

Aptima Assay Fluids Kit (Tigris® DTS® System)

For *in vitro* diagnostic use.

Rx only

Intended Use

The Aptima Assay Fluids Kit is used with the Aptima Assays on the Tigris DTS System. Use the Assay Fluids 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 Assay Fluids Kit are provided below for the Tigris DTS System. Reagent identification Symbols are also listed next to the reagent name.

Materials Provided

Aptima Assay Fluids Kit (1 box) (Cat No. 302382)

Symbol	Component	Quantity	Description
W	Aptima Wash Solution	1 x 2.9 L	10 mM HEPES buffered solution containing less than 2% preservative
O	Aptima Oil Reagent	1 x 260 mL	Silicone Oil
DF	Aptima Buffer for Deactivation Fluid	1 x 1.4 L	800 mM Bicarbonate buffered solution. Must be mixed 1:1 with bleach (5% to 7% sodium hypochlorite) before use

Materials Required But Not Provided

- Appropriate Aptima Assay Kit(s)
- Tigris DTS System
- Household bleach (5%-7% sodium hypochlorite)





Materials Available from Hologic

- Appropriate Aptima Assay Kit(s)
- Tigris DTS System (Cat. No. 105118)

Warnings and Precautions

- A. Fluids in the kit are not corrosive.
- B. 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.
- C. Avoid microbial and ribonuclease contamination of Aptima Assay Fluids.
- D. Do not top off Assay Fluids 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.hologicds.com.

US Hazard Information	
	<p>Aptima Oil POLYDIMETHYLSILOXANE 95 – 100% WARNING H315 - Causes skin irritation H319 - Causes serious eye irritation 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 P337 + P313 - If eye irritation persists: Get medical advice/attention P302 + P352 - IF ON SKIN: Wash with plenty of soap and water P332 + P313 - If skin irritation occurs: Get medical advice/attention P362 - Take off contaminated clothing and wash before reuse</p>
	<p>Buffer for Deactivation Fluid SODIUM HYDROXIDE 1 – 5% WARNING H315 - Causes skin irritation H319 - Causes serious eye irritation 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 P337 + P313 - If eye irritation persists: Get medical advice/attention P302 + P352 - IF ON SKIN: Wash with plenty of soap and water P332 + P313 - If skin irritation occurs: Get medical advice/attention P362 - Take off contaminated clothing and wash before reuse</p>
EU Hazard Information	
	<p>Aptima Oil POLYDIMETHYLSILOXANE 100% WARNING H315 - Causes skin irritation H319 - Causes serious eye irritation</p>
	<p>Buffer for Deactivation Fluid SODIUM HYDROXIDE 1 – 5% SODIUM HYPOCHLORITE <1% WARNING H315 - Causes skin irritation H319 - Causes serious eye irritation</p>

Storage and Handling Requirements

- A. The Aptima Assay Fluids are 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 Assay Fluids are stable for 30 days when stored at room temperature.
- C. The Aptima Assay Fluids may be used between 15° and 30°C and 20% to 85% relative humidity.

Procedural Notes

Deactivation Fluid

Pour undiluted bleach into an empty Tigris DTS System Deactivation Fluid bottle until the liquid level is between the two solid lines on the bottle. Open a new bottle of Buffer for Deactivation Fluid and pour the contents into the Deactivation Fluid bottle. After adding the Buffer for Deactivation Fluid, make sure that the liquid level is above the Minimum Total Fill mark on the Deactivation Fluid bottle. Deactivation 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 Assay Fluids may produce erroneous results.

Expected Values

Please reference the appropriate assay package insert for expected results.



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