

Example of the NOW! Test™ and/or the NOW! Swab Test™ Policy to check for Gram-negative bacteria in flexible endoscopes.

NOTE: This document is an example of a policy that may be instituted in a healthcare 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.

Subject: Detection of Gram-negative bacteria in flexible endoscopes using the NOW! Test™ and/or the NOW! Swab Test™.

Department: Central Service/Endoscopy Department

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter date when this will take effect]

Revised: May 2022

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 (approximately ≈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.¹

Method: The NOW! Test™, and the NOW! Swab Test™ detect enzyme mechanisms typical to Gram-negative bacteria. The NOW! tests use a fluorogenic substrate, which, when hydrolyzed by a specific enzyme present in Gram-negative bacteria, produces fluorescence that is then read by the fluorometer.¹

Standards and Professional Society Recommendations:

1. Highlights from ANSI/AAMI ST91: 2021 Flexible and semi-rigid endoscope processing in health care facilities²:
 - **“Two published studies evaluated the efficacy of a rapid test method for gram negative bacteria and did find this method proved to correlate with traditional culture methods for detecting gram negative bacteria”**

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- 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.
 - They include a) protein, b) carbohydrate, c) hemoglobin (blood), and d) adenosine triphosphate (ATP) and e) **an enzyme that detects specific bacteria.**
 - This enzyme refers to this type of testing, such as the NOW! Test™.
- Defining a cleaning process that can be accomplished with:
 - Comprehensive personnel training and verified through observation that it can be followed consistently
 - Implementing a testing system that verifies adequate, consistent results.
- The healthcare facility should establish a multidisciplinary, comprehensive, written quality assurance, and safety program for all aspects of endoscope processing.
- The benchmarks for residual soil and bioburden levels after cleaning might become more definitive as more data become available and/or more efficient cleaning methods are developed.
- High-risk endoscopes and/or those that are of complex design (e.g., duodenoscopes, linear ultrasound [EUS] endoscopes, bronchoscopes, endobronchial ultrasound [EBUS] endoscopes, ureteroscopes, cystoscopes, and as determined by the facility) shall be monitored with cleaning verification tests after each cleaning.

FDA Safety Communication – August 2019³:

- 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 (Mfr.'s) instructions for use (IFU). Refer to the PDF links below to perform successful testing using the NOW! Test™ and/or the NOW! Swab Test™:

- [NOW! Test™ IFU.pdf](#)
- [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 PDF links below for instructions on how to perform negative controls:

- [Flush method.pdf](#)

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- [Swab.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.

Appendix A

Sample 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: _____

Critical Behavior	1	2	3
Have the IFU for the NOW! Test™ available.			
Read the IFU for the NOW! Test™ in advance.			
Understands the concept of the NOW! Test™ to check flexible endoscopes for Gram-negative bacteria growth after processing.			
Assembles the NOW! Test™ kit and all the supplies per the IFU.			
Make sure you are wearing gloves during the test process.			

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

With the incubator powered on simultaneously press and hold the two small buttons on the rear of the incubator (Fig. 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.			
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.			
<i>Run a Negative Test to ensure the unit is working properly.</i>			
Testing A Scope	1	2	3
Pick an endoscope already reprocessed for testing.			
Place supplied zipper 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			
<i>Follow the endoscope Mfr.'s IFU for drying procedures of the flexible endoscope.</i>			
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.			
Critical Behavior	1	2	3
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: <ul style="list-style-type: none"> • <i>Room temperature:</i> Remove the cuvette and place in the supplied holder and allow cooling for a minimum of 1-hour but not greater than 3 hours. • <i>Refrigerator:</i> Remove the cuvette and place in a supplied holder. Place in a refrigerator (≈ 4 °C) for 15 minutes. Remove from refrigerator at 15 minutes. NOTE: 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.			

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

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 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 " Measure ", then " Blank ".			
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). NOTE: 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.			

Appendix B

Sample 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. 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: _____

Critical Behavior	1	2	3
Have the IFU for the NOW! Test™ available.			
Read the IFU for the NOW! Test™ in advance			
Understand the concept of the NOW! Test™. To check flexible endoscopes for Gram-negative bacteria growth after processing.			
Get the NOW! Test™ kit and all the supplies per the IFU.			
<i>Running a Negative Test to ensure the unit is working properly</i>			
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 (Fig. 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 set temperature.			
<i>Running a Negative Test to ensure the unit is working properly</i>			
Testing A Scope	1	2	3
Pick an endoscope already reprocessed for testing.			
The NOW! Swab Test™ includes prepackaged water and a small-zipper bag. Empty water into the bag.			
Draw up 0.5 ML of water from small-zipper bag with the included pipette.			
Expel the water from the pipette into the provided cuvette (with growth medium) 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.			

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

Place cuvette into incubator at 37 °C and let it incubate for at least 12 hours.			
After incubation, allow the cuvette to cool down. One of two methods can be employed: <ul style="list-style-type: none"> • <i>Room temperature</i>: Remove the cuvette and place in the supplied holder allowing to cool for minimum of 1-hour, but not greater than 3 hours. • <i>Refrigerator</i>: Remove the cuvette and place in a supplied holder. Place in a refrigerator ($\approx 4\text{ }^{\circ}\text{C}$) for 15 minutes. Remove from refrigerator at 15 minutes. NOTE: You can use either method.			
Switch “ON” the power source of the fluorometer at the upper right corner.			
Remove the swab from the vial using tweezers. <ul style="list-style-type: none"> • 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 the sample.			
Place the cuvette in the fluorometer. <ul style="list-style-type: none"> • Line up the pointy side of the cuvette with the black line in the reader. • Place the black cap firmly on the fluorometer. 			
On the fluorometer’s screen, press “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). NOTE: The value displayed before 10 minutes is disregarded. 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.			

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

References:

- ¹ Kulkarni, Kaumudi. (October 2016). The NOW! Test™ Validation Testing. http://www.healthmark.info/CleaningVerification/NowTest/NOW!_Kit_White_Paper.pdf. Healthmark Industries Company, Inc.
- ² Association for the Advancement of Medical Instrumentation. (2021). *ANSI/AAMI ST91:2021 Flexible and semi-rigid endoscope processing in health care facilities*.
- ³ U.S. Food and Drug Administration (FDA). (August 2019 [updated April 2020]). *The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication*. <https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication>.