

ARTIFICIAL TEST SOIL

REAL | SIMPLE | VERSATILE | STABLE | COMPLETE

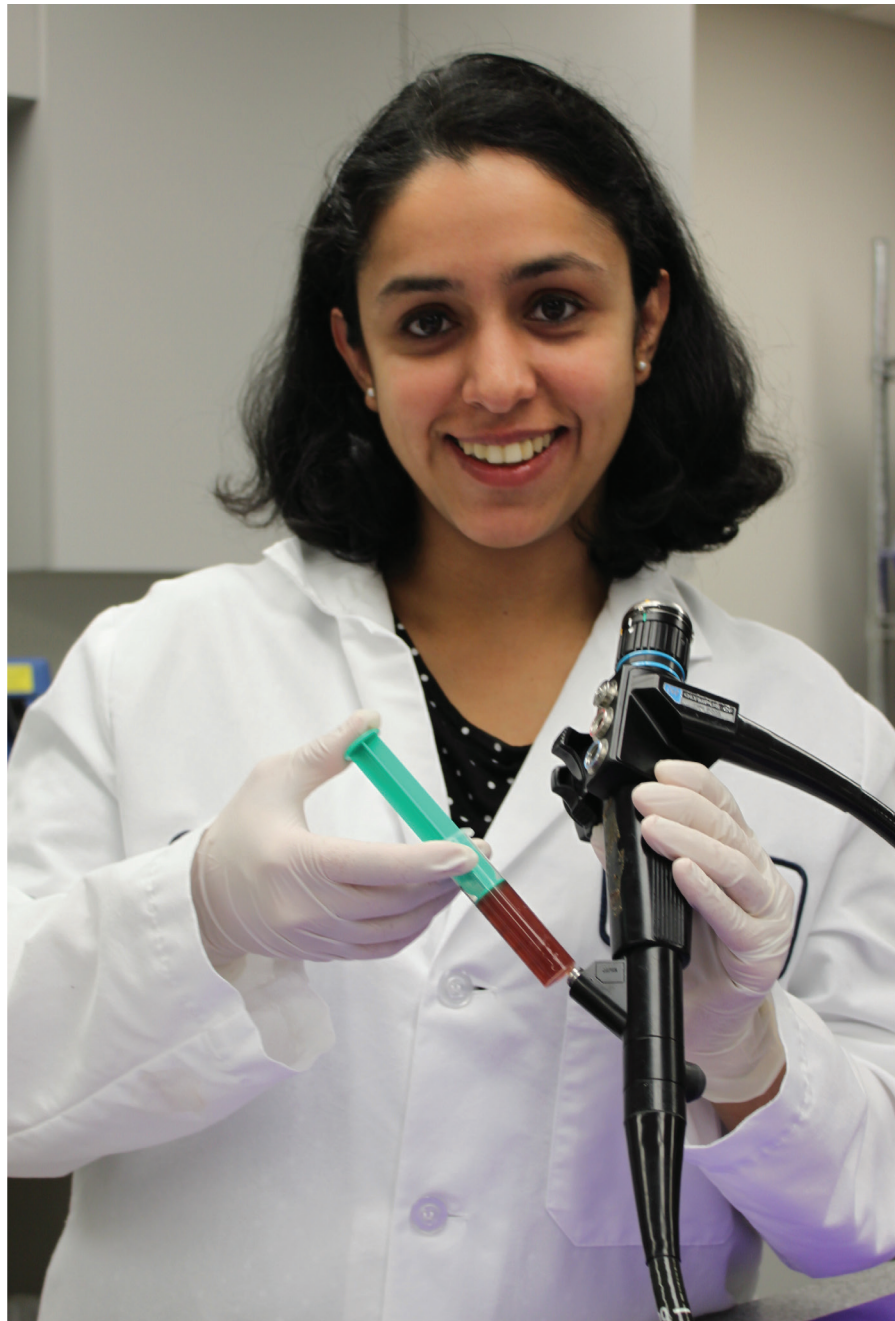
MEDICAL DEVICE
MANUFACTURERS

THIRD PARTY
REPROCESSORS

TESTING LABS &
RESEARCH FACILITIES

STERILE REPROCESSING
EQUIPMENT
MANUFACTURERS

COMPARITIVE TESTING
OF DETERGENTS FOR
CLEANING



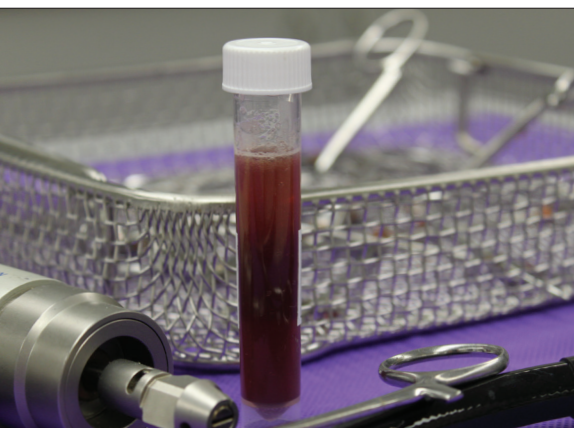
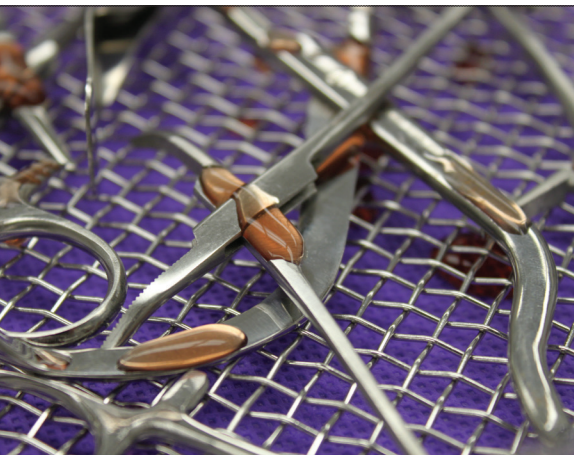
WHAT IS ATS?

Artificial Test Soil is a test soil comprised of proteins, carbohydrates and hemoglobin.

It simulates the “worst case” soiling of medical devices that have been used on patients.

ATS is used for both testing and validating cleaning procedures of medical devices and cleaning equipment.

Healthmark ATS is based on extensive scientific research to comply with regulatory requirements.



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If you are a medical device manufacturer (MDM), 3rd Party Reprocessor or independent testing lab that needs to comply with AAMI, FDA, CDC, CEN, Health Canada, CSA and other regulatory agencies, Healthmark ATS is an easy and affordable answer. Formulated from extensive study of instruments soiled in real world situations, our Artificial Test Soil (ATS) contains the actual contaminants likely to remain on medical devices after clinical use. Use of ATS to soil your device, can help you validate your reprocessing instructions in compliance with regulatory requirements.

REAL

Artificial Test Soil is comprised of the organic contaminants remaining on surgical instruments after clinical use, including protein (~23mg/ml), hemoglobin (~10mg/ml) and carbohydrates (~6.5mg/ml). These quantities are reflective of the “worst case” levels found to remain on instruments after patient use, but before reprocessing. The FDA and other international regulatory agencies specify that simulated-use testing should approximate as closely as possible the actual soiling the instrument is exposed to during clinical use. ATS meets this requirement with extensive research (available upon request) to support it.

SIMPLE

Our standardized soil is ready-to-mix. You simply add sterile water.

Medical device manufacturers must employ an organic challenge. ATS is easy to use to determine and document the effectiveness of your cleaning protocol to remove organic materials from instruments or equipment.

VERSATILE

Healthmark ATS can be applied to several applications, such as:

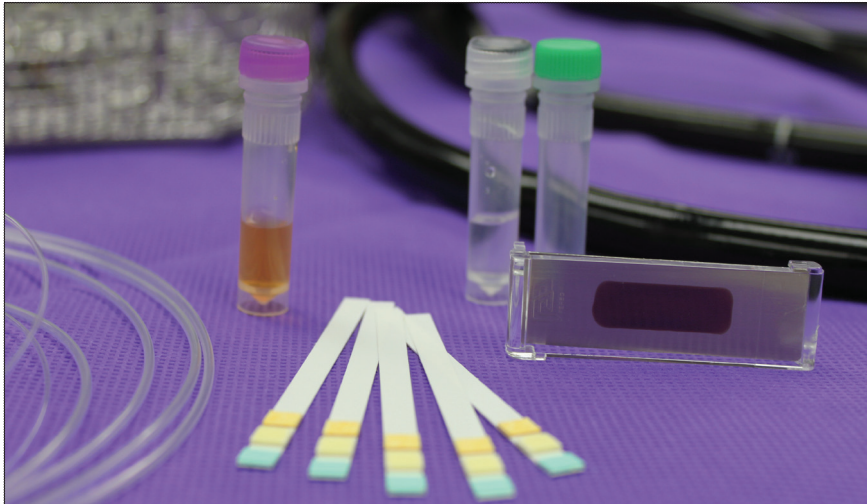
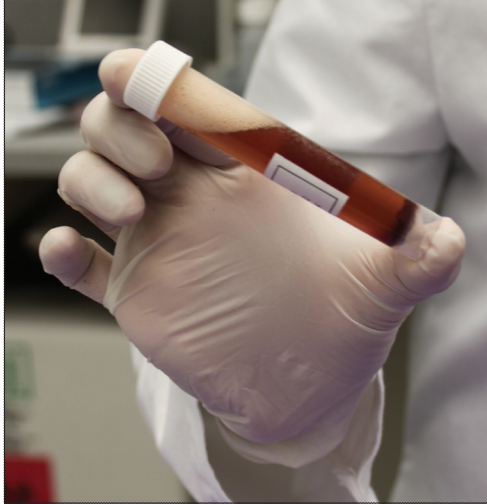
- Testing the cleaning instructions of medical devices
- Ensuring reprocessing adequacy and assurance
- Testing microbial load (bioburden) reduction
- Training personnel

ATS can be inoculated with endotoxin, microorganisms, or other biologics to represent the residuals present on devices after patient use.

STABLE

Unlike the current organic challenge manufacturers use, ATS offers less variability between batches. ATS is described in various AAMI and ISO standards and FDA Guidance Documents and is well documented in peer-reviewed literature.

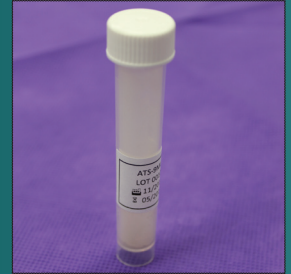
Our ATS provides long shelf life and is easily stored at room temperature until rehydrated for use.



6 SIMPLE STEPS

1

Lyophilized soil in 9ml bottle.



2

Add sterile water. Hard water (400 ppm) may be used.



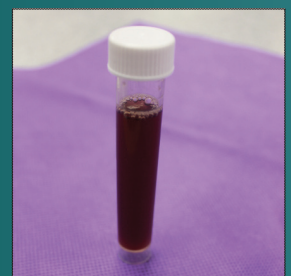
3

Shake well.



4

Mixed ATS ready for use.



5

Draw out ATS.



6

Soil instrument with ATS.



COMPLETE

To provide a complete testing solution, ATS can be used with other Healthmark Performance™ products to validate the removal of organic soils based on the manufacturer's cleaning protocol. Further, Performance products provide a solution for manufacturers to provide their users with a recommended method to verify the cleaning process, as indicated by AAMI standards:

HEMOCHECK™

The HemoCheck blood test kit is an all-in-one test, providing easy to interpret results of blood residue to 0.1ug in just 30 seconds.

PROCHECK-II™

The ProCheck-II protein swab test kit is an all-in-one test, providing rapid results to measure residual protein on surfaces to 1.0ug.

CHANNELCHECK™

The ChannelCheck tests for blood, protein and carbohydrates simultaneously in virtually any lumened instrument, almost instantly.

TOSI®

The TOSI Instrument Washer Test is a surrogate device for stainless steel instruments that correlates directly to instruments soiled with blood during clinical use. It can be used for simulated-use testing to recommend cleaning protocols for such instruments as well as recommended for healthcare facilities as a method for verifying cleaning effectiveness.

BLOOD TEST SOIL (BTS)

Quick, easy and affordable

Blood Test Soil (BTS) is a simple, simulated blood soil that visually mimics blood on the exterior of patient-used instruments. The soil is composed of hemoglobin and protein and can easily be used to coat surrogate instruments for cleaning verification with Healthmark's Proformance™ line of products. It has a long, stable shelf life in its lyophilized form. Just rehydrate with sterile water and it is ready to use.

KEEP IT CLEAN

In addition to our products, Healthmark also has the expertise and knowledge to be of assistance in devising tailored cleaning and verification protocols that comply with international standards.