

Central Sterile Service Department and Pro-tect[®] M: A new tool for validation

The Health Technical Memorandum (HTM) 2030 lays down the requirements for the verification and validation of Washer-Disinfectors (WDs) used for processing medical devices, instruments and other sanitary products in the National Health Service. The guidelines and information in the HTM are aligned with existing ⁽¹⁾ or imminent ⁽²⁾ standards for WDs.

Part of the requirement of the HTM 2030 (section 10.37 to 10.51) is that periodic cleaning efficacy tests are performed to ensure that instruments/equipment processed in the WDs are free from 'residual soil'. It is recommended that items processed in the WDs in hospital Sterile Services departments be tested for 'residual soil' after cleaning at least once a week although internal quality assurance policies often require this testing to be done on a more frequent basis.

The HTM 2030 dictates that a protein detection method should be used to test for residual soil. The standard method recommended by the HTM 2030 is a laborious and complex process, involving an oven set at 110°C, swabs, sterile water and ninhydrin; a light-sensitive chemical rated as harmful by COSHH guidelines, requiring the use of protective clothing. However, (section 10.49), HTM 2030 does permit the use of other methods of protein detection, including those based on a reaction known as the Biuret reaction.

The Pro-tect[®] M test from Biotrace is a rapid, sensitive and easy to use protein detection test that can be used to measure the cleaning efficiency of washer-disinfectors in hospitals. Pro-tect[®] M uses an enhanced Biuret reaction to detect residual protein. If protein is present, the test will change from green to purple.

Test method

The precise chemistry of the Pro-tect[®] M test is based upon the patented enhanced biuret colour change chemistry (Numa, 1996). Its use as a method for validating cleaning has been regularly demonstrated (Tebbutt, 1999; Patrick & Bayliss, 1997).

Pro-tect[®] M is a very simple test to perform. The swab is removed from the tube, and used to swab the area required for testing. The swab is then replaced in the tube and pushed to the bottom. This releases the colour-change chemicals. The test is then incubated at 37°C for 45 minutes. If, at the end of this period, the test remains green, the surface tested is free of residual protein. If it has turned grey or purple, this indicates that residual protein remains on the surface. This shows that cleaning by the washer-disinfectant was not effective, and allows remedial action to be taken immediately.

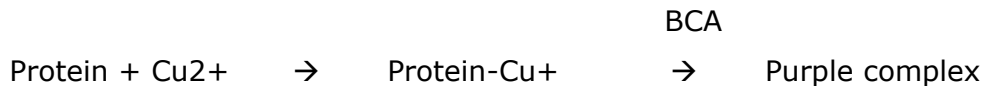
⁽¹⁾ **British Standard 1993**

⁽²⁾ **European Standard, due 2003**

Principle of test

The test works on the principle that peptide bonds in the protein will form a complex with copper ions (Cu^{2+}), reducing them. A chemical called bicinchoninic acid (BCA) then forms another complex with the protein and reduced copper ions (Cu^+), and causes a colour change from green to purple. Thus, a purple colour shows the presence of protein. The colour can be assessed visually, or in a Biotrace colorimeter, which ensures a consistent result.

The enhanced biuret reaction proceeds as follows:



The table below (Table 1) shows a comparison between the sensitivity of the ninhydrin method and Pro-*tect*[®] M. Both tests could reliably detect 3µg of protein in 100µl of liquid. This approximates to 3mg/m² for a 1x10cm area.

Table 1. A comparison of the sensitivity of the ninhydrin method and Pro-*tect*[®] M to detect protein at varying concentrations:

	4µg/100µl	3µg/100µl	2µg/100µl	Control
Ninhydrin (Test 1)	Y	Y	Y	N
Ninhydrin (Test 2)	Y	Y	N	N
Ninhydrin (Test 3)	Y	Y	Y	N
Pro-<i>tect</i>[®] M (Test 1)	Y	Y	N	N
Pro-<i>tect</i>[®] M (Test 2)	Y	Y	Y	N
Pro-<i>tect</i>[®] M (Test 3)	Y	Y	Y	N
Pro-<i>Lite</i>[™] (avg RCU)	349.7	323.7	263.3	171.3

(RCU = relative colour units)

This data demonstrates that the Pro-*tect*[®] M test has a sensitivity of 3µg of protein (BSA), which is comparable to the ninhydrin method.

Pro-*tect*[®] M has the advantages of being exceptionally simple to use and involves very little training. It requires no pipetting of hazardous chemicals in specialist labs, or ovens set at high temperatures.

For customers needing a hard copy of the result to prove due diligence, the Pro-*tect*[®] M device can be read in a colorimeter called Pro-*Lite*[™]. Pro-*Lite*[™] generates consistent results that can be printed out or uploaded to a PC where a database can be created and trends studied.

References

Numa M. (1996). Hygiene Monitoring Kit Konica Swab'N'Check. *Konica Technical Report*, **9**, 113-116.

Tebbutt G.M. (1999). Comparison of traditional and rapid methods for assessing the risk of bacterial contamination from cutting boards. *International Journal of Environmental Health Research*, **9**, 67-74.

Patrick M. & Baylis, C.L. (1997). Evaluation of the Konica Swab & Check – Marketed as Ruskinn hygiene monitoring kit in the UK. *British Food Manufacturing Industries Research Association Technical Notes*, **123**.