

Aptima™ SARS-CoV-2/Flu Controls Kit

For in vitro diagnostic use.

For use in Australia only.

Intended Use

The Aptima™ SARS-CoV-2/Flu Controls Kit is intended to be used with the Aptima SARS-CoV-2/Flu assay only. Additional information on Aptima SARS-CoV-2/Flu Controls Kit can be found in the Aptima SARS-CoV-2/Flu assay package insert which may be referenced online at www.hologic.com.

Product Description

Aptima SARS-CoV-2/Flu Controls Kit (PRD-06816) (store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
Control-	Aptima SARS-CoV-2/Flu Negative Control	5 x 1.7 mL
	Buffered solution containing < 5% detergent.	
Control+	Aptima SARS-CoV-2/Flu Positive Control	5 x 1.7 mL
	Non-infectious nucleic acid in a buffered solution containing < 5% detergent.	

Storage Condition

Store at 2-8°C. Controls are single use only.

Warnings and Limitations

A. Use routine laboratory precautions. Do not eat, drink or smoke in designated work areas. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

Note: As in any reagent system, excess powder on some gloves may cause contamination of opened tubes. Powderless gloves are required.

- B. Dispose of all materials that have come in contact with specimens and reagents in accordance with applicable national, international, and regional regulations.
- C. Avoid cross-contamination during the controls handling steps. Be especially careful to avoid contamination by the spread of aerosols when loosening or uncapping the controls. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. Change gloves if they come in contact with the controls.

Quality Control

Each laboratory should establish their own frequency of Quality Control testing based on applicable local laws, regulations, and standard good laboratory practice.





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