

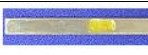






<b>Brand Name of Product</b>	FlexiCheck™
<b>Generic Name of Product</b>	Cleaning challenge device for automated endoscope reprocessors (AER's)
<b>Product Code Number(s)</b>	FLEXCHK-101, FLEXCHEK-102
<b>Purpose of Product</b>	To provide a standardized challenge to cleaning function of AER's.
<b>Range of Applications for Product</b>	For use in AER's with a cleaning cycle
<b>Key specifications of product</b>	<ul style="list-style-type: none"> <li>• Test coupon with 2 test soils representative of soils found in flexible endoscopes: blood and polysaccharide</li> <li>• Single channel lumen holder and flexible tube designed as a surrogate to the internal channel of a flexible endoscope. 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 in an individual water tight foil pouch.</li> <li>• 25 tests per box.</li> <li>• Holder sold separately.</li> </ul>
<b>Shelf Life</b>	18 months from date of manufacturer. Consult package for expiration date.

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	To challenge the cleaning function of AER's with a standardized soil test inside a surrogate device.
<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 by 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 of the AER (luer-lock).</li> <li>6. Start the wash cycle according to the AER manufacturer's IFU.</li> <li>7. At the end of the cycle, retrieve the holder from the AER.</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>	EndoCheck™ for Blood, EndoCheck™ for Protein, 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 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com