



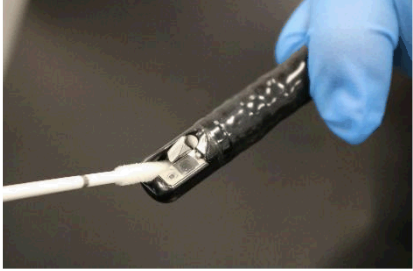

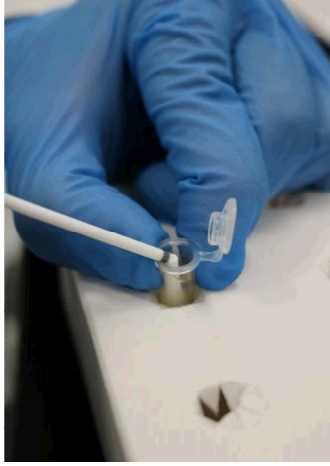
|  |  |
|--|--|
| <b>Brand Name of Product</b>             | NOW-1100   |
| <b>Generic Name of Product</b>           | Rapid Gram-negative Swab Test  |
| <b>Product Code Number(s)</b>            | NOW-1100, NOW-1100SK   |
| <b>Intended Use</b>                      | The NOW! Swab Test™ is to test for viable Gram-negative bacteria at or above 10 CFU.   |
| <b>Range of Applications for Product</b> | Sampling for Gram-negative bacteria using a swab.  |
| <b>Key Specifications of Product</b>     | <ul style="list-style-type: none"> <li>• A fluorometric diagnostic system that can be used to provide a fast diagnosis (≈12 hours) of low levels of Gram-negative bacteria (&gt;10 CFU).</li> <li>• The NOW! Swab Test™ works by detecting an enzyme mechanism typical to Gram-negative bacteria.</li> <li>• Reagent A bottle</li> <li>• 50 Swabs- 30 mm breakpoint from swab tip</li> <li>• 50 Cuvettes with growth medium</li> <li>• 50 Pre-packaged Water vials (five [5] mL)</li> <li>• 50 Pipettes</li> <li>• 50 Tweezers</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>• The reagent does not need to be refrigerated when shipped.</li> <li>• Once received, refrigerate the reagent bottle approximately 4 °C.</li> <li>• The reagent needs to be cold when it is being used and thus should be refrigerated before use.</li> <li>• The rest of the kit should be stored at room temperature.</li> </ul> |
| <b>Packaging Conditions</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! Swab Test™ is to check for Gram-negative bacteria growth using the swabbing method.  |
| <b>Preparation for Use</b>            | <ul style="list-style-type: none"> <li>• Run a negative control when you open the NOW! Swab Test™ box. (See <b>NOW! Swab Test™ Negative Control Protocol</b>).</li> <li>• Set the temperature on the incubator to 37 °C.               <ol style="list-style-type: none"> <li>1. With the incubator powered on, simultaneously press, and hold the two small buttons on the rear of the incubator (<b>Fig. 1</b>) for ≈ two (2) seconds until the currently selected temperature set point blinks on the LED display.</li> <li>2. Release the buttons, then press either button repeatedly to toggle between the available temperature set points (37 °C, 57 °C, or 6 °C).</li> <li>3. When the 37 °C set point is blinking on the display, press and hold both buttons for ≈ two (2) seconds.</li> <li>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.</li> </ol> </li> </ul> |



**Figure 1**

| Diagrams (drawings, pictures)          | N/A  |
|--|--|
| <p><b>Steps for Use of Product</b></p> | <ol style="list-style-type: none"> <li>1. Don clean gloves.</li> <li>2. Draw up 0.5 mL of supplied pre-packaged water (emptied in the provided zipper bag or a sterile container (e.g., urine cup) using the supplied pipette.</li> <li>3. Add the water to a provided cuvette with the growth medium.</li> <li>4. Remove the swab from the packaging and moisten the supplied swab with water. (<b>Fig. 2, 2A</b>).</li> </ol> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p><b>Figure 2</b></p> </div> <div style="text-align: center;">  <p><b>Figure 2A</b></p> </div> </div> <ol style="list-style-type: none"> <li>5. Swab around the area to be sampled.</li> </ol> <div style="text-align: center;">  <p><b>Figure 3</b></p> </div> <ol style="list-style-type: none"> <li>6. Put the swab in the vial with the growth medium, and then break it at the scored break point by bending the shaft over the lip of the cuvette. (<b>Figs. 4, 4A</b>).</li> </ol> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p><b>Figure 4</b></p> </div> <div style="text-align: center;">  <p><b>Figure 4A</b></p> </div> </div> <ol style="list-style-type: none"> <li>7. Close the cuvette.</li> <li>8. Mix well.</li> <li>9. Place vials in the block incubator and allow 12 hours or more of incubation. The incubator should be set to 37°C. (<b>Fig. 5</b>).</li> </ol> |



**Figure 5**

10. After incubation, the cuvette needs to be cooled down. One of the following two methods can be employed:

**A. Room temperature**

- Remove the cuvette.
- Place in the supplied holder. (**Fig. 6**).
- Allow cooling for a minimum of one (1)-hour but not greater than three (3) hours.
- Continue on to Step 11.



**Figure 6**

**B. Refrigerator**

- Remove the cuvette and place it in the supplied holder.
- Place the cuvette in refrigerator (approximate temperature of 4 °C) for 15 minutes.
- Remove from the refrigerator after exactly 15 minutes and immediately continue to Step 12. (**Fig. 7**).



**Figure 7**

11. While the cuvette is cooling down, switch the power source of the fluorometer at the upper right corner to 'ON'. (**Fig. 8**).



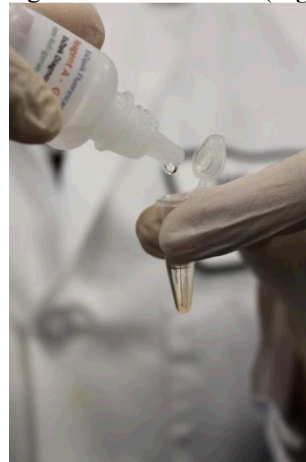
**Figure 8**

12. Remove the swab from the vial using tweezers. When removing, swipe the swab against the inside edge of the vial to remove excess fluid. (**Fig. 9**).



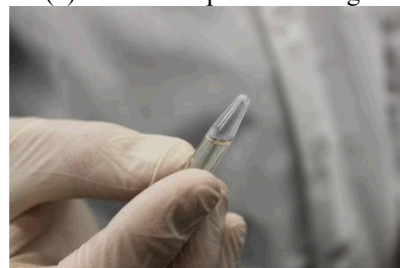
**Figure 9**

13. Dispose the swab as a biohazard.
14. Add two (2) drops of Reagent A to the cuvette. (**Fig. 10**).



**Figure 10**

15. Gently invert it four (4) times to help mix the reagent with the sample. (**Fig. 11**).



**Figure 11**

**IMMEDIATELY CONTINUE WITH INSTRUCTIONS FOR TESTING WITH THE FLUOROMETER**

16. Place the cuvette in the fluorometer
  - a. Line up the pointy side of the cuvette with the black line in the reader.
  - b. Place the black cap firmly on the fluorometer. (**Fig. 12**).



**Figure 12**

17. This screen (**Fig. 13**) will appear. Press the 'Measure' button. (**Fig. 13a**).



**Figure 13**



**Figure 13a**

18. Press 'Blank'. The timer will start counting in seconds. (**Fig. 14**).



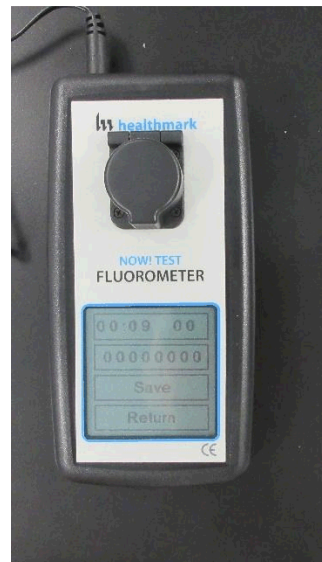
**Figure 14**

19. Press **'Measure'** and wait 10 minutes to view the reading. (**Fig. 15**).



**Figure 15**

20. At 10 minutes, the fluorometer will automatically take a reading. The value will be displayed in the second box (below the timer). (**Fig. 16**).  
Note: Disregard value displayed before 10 minutes. The timer on the fluorometer's display will continue to run, but the reading taken is exactly at the 10-minute mark.



**Figure 16**



**Figure 17**

|  |   |
|--|---|
|  |   |
|  | <p>21. (If desired), to test a new sample, press <b>‘Return’</b> (twice) to begin a new sample. <b>(Fig. 17).</b></p>   |
| <b>Interpretation of Results</b>         | <ol style="list-style-type: none"> <li>1. A numerical value between 300–400 likely indicates the presence of Gram-negative bacteria (but could be due to insufficient cooling of cuvette). Reprocess the item and retest, ensuring sufficient time for cooling has occurred, according to the IFU.</li> <li>2. A numerical value greater than 400 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 for bacteria contamination and species identification.</li> </ol>   |
| <b>Contraindications of Test Results</b> | Other contaminants (e.g., loose debris) in the recaptured water can cause autofluorescence. This also necessitates a reprocessing of the item, as such debris should not be present on a clean surface.   |
| <b>Documentation</b>                     | Record results.   |
|  | N/A   |
| <b>Special Warnings and Cautions</b>     | <ul style="list-style-type: none"> <li>• Check the item manufacturer’s IFU for any drying procedures.</li> <li>• A negative test result does not ensure the item 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 quality process.</li> <li>• If there is a positive test result, additional steps should be taken in accordance with facility guidelines, including reprocessing, further investigation (including culturing for microbial contamination), etc.</li> <li>• Turn off the machine after use.</li> <li>• Always use proper plugs meant for that particular testing equipment. Switching the incubator and fluorometer plugs can cause a fire.</li> </ul> |
| <b>Disposal</b>                          | Dispose of the pipette, swab and zipper bag sample bag 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>             | NOW! Swab Negative Control, NOW-1100 IFU  |
| <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>hmark.com |