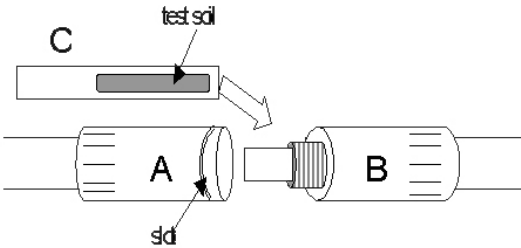




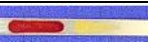


|                                          |                                                                                                                                                                                                                                                                          |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Brand Name of Product</b>             | FlexiCheck™                                                                                                                                                                                                                                                              |
| <b>Generic Name of Product</b>           | Coupon soiled with blood proteins and polysaccharides                                                                                                                                                                                                                    |
| <b>Product Code Number(s)</b>            | FLEXCHK-101, FLEXCHEK-102                                                                                                                                                                                                                                                |
| <b>Purpose of Product</b>                | To provide a standardized cleaning challenge                                                                                                                                                                                                                             |
| <b>Range of Applications for Product</b> |                                                                                                                                                                                                                                                                          |
| <b>Key Specifications of Product</b>     | <ul style="list-style-type: none"> <li>• Test coupon with 2 test representative test soils: blood and polysaccharide.</li> <li>• Single channel lumen holder and flexible tube designed as a surrogate. The holder unscrews for placement of the test coupon.</li> </ul> |

| <b>Shipping &amp; Storage</b>                 |                                                                                                                                                                                     |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Shipping Conditions &amp; Requirements</b> |                                                                                                                                                                                     |
| <b>Storage Conditions</b>                     | Store in the protective foil pouch at 2°C - 25°C                                                                                                                                    |
| <b>Packaging Conditions</b>                   | <ul style="list-style-type: none"> <li>• Each coupon is packaged in an individual watertight foil pouch.</li> <li>• 25 tests per box.</li> <li>• Holder sold separately.</li> </ul> |
| <b>Shelf Life</b>                             | 18 months from date of manufacture. Consult package for expiration date.                                                                                                            |

| <b>Instructions for Using Product</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Description of Use(s)</b>          | To challenge the cleaning function with a standardized test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <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. Unscrew the FlexiCheck™ holder.</li> <li>2. Detach part A (marked with slot) from part B</li> <li>3. Open protective pouch of FlexiCheck™ and insert the test coupon (part C) in part B. Do not touch the area covered with the test soil.</li> <li>4. Close FlexiCheck™ holder by screwing part A to part B.</li> <li>5. Connect the holder with one of the channel irrigation systems (luer-lock).</li> <li>6. Start the wash cycle according to the manufacturer's IFU.</li> <li>7. At the end of the cycle, retrieve the holder.</li> <li>8. Open the holder by unscrewing part A from part B and remove the test coupon without touching the soiled areas.</li> <li>9. Visually inspect the coupon for residual soils.</li> </ol> |

|                                          |                                                                                   |                                                                                   |                                                                                                |                                                                                                |                                                                                                 |                                                                                                                        |
|------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Interpretation of Results</b>         |  |  |              |             |              |                                                                                                                        |
|                                          | <b>Result</b>                                                                     | Both test soils completely removed                                                | Polysaccharide soil completely removed, but visible blood fibrin remains                       | Blood test soil completely removed, but visible polysaccharide remains                         | Polysaccharide soil completely removed, but visible blood remains                               | Some or all of both soils remain                                                                                       |
|                                          | <b>Indications</b>                                                                |                                                                                   | Protein hydrolyzing parameters not optimal                                                     | Polysaccharide dissolving parameters not optimal                                               | Water soluble proteins are being denatured by heat and/or disinfection chemicals                | Poor water flow                                                                                                        |
|                                          | <b>Optimization:</b>                                                              |                                                                                   | Insufficient cleaning time, incorrect temperature, poor detergent efficacy or incorrect dosing | Insufficient cleaning time, incorrect temperature, poor detergent efficacy or incorrect dosing | Water temperature is too high or disinfecting agents are being introduced during the wash cycle | Poor connection to the FlexiCheck, an incorrect or failed cleaning program, or major functional failure of the machine |
| <b>Contraindications of Test Results</b> |                                                                                   |                                                                                   |                                                                                                |                                                                                                |                                                                                                 |                                                                                                                        |
| <b>Documentation</b>                     | Record results on <a href="#">log sheet</a> located at hmark.com                  |                                                                                   |                                                                                                |                                                                                                |                                                                                                 |                                                                                                                        |
| <b>Special Warnings and Cautions</b>     |                                                                                   |                                                                                   |                                                                                                |                                                                                                |                                                                                                 |                                                                                                                        |
| <b>Disposal</b>                          | Dispose of in a biohazard container                                               |                                                                                   |                                                                                                |                                                                                                |                                                                                                 |                                                                                                                        |

| <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>     | ChannelCheck™, HangTimeKit™                                                                                                                                                                                  |
| <b>Other Product Support Documents</b> | ProFormance Brochure, ProFormance Price List,                                                                                                                                                                |
| <b>Reference Documents</b>             | FlexiCheck™ Videos, FlexiCheck™ Log Sheet, FlexiCheck™ Sample Policy, FlexiCheck™ Validation Study, Instructions for Ultrasonic & Lumen Tests, Troubleshooting Guide for FlexiCheck™                         |
| <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><a href="http://hmark.com">hmark.com</a> |