

NOW! Test Information

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Background: Flexible endoscopes are challenging to clean and disinfect or sterilize. The NOW! Test™ is a simple, rapid test (~12 hours) that checks the endoscope channel for Gram-negative bacteria thereby helping to determine whether it is safe to use on the next patient. Utilizing a unique enzyme detection method, a fluorometer checks for Gram-negative bacteria down to <10 Colony Forming Units (CFU) by reading fluorescence given off by those bacteria that may be present in the recaptured water. If the fluorometer reading gives a positive result for Gram-negative bacteria, simply reprocess the endoscope following manufacturer guidelines prior to use. Testing can be performed directly in the endoscopy clinic or healthcare facility, thus not requiring sending the sample to a laboratory for testing or waiting days for a culture result.

The NOW! Test detects Gram-negative bacteria such as *E. coli*, *Pseudomonas aeruginosa*, *Klebsiella* species, *Salmonella* species, *Helicobacter* species, *Serratia* species, and *Legionella* species, which have been associated with patient infections after endoscopic procedures. The NOW! Test can also detect multi-drug resistant strains of these organisms, such as Carbapenem-resistant Enterobacteriaceae (CRE). Gram-negative bacteria act as indicators for bacterial contamination in endoscopes and reduce the risk of false positives associated with the Gram-positive bacteria occurring normally as skin flora such as *Staphylococcus epidermidis*. Although there are no requirements for microbial surveillance testing of endoscopes, current standards and guidelines such as AAMI ST91, SGNA and AORN do discuss the value of conducting such testing as a means to identify reprocessing issues. Sampling of endoscopes for microbial contamination has been successful at identifying processing issues in facilities and can be used as part of a risk assessment for reprocessing quality or base line evaluation.

Process: After the endoscope has been cleaned and disinfected, simply flush the targeted scope channel with the provided 5 ml of sterile water. Draw off 0.5mL of the collected sample and transfer to a cuvette from the kit; place the cuvette in the provided incubator overnight (~12 hours). The next morning after the sample in the cuvette has cooled sufficiently, add 2 drops of the supplied reagent, gently mix and then place in the fluorometer and measure the sample. After 10 minutes, the fluorometer displays a final reading.

Validation: The NOW! Test was validated by two independent testing laboratories to evaluate the sensitivity of the NOW! Test in the detection of gram negative bacteria. Multi-drug resistant and non-drug resistant strains of gram negative bacteria, such as *E.coli*, *P. aeruginosa* and *K. pneumonia* were tested alongside traditional culturing.

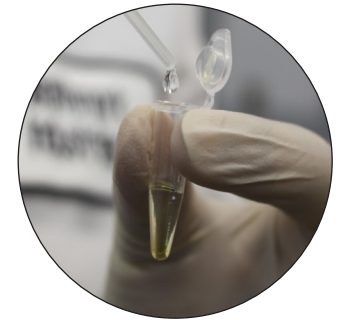
Results interpretation: A numerical value between **200 and 300** likely indicates the presence of Gram-negative bacteria. If this value is obtained, it is recommended that the endoscope be reprocessed and retested, ensuring that sufficient time for the incubated sample to cool down has occurred. Insufficient cooling could lead to elevated readings. Perform this testing according to the IFU and ensure that the mixing of Reagent A in the cuvettes is performed gently to avoid air microbubbles in the solution. Repeated readings in the 200-300 range may necessitate further investigation into reprocessing procedures and the NOW test procedure to determine if proper steps are being followed.

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.

Although a negative test result (**<200**) does not ensure the endoscope is free from contamination, it does indicate that Gram-negative bacteria are not present in the sample or are at levels below what the test can detect. Other contaminants, including Gram-positive bacteria, and organic soil can remain. It is recommended by AAMI ST91 and professional societies such as SGNA and AORN, that additional measures such as cleaning verification tests and visual inspection be implemented to further verify a quality reprocessing process.

Other contaminants (such as loose debris) in the recaptured water can cause auto- fluorescence. This also necessitates reprocessing of the scope as such debris should not be present in a clean endoscope. Improper cooling of the cuvettes prior to reading can also result in a positive result.

Discussion: Therefore, based on independent laboratories' results and Healthmark's internal testing, a numerical value greater than 300 strongly indicates the presence of more than 10 CFU of Gram-negative bacteria. If the readings are over 300, further steps including reprocessing and investigation of reprocessing procedures should be undertaken. One of these steps may be culturing of the endoscope for bacterial contamination and species identification.



Pipette/Cuvette



Cuvette/Incubator



Fluorometer

Sample Reading	Results Interpretation
< 200	No Gram-negative bacteria present in sample or levels are below what the test can detect
200-300	Likely indicates the presence of Gram-negative bacteria
> 300	Strongly indicates the presence of Gram-negative bacteria