

BioSign® Listeria

Rapid *Listeria monocytogenes* Test

For *in vitro* diagnostic use only

Intended Use

The **BioSign® Listeria** test detects the presence of *Listeria monocytogenes* in enriched cultures.

Kit Description

Each **BioSign® Listeria** test device contains a membrane strip coated with anti-*Listeria monocytogenes* antibody and a pad impregnated with the same antibody-dye conjugate in a protein matrix containing 0.1% NaN₃.

Each device has a Sample Well (marked “S”) and a result window with the Test position (marked “T”) and the Control position (marked “C”). Test samples are added in the Sample Well. If *L. monocytogenes* is present, a distinctive pink-purple line appears at the Test position. A line at the Control position forms to indicate the test worked properly. Therefore, two lines—one at the Control position and one at the Test position—indicate a positive result, while one line only at the Control position indicates a negative result.

Brief Test Procedure

1. Dispense 80 µL of sample in the Sample Well (2 drops).
2. Read the result in 8 minutes, but not later than 10 minutes.

Result Interpretation

Positive

Two colored lines—one each at the Test and Control positions—indicate that the *L. monocytogenes* have been detected. The test result can be read as soon as a distinctive pink-purple line appears at the Test position. In most strong positive cases, the Test line will appear before the Control line. The Test line may appear after the Control line in some weak positive cases, and the Control line may become darker than the Test line. The three possible positive cases, therefore, are:

- a. Two strong colored lines, one each at Test and Control positions.
- b. One strong colored line at the Test position and one lighter colored line at the Control position.
- c. One light colored line at the Test position and one strong colored line at the Control position.

Negative

Only one colored line at the Control position, with no distinctive colored line at the Test position other than the normal faint background color indicates the absence of *L. monocytogenes*.

Invalid

A distinctive pink-purple line should always appear at the Control position. The test is invalid if no line forms at the Control position.

Stability and Storage

The **BioSign® Listeria** test kit should be stored at 2–30°C in the sealed pouch. The expiration date given was established under these conditions.

