

ReadyNow™ Biofilm Test Carriers

INSTRUCTIONS FOR USE

INTENDED USE

ReadyNow™ Biofilm Test Carriers are intended to be used for anti-biofilm efficacy testing of disinfectants or other antimicrobial agents. This product is intended to meet the bacterial CFU specifications of test carriers defined in the Single Tube Method for Measuring Disinfectant Efficacy Against Biofilm Microorganisms (EPA MB-20) or Standard Test Method for Determining Disinfectant Efficacy Against Biofilm Growth in the CDC Biofilm Reactor Using the Single Tube Method (ASTM E2871). This product is intended to offer a similar challenge of biofilm microorganisms to that of biofilm grown in the CDC Biofilm Reactor.

PRODUCT DESCRIPTION

Each kit contains 24 ReadyNow™ Biofilm Test Carriers stored in a 24-well plate and a bottle of rehydration solution (50 mL). Each plate is sealed within a laminated pouch that contains a desiccant and an oxygen scavenger. The biofilm on each carrier contains microorganisms that are traceable to American Type Culture Collection (ATCC®) and will recover to the cell titer specification on the product label when processed and stored according to this instruction-for-use.

WARNINGS AND PRECAUTIONS

- This product is not intended for human, animal or pet consumption.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on our website at www.stratixlabs.com.
- Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling.
- This product contains viable microorganisms capable of causing infection and disease. Proper techniques must be employed to avoid exposure and contact with the microorganism it contains.
- The microbiology laboratory must be equipped and have the facilities to receive, process, maintain, store and dispose of biohazardous material.
- Only trained, qualified laboratory personnel should use this product.
- Agencies and statutes regulate the disposal of all biohazardous materials. Each laboratory must be aware of local, state and federal regulations and comply with the proper handling and disposal of biohazardous materials.

DISCLAIMER

This product is designed to be drop-in-ready for use in the Single Tube Method for Measuring Disinfectant Efficacy Against Biofilm Microorganisms (MB-20-01); however, this product has not been approved for Environmental Protection Agency (EPA) antimicrobial claims testing. This product is for research use only.

NOTE: ReadyNow™ Biofilm includes ascorbic acid as a preservation excipient. Ascorbic acid is known to quench chlorine. Due to the presence of ascorbic acid, chlorine-based disinfectant formulations are known to exhibit reduced antimicrobial efficacy when testing with ReadyNow™ Biofilm.

EVALUATING BIOFILM KILL USING READYNOW™ BIOFILM TEST CARRIERS INSTRUCTIONS FOR USE

1. Remove the foil pouch containing the ReadyNow™ Biofilm Test Carriers from the refrigerator.
2. Tear open the foil pouch and remove the 24-well plate from the pouch. Allow the plate to equilibrate to room temperature (20 – 23°C) for approximately 5 minutes.
3. Remove the lid from the plate and add 1 mL rehydration solution to each well containing a ReadyNow™ Biofilm Test Carrier. Replace lid on plate.
4. Maintain the ReadyNow™ Biofilm Test Carriers in the rehydration solution for 15 minutes at room temperature (20 – 23°C).
5. Aseptically transfer each ReadyNow™ Biofilm Test Carrier to an individual sterile, 50 mL conical tube (with or without splashguard, as necessary) using sterile forceps.
6. Proceed with disinfectant testing per the Single Tube Method (MB-20-01 or ASTM E2871).

Note: It is recommended to use all of the ReadyNow™ Biofilm Test Carriers within 1 hour of opening the foil pouch.

EVALUATING BIOFILM REMOVAL USING READYNOW™ BIOFILM TEST CARRIERS INSTRUCTIONS FOR USE

1. Remove the foil pouch containing the ReadyNow™ Biofilm Test Carriers from the refrigerator.
2. Tear open the foil pouch and remove the 24-well plate from the pouch. Allow the plate to equilibrate to room temperature (20 – 23°C) for approximately 5 minutes.
3. Remove the lid from the plate and add 1 mL rehydration solution to each well containing a ReadyNow™ Biofilm Test Carrier. Replace lid on plate.
4. Maintain the ReadyNow™ Biofilm Test Carriers in the rehydration solution for 15 minutes at room temperature (20 – 23°C).
5. Aseptically transfer each ReadyNow™ Biofilm Test Carrier to a well in a new, sterile 24-well plate using sterile forceps.



6. Add a disinfectant or antimicrobial agent to each well at a concentration and volume appropriate for your experiment.
7. Maintain each ReadyNow™ Biofilm Test Carrier in the disinfectant for a duration appropriate for your experiment.
8. Transfer each ReadyNow™ Biofilm Test Carrier to a new, sterile well using sterile forceps and wash each test carrier with 2 mL 1x phosphate-buffered saline (PBS).
9. Transfer each ReadyNow™ Biofilm Test Carrier to a new, sterile well using sterile forceps and add 1 mL 0.1% crystal violet solution (CAS# 548-62-9).
10. Maintain each ReadyNow™ Biofilm Test Carrier in the crystal violet solution for 10 minutes at room temperature.
11. Wash each ReadyNow™ Biofilm Test Carrier three times in 2 mL 1x PBS by transferring the carrier to a well with fresh 1x PBS each time.
12. Place each ReadyNow™ Biofilm Test Carrier in a new, sterile well with 2 mL 95% EtOH for approximately 10 minutes.
13. Measure the absorbance (540 nm) of the 95% EtOH colored with CV from each well.

Note: It is recommended to use all of the ReadyNow™ Biofilm Test Carriers within 1 hour of opening the foil pouch.

STORAGE AND EXPIRATION

Upon receipt of the ReadyNow™ Biofilm Test Carriers, remove the foil pouch(es) from the shipping package, and store the sealed pouch at 2°C to 8°C. Do not open the pouch until ready to use. Once the foil pouch is opened, it is recommended to use all of the test carriers within 1 hour of opening. While it is recommended to use all of the test carriers within 1 hour of opening, ReadyNow™ Biofilm is stable and able to be re-sealed for later use within 1 month if the protocol on page 4 is followed.

Store the rehydration solution at room temperature.

Do not use the product if the expiration date has passed.



PROTOCOL FOR USING A PORTION OF READYNOW™ BIOFILM TEST CARRIERS & RE-SEALING FOR LATER USE:

1. Open the foil pouch.
2. Aseptically transfer the carriers you want to a sterile 24-well plate or a similar container. Perform rehydration step according to IFU.
3. Immediately reseal the pouch that has the remaining carriers that will be tested on a different day and store the pouch at 2°C to 8°C.

Made in U.S.A by:

Stratix Labs Corporation
1000 Westgate Drive, Suite 132
St. Paul, MN 55114
www.stratixlabs.com
info@stratixlabs.com
833-787-2849 • (833-STRATIX)

Distributed in partnership with:

BioSurface Technologies Corporation
421 W Griffin Drive
Bozeman, MT 59715
www.biofilms.biz
sales@biofilms.biz
866-306-2620

Patents Pending

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