal viewing screen. The main trend we have seen in our data since October 2017 is that our automated cleaning process is below the DoH guidelines for residual protein, which is very reassuring. We have also seen that some old items and instruments hold on to more contamination than others due to the material they are made from. The benefit of having residual protein data, is that we can now use it to justify having old items which are resistant to cleaning replaced or removed from circulation, so they are not re-used on patients.

In summary, in situ testing is way ahead of swabbing for detecting residual protein and the numerical data the ProReveal generates provides peace of mind that our equipment, staff, chemicals and processes are working well to ensure the safety of the surgical instruments being used on our patients.

About the author

Robbie Cormie has been the decontamination lead at University Hospitals Coventry & Warwick NHS Trust SSD since 2014 and was the driving force behind implementing in situ testing in the department. Prior to this he was decontamination manager at Southport and Ormskirk Hospital NHS Trust where he was responsible for helping to redesign Southport Hospital’s SSD department with the addition of new washer-disinfector units and processes to reflect the work flow – and provide the highest quality decontamination environment. Robbie is a chartered member of the Institute of Decontamination Scientists and an Authorised Person (Decontamination).