biohelix®

next generation HDA nucleic acid analysis

IsoAmp® Rapid Staph Detection Kit

For Research Use Only

Catalog # D0100E
Size: 50 reactions
Store at -20°C

DESCRIPTION

The IsoAmp® Rapid Staph Detection Kit provides for the rapid detection of a *Staphylococcus aureus* specific gene. The IsoAmp® Rapid Staph Detection Kit is a nucleic acid test (NAT) that uses a target amplification method called Helicase-Dependent Amplification (HDA). Two sequence-specific primers amplify a *Staphylococcus aureus* sequence. A labeled probe hybridizes to the amplicon. The resulting complex is captured on the detection line on a test strip that is embedded in a disposable device called BESt™ (BioHelix Express Strip) Cassette. A visible test line is formed when the target sequence is present in the sample.

Advantages of the IsoAmp® Rapid Staph Detection Kit:

Near "instrument-free" - isothermal reaction plus disposable detection cassette
High sensitivity & specificity - target amplification and nucleic acid probe test
Amplicon containment - closed disposable cassettes reduce amplicon cross contamination
Rapid test - total turnaround time is 1.5 hour

Intended Use:

The kit may be used as an aid to detect *Staphylococcus aureus* in positive blood cultures in a research setting. This kit is not intended for diagnostic use.

REAGENTS

Reagent information for the IsoAmp® Rapid Staph Detection Kit is provided below.

Materials Provided:

IsoAmp® Rapid Staph Detection Kit (Cat. No. D0100E)

IsoAmp® Enzyme Mix (50 tests)	175 µl
IsoAmp® Staph Reaction Mix (50 tests)	5 x 215 µl
SA Control Template pSA101 (1 ng/µl)	2 x 100 µl
BESt™ Cassette: Type I	50 units

Materials Required But Not Provided

3 Micropipettors: 1 - 20 µl, 20 - 200 µl, and 200 – 1,000 µl
2 water baths or heat blocks (65°C ± 1°C & 95°C)
mineral oil

Materials Available from BioHelix

IsoAmp® II Universal tHDA kits and reagents
BESt™ Cassette
IsoAmp® Rapid mecA Detection Kit

RECOMMENDED STORAGE CONDITIONS

The BESt™ Cassette can be stored at room temperature. All other reagents should be stored at -20°C for storage shorter than 6 months and at -70°C for storage greater than 6 months. The IsoAmp® Staph Reaction Mix is sensitive to light and should be kept in the dark upon receipt. Avoid repeated freeze-thaw cycles.

WARNINGS AND PRECAUTIONS

A. This kit has not been evaluated in a clinical trial and its performance in a clinical setting has not been determined.

B. Use routine laboratory precautions. Wear disposable, powder-less gloves, protective eye wear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly.

C. Since the IsoAmp® Rapid Staph Detection Kit utilizes an exponential amplification reaction, extra attention should be paid to avoid sample cross-over and carry-over contamination.

- ➜ Reaction assembly, amplification and detection steps should be carried out in physically separated locations.
- ➜ Always wear gloves.
- ➜ Open the reaction tubes only when adding reagents into them during reaction setup and keep them closed at any other time.
- ➜ Never open the tubes after the reactions are completed.
- ➜ The kit performance is extremely sensitive to changes in the magnesium and salt concentrations of the reaction; avoid introducing any substances that may affect these concentrations.
- ➜ Every freshly thawed reagent should be gently vortexed and spun down before being added to the reaction.

TEST PROCEDURE

1. Sample Preparation

1.1. Dilute blood culture 1:100 by combining 5.0 µl of culture with 495.0 µl distilled water in a 1.5 ml microcentrifuge tube. Vortex briefly to mix.

1.2. Transfer 25.0 µl of the diluted blood culture into a 0.2 ml PCR tube. Overlay 50 µl mineral oil and close the tube.

1.3. Place the tube in a 95°C water bath or heat block for 5 minutes. Place on ice when done.

2. Amplification

2.1. Positive and negative controls can be set up during the sample incubation. For the negative control, pipette 25 µl water into a sterile PCR tube and overlay with 50 µl mineral oil. For the positive control, combine 5 µl SA Control Template with 20 µl water in a sterile PCR tube and overlay with 50 µl mineral oil.

2.2. Combine 21.5 µl of the IsoAmp® Staph Reaction Mix and 3.5 µl IsoAmp® Enzyme Mix in a separate sterile 0.2 ml PCR or 0.5 ml microcentrifuge tube. Mix gently by pipetting. Keep the tube on ice until ready for use. Add 25 µl of this mix to each of the preheated samples and the controls below the mineral oil layer; mix gently by pipetting.

2.3. Incubate the reaction tube in a water bath or heat block at 65°C for 60 minutes.

3. Detection

Important:

- *Do not open the reaction tube!*
- *Once assembled with the reaction tube, never open the BESt™ cassette!*

3.1 BESt™ cassette consists of two parts: an inner amplicon cartridge and an outer detection chamber. The amplicon cartridge holds running buffer and the reaction tube in place and the detection chamber holds a DNA test strip.

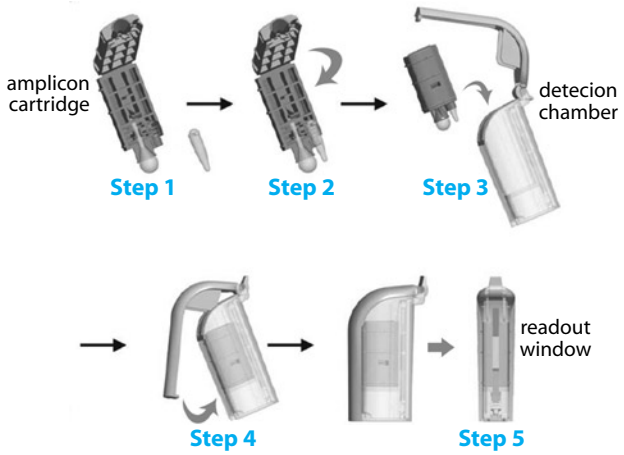

Figure 1. Diagrams for detection procedure.

3.2 Insert the reaction tube in an amplicon cartridge next to running buffer (Fig. 1, step 1). Fold the cartridge in half and firmly close it (Fig. 1, step 2), revealing an arrow on the top.

3.3 Insert the closed cartridge halfway in a detection chamber (Fig. 1, step 3), with the arrow pointing the DNA test strip: do not use force to push it down.

3.4 Keep the assembled cassette upright and lower the handle and push it into the chamber body to close the cassette (Fig. 1, step 4). The handle will push the cartridge down, and lock into place when closed completely (Fig. 1, step 5).

3.5 Read the result after 10 to 15 minutes through the readout window*. The readout is invalid after 30 minutes. A *S. aureus* positive sample displays a **T** (test) line and a **C** (control) line on the DNA test strip (Fig. 2A). The presence of a **C** line alone indicates a negative test result for *S. aureus* in the blood culture (Fig. 2B). No line indicates device failure and the result is invalid (Fig. 2C). In this case, the corresponding sample needs to be retested (go back to Amplification step 2.1).

3.6 Record the result.

** Note: If the control line is not displayed after 5 minutes, keep the cassette upright and tap it gently on the bench several times to accelerate the flow.*

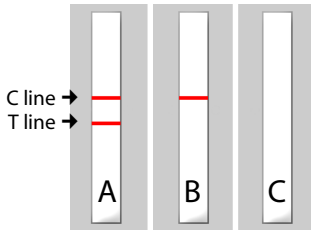

Figure 2. Diagrams of typical test results on BESt™ Cassette.

A. Two lines - positive.
B. One line - negative.
C. No line- failure or invalid.

For technical support:

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