



Cat. No. M- 3001

MoniTekTM (Gram Negative)

A Rapid Test for Gram Negative Bacteria

The MoniTek test is an enzymatic assay for the detection of gram negative microorganisms directly from a contaminated source. MoniTek is a presumptive test for monitoring equipment and surfaces. It should be noted that the detection of any microorganism in sufficient quantities can be an indicator of the presence of potential pathogens.

SUMMARY AND EXPLANATION OF THE TEST:

Bacteria are responsible for the majority of food borne illnesses, and food spoilage, caused by improper cleaning and sanitation. The traditional method for detection of these bacteria is to culture for 48 hours, and then determine whether the surface had been contaminated at the time the sample was obtained. The MoniTek test does this in 20 minutes. The MoniTek assay is an enzyme detection system consisting of a synthetic substrate which, in the presence of a specific enzyme, causes a chemical reaction. This reaction, when coupled with a developer, causes a color reaction to occur directly on the test membrane.

PRINCIPLE:

MoniTek is a rapid screening test for the detection of gram negative bacteria directly from surfaces. It has been suggested (3) that each surface, or piece of equipment, be checked at 5 randomly selected sites to give an overall assessment of cleanliness of the area. These surfaces should be tested frequently depending on the usage.


CONTENTS OF THE KIT: (No additional materials required)

- 50 Membrane Test Strips
- 1 Bottle of Reagent A
- 1 Bottle of Reagent B
- 1 Bottle of Reagent C
- 1 Bottle of Positive Control
- 1 Product Insert

REAGENTS:

- Reagent AWetting Buffer
- Reagent B.....Synthetic Substrate
- Reagent C.....Color Developer
- Positive Control.....Positive Control

WARNINGS AND PRECAUTIONS:

- Do not use reagents after the expiration date.
- Store test at refrigerator temperature.
- Refrain from touching the membrane surface at all times.
- Wash hands after use.
- Reagent C is **acidic**  and may stain hands if it comes into skin contact. This is a temporary cosmetic discoloration and can be reduced by washing hands immediately with soap and hot water.
- Use only the membrane filter apparatus supplied with the kit. Do not use any other type of collection device (such as a swab) as false reactions may occur

STORAGE CONDITIONS

- The MoniTek test is intended to be performed immediately after the surface has been tested. Testing should be done as soon as possible after the sample has been obtained, in order to get the best results. (within 30 minutes)
- Store tests 2-15°C.
- Tests can be transported between 2-30°C

CULTURE COMPARISON:

Although definite acceptable levels of contamination have not been set for most surfaces, literature ^(1,2,4) states that if a surface tested has greater than 10^6 organisms present, the potential for illness and spoilage exists. The lower limit of detection for the MoniTek test is 10^3 organisms per test membrane, which allows for the presence of normal background bacteria, while not causing a reaction to occur. If a surface is to be tested, and the results compared with culture, it is important that equal areas be surveyed, and that equal conditions exist on both surfaces ⁽⁵⁾.

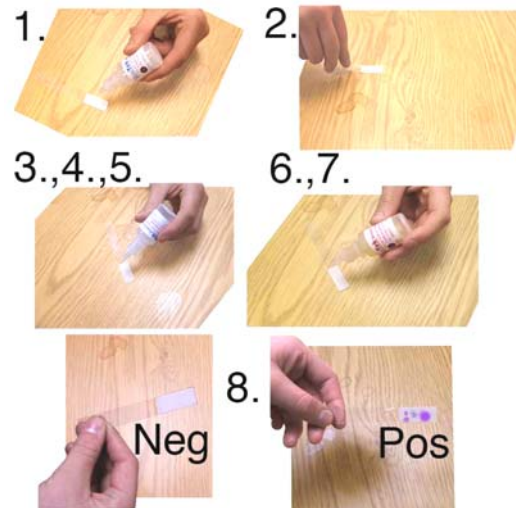
SPECIMEN COLLECTION:

Add 1 drop of Reagent A to the test membrane.

Rub the membrane, using moderate pressure over the surface to be tested, covering 40 square inches for each piece of equipment or surface sampled. If 40 square inches are not available (ie. food slicing blade), then collect sample from as large a surface as available.

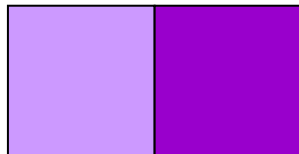
TESTING PROCEDURES:

1. Add 1 drop of Reagent A to the center of the test membrane to allow it to flow to both ends. Add a second drop if necessary.
2. Obtain a specimen from a surface. (40 square inches).
3. Put the membrane holder on a flat smooth surface, face up. Place a paper towel under the strip to absorb any overflow.
4. Add 1 drop of Reagent B to the test membrane. Be sure that the reagent bottle tip does not come into contact with the membrane. If one drop does not cover the entire strip, add a second drop.
5. Wait at least 20 minutes (no longer than 60 minutes).
6. Add 1 drop of Reagent C to the membrane. Be sure that the reagent bottle tip does not come into contact with the membrane. If one drop does not cover the entire strip, add a second drop.
7. Wait 1 minute.
8. Read the test results on the membrane immediately. (see color chart)



A POSITIVE TEST:

A positive test will be indicated by a light to dark purple color on the membrane, usually in spots or splashes. These spots can be anywhere on the surface of the membrane in a spotty or streaky configuration due to the number and placement of the bacteria collected on the membrane.



A NEGATIVE TEST:

A negative test will be indicated by the absence of a purple color as illustrated. Occasionally, after 1 minute, a negative test will turn darker. Therefore, it is important to read the results immediately within 1 minute after the additional of Reagent C.

LIMITATIONS OF THE TEST:

MoniTek is a screening test for the presence of gram negative bacteria. It does not distinguish between different types of bacteria. However, a positive reaction is indicative for the potential presence of pathogenic bacteria which may be in sufficient quantities to cause illness or spoilage.

Technical Alert for Quality Control: MoniTek detects bacterial enzymes, which may dissolve in liquids. Serial dilutions of bacteria may not give a positive reaction. Therefore, all comparison testing must be done with plated colonies

USER QUALITY CONTROL:

The positive reagent control test should be performed on a weekly basis. A strong reaction should occur within 1 minute after applying the Positive Reagent Control and Reagent C to the membrane. If a weak reaction or no reaction takes place, the reagents should not be used. When performing a negative reagent control test, the membrane should remain colorless to a pale pink color during the one minute time period of the test.

NOTE: Before performing the test, first time users of the MoniTek test should perform a positive and negative reagent control to become familiar with the positive and negative color reactions.

POSITIVE REAGENT CONTROL TEST:

NOTE: The reagent control tests contain no active bacteria. Be sure that the reagent bottles do not come in contact with the test membrane.

1. On a clean membrane, add 1 drop of Positive Control Reagent, and 1 drop of Reagent A
2. Add 1 drop of Reagent C to the membrane.
3. Wait 1 minute.
4. Examine the membrane for the appearance of a light or dark purple color (see color chart).
5. Repeat the test if the purple color does not appear.

NEGATIVE REAGENT CONTROL TEST:

1. On a clean membrane, add 1 drop of Reagent B, and 1 drop of Reagent A.
2. Add 1 drop of Reagent C.
3. Wait 1 minute.
4. Examine the membrane. A negative test will remain colorless or turn a light yellow or pale pink color.
5. Repeat the test if any light to dark purple color appears.

REFERENCES:

1. Microbial Ecology of Foods. by the International Commission on Microbiological Specifications for Foods: 1980 , pp 72-77, 104-125.
2. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients by the Subcommittee on Microbiological Criteria for Foods and Food Ingredients: 1985, pp 43-71, 76-79.
3. Millipore Catalogue. Millipore Corporation, Bedford, MA 01730: 1987, pp 16-18.
4. Sanitation, Safety & Environmental Standards. Lewis J. Minor: 1983, pp 82-89.
5. Protocol on file. Ask distributor.



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