



Pyromol-Test

Detection of protein residue

Introduction

Following monitoring the performance of cleaning procedures with indicators, testing for protein residue plays also an important role for quality assurance in CSSD. The efficacy of automated cleaning procedures can be validated and monitored on a routine base with the TOSI product line. Manual cleaning procedures cannot be validated and are best controlled by testing the result, the cleanliness of the instruments. Protein is a common compound on contaminated instruments. After cleaning, instruments must be completely free of any residue. Methods for the detection of protein are manifold and often used in food or pharmaceutical industries. Unfortunately the adaption of those techniques for CSSD application is often difficult and the outcome is unsatisfactory. Since protein residue left on instruments are mainly insoluble and the chemical properties may also be altered by the cleaning and/or disinfection process. Pereg GmbH has already introduced a very sensitive test for blood residue which originated from clinical chemistry and was adapted to CSSD use. It is therefore not surprising that PEREG's latest protein test is also originating from clinical chemistry: The Pyrogallol-red method for protein measurement was integrated into the Pyromol-Test for detecting protein residue on instruments and surfaces.

Test methods

a) Swabbing

Swabbing is the preferred sampling technique due to the fact that it can remove completely insoluble residue and hence make it available for the detection method. In order to apply sufficient pressure to remove persistent residue on surfaces and standard instruments short swabs are used. For cannulated instruments and channels of flexible endoscopes the right size of swab must be chosen in order to achieve an effective sampling.

b) Testing

In order to detect tiny amount of residue a sensitive test method is necessary for a safe test result. Spots of dried blood in the μg range are clearly visible on stainless steel therefore a chemical test method must at least be within this range. Our Pyromol-Test can detect $1\mu\text{g}$ of protein residue and can also distinguish it from other substances like water spots or corrosion.

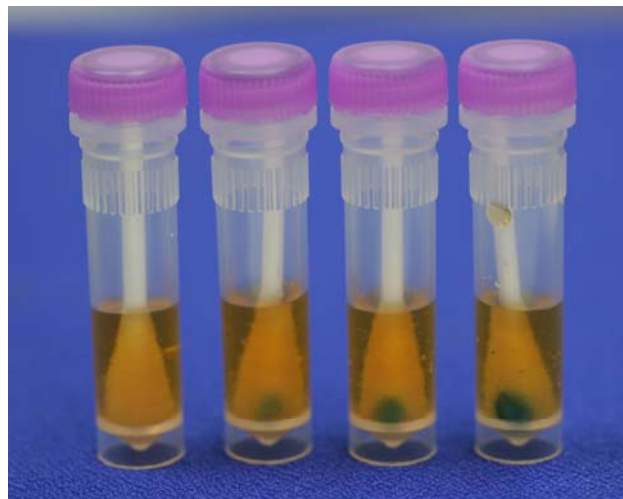
Validation of the detection limit of the Pyromol-Test

The detection limit of the Pyromol-Test was verified with 1, 2 and 5µg denaturated Albumin which was achieved by dosing 1µl of corresponding solutions onto heated steel plates at 100°C.

Proof of no interference was achieved by reaction of the Albumin solutions with 3% Glutaraldehyde and 3% Hydrogenperoxide for 1 hour before performing the same test. In addition to the protein samples, a blind test without protein was performed. All tests were repeated 3 times.

Results

The Picture shows the Pyromol-Test results for the denaturated protein samples (from left to right: 0µg, 1µg, 2µg, 5µg). All samples except the blind control gave a positive result indicated by the colour change to blue. While larger amount of protein show a visible spot after less than 1 minute however, a 5 minutes waiting time is recommended to clearly detect small amount of protein. Soluble protein, normally not found on reprocessed surgical instruments, can change the colour of the liquid to blue. The protein samples chemically altered by glutaraldehyde and hydrogenperoxide gave corresponding results.



Pyromol-Test results from 0-5µg protein (0µg / 1µg / 2µg / 5µg)

Discussion

The Pyromol-Test is based on the formation of a protein-dye complex. This reaction detects the protein chain itself, therefore it can still show chemically altered and denaturated protein. This is mandatory for the detection of residue after chemical disinfection processes. The detection limit of 1µg is low enough and necessary for a safe test result. **Medical devices must be completely free of residue!** Compared to other tests like the OPA method, the Ninhydrin test or the Biuret test, the Pyromol-Test is more sensitive and selective in performance and is considered according to the EN ISO 15883 standards.

Hazard Identification

- The Pyromol-Test solution is slightly acidic and may cause irritation when in contact with skin or eyes.
- The Pyromol-Test can be disposed of as non-risk waste.

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