healthmark
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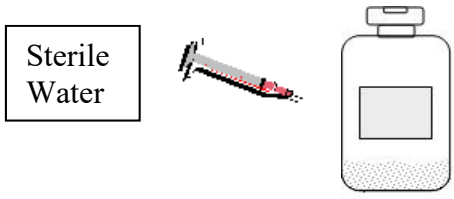
Instructions for Use: ATS2015 Test Soil

Brand Name of Product	Artificial Test Soil 2015 (ATS2015)
Generic Name of Product	Artificial Test Soil 2015 (ATS2015)
Product Code Number(s)	ATS2015-1ML, ATS2015-9ML, ATS2015-100ML, ATS2015-500ML, ATS2015-500ML-2, ATS2015-B-9ML, ATS2015-B-100ML, and ATS2015-B-500ML.
Purpose of Product	Hemoglobin, protein and carbohydrate based standardized test soil in proportion found on clinically used medical devices.
Range of Applications for Product	ATS2015 has been formulated for simulated use soiling of medical devices, including flexible endoscopes, for the purpose of conducting cleaning validations and cleaning verifications. The reconstituted ATS2015 test soil contains the following markers: protein, hemoglobin, carbohydrate, lipids and insoluble fibers. Bone can be added if requested.
Key Specifications of Product	• 1X Vial with dry test soil component. • Dry mixture includes purified bovine proteins (hemoglobin, albumin), physiological salt, mucin, xanthan gum, egg yolk, and cellulose. • 20% defibrinated sheep blood is added after the dry mixture is reconstituted. • Viscosity of reconstituted ATS2015 is ~ 9cP using a vibrational viscometer. • ASTM D3359-97 Standard adhesion testing shows < 8% soil removal of ATS2015 when dried onto a stainless-steel surface.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	• Store vials with dry test soil at room temperature. • Store vials reconstituted at 2°C- 5°C for up to 2 weeks. Keep away from light and heat.
Packaging Conditions	
Shelf Life	18 months: See imprint.

Instructions for Using Product	
Description of Use (s)	The reconstituted ATS2015 has excellent adhesive characteristics for flexible endoscope applications such as cleaning validation or harvesting validation studies.
Preparation for Use	
Diagrams (drawings, pictures)	
Steps for Use of Product	A. **Reconstitute the dry powder and homogenize as follows:** ATS2015 1mL: add 0.8 mL sterile water and vortex/shake for ~5 minutes ATS2015 9 mL: add 7.2 mL sterile water and vortex/shake for ~10 minutes ATS2015 100 mL: add 80 mL sterile water and vortex/shake for ~10 minutes ATS2015 250 mL: add 200 mL sterile water and vortex/shake for ~10 minutes ATS2015 500 mL: add 400 mL sterile water and vortex/shake for ~10 minutes After complete mixing, let the foam settle for ~20 minutes. B. **Add sterile defibrinated sheep blood as follows:** ATS2015 1 mL: add 0.2 mL and mix gently ATS2015 9 mL: add 1.8 mL and mix gently ATS2015 100 mL: add 20 mL and mix gently ATS2015 250 mL: add 50 mL and mix gently ATS2015 500 mL: add 100 mL and mix gently

	Inoculation of Medical Device: Contaminate the medical device in a manner that reflects soiling during clinical use. For inoculation with test soil- in addition to immersing devices in the test soil, specific volumes of test soil can be spread/pipetted onto a defined surface area of the test device or the test soil can be aspirated or flushed through lumens. The soil can also be applied to the device using soiled gloves, or by painting the soil on the device. Note: In case of microbiological test, add the microbe-suspension after dissolving of the dry powder. To avoid dilution of the test soil, subtract the volume of the microbial suspension from the amount of sterile water to be added to rehydrate the dry powder.
Interpretation of Results	**A. Negative device control:** sample collected from a defined surface area (e.g. channel or surface area) on a test device that has not been soiled with ATS2015. Determine ug/cm^2 for marker of interest. **B. Positive device control:** sample collected from a defined surface area (e.g. channel or surface area) on a test device that has been soiled with ATS2015 and allowed to dry for a defined length of time (e.g. 1 to 2 Hours or overnight). Determine ug/cm^2 for marker of interest. **C. Test Device:** sample collected from a defined surface area (e.g. channel or surface area) on a test device that has been soiled with ATS2015, allowed to dry for a defined length of time and then cleaned by a defined method. Determine ug/cm^2 for marker of interest. ***Cleaning can be defined as:*** 1. Residual level of marker post-cleaning (ug/cm^2) = C – A 2. % removal of marker = ((B – A) – (C – A)) x 100/(B-A) Note: An adequate number of replicates (e.g. at least three) should be used to evaluate cleaning efficacy. **For details of cleaning validation of medical device see the FDA and AAMI Guidance documents.[1,2,3]**
Contraindications of Test Results	
Documentation	

Special Warnings and Cautions	• Hazard Information
	  o May be harmful if ingested or inhaled
	  o May cause skin irritation
	  o May cause eye irritation
	  o May be irritant to mucous membranes and upper respiratory tract
	• First Aid Measures
	  o After inhalation: Fresh air.
	  o After skin contact: Wash off with plenty of water. Remove contaminated clothing.
	  o After eye contact: Rinse with plenty of water with the eyelid held wide open. Call an Ophthalmologist.
	  o After swallowing: Make victim drink plenty of water. Call a physician.
	• Accidental release measures
	  o After spillage. Dilute spilled substance with plenty of water and absorb with absorbent material.

Disposal	Dispose of in accordance with regional and/or national regulations.

Related Healthmark Products	
Other Product Support Documents	
Reference Documents	1. ASTM F3208 – 18, Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices. 2. FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff. March 17, 2015. U.S. Department of Health and Human Services, Food and Drug Administration Publishers, Silver Spring, MD.

	3. AAMI TIR12, Designing, testing and labeling reusable medical devices for reprocessing in health care settings: A guide for medical device manufacturers. AAMI TIR12 Technical Information Report 2010. Association for the Advancement of Medical Instrumentation (AAMI) Publishers. 4. AAMI TIR30. A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices. AAMI TIR30 Technical Information Report 2011. Association for the Advancement of Medical Instrumentation (AAMI) Publishers.
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