Aptima System Fluid Preservative Kit (Tigris® DTS® System)

For in vitro diagnostic use.
Rx only

Intended Use
The Aptima System Fluid Preservative Kit is used with the Aptima Assays on the Tigris DTS System. Use the System Fluid Preservative Kit according to the instructions outlined in the appropriate assay package insert and the Tigris DTS System Operator’s Manual.

Reagents
Reagents for the Aptima System Fluid Preservative Kit are provided below for the Tigris DTS System. Reagent identification Symbols are also listed next to the reagent name.

Materials Provided
Aptima System Fluid Preservative Kit (1 box) (Cat. No. 302380)

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Fluid Preservative</td>
<td>1 x 200 mL</td>
<td>System Fluid Preservative contains 2.5% sodium hypochlorite that inhibits microbial growth in aqueous media.</td>
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</tbody>
</table>

Materials Required But Not Provided
Appropriate Aptima Assay Kit(s)
Tigris DTS System

Materials Available from Hologic
Appropriate Aptima Assay Kit(s)
Tigris DTS System (Cat. No. 105118)

Warnings and Precautions
A. Undiluted System Fluid Preservative is corrosive.
B. Avoid System Fluid Preservative contact with skin, eyes, and mucous membranes. Wash with water if contact with this fluid occurs. If a spill of this fluid occurs, dilute with water before wiping dry.
C. Use routine laboratory precautions. Do not pipette by mouth, do not eat, drink, or smoke in the laboratory work area. Wash hands thoroughly after handling Aptima Assay Fluids.
D. Do not top off System Fluid Preservative containers.
E. 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

System Fluid Preservative
SODIUM HYPOCHLORITE 1 – 5%
DANGER
H314 – Causes severe skin burns and eye damage
H410 – Very toxic to aquatic life with long lasting effects.
H400 – Very toxic to aquatic life.
EUH031 – Contact with acids liberates toxic gas
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
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

System Fluid Preservative
SODIUM HYPOCHLORITE 1 – 5%
DANGER
H314 – Causes severe skin burns and eye damage
H410 – Very toxic to aquatic life with long lasting effects
EUH031 – Contact with acids liberates toxic gas
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
P273 – Avoid release to the environment
P280 – Wear eye protection/ face protection

Storage and Handling Requirements
A. The Aptima System Fluid Preservative is stable when stored unopened at 15° to 30°C until the expiration date.
B. Do not use after the expiration date. Do not freeze. Once opened, Aptima System Fluid Preservative is stable for 30 days when stored at room temperature.
C. The Aptima System Fluid Preservative may be used between 15° and 30°C and 20% to 85% relative humidity.

Procedural Notes
System Fluid
Pour the entire bottle of System Fluid Preservative into an empty Tigris DTS System Fluid Container. Fill the System Fluid Container with water for the Tigris DTS System until the liquid level is between the two solid lines on the container. For water specifications for the Tigris DTS System, see the Tigris DTS System Operator’s Manual. System Fluid is stable for 30 days when stored at room temperature (15° to 30°C) and can be used for up to 14 days after loading onto the Tigris DTS System.

Limitations
Assay must be performed, and results interpreted according to the procedures of the appropriate assay kit package insert and the Tigris DTS System Operator’s Manual.
Deviations from these procedures may produce unreliable results. Use of outdated Aptima System Fluid Preservative may produce erroneous results.

**Expected Values**

Please reference the appropriate assay package insert for expected results.