

## **Example policy of the NOW! Test™ to check for Gram-negative bacteria in flexible endoscopes.**

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**NOTE:** This document is an example of a policy that may be instituted in a health-care facility for the NOW! Test™ for the detection of Gram-negative bacteria in flexible endoscopes. The actual policy in a facility must be based on variables, logistics, and risk-assessments that are specific to your facility.

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**SUBJECT:** Detection of Gram-negative bacteria in flexible endoscopes using the NOW! Test™ and or the NOW! Swab Test™

**DEPARTMENT:** Central Service or Endoscopy Department

**APPROVED BY:**

**EFFECTIVE:** September 27, 2019

**REVISED:** February 20, 2020

**PURPOSE:** To check flexible endoscopes for Gram-negative bacteria growth after processing.

**POLICY:** The NOW! Test™, and the NOW! Swab Test™ are fluorometric diagnostic systems used to provide a fast reading (~12 hours) of low levels of gram-negative bacteria. Testing can be performed in the endoscope processing area or within the facility, thus not requiring sending the sample to a laboratory for testing.<sup>1</sup>

**METHOD:** The NOW! Test™, and the NOW! Swab Test™ work by detecting an enzyme mechanism typical to gram-negative bacteria. The test utilizes a fluorogenic substrate which, when hydrolyzed by a specific enzyme present in gram-negative bacteria, produces fluorescence that is then read by the fluorometer.<sup>1</sup>

### **STANDARDS AND REGULATORY RECOMMENDATIONS**

Highlights from ANSI/AAMI ST91: 2015

- The facility has established an education, training, and competency assessment program that verifies personnel are consistently achieving the expected level of cleaning.
- The published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes by the user.

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- They include protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP) and **an enzyme that detects specific bacteria** (Alfa 2012, Alfa 2013, Alfa 2014, Visrodia 2014).
  - This enzyme refers to this type of testing, such as the NOW! Test™.
- “The health care facility should establish a comprehensive quality assurance and safety program for all aspects of endoscope processing. The program should... Establish a procedure to investigate lapses in processing.”
- “While currently there is no universal consensus of the value of performing testing on endoscopes that have been through a high-level disinfection process, numerous studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing.”
- “Identification of non-environmental pathogens demonstrates clear evidence of a failure of the high-level disinfection process. An approach to test for the presence of these pathogens can be considered as part of a quality assurance process. This should be done in collaboration with infection prevention and risk management personnel...”

FDA Safety Communication – August 2019:

- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.
- Monitor your reprocessing procedures.

**PROCEDURE:**

NOW! Test™ and NOW! Swab Test™ will be performed by personnel that have received training and demonstrated competency.

Competency of personnel will be demonstrated by following the manufacturer’s instructions for use (IFU) to perform successful testing using either the NOW! Test™ and/or the NOW! Swab Test™.

Refer to this link for the NOW! Test™ IFU:

[http://www.healthmark.info/CleaningVerification/NowTest/NowTest\\_IFU.pdf](http://www.healthmark.info/CleaningVerification/NowTest/NowTest_IFU.pdf)

Refer to this link for the NOW! Swab Test™ IFU.

[http://www.healthmark.info/CleaningVerification/NowTest/Now\\_Swab\\_Test\\_IFU.pdf](http://www.healthmark.info/CleaningVerification/NowTest/Now_Swab_Test_IFU.pdf)

Before running either of these tests for cleaning verification surveillance, a negative control must be run for each lot of test materials. Refer to the links below for instructions on how to perform negative controls.

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Flush method:

[http://www.healthmark.info/CleaningVerification/NowTest/NOW\\_Swab\\_Negative\\_Control\\_Protocol\\_Feb.2020.pdf](http://www.healthmark.info/CleaningVerification/NowTest/NOW_Swab_Negative_Control_Protocol_Feb.2020.pdf)

Swab:

[http://www.healthmark.info/CleaningVerification/NowTest/NOW\\_Swab\\_Negative\\_Control\\_Protocol\\_Feb.2020.pdf](http://www.healthmark.info/CleaningVerification/NowTest/NOW_Swab_Negative_Control_Protocol_Feb.2020.pdf)

Document competency for the NOW! Test™ using the competency form in Appendix A.

Document competency for the NOW! Swab Test™ using the competency using the form in Appendix B.

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**Example policy of the NOW! Test™ to check for Gram-negative bacteria in flexible endoscopes.**

**Appendix A**

**Competency Record for Using the NOW! Test™**

**Name:** \_\_\_\_\_

**Competency Statement:** Complies with policy and procedure for testing channeled flexible endoscopes for gram negative organisms.

**Key**

**1** = Performs independently and consistently. Asks for assistance in new situations.

**2** = Performs with minimal guidance and direction. Asks for assistance when necessary.

**3** = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

**Comments:**

**Competency Achieved:** \_\_\_\_\_ **(Date)**

**Evaluator:** \_\_\_\_\_

**Learner:** \_\_\_\_\_

<b>Critical Behavior</b>	<b>1</b>	<b>2</b>	<b>3</b>
Have the IFU for the NOW! Test available			
Have read the IFU for the NOW! Test in advance			
Understands the concept of the NOW! Test <ul style="list-style-type: none"> <li>• To check flexible endoscopes for Gram-negative bacteria growth after processing.</li> </ul>			
Assembles the NOW! Test kit and all of the supplies per the IFU			
Make sure you are wearing gloves during the test process			
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 LED display			
Release the buttons, then press either button repeatedly to toggle between the available temperature set points (37°C, 57°C, or 60°C)			

**Example policy of the NOW! Test™ to check for Gram-negative bacteria in flexible endoscopes.**

When the 37°C set point is blinking on the display, press and hold the buttons for ~ 2 seconds			
Recognizes that 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			
<b>Running a Negative Test to ensure the unit is working properly</b>			
<b>Testing A Scope</b>			
Pick an endoscope that has been reprocessed for testing			
Place supplied zip-top bag at the distal tip of the endoscope and partially seal bag so that it stays in place			
Flush the lumen with the blue vial of water, (i.e., the biopsy channel).			
Draw up 30 cc of air in a syringe			
Purge the lumen with 30 cc of air			
Recapture water in the provided zip-top bag			
<b>Follow the endoscope manufacturer’s IFU for drying procedures of the flexible endoscope</b>			
Prepare the sample for the incubator			
Draw up 0.5 mL of sample water to the provided cuvette with the growth medium. Mix by shaking gently.			
<b>Critical Behavior</b>	<b>1</b>	<b>2</b>	<b>3</b>
Place vials in the block incubator and allow 12 or more hours of incubation. The incubator should be set to 37°C			
After incubation, the cuvette needs to be allowed to cool down. One of the 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. Refrigerator: remove the cuvette and place in a supplied holder. Place in a refrigerator (approximate temperature of 4°C) for 15 minutes. Remove from refrigerator at 15 minutes. You can use either method			
Switch the power source of the fluorometer at the upper right corner to “ON”			
After “Cool Down time” you will add a reagent called Reagent A			
Add 2 drops of Reagent A to the cuvette			
Gently invert it four times to help mix the reagent with the sample			
Place the cuvette in the fluorometer, line up the pointy			

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side of the cuvette lid with the black line in the reader (9 o'clock position). Place the black cap firmly on the fluorometer			
Look at the fluorometer and the screen will show up, press the " <b>Measure</b> ", then " <b>Blank</b> ".			
Wait for the screen to change, then Press "Measure" and wait for 10 minutes to get the reading.			
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.			
Record the number on the screen			
Follow departmental policy on interpretation of results and informing management of results			
Refer to the NOW! Test IFU for interpretation of the number on the screen			

EXAMPLE

**Example policy of the NOW! Test™ to check for Gram-negative bacteria in flexible endoscopes.**

## Appendix B

### Competency Record for Using the NOW! Swab Test™

**Name:** \_\_\_\_\_

**Competency Statement:** **Complies** with policy and procedure for testing scopes for gram negative organisms.

**Key**

**1** = Performs independently and consistently. Ask for assistance in new situations.

**2** = Performs with minimal guidance and direction. Asks for assistance when necessary.

**3** = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

**Comments:**

**Competency Achieved:** \_\_\_\_\_ **(Date)**

**Evaluator:** \_\_\_\_\_

**Learner:** \_\_\_\_\_

<b>Critical Behavior</b>	<b>1</b>	<b>2</b>	<b>3</b>
Have the IFU for the NOW! Test available			
Have read the IFU for the NOW! Test in advance			
Understand the concept of the NOW! Test <ul style="list-style-type: none"> <li>• To check flexible endoscopes for Gram-negative bacteria growth after processing.</li> </ul>			
Get the NOW! Test kit and all of the supplies per the IFU			
<b>Running a Negative Test to ensure the unit is working properly</b>			
Make sure you are wearing gloves during the test process			
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 LED display			
Release the buttons, then press either button repeatedly to toggle between the available temperature set points (37°C, 57°C, or 60°C)			

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When the 37°C set point is blinking on the display, press and hold the buttons for ~ 2 seconds			
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			
<b>Running a Negative Test to ensure the unit is working properly</b>			
<b>Testing A Scope</b>			
Pick an endoscope that has been reprocessed for testing			
Empty water provided into small zip-top bag that is provided.			
Draw up 0.5 ml of water from small zip-top bag with the provided pipette.			
Expel the water from the pipette into the provided cuvette and place cuvette in holder.			
Use remaining water to moisten the tip of the swab.			
Swab elevator channel with elevator in fully lowered position.			
Swab behind elevator with elevator in fully raised position.			
Place swab in cuvette (contains water and growth medium) and snap off the tip of the swab inside the cuvette at the scored breaking point.			
Close the cuvette			
Mix the contents of the cuvette			
Place cuvette into incubator at 37°C and let it incubate for at least 12 hours.			
After incubation, the cuvette needs to be allowed to cool down. One of the 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. Refrigerator: remove the cuvette and place in a supplied holder. Place in a refrigerator (approximate temperature of 4°C) for 15 minutes. Remove from refrigerator at 15 minutes. You can use either method			
Switch the power source of the fluorometer at the upper right corner to “ON”			
Remove the swab from the vial using tweezers. When removing, swipe the swab against the inside edge of the vial to remove excess fluid. Discard swab into biohazard container.			
Add 2 drops of Reagent A to the cuvette.			
Gently invert it four times to help mix to reagent with			

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the sample.			
Place the cuvette in the fluorometer, line up the pointy side of the cuvette with the black line in the reader. Place the black cap firmly on the fluorometer.			
Look at the fluorometer and the screen will show up, press the “Measure” then “Blank”.			
Press “Measure” and wait for 10 minutes to get the reading.			
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.			
Record the number on the screen.			
Follow departmental policy on interpretation of results and informing management of results.			
Refer to the NOW! Swab Test IFU for interpretation of the number on the screen.			

**References:**

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1. [http://www.healthmark.info/CleaningVerification/NowTest/NOW!\\_Kit\\_White\\_Paper.pdf](http://www.healthmark.info/CleaningVerification/NowTest/NOW!_Kit_White_Paper.pdf)
  2. ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities.
  3. FDA Safety Communication, August 2019. <https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication>