



**Instructions for Use: Blood Test Soil (BTS)**

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| <b>Brand Name of Product</b>             | Blood Test Soil (BTS)                                      |
| <b>Generic Name of Product</b>           | Blood Test Soil (BTS)                                      |
| <b>Product Code Number(s)</b>            | BTS-7ML, BTS-100ML, BTS-500ML                              |
| <b>Purpose of Product</b>                | Blood proteins based standardized test soil.               |
| <b>Range of Applications for Product</b> | Simulated use test soil for cleaning validations.          |
| <b>Key Specifications of Product</b>     | Mixture of purified bovine proteins (hemoglobin, albumin). |

| <b>Shipping &amp; Storage</b>                 |   |
|---|---|
| <b>Shipping Conditions &amp; Requirements</b> | N/A   |
| <b>Storage Conditions</b>                     | Store vials with dry test soil at room temperature. |
| <b>Packaging Contents</b>                     | Blood Test Soil vial(s), Solution A                 |
| <b>Shelf Life</b>                             | Twelve (12) months                                  |

| <b>Instructions for Using Product</b>    |   |               |                      |      |      |        |       |        |        |
|--|---|---------------|----------------------|------|------|--------|-------|--------|--------|
| <b>Description of Use (s)</b>            | N/A   |               |                      |      |      |        |       |        |        |
| <b>Preparation for Use</b>               | N/A   |               |                      |      |      |        |       |        |        |
| <b>Diagrams (drawings, pictures)</b>     | N/A   |               |                      |      |      |        |       |        |        |
| <b>Steps for Use of Product</b>          | <p>1. For the BTS component, add room temperature sterile water based on vial size. (NOTE: Less water may be used to obtain a thicker soil, but more time may be needed to dissolve the soil. *Sterile water is not provided.)</p> <table border="1" data-bbox="808 949 1260 1108"> <thead> <tr> <th>BTS Vial Size</th> <th>Sterile Water Volume</th> </tr> </thead> <tbody> <tr> <td>7 mL</td> <td>6 mL</td> </tr> <tr> <td>100 mL</td> <td>90 mL</td> </tr> <tr> <td>500 mL</td> <td>450 mL</td> </tr> </tbody> </table> <p>2. Add the provided Solution A to the hydrated soil.</p> <p>3. Dissolve the components by shaking it for 5 minutes.</p> <ol style="list-style-type: none"> <li>A laboratory vortex mixer may be used.</li> <li>Use within 15 minutes of rehydrating.</li> </ol> <p>4. Contaminate the item in a manner which reflects real-life soiling from use.</p> <p>(NOTE: In case of microbiological testing, add the microbe-suspension after hydrating and shaking the soil. To avoid dilution of the test soil, subtract the amount of suspension from the solvent.)</p> | BTS Vial Size | Sterile Water Volume | 7 mL | 6 mL | 100 mL | 90 mL | 500 mL | 450 mL |
| BTS Vial Size                            | Sterile Water Volume  |               |                      |      |      |        |       |        |        |
| 7 mL                                     | 6 mL  |               |                      |      |      |        |       |        |        |
| 100 mL                                   | 90 mL   |               |                      |      |      |        |       |        |        |
| 500 mL                                   | 450 mL  |               |                      |      |      |        |       |        |        |
| <b>Interpretation of Results</b>         | N/A   |               |                      |      |      |        |       |        |        |
| <b>Contraindications of Test Results</b> | N/A   |               |                      |      |      |        |       |        |        |
| <b>Documentation</b>                     | N/A   |               |                      |      |      |        |       |        |        |
| <b>Special Warnings and Cautions</b>     | <ul style="list-style-type: none"> <li>• <b>⚠ Hazardous Information</b> <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>• <b>⚠🚑 First Aid Measures</b> <ul style="list-style-type: none"> <li>○ After inhalation: exposure to 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> <li>○ After swallowing: have the victim drink plenty of water and call a physician.</li> </ul> </li> <li>• <b>⚠ Accidental Release Measures</b> <ul style="list-style-type: none"> <li>○ After spillage: dilute spilled substance with plenty of water.</li> </ul> </li> </ul>  |               |                      |      |      |        |       |        |        |

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|-----------------|--|
|                 | <ul style="list-style-type: none"> <li>○ Absorb diluted spillage: use an absorbent material (e.g., provide an example) to clean up the diluted substance.</li> </ul> |
| <b>Disposal</b> | Dispose of in accordance with regional and/or national regulations.  |

| <b>Reprocessing Instructions</b>            |     |
|---|-----|
| <b>Point of Use</b>                         | N/A |
| <b>Preparation for Decontamination</b>      | N/A |
| <b>Disassembly Instructions</b>             | N/A |
| <b>Cleaning – Manual</b>                    | N/A |
| <b>Cleaning – Automated</b>                 | N/A |
| <b>Disinfection</b>                         | N/A |
| <b>Drying</b>                               | N/A |
| <b>Maintenance, inspection, and testing</b> | N/A |
| <b>Reassembly Instructions</b>              | N/A |
| <b>Packaging</b>                            | N/A |
| <b>Sterilization</b>                        | N/A |
| <b>Storage</b>                              | N/A |
| <b>Additional Information</b>               | N/A |

|  |   |
|--|---|
| <b>Related Healthmark Products</b>     | N/A   |
| <b>Other Product Support Documents</b> | N/A   |
| <b>Reference Documents</b>             | ASTM F3208 – 20, Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.  |
| <b>Customer Service Contact</b>        | Healthmark Industries Company, Inc.<br>18600 Malyn Blvd.<br>Fraser, MI 48026<br>1-586-774-7600<br><a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a><br>hmark.com |