Aptima Auto Detect Kit

For in vitro diagnostic use.

Intended Use

The Aptima Auto Detect Kit is to be used with the Leader® HC+ Luminometer and the Tigris® instrument system.

Materials Provided

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Aptima Auto Detect Kit- Cat. No. 1048

Symbol	Component	Description	Quantity
R1	Aptima Auto Detect 1	Aqueous solution containing 0.1% hydrogen peroxide and 0.001 N nitric acid	1 x 245 mL
R2	Aptima Auto Detect 2	1.6 N sodium hydroxide	1 x 245 mL

Warnings and Precautions

- A. For in vitro diagnostic use.
- B. Avoid contact of Auto Detect 1 and 2 with skin, eyes, and mucous membranes. Wash with water if these fluids come into contact with skin or eyes. If spills of these fluids occur, dilute with water and wipe dry. Use routine laboratory precautions.

Storage and Handling Requirements

The fluids contained in the Aptima Auto Detect Kit are to be stored at 15° C to 30° C. If the fluids freeze during shipping or storage, a precipitate may form. Heating the fluids at 37° C to 60° C facilitates dissolution of the precipitate. If heating is necessary, cool the fluids to room temperature and thoroughly mix prior to use. Fluids must be at 18° C to 28° C before use with the Leader HC+ Luminometer and at 15° C to 30° C before use with the Tigris System.

Procedure

- 1. Remove the existing Auto Detect bottles.
- 2. Install the new Auto Detect bottles in the instrument as outlined in the appropriate instrument's Operator's Manual.

Procedural Notes

- 1. Ensure the instrument is primed with Auto Detects prior to use.
- 2. Possible sources of error include operator error during installation of bottles or use of outdated Auto Detect 1 and Auto Detect 2.



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