

ATP: a validation target for decontamination

SUZANNE CALLANDER reports on the evidence that supports the use of ATP bioluminescence testing for the validation of decontamination processes in endoscopy units and sterile services departments.

Hospital acquired infections are costly for the NHS and can have far-reaching and long-term consequences for the patient. It is therefore vital to reduce the possibility of any cross-contamination from endoscopes, surgical instruments and other medical devices and equipment. For this reason all reusable devices that have been used on a patient need to be thoroughly decontaminated between each use.

Health Technical Memorandum (HTM) 2030 (revised CFPP 0106/CFPP 0101) offers guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer disinfectors, automated endoscope reprocessors and sterilisers in use in the NHS for processing medical devices. The guidance advises that testing be carried out on a regular basis to validate the effectiveness of decontamination equipment, and it also advises on a suitable regime for this validation testing.

Residual soil testing

HTM 2030 recommends that regular testing for residual soil after device decontamination be conducted to ensure that the effective cleaning of equipment is being undertaken. The guidelines state that this test 'will detect a broad spectrum of substances which may occur as residuals from body fluids'.

"ATP is a common component of all body fluids and it is present in large amounts. It can be measured very sensitively and quickly and gives an objective measurement of the presence of



a bodily fluid," said Dr Martin Easter, general manager at Hygiena International. "HTM 2030 does not specify that the test needs to be a protein test, which is wrongly assumed by many people... it specifies that it needs to be a test of a common component of body fluids and this means that ATP is a particularly useful target for testing whether any bodily fluids remain after the decontamination process."

When ATP (adenosine triphosphate) reacts with luciferin in the presence of luciferase, it produces a release of energy in the form of light, this is called

bioluminescence. This enables the presence of ATP, which indicates residual body fluid, to be detected as a light output using bioluminescence testing techniques. There are many applications of the ATP test that have been developed over 30 years but the simplest manifestation and most widely used is that of an objective cleaning verification test.

ATP test systems use a detection swab to take a specimen from the surface to be tested. The swab is then inserted into a reader and a numeric reading (Relative Light Units, RLU) is produced. The test is specific for ATP, it is linear and is extremely rapid and sensitive, being able to detect in the picogram (pg) range.

However, like all biological methods it has less precision than chemical test methods and the RLU is not a standardised unit of measurement so different systems may have different RLU scales.

"The ATP bioluminescence test methodology has been in use in the healthcare sector for around eight years and it is gradually gaining acceptance in the healthcare environment as its advantages are recognised. Currently, there are around 200 Hygiena ATP test systems being used in sterile services departments across the country," said Dr Easter.

'The previously used test offered us no way of recording the test results, whereas we found that the ATP test solution allows us to record all the necessary information relating to the test.'

The ATP test is very simple and easy to undertake and has many applications. It is commonly used to monitor, validate and verify cleaning procedures in many industries. “Unlike some other tests, ATP is not a comparative or subjective test. It is a direct, objective and quantitative test and can provide results quickly – within 15 seconds,” continues Dr Easter.

Evidence for the use of ATP testing

There is evidence to support the use of ATP testing for decontamination validation. In sterile services, for example, it has been used to monitor washer disinfectors and the cleaning of surgical equipment. Heathcote and Stadelmann¹ stated that the reliance on visual inspection to assess the adequacy of decontamination process is outdated and prone to error. They also demonstrated that the use of ATP bioluminescence provides valuable and objective data concerning the ability of washer disinfectors to deliver measurably cleaner instruments, thereby contributing to quality control mechanisms and validating the washer disinfectant.

Heathcote and Stadelman also identified that protein detection methods, described in ISO-15883, are more complicated and time consuming, taking up to 35 minutes. The ATP bioluminescence test method takes no more than two minutes in total and requires no specialised laboratory equipment, beyond swabs and a handheld reading device.

The ATP test was also used to measure the cleanliness of endoscopes, as reported by Hansen *et al.*² The authors believe that methods for quality control should be easy to perform and that results should be available in time for corrective action to be taken. They found ATP bioluminescence to be an appropriate method to verify success of cleaning in the reprocessing of medical devices and that determination of residual ATP is superior to determination of residual protein by a modified Biuret reaction. The authors concluded that the determination of residual ATP on surgical instruments after washing is suitable for quality control of the cleaning process and advised that this method should be applied more often.

Hansen *et al.*³ also concluded that ‘the ATP bioluminescence does not replace



routine microbiologic methods but it should be applied additionally to check endoscope reprocessing’. The report also concluded that ‘a clean endoscope should not only show a less amount of viable organisms but also a less amount of all organic contamination and ATP sources. The presence of any ATP source may indicate an infectious risk for consecutively examined patients and should be avoided irrespective of cultivable bacteria’.

More recently, Fernando, Collingnon and Beckingham⁴ carried out a prospective study at a gastroenterology hepatology unit to evaluate ATP bioluminescence to validate the decontamination processing of endoscopes. The study involved flushes

‘HTM 2030 does not specify that the test needs to be a protein test, which is wrongly assumed by many people.’

from endoscopes involved in 120 endoscopic procedures at four different stages – pre-patient, post-patient, post-cleaning and post-disinfection – being examined by ATP testing and microbiological culture. When the disinfection process failed, the process was repeated. The study concluded that ATP bioluminescence has the potential to play an important role in the validation process. The authors said that ‘the ATP process allows a quick turnaround time following a simple check procedure to be classified as safe in a busy endoscopic unit’.

At very low soil detection levels, there will be an increase in variation of results of any detection method such that absolute determinations become more unreliable, particularly if only single test replicates are performed. Under these circumstances the trend analysis of results can provide a good measure of quality control. Because the test results can be electronically downloaded it offers test tracking and

traceability capabilities and, together with data analysis software, can provide an effective system to deliver evidence of due diligence and can offer a valuable trend analysis tool for management purposes.

Standardising on ATP

The Shrewsbury and Telford Hospital NHS Trust has standardised on the use of ATP testing to monitor for the effectiveness of its sterile services and endoscope cleaning procedures. Peter McIntyre, a decontamination specialist, based at the Princess Royal Hospital, explained why: “We have used ATP as part of our regular testing procedures in the hospital for several years. Initially we used it just in the endoscopy unit, where it

was successful in helping us to highlight a particular problem with an endoscope, which our original Ninhydrin protein test was unable to find.”

To comply with decontamination guidelines

‘The ATP test has many uses in support of infection control procedures – from monitoring equipment cleaning and process control through to environment cleaning and cross-contamination hazard testing.’



the Trust needs to undertake regular weekly validation tests on all of its decontamination equipment. “The previously used test offered us no way of recording the test results, whereas we found that the ATP test solution does allow us to record all the necessary information relating to the test, offering us greater traceability of test results. Test data are stored in the handheld unit and we download this information on a weekly basis onto a spreadsheet,” explained Peter McIntyre.

The success of the introduction of ATP testing into the endoscopy unit at the Trust, led to its wider use across all three Trust sites, which includes a dedicated sterile services unit. Peter McIntyre added: “We have since purchased a much more sensitive ATP test solution – Hygiena’s EnSURE. Our endoscopy unit and the sterile services department now

exclusively uses ATP for the weekly validation of cleaning equipment – testing a random sample of scopes. Our next step with the EnSURE system is to enable the network capabilities of the system, so that I am able to see the test results from remote locations.”

Conclusion

The ATP test has many uses in support of infection control procedures – from monitoring equipment cleaning and process control through to environment cleaning and cross-contamination hazard testing. The test is simple to undertake and provides fast results. Importantly, it can also offer valuable test data to assist with trend analysis and ensures traceability of all test results. +

References

- 1 Heathcote R, Stadelmann B. Measuring of ATP bioluminescence as a means of assessing washer disinfector performance and potentially as a means of validating the decontamination process. *Healthc Infect* 2009; 14: 147-51.
- 2 Hansen *et al.* ATP bioluminescence – for kitchen hygiene and cleaning control of surgical instruments. *Int J Infect Contr* 2008; 4:1 doi:10.3396/ijic.V4i1.010.08

‘The success of the introduction of ATP testing into the endoscopy unit at the Trust, led to its wider use across all three Trust sites.’

- 3 Hansen *et al.* ATP measurement as a method to monitor the quality of reprocessing flexible endoscopes *Ger Med Sci.* 2004; 2: Doc04. Published online Apr 26, 2004. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2703208>
- 4 Fernando, Collignon & Beckingham. (2014) ATP bioluminescence to validate the decontamination process of gastrointestinal endoscopes *Healthcare Infection* <http://dx.doi.org/10.1071/HI13034>

