




Instructions for Use: NOW! Test™

<b>Brand Name of Product</b>	NOW! Test™
<b>Generic Name of Product</b>	Rapid gram-negative bacteria test
<b>Product Code Number(s)</b>	NOW-1000SK, NOW-1000
<b>Intended Use</b>	The NOW! Test™ is a surveillance test used to detect viable gram-negative bacteria at or above 10 CFU.
<b>Range of Applications for Product</b>	N/A
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>● A fluorometric diagnostic system used to provide fast diagnosis (≈ 12 hours) of low levels of gram-negative bacteria (greater than equal to <math>\geq</math> 10 CFU).</li> <li>● The NOW! Test™ works by detecting an enzyme mechanism typical to gram-negative bacteria.</li> <li>● Reagent bottle</li> <li>● 50 Cuvettes with growth medium</li> <li>● 50 Prepackaged Water vials (5 ml)</li> <li>● 50 Pipettes</li> <li>● 50 2- x 3 inches zipper bags</li> <li>● Incubator</li> <li>● Cardboard Cuvette holder</li> </ul>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	<ul style="list-style-type: none"> <li>● Upon receipt refrigerate and store the Reagent bottle at ≈ four (4) °C (39.2 °F). Retrieve it from the refrigerator for use.</li> <li>● Reagent does not need to be refrigerated when shipped.</li> <li>● Remainder of the NOW! Test™ kit must be stored at room temperature.</li> </ul>
<b>Packaging Contents</b>	N/A
<b>Shelf Life</b>	One-year from date manufactured.

<b>Instructions for Using Product</b>	
<b>Description of Use(s)</b>	The NOW! Test™ checks for viable gram-negative bacteria.
<b>Preparation for Use</b>	<ul style="list-style-type: none"> <li>● Run a gram-negative control when you open the NOW! Test™ box.</li> <li>● Set the temperature on the incubator to 37 °C.               <ol style="list-style-type: none"> <li>1. Power on the incubator.</li> <li>2. Simultaneously press and hold the two small buttons on the incubator's rear (<b>Fig. 1</b>) for ≈ two (2) seconds until the temperature set point blinks on the LED display.</li> <li>3. Release the buttons, then press either button repeatedly to toggle between the three available temperature set points:                   <ol style="list-style-type: none"> <li>a. 37 °C (98.6 °F)</li> <li>b. 57 °C (134.6 °F)</li> <li>c. 60 °C (140 °F).</li> </ol> </li> <li>4. When 37 °C is blinking on the LED display, press and hold both buttons for ≈ 2 seconds to confirm setting.</li> <li>5. The configured set point will fade in and out on the LED screen until the incubator has reached the selected temperature of 37 °C.</li> </ol> </li> </ul>
	
	Figure 1

**Diagrams (drawings, pictures)**

**Steps for Use of Product**

**FLUSHING WATER THROUGH LUMEN:**

1. Pick the reprocessed item to be tested.
2. Don clean gloves.
3. Place supplied zipper bag at the distal end of the item and partially seal the bag to stay in place.



Figure 2

4. Flush the lumen with the blue vial of water.



Figure 3

5. Draw up 30 cc of air in a syringe.
6. Purge the lumen with 30 cc of air.



Figure 4

7. Recapture the sample water in the provided zipper bag.

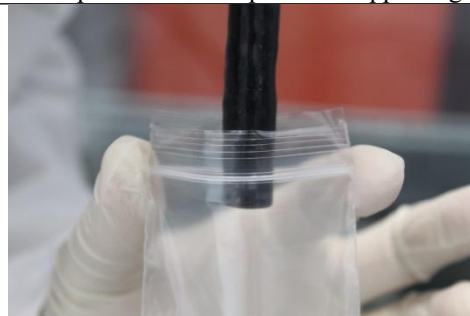


Figure 5

*Note: Follow the item Mfr.'s IFU for drying procedures.*

**PREPARING THE SAMPLE FOR THE INCUBATOR:**

8. Draw up 0.5 ml of sample/extract water.



Figure 6

Hint: Push pipette ball, then submerge into solution. Slowly release ball until you reach 0.5 ml, then draw pipette from solution.

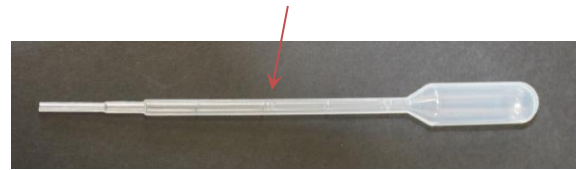


Figure 7

9. Add the 0.5 ml of sample/extract water to the provided cuvette with growth medium. Mix by shaking gently.



Figure 8

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



Figure 9

11. After incubation, the cuvette needs to cool. Employ one of these methods:
- Room temperature:* Remove the cuvette and place in the supplied holder and allow cooling for a minimum of one (1)-hour but not greater than three (3) hours. Continue to step 11.



Figure 10

- b. *Refrigerator*: Remove the cuvette and place it in the supplied holder.
  - i. Place in a refrigerator (approximate temperature of four [4] °C) for 15 minutes.
  - ii. Remove from refrigerator exactly at 15 minutes and continue to step 12.



Figure 11

12. Before adding Reagent A, switch “ON” the fluorometer's power source at the upper right corner.



Figure 12

13. Add two (2) drops of Reagent A to the cuvette.



Figure 13

14. Gently invert the cuvette four (4) times to help mix the reagent with the sample.



Figure 14

Immediately proceed to the next steps for testing.

#### INSTRUCTIONS FOR THE FLUOROMETER

15. a) Place the cuvette in the fluorometer, b) line up the pointy side of the cuvette with the black line in the reader, and c) place the black cap on the fluorometer.

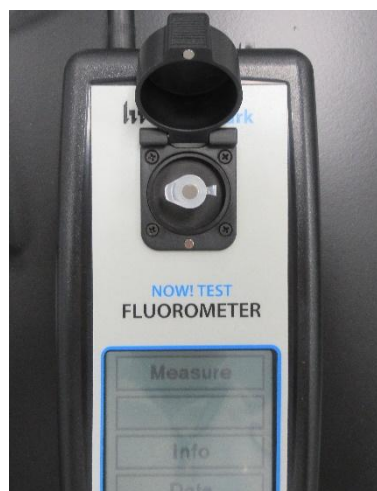


Figure 15

16. This screen (**Fig. 16**) will show up. Press the *Measure* (**Fig. 17**).

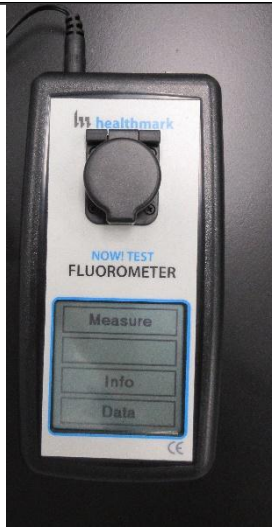


Figure 16



Figure 17

17. Press **Blank** (Fig. 18). Timer will start counting seconds.



Figure 18

18. Press **Measure** (Fig. 19) and wait 10 minutes to get the reading.



Figure 19

19. At 10-minute mark, the fluorometer will automatically take a reading—value displayed in the second field box below the timer. (Note: Disregard the value displayed before 10 minutes.)

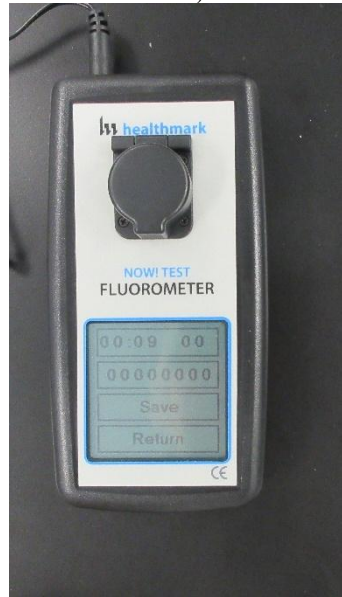


Figure 20

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



Figure 21

If desired to test a new sample, press **Return** (twice).

**Interpretation of Results**

1. A numerical value between 200 and 300 likely indicates the presence of gram-negative bacteria; though, could be due to insufficient cooling of cuvette. Reprocess the item and retest ensuring sufficient time for cooling has occurred, according to this 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 item for bacteria contamination and species identification.

**Contraindications of Test Results**

Other contaminants (i.e., loose debris) in the recaptured water can cause auto-fluorescence. This also necessitates a reprocessing of the item, as such debris should not be present in a clean lumen.

**Documentation**

Record results.

<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• Check the item Mfr.'s IFU for any drying procedures.</li> <li>• A negative test result does not ensure the item is free from contamination. It indicates gram-negative bacteria is not present or is at levels below what the test can detect. Other contaminants (e.g., gram-positive bacteria and organic soil) can remain. Take other measures, including cleaning verification tests, to further verify a quality process.</li> <li>• If there is a positive test result, further steps should be taken in accordance with facility guidelines, including: <ul style="list-style-type: none"> <li>○ Reprocessing</li> <li>○ Investigation (including culturing for microbial contamination)</li> <li>○ Etc.</li> </ul> </li> <li>• Turn off the fluorometer after use.</li> <li>• Always use the proper plugs meant for the respective piece of testing equipment.</li> <li>• <b><i>⚠ Caution: Switching incubator and fluorometer plugs can cause a fire.</i></b></li> </ul>
<b>Disposal</b>	Dispose of the pipette and zipper bag sample in a biohazard container.

<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>	ProFormance™ Brochure, ProFormance™ Price List
<b>Reference Documents</b>	N/A
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com