Aptima Auto Detect Kit

For in vitro diagnostic use.
Rx only

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

Materials Provided
Aptima Auto Detect Kit- Cat. No. 301048

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Component</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>Aptima Auto Detect 1</td>
<td>Aqueous solution containing 0.1% hydrogen peroxide and 0.001 N nitric acid</td>
<td>1 x 245 mL</td>
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<tr>
<td>R2</td>
<td>Aptima Auto Detect 2</td>
<td>1.6 N sodium hydroxide</td>
<td>1 x 245 mL</td>
</tr>
</tbody>
</table>

Warnings and Precautions
A. For in vitro diagnostic use.
B. Avoid contact of Auto Detect 2 with skin, eyes, and mucous membranes. If this fluid comes into contact with skin or eyes, wash with water. If this fluid spills, dilute the spill with water before wiping dry.
C. Some reagents of this kit are labeled with risk and safety symbols.

Note: Hazard Communication information for labeling of globally marketed products reflects the US and EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com.

US Hazard Information

Auto Detect 2
SODIUM HYDROXIDE 5 – 10%

DANGER
H314 – Causes severe skin burns and eye damage
P260 – Do not breathe dust/fume/gas/mist/vapors/spray
P264 – Wash face, hands and any exposed skin thoroughly after handling
P280 – Wear protective gloves/protective clothing/eye protection/face protection
P310 – Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 – Immediately call a POISON CENTER or doctor/physician
P303 + P361 + P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 – Wash contaminated clothing before reuse
P304 + P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 – Immediately call a POISON CENTER or doctor/physician
P301 + P330 + P331 – IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P405 – Store locked up
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.