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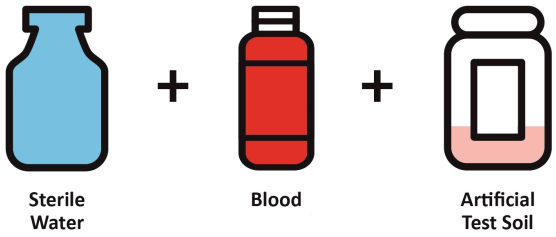
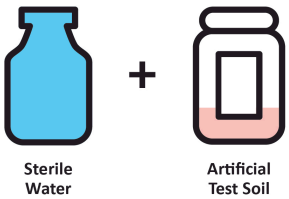
Instructions for Use: Artificial Test Soil 2015 (ATS2105)

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 and ATS2015-500ML-2.
Purpose of Product	Standardized test soil with protein, hemoglobin, carbohydrates, cellulose, lipids and mucin, for simulated use testing.
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. The reconstituted ATS2015 test soil contains the following markers: protein, hemoglobin, carbohydrate, mucin, lipids, and cellulose. Bone particulates can be added if requested.
Key Specifications of Product	• 1X vial with dry test soil components. • Dry mixture includes purified bovine proteins (hemoglobin, albumin), physiological salt, xanthan gum, egg yolk, cellulose and mucin. • Depending on the application, 20% defibrinated sheep blood is added after the dry mixture is reconstituted with sterile water.

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	• Store vials with dry test soil at room temperature. • Store reconstituted vials at 2 °C- 5 °C for up to 2 weeks. Keep away from light and heat.
Packaging Contents	N/A
Shelf Life	12 months: See imprint.

Instructions for Using Product	
Description of Use (s)	The reconstituted ATS2015 is a standardized test soil used for simulated use testing in cleaning validations.
Preparation for Use	N/A
Diagrams (drawings, pictures)	**ATS2015 with Defibrinated Sheep Blood**  **ATS2015 with No Defibrinated Sheep Blood** 
Steps for Use of Product	**ATS2015 with Defibrinated Sheep Blood-** For devices that are intended to primarily come in contact with blood. 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 **ATS2015 with No Defibrinated Sheep Blood-** For devices that are not intended to primarily come in contact with blood. A. **Reconstitute the dry powder and homogenize as follows:** ATS2015 1 mL: add 1 mL sterile water and vortex/shake for ~5 minutes ATS2015 9 mL: add 9 mL sterile water and vortex/shake for ~10 minutes ATS2015 100 mL: add 100 mL sterile water and vortex/shake for ~10 minutes. ATS2015 250 mL: add 250 mL sterile water and vortex/shake for ~10 minutes ATS2015 500 mL: add 500 mL sterile water and vortex/shake for ~10 minutes After complete mixing, let the foam settle for ~20 minutes. **Inoculation of Medical Device:** Contaminate the medical device in a manner that reflects soiling during clinical use. This can be done a variety of methods like immersing devices in the test soil, pipetting/ spreading specific volumes of test soil onto a defined surface area of the test device, aspirating or flushing test soil through lumens, applying to the device by 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 on a test device that has not been soiled with ATS2015. Determine ug/cm^2 for the analyte of interest. **B. Positive device control:** sample collected from a defined 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 the analyte of interest. **C. Test Device:** sample collected from a defined 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 the analyte of interest. ***Cleaning can be defined as:*** 1. Residual level of analyte post-cleaning (ug/cm^2) = C – A 2. % removal of analyte = ((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	N/A
Documentation	N/A
Special Warnings and Cautions	• Hazard Information o May be harmful if ingested or inhaled o May cause skin irritation o May cause eye irritation

	○ May be irritant to mucous membranes and upper respiratory tract • First Aid Measures ○ After inhalation: Fresh air. ○ After skin contact: Wash off with plenty of water. Remove contaminated clothing. ○ After eye contact: Rinse with plenty of water with the eyelid held wide open. Call an Ophthalmologist. ○ After swallowing: Make victim drink plenty of water. Call a physician. • Accidental release measures ○ 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	N/A
Other Product Support Documents	N/A
Reference Documents	1. 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. 2. 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. 3. 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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