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800-521-6224
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Instructions for Use: NOW! Swab Test

Brand Name of Product	NOW-1100
Generic Name of Product	Rapid Gram-negative Swab Test
Product Code Number(s)	NOW-1100, NOW-1100SK
Intended Use	The NOW! Swab Test is to test for Gram-negative bacteria after processing.
Range of Applications for Product	Sampling for Gram-negative bacteria using a swab.
Key Specifications of Product	● 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! Swab Test works by detecting an enzyme mechanism typical to Gram-negative bacteria. ● 50 Swabs- 30mm breakpoint from swab tip ● 50 Cuvettes with growth medium ● 50 Pre-packaged Water vials (5mL) ● 50 Pipettes ● 50 Tweezers ● 50 2" x 3" Ziplock Bags ● Incubator

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	● The reagent does not need to be refrigerated when shipped. ● Once received, refrigerate the reagent bottle (approximately 4°C). ● The reagent needs to be cold when it is being used and thus should be refrigerated before use. ● The rest of the kit should be stored at room temperature.
Packaging Conditions	
Shelf Life	One year from date manufactured.

Instructions for Using Product	
Description of Use(s)	The NOW! Swab Test is to check for Gram-negative bacteria growth using the swabbing method.
Preparation for Use	● Run a negative control when you open the NOW! Swab Test box. **(See NOW! Swab Test Negative Control NOW-1100 IFU)**. ● Set the temperature on the incubator to 37°C. 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 hold 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.  **Fig. 1**
Diagrams (drawings, pictures)	

Steps for Use of Product	1. Draw up 0.5 mL of supplied pre-packaged water (emptied in the provided ziplock bag or a sterile container, e.g. urine cup) using the supplied pipette. 2. Add the water to a provided cuvette with the growth medium. 3. Remove the swab from the packaging and moisten the supplied swab with water. **Figure 2, 2A.**

Fig. 2

Fig. 2A

4. Swab around both sides of the elevator lever with the elevator in 3 different positions: 1) fully lowered; 2) raised to 45 degrees; 3) fully raised. **Figure 3**

Fig. 3 Fully Lowered

Fig. 3 Raised 45 degrees

Fig. 3 Fully Raised

5. 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. **Figures 4, 4**

Fig. 4

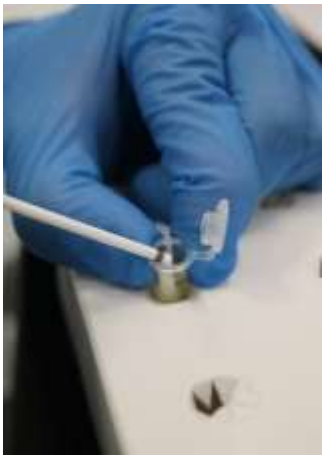

Fig. 4A

6. Close the cuvette.
7. Mix well.

8. Place vials in the block incubator and allow 12 or more hours of incubation. The incubator should be set to 37ºC. **Figure 5**

Fig. 5

9. 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. **Figure 6**
      - Allow cooling for a minimum of 1 hour, but not greater than 3 hours.
      - Continue on to Step 12.

Fig. 6

   B. Refrigerator
      - Remove the cuvette and place in the supplied holder.
      - Place in a refrigerator (approximate temperature of 4ºC) for 15 minutes.
      - Remove from the refrigerator after 15 minutes and immediately continue to Step 12. **Figure 7**

Fig. 7

10. While the cuvette is cooling down, switch the power source of the fluorometer at the upper right corner to **'ON'**. **Figure 8**

Fig. 8

11. Remove the swab from the vial using tweezers. When removing, swipe the swab against the inside edge of the vial to remove excess fluid. **Figure 9**

Fig. 9

12. Dispose the swab as a biohazard.

13. Add 2 drops of Reagent A to the cuvette. **Figure 10**

Fig. 10

14. Gently invert it four times to help mix the reagent with the sample. **Figure 11**

Fig. 11

Immediately proceed to the next steps for testing.

INSTRUCTIONS FOR THE FLUOROMETER

15. Place the cuvette in the fluorometer (the hinge of the cuvette should be pointing towards the screen). Place the black cap firmly on the fluorometer. **Figure 12**

Fig. 12

16. This screen (**Figure 13**) will appear; press the **'Measure'** button.

Fig. 13

17. Press **'CH360'**. **Figure 14**

Fig. 14

18. Press **'Blank'** (timer will start counting seconds). **Figure 15**

Fig. 15

19. Press **'Measure'** and wait 10 minutes to view the reading. **Figure 16**

Fig. 16

20. At 10 minutes, the fluorometer will automatically take a reading. (A valve will be displayed in the box below the timer.) The value displayed before 10 minutes is disregarded. **Figure 17**

Fig. 17

Note: The timer on the fluorometer will continue to run, but the reading displayed is taken exactly at the 10 minute mark. Figure 18

	 **Fig. 18** 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, ensuring 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.
Contraindications of Test Results	Other contaminants (such as loose debris) in the recaptured water can cause autofluorescence. 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	● Follow the endoscope manufacturer's IFU for drying procedures of the flexible endoscope. ● A negative test result does not ensure 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 process. High level disinfect after performing the NOW! Swab Test. ● 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	Dispose of the pipette and ziplock 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	

Related Healthmark Products	EndoCheck™ for Blood, EndoCheck™ for Protein, ChannelCheck™, FlexiCheck™
Other Product Support Documents	ProFormance™ Brochure, ProFormance™ Price List
Reference Documents	NOW! Swab Negative Control, NOW-1100 IFU
Customer Service Contact	Healthmark Industries Company, Inc. 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2018-12-03 Ralph J Basile

Rev. B