




**Instructions for Use: ATS Test Soil**

<b>Brand Name of Product</b>	Artificial Test Soil (ATS)
<b>Generic Name of Product</b>	Artificial Test Soil (ATS)
<b>Product Code Number(s)</b>	ATS-1ml, ATS-9ml and ATS-100ml
<b>Purpose of Product</b>	Hemoglobin, protein and carbohydrate based standardized test soil in proportion found on clinically used medical devices.
<b>Range of Applications for Product</b>	For simulated use soiling of medical devices for the purpose of conducting cleaning validations and cleaning verifications.
<b>Key specifications of product</b>	<ul style="list-style-type: none"> <li>• 1X Vial with dry test soil component.</li> <li>• Mixture of purified bovine proteins (hemoglobin, albumin), amino acids, vitamins and carbohydrates.</li> </ul>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	<ul style="list-style-type: none"> <li>• Store vials with dry test soil at room temperature.</li> <li>• Store vials reconstituted with water at 2°C- 5°C for up to 2 weeks. Keep away from light and heat.</li> </ul>
<b>Packaging Conditions</b>	
<b>Shelf Life</b>	18 months: See imprint.

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	
<b>Preparation for Use</b>	
<b>Diagrams (drawings, pictures):</b>	
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Add 1ml sterile water (room temperature) for 1ml size vial, 9ml of sterile water for 9ml size vial or 100ml of sterile water for 100ml size vial of the ATS component.</li> <li>2. Dissolve the components by shaking it: ~5 minutes for a 1ml vial; ~10 minutes for 9ml and 100ml vials. Let the foam settle for another ~20 minutes.</li> <li>3. After mixing, the solution can be stored for 2 weeks in a fridge at 0°C – 5°C.</li> <li>4. Contaminate the medical device in a manner which reflects real-life soiling from use.</li> </ol> <p>Note: In case of microbiological test, add the microbe-suspension after dissolving of the component. To avoid dilution of the test soil, subtract the amount of suspension from the solvent.</p>
<b>Interpretation of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation</b>	
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• Hazard Information <ul style="list-style-type: none"> <li>○ May be harmful if ingested or inhaled</li> <li>○ May cause skin irritation</li> <li>○ May cause eye irritation</li> <li>○ May be irritant to mucous membranes and upper respiratory tract</li> </ul> </li> <li>• First Aid Measures <ul style="list-style-type: none"> <li>○ After inhalation: Fresh air.</li> <li>○ After skin contact: Wash off with plenty of water. Remove contaminated clothing.</li> <li>○ After eye contact: Rinse with plenty of water with the eyelid held wide open. Call an Ophthalmologist.</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ After swallowing: Make victim drink plenty of water. Call a physician.</li> <li>● Accidental release measures <ul style="list-style-type: none"> <li>○ After spillage. Dilute spilled substance with plenty of water and absorb with absorbent material.</li> </ul> </li> </ul>
<b>Disposal</b>	Dispose of in accordance with regional and/or national regulations.

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	
<b>Cleaning – Automated:</b>	
<b>Disinfection:</b>	
<b>Drying:</b>	
<b>Maintenance, inspection, and testing:</b>	
<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	
<b>Storage:</b>	
<b>Additional Information:</b>	

<b>Related Healthmark Products</b>	
<b>Other Product Support Documents</b>	
<b>Reference Documents</b>	
<b>Customer Service contact:</b>	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com

2012-10-08 msmith