

Remarks on: Test soils, cleaning indicators and protein residual tests in comparison

Quality assurance of cleaning efficacy in CSSD is an important task in order to supply clean surgical instruments for patient safety. For 12 years PEREG has been manufacturing practical orientated, efficient and standardised cleaning indicators according to EN ISO 15883 but somehow the ÖGSV had problems testing our tests and even published some odd conclusions:

Conclusions: HemoCheck-S is not suitable for medical devices and the information value of TOSI is very low.

Different test methods can only be compared if they are comparable. If one wants to compare protein test kits it does not make sense to include tests for other substances and conclude that the test does not work. Residue on surgical can be of various chemical nature, where protein is amongst the most common organic substances. A special case is a test for blood residue (peroxidise based according to EN ISO 15883) which are far more sensitive than most general protein tests but will only give a test result for blood protein (Haemoglobin) and not for other sources of protein. This is an excellent advantage because HemoCheck-S gives a very reliable result within seconds and will not give a false positive test result for harmless fingerprints like the Ninhydrin test of BCA test will often do. Of course there are situations where one does not want to detect blood only but other protein and for this case we offer a special protein test. This fact was discussed in detail with the ÖGSV so it is not understandable why HemoCheck-S was tested with Albumine (which cannot give a test result) instead of using our Pyromol-Test which has even a lower detection limit for more patient safety compared to the protein kits tested. The same incorrect conclusion was drawn for the ATP test, again it was concluded as not suitable for medical devices. An ATP test is obviously designed to detect ATP and not protein, so why testing it with Albumin in the first place?

Another important factor is that protein tests must be able to detect insoluble residue one will find on instruments after a reprocessing cycle and not easily soluble proteins like BSA which was used in this "comparison". Reason is that certain tests can easily detect dissolved protein but not insoluble protein found on surgical instruments. This also was discussed with the ÖGSV and should have been implemented into the study to make the results useful.

A test result is only diagnostically conclusive and reliable if it comes with the necessary practical relevance. A comparison of different methods/Indicators without taking the practical situation into consideration is meaningless. Not the indicator which is hardest to clean is the best but the one which is most comparable to the practical situation.

For example the Austrian test method accept up to 5% of instruments with visible (!) blood residue while in practise, visible blood after a reprocessing cycle is completely unacceptable and compromises patient safety!

What should our conclusion be after evaluating the presentation? Not suitable for a scientific conference? No of course not! Scientific errors need to be discussed in order to improve and move forward.