

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

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 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

EU Hazard Information



Auto Detect 2

SODIUM HYDROXIDE 5 – 10%

DANGER

H314 - Causes severe skin burns and eye damage

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P280 - Wear eye protection/ face protection

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

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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This product may be covered by one or more U.S. patents identified at www.hologic.com/patents.

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