INTENDED USE

The reagents in the Detection Reagent Kit are used with tests according to the instructions outlined in the respective package inserts and the Instrument Operator’s Manual.

REAGENTS AND MATERIALS PROVIDED

Hologic Detection Reagent Kit
Catalog No. 201791   1200 Tests

Detection Reagent I
0.1% Hydrogen Peroxide in 0.001 N Nitric Acid. 1 x 240 mL

Detection Reagent II
1 N Sodium Hydroxide. 1 x 240 mL

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use.

Avoid contact of Detection Reagents I and II 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 Detection Reagent Kit are to be stored at 2°C to 25°C and are stable until the date stamped on the container. If the reagents freeze during shipping or storage, a precipitate may form. Heating the reagents at 37°C to 60°C facilitates dissolution of the precipitate. If heating is necessary, cool the reagents to room temperature and thoroughly mix prior to use.

PROCEDURE

1. Remove the old Detection Reagents and empty lines using WASH protocol.

2. Invert bottles to thoroughly mix the contents of the new Detection Reagents.

3. Install the reagents in the instrument as outlined in the appropriate Operator’s Manual. For instruments which require the use of secondary Detection Reagent reservoirs, refer to Operator's Manual for instructions on proper use of reservoirs.

PROCEDURAL NOTES

1. Ensure that all lines are primed with Detection Reagents prior to using the instrument.

2. Check the background count of newly transferred reagents when operating instruments requiring the use of secondary Detection Reagent reservoirs. The mean background count should be below the specifications listed in the Instrument Operator’s Manual.

3. If applicable, program the instrument software with the new volumes of the Detection Reagents.