

Aptima® Auto Detect Kit (Panther® System)

Instructions for Use
For *in vitro* diagnostic use
Rx only

Intended Use

The Aptima® Auto Detect Kit is an ancillary that facilitates a chemiluminescent reaction that enables the detection of Internal Control (IC) and target amplicon bound to Acridinium Ester (AE) labeled probe oligos. The reaction emits light, which is measured and reported as Relative Light Units (RLUs). The Aptima Auto Detect Kit is used to perform Aptima assays on the Panther® System.

Materials Provided**Aptima Auto Detect Kit (Cat. No. 303013)**

(Store at 15°C to 30°C upon receipt)

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



Warnings and Precautions

- 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.
- For professional use.
- Use routine laboratory precautions.

Storage and Handling Requirements

- Store the Aptima Auto Detect Kit at 15°C to 30°C.
- Fluids must be at 15°C to 30°C before use. Once opened, fluids are stable for 60 days.
- If precipitate has formed, heat the fluids at 37°C to 60°C to facilitate dissolution of the precipitate. Cool the fluids to room temperature and thoroughly mix prior to use.
- Do not use after the expiration date.

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.hologicds.com.

US Hazard Information	
	<p>Auto Detect 2 SODIUM HYDROXIDE 5 – 10% DANGER</p> <p>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</p>
EU Hazard Information	
	<p>Auto Detect 2 SODIUM HYDROXIDE 5 – 10% DANGER</p> <p>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</p>

Procedure

Replace bottles in the Universal Fluids Drawer when notified by the system. Refer to the *Panther/Panther Fusion® System Operator's Manual*.

Contact Information and Revision History



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For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

This product is intended for use only in the field of human *in vitro* diagnostics.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

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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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Revision History	Date	Description
AW-26510-001 Rev. 001	May 2022	<ul style="list-style-type: none"> Created Aptima Auto Detect Kit IFU AW-26510-001 Rev. 001 based on 502180EN Rev.005 for regulatory compliance with IVDR Added Instructions for Use Updated the Intended Use section Added Global GHS notification Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support