




Instructions for Use: NOW! Test

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| Brand Name of Product | NOW! Test |
| Generic Name of Product | Rapid Gram-negative bacteria test |
| Product Code Number(s) | NOW-1000SK, NOW-1000 |
| Intended Use | The NOW! Test is to check flexible endoscopes for Gram-negative bacteria after reprocessing. |
| Range of Applications for Product | |
| Key Specifications of Product | <ul style="list-style-type: none"> • A fluorometric diagnostic system that can be used to provide a fast diagnosis (~12 hours) of low levels of Gram negative bacteria (<10 CFU). • The NOW! Test works by detecting an enzyme mechanism typical to Gram negative bacteria. |

| Shipping & Storage | |
|---|---|
| Shipping Conditions & Requirements | |
| Storage Conditions | <ul style="list-style-type: none"> • Once received, the Reagent bottle needs to be stored in the refrigerator at (2 - 8°C) and retrieved from the refrigerator for use. • The reagent does not need to be refrigerated when shipped. • Rest of the kit should be stored at room temperature. |
| Packaging Conditions | |
| Shelf Life | One year from date manufactured. |

| Instructions for Using Product | | | | |
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| Description of Use (s) | The NOW! Test is to check for Gram-negative bacteria growth. | | | |
| Preparation for Use | <ul style="list-style-type: none"> • Run a negative control when you open the NOW! Test box. • Set the temperature on the incubator to 37°C <ol style="list-style-type: none"> 1. With the incubator powered on, simultaneously press and hold the two small buttons on the rear of the incubator (see Figure 1) for ~2 seconds until the currently selected temperature set point blinks on the LED display. 2. Release the buttons, then press either button repeatedly to toggle between the available temperature set points (37°C, 57°C, or 60°C). 3. When the 37°C set point is blinking on the display, press and holds both buttons for ~2 seconds. 4. The configured set point will fade in and out on the LED screen until the incubator has reached temperature, after which the actual temperature of the incubator will be displayed. | | | |
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| | Fig. 1 | | | |
| Diagrams (drawings, pictures) | | | | |
| Steps for Use of Product | <table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: center;">FLUSHING WATER THROUGH LUMEN:</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1. Pick an endoscope that has been reprocessed for testing.</td> </tr> <tr> <td style="text-align: center;">2. Place supplied zip-lock bag at the distal tip of the endoscope and partially seal bag so that it stays in place.</td> </tr> </tbody> </table> | FLUSHING WATER THROUGH LUMEN: | 1. Pick an endoscope that has been reprocessed for testing. | 2. Place supplied zip-lock bag at the distal tip of the endoscope and partially seal bag so that it stays in place. |
| FLUSHING WATER THROUGH LUMEN: | | | | |
| 1. Pick an endoscope that has been reprocessed for testing. | | | | |
| 2. Place supplied zip-lock bag at the distal tip of the endoscope and partially seal bag so that it stays in place. | | | | |



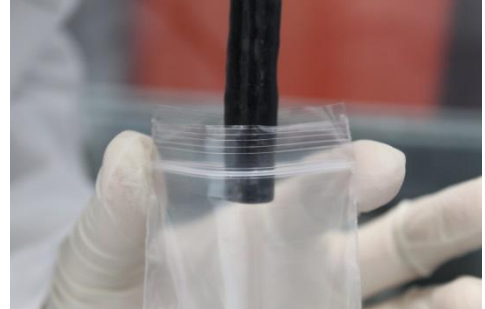
3. Flush the lumen with 5 mL of sterile water using the provided blue vial of water. (i.e., the biopsy channel).



4. Draw up 30 mL of air in a sterile syringe.
5. Purge the lumen with 30 mL of air.



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

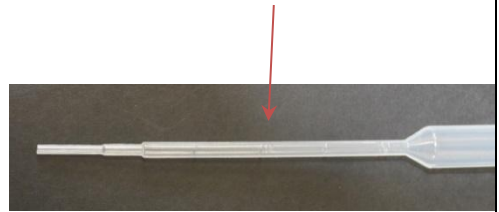


Follow the endoscope manufacturer's IFU for drying procedures of the flexible endoscope.

PREPARING THE SAMPLE FOR THE INCUBATOR:

7. Draw up 0.5 mL of water.

Hint: Push pipette ball, then submerge into solution. Slowly release ball until you reach .5 ml. Then draw pipette from solution.



7. Add the 0.5 mL of water to the provided sterile cuvette with the growth medium. Mix by shaking gently.



8. Place vials in the block incubator and allow 12 or more hours of incubation. The incubator should be set to 37°C.



9. After incubation, the cuvette needs to be allowed to cool down. One of two methods can be employed:

- Room temperature: remove the cuvette and place in the supplied holder and allow cooling for a minimum of 1 hour, but not greater than 3 hours. Continue on to step 11.



- Refrigerator: remove the cuvette and place in the supplied holder. Place in a refrigerator (approximate temperature of 4°C) for 15

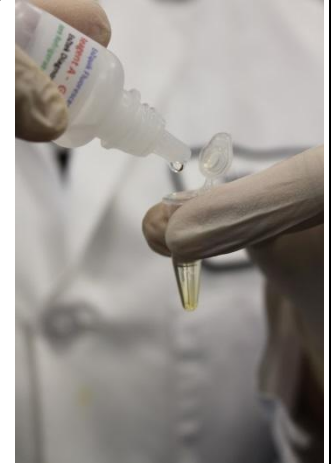
minutes. Remove from refrigerator at 15 minutes and continue on to step 11. If testing multiple samples, refrigerate only one sample per fluorometer.



10. Before adding Reagent A, switch the power source of the fluorometer at the upper right corner to "ON".



11. Add 2 drops of Reagent A to the cuvette.



12. Gently invert it four times to help mix the reagent with the sample.



13. Immediately proceed to the next steps for testing.

14. Place the cuvette in the fluorometer, the hinge of the cuvette should be pointing to the right and place the black cap firmly on the fluorometer.



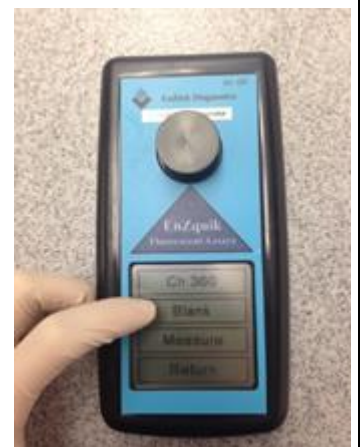
15. This screen will show up, press the “Measure”.



16. Press “CH 360”.



17. Press “Blank” (timer will start counting seconds).



18. Press “**Measure**” and wait **10** minutes to get the reading.



19. At 10 minutes, the fluorometer will automatically take a reading. (A value will be displayed in the box below the timer). The value displayed before 10 minutes is disregarded.



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**” twice to begin a new sample.



Interpretation of Results

1. A numerical value between 200 – 300 likely indicates the presence of Gram negative bacteria (but could be due to insufficient cooling of cuvette). Reprocess the endoscope and retest, insuring that sufficient time for cooling has occurred, according to the IFU.
2. A numerical value greater than 300 strongly indicates the presence of Gram negative bacteria. Further steps, including reprocessing and investigation of reprocessing procedures (perhaps involving Risk Management, Infection Control, etc.) should be undertaken. One of these steps may be culturing of the endoscope for bacteria contamination and species identification.

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| Contraindications of Test Results | Other contaminants (such as loose debris) in the recaptured water can cause auto fluorescence. This also necessitates a reprocessing of the scope as such debris should not be present in a clean endoscope. |
| Documentation | Record results |
| Special Warnings and Cautions | <ul style="list-style-type: none"> Follow the endoscope manufacturer's IFU for drying procedures of the flexible endoscope. A negative test result does not insure the endoscope is free from contamination. It indicates that Gram negative bacteria is not present or is at levels below what the test can detect. Other contaminants, including Gram positive bacteria, and organic soil can remain. Take other measures, including cleaning verification tests, to further verify a quality reprocessing process. If there is a positive test result, further steps should be taken in accordance with facility guidelines, including reprocessing, further investigation (including culturing for microbial contamination), etc. Turn off the machine after use. Always use proper plugs that are meant for that particular device. Switching incubator and fluorometer plugs can cause a fire. |
| Disposal | <ul style="list-style-type: none"> Dispose of the pipette and zip lock sample bag in a 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 | |

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| Related Healthmark Products | EndoCheck™ for Blood, EndoCheck™ for Protein, ChannelCheck™, FlexiCheck™ |
| Other Product Support Documents | ProFormance™ Brochure, ProFormance™ Price List |
| Reference Documents | |
| Customer Service Contact | Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com |