FAST EXPRESS REAGENT KIT

INTENDED USE:

The intended use of the Gen-Probe FAST Express Reagent Kit is to improve the handling of excessively viscous urogenital specimens in the Gen-Probe transport medium.

REAGENTS

DILUENT (A): Buffered solution with 0.02% sodium azide.

REAGENT (B): Lyophilized reagent in buffer.

WARNINGS AND PRECAUTIONS:

The FAST Express reagents are for in vitro diagnostic use. Avoid contact of the FAST Express reagents with skin, eyes and mucous membranes. Wash with water if these reagents come into contact with skin or eyes. If spills of these reagents occur, dilute with water and wipe dry.

STORAGE AND HANDLING REQUIREMENTS:

The reagents contained in the Gen-Probe FAST Express Reagent kit are to be stored at 2° to 8°C and are stable until the date stamped on the container. If the reagents freeze during shipping, allow to come to room temperature, and vortex before use.

The FAST Express Reagent is stable for four weeks after reconstitution when stored at 2° to 8°C.

REAGENT PREPARATION:

1. Remove the caps from Diluent (A) and Reagent (B).
2. Pour the contents of Diluent (A) into the Reagent (B) vial. (DO NOT DISCARD DILUENT (A) VIAL.)
3. Recap the Reagent (B) vial and dissolve the contents of the Reagent (B) vial by gently inverting several times. The resulting solution is the FAST Express Reagent.
4. Pour the reconstituted FAST Express Reagent back into the Diluent (A) vial. Discard the Reagent (B) vial.
5. Place the dropper tip onto the Diluent (A) vial.
6. When not using the FAST Express Reagent, store at 2° to 8°C.

PROCEDURE:

1. Allow the urogenital specimens to reach room temperature.
2. Vortex each Gen-Probe Transport Tube prior to processing.
3. Pull the collection swab partially out of the Transport Tube and visually assess the viscosity.

   For non-viscous specimens, express the swab and process as described in the PACE® 2 package insert.
4. For viscous specimens replace the swab into Transport Tube.
5. Add one drop of FAST Express Reagent to the viscous specimen, and recap the transport tube.
6. Incubate the treated specimens for 10 minutes in a 60°C water bath.
7. Remove the treated specimens from the water bath, vortex, and express the swab and process as described in the PACE 2 package insert.

LIMITATIONS:

These reagents and this procedure have been tested using urogenital specimens only. Performance with other types of specimens has not been assessed.

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