Residual Organic Soils on Patient-used Instruments

Key Considerations for User Verification

Ralph J Basile, MBA
Vice President
Healthmark Ind. Co., Inc.
What types of soil found on patient-used instruments?

- blood
- carbohydrates
- synovial fluids
- lipids
- bone
- tissue
- other
Is there one soil or marker that is present on all patient-used instruments?

- Protein
- Adenosine Triphosphate (ATP)
- Total Organic Carbon (TOC)
- Others?
Protein

Advantages
• Present in almost any human secretion can identify.
• Present in other microbial contamination.
• Are quick and well studied methods for testing.

Disadvantages
• False positives? Protein is so ubiquitous that poor testing technique could yield a result (i.e., fingerprints)
• Is it harmful? Being so ubiquitous, it is not possible to determine whether a threat to patient (if present must assume harmful).
• Steps in reprocessing can render it difficult to detect (denaturing and insoluble).
ATP (adenosine triphosphate)

**Advantages**
- Is present in bacteria and viable human cells.
- Quick and easy to interpret test are available.
- Provides a numeric result, more objective than colormetric result.

**Disadvantages**
- Like protein, ubiquitous nature can lead to false positives.
- ATP degrades rapidly, particularly in presence of reprocessing conditions (heat, detergents) rendering it undetectable even when organic soils remain.
- Like protein, what is a safe level?
TOC (total organic carbon)

**Advantages**

- Carbon is present in all organic soils.
- Quick test methods are available.

**Disadvantages**

- Like protein and ATP, ubiquitous nature can lead to false positives.
- Like the other two markers, what is a safe level?
- Currently available test methods necessitate reprocessing any instrument which is tested.
More Specific Soils/Markers for Specific Instruments (i.e. hemoglobin)?

Advantages
• Reduce chance for false positives.
• Provide faster results.
• More sensitive tests (lower level of detection).
• Can identify the risk (in case of blood - none should remain to eliminate risk to patient).

Disadvantages
• Reprocessing staff need to be better educated - which test for which instrument.
• Greater the number of tests, the greater the diversity of results (e.g., different colors, or different numbers, etc.).
Commercial products in the market

- hemoglobin
  - sensitive down to 0.1ug hemoglobin.
  - colormetric result - easy to interpret.
  - limited chance for false positives (e.g., oxidizing agents which might be in cleaners or disinfectants).
  - not appropriate for all instruments.
Commercial products in the market, cont’d

- multi-parameter test strip
  - hemoglobin/protein/carbohydrates.
  - colormetric result - easy to interpret.
  - flush method lends itself to testing lumens, but not external surfaces.
  - not as sensitive as specific tests.
Commercial products in the market, cont'd

• protein
  • variety of available tests.
  • all feature a colorimetric result that is easy to interpret.
  • some will only work for soluble proteins - which often is not the state of proteins after reprocessing.
  • some take an extended time to detect insoluble proteins.
  • sensitivity levels vary between products - confusion for users.
  • susceptible to false positives.
Commercial products in the market, cont'd

• ATP Tests
  • quick result (less than 1 minute).
  • provides an objective measure (number).
  • ATP is prevalent with viable cells/organisms.
  • ATP degrades over time and that is accelerated in the conditions of reprocessing. Organic soils may remain when ATP no longer present.
  • Different brands of tests have different RLU scales - confusion for users.
Surrogate Device -
An alternative solution

For some device manufacturers, the best solution may be to provide or recommend a surrogate test device rather than specify the soil and methods for testing:

- Can be simple pass/fail.
- Will have the "right soil" for the target device.
- Can be "visually" clean not requiring chemistry, readers, etc.
- Only for automated processes - not appropriate for manual cleaning
Questions for the Summit to consider:

• Is there a universal soil/marker that is always present on patient-used instruments? Or should the marker(s) change with the device?
• Is (are) there a soil(s)/marker(s) that can be practically tested for in non-lab setting?
• What interference will reprocessing steps cause in testing for targeted soil(s)?
• Is a surrogate testing device a better option when practical?
• What is a safe level? What is clean? What is the level of detection?
• What guidance can we give the user for frequency of testing, etc.?
References

AAMI Documents:
- AAMI TIR30:2011: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- AAMI TIR12:2010: Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- ANSI/AAMI ST15883-1:2009 (ISO 15883-1:2006, MOD), Washer-disinfectors, Part 1: General requirements, terms and definitions and tests

Other Reference Documents:
- Alfa, MJ. Artificial Test Soil. US Patent 6,447,990; 2002
References

References

- Pfeifer M. Blood as a soil on surgical instruments: Chemical profile, cleaning, detection. Zentr Steril, 6:381–385, 1998a
- Whitfield N. ChannelCheck verification test as a tool to assess endoscope cleanliness: A case study. Infect Control Today, January 2011, p. 26