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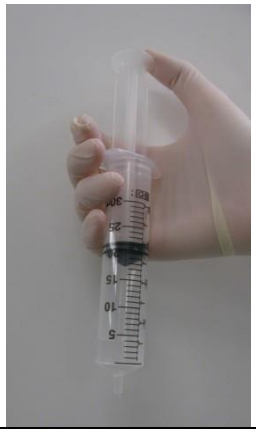
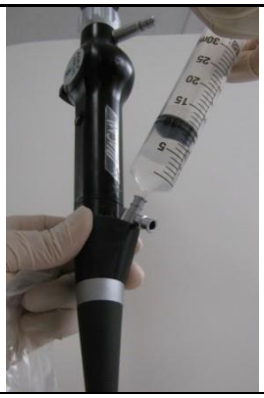
Instructions for Use: HangTimeKit™

Brand Name of Product	HangTimeKit™
Generic Name of Product	Kit for managing and checking safe storage of flexible endoscopes
Product Code Number(s)	HTK-1, HTK-FV1041, FQ360
Intended Use	The HangTime test is to check scopes in storage for Gram-negative bacteria.
Range of Applications for Product	
Key specifications of product	• A new fluorometric diagnostic system that can be used to provide a fast diagnosis of low levels of Gram negative bacteria, in 10 minutes. • The HangTimeKit™ works by detecting an enzyme mechanism typical to the Gram negative bacteria. • The fluorometer reads the fluorescence tagged to the Gram negative bacterial enzymes and gives a reading corresponding to the amount of enzyme detected, which in turn relates directly to the number of Gram negative bacterial cells present. • Two cords plug in for AC power, the second to the USB • 4 AA batteries required (not included)

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	Refrigerate Gram-negative bacteria reagent bottle (approximate 4°C). Ensure that sterile packaging of pipette is maintained.
Packaging Conditions	
Shelf Life	Two years from date manufactured.

Instructions for Using Product	
Description of Use (s)	• The label is for recording and documenting the last date that the flexible endoscope was reprocessed. • The Gram-negative test is to check for bacterial growth while the endoscope was in storage.
Preparation for Use	
DiaGrams (drawings, pictures):	
Steps for Use of Product	FLUSHING WATER THROUGH LUMEN: 1. Pick an endoscope in storage to be tested.  2. Using at least a 20ml syringe, fill with **5ml of** company accessible pre-packaged **sterile water** and 15cc of air.



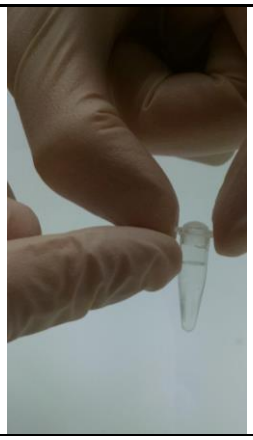
3. Flush the lumen (e.g. the biopsy channel, air and water channels, the elevator channel), with company accessible pre-packaged sterile water followed by the air that is still in the syringe.

4. Recapture water in the provided zip-lock bag.

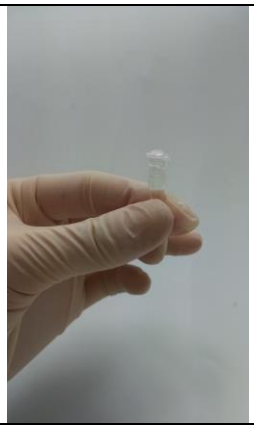
PREPARING THE SAMPLE FOR THE FLUOROMETER**:**

5. Add two drops (50µL) of the supplied reagent into the supplied cuvette.

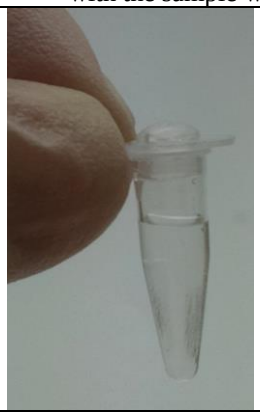
6. With the provided sterile pipette, draw up approx.1 ml of water by squeezing the bulb on top of the pipette.



7. From the pipette, fill the flushed water in the supplied cuvette to approximately ¾ full (just under the cusp of the cuvette, as seen in the picture) with the recaptured water (water sample, approx. 150µL). Close lid of the cuvette.

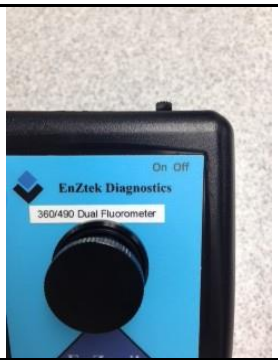


8. Gently roll the bottom of the cuvette (holding it upright) to help mix the reagent with the sample water.



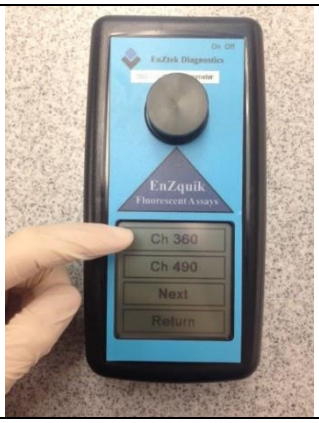
9. Holding test vial upright, shake to remove bubbles from the solution (bubbles will interfere with the reading of the fluorescence and may produce inaccurate test results).

STEP BY STEP INSTRUCTIONS FOR THE FLUOROMETER



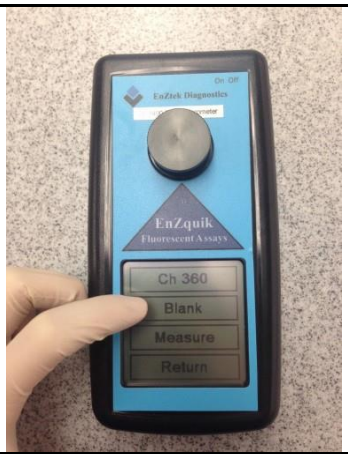
10. Switch the power source of the fluorometer at the upper right corner to **"ON"**.

11. This screen will show up, press the **"MEASURE"** button.

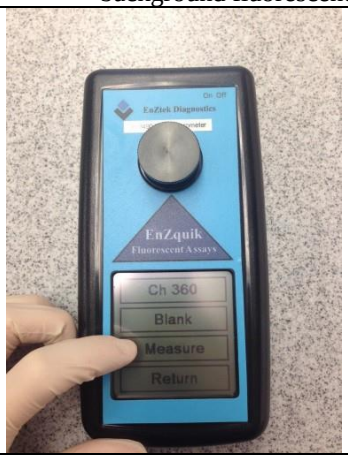


12. Press **"Ch 360"**.

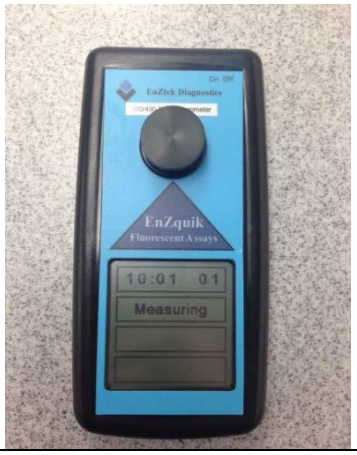
13. Place the cuvette in the fluorometer, line up the pointy side of the cuvette with the black line in the reader, and place the black cap on the fluorometer.



14. Press "**Blank**" (timer will start counting seconds). This function zeros out any background fluorescence.

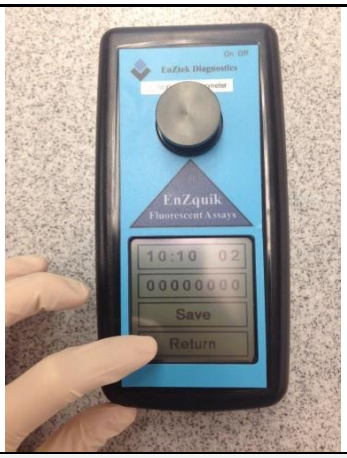


15. Press "**Measure**" and wait **10** minutes to get the reading.



16. At 10 minutes, the fluorometer will automatically take a reading. (A value will be displayed in the box below the timer) **Any numerical value displayed is a positive result. A zero reading is a negative.**

Please Note: The timer on the fluorometer will continue to run, but the reading displayed is taken exactly at the 10 minute mark.

	 If desired to test a new sample, press "**Return**" to begin a new sample. Instructions for negative control A negative control should be run once, every time a new reagent bottle is received. • Add 2 drops of reagent in the cuvette. • Add sterile water up to the fill line. • Mix the reagent and water. • Follow the fluorometer instructions above • Reading should be zero at the end of 10 minutes.
Interpretation of Results	After 10 minutes the fluorometer will automatically take a reading. (A value will be displayed in the box below the timer. The timer will continue to run). Any number above "0" indicates contamination and requires reprocessing.
Contraindications of Test Results	Other contaminants (such as loose debris) in the recaptured water can cause an autofluorescence. This also necessitates a reprocessing of the scope as such debris should not be present in a clean endoscope.
Documentation	Record results (it can be in a log book (sheet) or electronically).
Special Warnings and Cautions	• If there is a negative result, the endoscope needs to be alcohol flushed and air dried according to manufacturer's guidelines before being put back in storage. • Turn off the machine after use.
Disposal	• Dispose of the pipette and zip lock sample bag in an approved biohazard container.

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

Related Healthmark Products	EndoCheck™ for Blood, EndoCheck™ for Protein, ChannelCheck™, FlexiCheck™
Other Product Support Documents	HangTimeKit™ Specification Sheet, HangTimeKit™ Pocket Brochure, HangTimeKit™ Whitepaper, HTK-FV1041 Gram Negative Test Specification Sheet,
Reference Documents	
Customer Service contact:	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600

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2017-08-02 Ralph J Basile