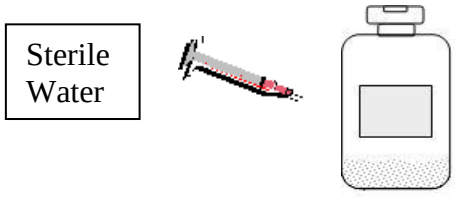
healthmark
INDUSTRIES CO.
health care products
800-521-6224
www.hmark.com

Instructions for Use: Artificial Test Soil with Bone

Brand Name of Product	Artificial Test Soil 2015 with Bone (ATS2015- Bone)
Generic Name of Product	Artificial Test Soil 2015 Bone (ATS2015- Bone)
Product Code Number(s)	ATS2015-B-9ML, ATS2015-B-100ML and ATS2015-B-500ML
Purpose of Product	Hemoglobin, protein, carbohydrate and bone based standardized test soil in proportion found on clinically used medical devices.
Range of Applications for Product	ATS2015-Bone has been formulated for simulated use soiling of medical devices that come in contact with bone for the purpose of conducting cleaning validations. The reconstituted ATS2015 test soil contains the following markers: protein, hemoglobin, carbohydrate, lipids, insoluble fibers, and bone.
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, cellulose and bone particulates. • 20% defibrinated sheep blood is added after the dry mixture is reconstituted.

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 Contents	
Shelf Life	18 months: See imprint.

Instructions for Using Product	
Description of Use (s)	The reconstituted ATS2015-B is used in cleaning validation studies for medical devices coming in contact with bone.
Preparation for Use	
Diagrams (drawings, pictures)	
Steps for Use of Product	***1)To prepare ATS2015-Bone with 20% Sheep's Blood, complete steps A and B:*** A. **Reconstitute the dry powder as follows:** ATS2015 *a.* ATS2015-B-9 mL: add 7.2 mL sterile water and shake for 10 minutes *b.* ATS2015-B-100 mL: add 80 mL sterile water and shake for 10 minutes ATS2015-B-500 mL: add 400 mL sterile water and shake for 10 minutes c. After shaking, let the foam settle for ~20 minutes. B. **Add sterile defibrinated sheep blood as follows:** ATS2015-B-9 mL: add 1.8 mL and mix gently ATS2015-B-100 mL: add 20 mL and mix gently ATS2015-B-500 mL: add 100 mL and mix gently

	2)To prepare ATS2015 with water alone, complete the following steps: Reconstitute the dry powder as follows: ATS2015-B-9ML: add 9ML sterile water and shake for 10 minutes ATS2015-B-100ML: add 100ML sterile water and shake for 10 minutes ATS2015-B-500ML: add 500ML sterile water and shake for 10 minutes **Inoculation of Medical Device:** Contaminate the medical device in a manner that reflects soiling during clinical use. ATS2015-B can be pipetted. So, 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 – D 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. 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.
Customer Service Contact	Healthmark Industries Company, Inc 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2018-03-09