

**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™

**DEPARTMENT:** Central Service or Endoscopy Department

**APPROVED BY:**

**EFFECTIVE:** September 27, 2019

**REVISED:**

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

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

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

**STANDARDS AND PROFESSIONAL SOCIETY RECOMMENDATIONS**

Highlights from ANSI/AAMI ST91: 2015

- Cleaning verification tests are performed following cleaning and are used to verify the effectiveness of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of an endoscope.

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- Facilities should develop a defined program of cleaning verification that includes frequency of testing, number, and types of endoscopes to be tested.
- Cleaning verification results are documented.
- The facility has established, clarified and documented a process to address cleaning verification failures.
- The facility has established an education, training, and competency assessment program that verifies personnel are consistently achieving the expected level of cleaning. (Section 12.4.1)
- 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.
- **They include protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP) and an enzyme** that detects specific bacteria (Alfa 2012, Alfa 2013, Alfa 2014, Visrodia 2014). (Section 12.4.3)
  - This enzyme refers to this type of testing, such as the NOW! Test™.

**PROCEDURE FOR INSPECTION:**

Perform testing after the disinfection process is complete.

- Run a negative control when you open the NOW! Test box.
- 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 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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The NOW! Test™

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 the blue vial of water. (i.e., the biopsy channel).



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



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

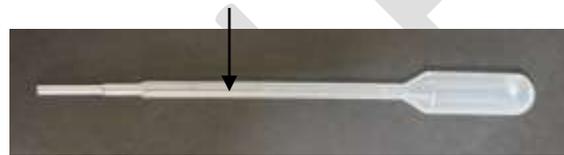


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Follow the endoscope manufacturer's IFU for drying procedures of the flexible endoscope.

Prepare 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 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.

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9. After incubation, the cuvette needs to be allowed to cool down. One of two methods can be employed:
  - a. 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 to step 12.



- b. 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 and continue on to step 12.



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

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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.

Instructions for the Fluorometer:

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14. 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.



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



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

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



18. 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.

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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.

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Results:

- Immediately report any test failure to department management or supervisor.
- The frequency of testing should be determined by the facility. Often this test performed daily or weekly on flexible endoscopes.
- Record all results on a log sheet.

Responsibility: The department personnel (Manager, Supervisor or Designee) are responsible for the proper use, results interpretation, and documentation of the NOW! Test™ when used on flexible endoscopes.

Staff in-service and training on the flexible endoscopes and proper use of and the NOW! Test™ should be conducted at least once each year.

**NOW! Test™ Log Sheet Click on Link below:  
NOW! Test Log Sheet:**

[http://www.healthmark.info/CleaningVerification/NowTest/NOW\\_Log\\_Sheet.pdf](http://www.healthmark.info/CleaningVerification/NowTest/NOW_Log_Sheet.pdf)

**Competency Record for Using the NOW! 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:** \_\_\_\_\_

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<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 reprocessing.</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)			
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>Testing A Scope</b>			
Pick an endoscope that has been reprocessed for testing			
Place supplied zip-lock 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 mL of air in a syringe			
Purge the lumen with 30 mL of air			
Recapture water in the provided zip-lock 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 water to the provided cuvette with the growth medium. Mix by shaking gently			

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<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 on 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 to reagent with 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”			
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			

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**References:**

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1. <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.

EXAMPLE