

Aptima SARS-CoV-2 Assay Kit for use with Panther® System by **Hologic, Inc.** is available for procurement through the Supply Division and offered at all-inclusive* price US\$12.00 per test. A technical and commercial description of the product is presented in Table 1 below.

Table 1 Aptima SARS-CoV-2 Assay Kit

UNICEF Material Number	Product Description	Product Code	Pack Size	Price* per Pack, USD	Lead Time, <i>indicative</i>	Incoterms
S0003898	<p>Aptima SARS-CoV-2 Assay Kit/250 tests, which includes:</p> <ul style="list-style-type: none"> - Aptima SARS-CoV-2 Refrigerated Box (Box 1 of 2); - 1 Vial, (A) Aptima SARS-CoV-2 Amplification Reagent; - 1 Vial, (E) Aptima SARS-CoV-2 Enzyme Reagent - 1 Vial, (P) Aptima SARS-CoV-2 Probe Reagent; - 1 Vial, (IC) Aptima SARS-CoV-2 Internal Control; - Aptima SARS-CoV-2 Room Temperature Box (Box 2 of 2); - 1 Vial, (AR) Aptima SARS-CoV-2 Amplification Reconstitution Solution (27.7 mL); - 1 Vial, (ER) Aptima SARS-CoV-2 Enzyme Reconstitution Solution (11.1 mL); - 1 Vial, (PR) Aptima SARS-CoV-2 Probe 	PRD-06419	250	3,000.00	3 - 8 weeks	DAP

	Reconstitution Solution (35.4 mL).					
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The price is all-inclusive under the Global Access Initiative (GAI) Pricing for Eligible Countries. This all-inclusive pricing applies only to sites with previously installed Panther instruments. The all-inclusive price includes all the necessary supplies and services needed to generate a patient result, including annual service and maintenance for Panther instrument, reagents and consumables, replacement tests (for one set of controls and calibrators and documented instrument errors), and freight and logistics. The supplier is responsible for shipping costs and the customer is responsible for import duties and taxes unless waived.

Intended use:

Aptima SARS-CoV-2 Assay Kit is a nucleic acid amplification in vitro diagnostic test intended for qualitative detection of NRA from the SARS-CoV-2 virus isolated and purified from upper respiratory tract specimens obtained from individual who meet COVID-19 clinical and /or epidemiological criteria.

The following PCR equipment with relevant software are compatible with the test:

- Panther® System (Cat. No. 303095)

The following are not a part of the kit but required to run the test and provided in corresponding quantities free of charge when ordered with APTIMA SARS-CoV-2 Assay:

- Aptima Assay Fluids Kit (Cat. No. 303014; 1000 tests: Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)
- Aptima Auto Detect Kit (Cat. No. 303013; 1000 tests)
- Multi-tube units (Cat. No. 104772-02)
- Panther Waste Bag Kit (Cat. No. 902731)
- Panther Waste Bin Cover (Cat. No. 504405)
- Panther Run Kit (Cat. No. 303096; 5000 tests: contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects)
- Tips, 1000 µL conductive, liquid sensing (Cat. No. 10612513 (Tecan))
- Hologic specimen lysis tube, solid cap (100 tubes and caps per bag) (#ASY-14723, #M995133) (Cat. No. PRD-06554)
- Replacement Caps for the 250-test kits:

- Amplification and Probe reagent reconstitution solutions - CL0041 (100 caps)
- Enzyme Reagent reconstitution solution - 501616 (100 caps)
- TCR and Selection reagent - CL0040 (100 caps)

The following materials are not a part of the kit but required to run the test:

- Aptima Multitest Swab Specimen Collection Kit (Cat. No. PRD-03546)
- Bleach, 5% to 7% (0.7M to 1.0M) sodium hypochlorite solution
- Hologic Bleach Enhancer for Cleaning - 302101
- Disposable gloves
- Tube rocker

Reagent Storage and Handling Requirements:

A. The following reagents are stable when stored at 2°C to 8°C (refrigerated):

Aptima SARS-CoV-2 Amplification Reagent.
Aptima SARS-CoV-2 Enzyme Reagent.
Aptima SARS-CoV-2 Probe Reagent.
Aptima SARS-CoV-2 Internal Control.
Aptima SARS-CoV-2 Positive Control.
Aptima SARS-CoV-2 Negative Control.

B. The following reagents are stable when stored at 2°C to 30°C:

Aptima SARS-CoV-2 Amplification Reconstitution Solution.
Aptima SARS-CoV-2 Enzyme Reconstitution Solution.
Aptima SARS-CoV-2 Probe Reconstitution Solution.
Aptima SARS-CoV-2 Selection Reagent.

C. The following reagents are stable when stored at 15°C to 30°C (room temperature):

Aptima SARS-CoV-2 Target Capture Reagent.
Aptima Wash Solution.
Aptima Buffer for Deactivation Fluid.
Aptima Oil Reagent.

Shipping Stability:

Ambient

Shelf life:

12 months

Should you have any questions regards to ordering please contact Tatsiana Ptashnik tptashnik@unicef.org

Should you have any technical questions regards to the test please contact Wandani Sebonego wsebonego@unicef.org