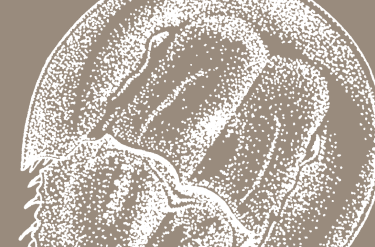


# Endosafe<sup>®</sup> Rapid Single Test Vials

## Assay Guide



Gently tap the bottom of the LAL and Positive Product Control (PPC) and Single Test Vials (STV) on hard surface.



Collect sample into sterile non-pyrogenic container.



Aseptically add 0.2 mL of sample into green cap LAL assay tube; gently mix.



Aseptically add 0.2 mL of sample into red cap PPC assay tube; gently mix.



Immediately place reaction tubes in 37°C dry bath or water bath.



Incubate for times indicated on vial label (+/- 2 minutes); timing is critical.



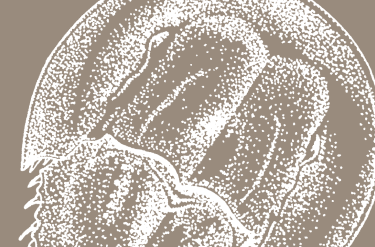
Invert tube 180 degrees.



Record results: + if firm gel, - if no firm gel; PPC must gel for test to be valid.

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## Assay Guide



### Reagents Provided

Lyophilized LAL in single-test vials. Do not add samples until immediately prior to use.

### Storage

Lyophilized LAL should be stored at 2-8°C; avoid exposure to temperatures above 25°C. The tube should be discarded if there is any yellow discoloration.

All materials coming into contact with specimen or test material must be endotoxin-free. Glassware must be depyrogenated by validated conditions. Plasticware labeled as sterile and disposable is usually endotoxin-free. However, it is prudent to test for endotoxin those materials that cannot be heat sterilized or those which are sold without an endotoxin-free label.

### Reagents and Materials Not Provided

LAL Reagent Water (non-interfering; must be used as a negative water control to prepare samples and positive controls).

A water bath or heating block is required to incubate the assay mixture at a temperature of 37°C, plus or minus 1°C. Note: An incubator is not suitable for the necessary heat transfer.

Sterile, endotoxin-free accessories are needed which include: depyrogenated borosilicate tubes for sample dilution; a calibrated mechanical pipettor with endotoxin-free, disposable plastic tips for accurate delivery of volumes less than 0.2mL.

Test tube racks are needed for holding reaction tubes. Timers are useful in measuring incubation times and endotoxin mixing periods.

### Reagent Preparation

Single-test LAL must be incubated immediately after rehydration with test sample. The LAL is reconstituted by adding directly into the test vial, 0.2 mL of control solution or sample to be tested.

### Specimen Collection and Preparation

Specimens must be collected and prepared using depyrogenated materials and endotoxin-free reagents. Since the LAL-endotoxin reaction is pH dependent, an equal volume of the specimen to be tested and LAL should be mixed and demonstrated to have a pH within the range of 6.0 to 8.0. If pH adjustment is necessary, use buffer accordingly. Do not adjust the pH of unbuffered saline or water. Use aseptic technique at all times. If the specimen contains interfering substances, dilute or modify the specimen to an extent that eliminates interference.

### Test controls

Prepare the Negative Control by adding 0.2 mL of the LAL Reagent Water to the assay tube. For a Positive Product Control, add 0.2 mL of the test specimen, which may be modified or diluted consistent with validated conditions to the PC200 tube.

**Expected Values:** Gelation of PC200 and no gels in samples free of detectable endotoxin