Use of Aptima® Specimen Transfer Tube for Specimen Processing with the Aptima® SARS-CoV-2 Assay

US only: This workflow for the test has not been reviewed by the FDA. This workflow is being distributed in accordance with Section IV.C. of the FDA's policy for diagnostic tests for Coronavirus disease – 2019 during the public health emergency at *https://www.fda.gov/media/135659/download [fda.gov].*

For Worldwide Distribution

Purpose

The purpose of this Customer Technical Bulletin (CTB) is to notify our customers of an alternative specimen processing tube, the Aptima® Specimen Transfer tube from the Aptima Specimen Transfer Kit (Cat. No. 301154C or PRD-05110), for use with the Aptima SARS-CoV-2 assay on the Panther® system and Panther Fusion® system.

The following information is provided in this CTB:

A. Product Information
B. Implementation Information
C. Specimen Processing Using the Aptima Specimen Transfer Tube
D. Specimen Handling Using the Aptima Specimen Transfer Tube
E. Assay Performance with the Aptima Specimen Transfer Tube

Scope

This CTB is effective upon receipt and is intended for site administrators, laboratory supervisors, and users of the Aptima SARS-CoV-2 assay on the Panther system and Panther Fusion system.

Hologic is committed to providing solutions to meet customer needs under the current conditions. To accommodate the high demand for COVID-19 testing, Hologic has provided the additional option to use an alternative specimen processing tube, the Aptima Specimen Transfer tube from the Aptima Specimen Transfer Kit, for processing specimens for testing with the Aptima SARS-CoV-2 assay.

Description	Catalog Number
Aptima Specimen Transfer Kit	301154C or PRD-05110

The Aptima Specimen Transfer tube is for use in specimen processing following sample collection of nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals meeting COVID-19 clinical and/or epidemiological criteria.

What is Affected

A. Product Information

Refer to Table 1 for the Aptima Specimen Transfer Kit/tube catalog numbers.

Table 1. Aptima Specimen Transfer Kit/Tube Catalog Numbers

Kit Description	Catalog Number	Component Description	Quantity
Aptima Specimen Transfer Kit	301154C or PRD-05110	Tube containing Specimen Transport Medium (STM), 2.9 mL	100 tubes

B. Implementation Information

Refer to the appropriate package insert for the Aptima SARS-CoV-2 assay for detailed information for specimen handling and testing. Refer to the Safety Data Sheet for the Aptima Specimen Transfer Kit for any hazards and precautions.

***Warning & Precaution**:* Expiration dates listed on the Aptima Specimen Transfer tubes pertain to the transfer of sample into the tube and not to testing of the sample. Specimens transferred any time prior to these expiration dates are valid for testing provided they are transported and stored in accordance with the appropriate package insert, even if these expiration dates have passed.

C. Specimen Processing Using the Aptima Specimen Transfer Tube

1. Prior to testing on the Panther system, transfer 1 mL of the collected specimen* to an Aptima Specimen Transfer tube.
2. Recap the Aptima Specimen Transfer tube tightly.
3. Gently invert the tube 2 to 3 times to ensure complete mixture of the specimen.

***Note**: When testing frozen specimen, allow specimen to reach room temperature prior to processing.*

4. Storing specimens before testing
   a. After collection, specimens collected in VTM/UTM can be stored at 2°C to 8°C up to 96 hours before transferred to the Aptima Specimen Transfer tube. Remaining specimen volumes can be stored at ≤-70°C.
   b. Specimens in the Aptima Specimen Transfer tube may be stored under the following condition:
      - 2°C to 30°C up to 6 days

      Note: *It is recommended that specimens transferred to the Aptima Specimen Transfer tube are stored capped and upright in a rack.*

D. Specimen Handling Using the Aptima Specimen Transfer Tube

Note: Prepare specimens as outlined in Step C. before loading specimens onto the Panther system or Panther Fusion system.

1. **Do not vortex samples.**
2. Inspect sample tubes before loading into the rack. If a sample tube contains bubbles or has a lower volume than is typically observed, gently tap the bottom of the tube to bring contents to the bottom.

Note: *To avoid a processing error, ensure adequate specimen volume is added to the Aptima Specimen Transfer tube. When 1 mL of collected specimen is added to the Aptima Specimen Transfer tube, there is sufficient volume to perform 3 nucleic acid extractions.*

E. Assay Performance with the Aptima Specimen Transfer Tube

Analytical Sensitivity

The determined 0.01 $TCID_{50}$/mL analytical sensitivity (limit of detection) of the Aptima SARS-CoV-2 assay was confirmed using the Aptima Specimen Transfer tube specimen preparation workflow. Confirmation was performed using inactivated cultured SARS-CoV-2 virus (USA-QA1/2020; BEI Resources; NR-52281) in negative clinical nasopharyngeal (NP) swab, saline, Liquid Amies and specimen transport medium (STM) swab collection media by testing 20 replicates with one reagent lot (Table 2).

Table 2. LoD Confirmation with the Aptima Specimen Transfer Workflow

Target	Matrix	N Valid	N Positive	% Positive	Avg kRLU	StdDev kRLU	%CV
Inactivated SARS-CoV-2 virus	NP Swab	20	20	100%	1063	61	5.8%
	STM	20	20	100%	1064	116	10.9%
	Saline	20	20	100%	1102	60	5.4%
	Liquid Amies	20	20	100%	1101	51	4.7%

Clinical Performance with Contrived Panel

The clinical performance of the Aptima SARS-CoV-2 assay using the Aptima Specimen Transfer tube specimen preparation workflow was evaluated in comparison to a panel of contrived specimens. For the study, a panel of 115 remnant clinical nasopharyngeal specimens was tested using both the Panther Fusion Specimen Lysis Tube (Specimen Lysis Tube) and Aptima Specimen Transfer tube workflows. All specimens were collected from US patients with signs and symptoms of respiratory infection. The panel consisted of 65 SARS-CoV-2 positive and 50 SARS-CoV-2 negative specimens. Of the 65 positive specimens, 40 were at concentrations 0.5-2x LoD and 25 were at concentrations 3-5x LoD using inactivated cultured SARS-CoV-2 virus (USA-QA1/2020; BEI Resources; NR-52281) as the target.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for both specimen preparation workflows were calculated in relation to the expected result of the contrived specimen panel, as shown in Table 3 for the Aptima Specimen Transfer tube and Table 4 for the Specimen Lysis Tube. Detection characteristics for the contrived specimens were calculated by target concentration, as shown in Table 5. Both specimen preparation workflows showed 100% agreement for the evaluated panels.

Table 3. Performance of the Aptima Specimen Transfer Workflow Relative to Expected Results

		Expected Result		
		Positive	**Negative**	Total
Aptima Specimen Transfer Result	**Positive**	**65**	0	**65**
	Negative	0	**50**	**50**
	Total	**65**	**50**	**115**

Overall Agreement	100%	(96.8% - 100%)
Positive Agreement	100%	(94.4% - 100%)
Negative Agreement	100%	(92.9% - 100%)

Table 4. Performance of the Specimen Lysis Tube Workflow Relative to Expected Results

		Expected Result		
		Positive	**Negative**	Total
Specimen Lysis Tube Result	**Positive**	**65**	0	**65**
	Negative	0	**50**	**50**
	Total	**65**	**50**	**115**

Overall Agreement	100.0%	(96.8% - 100.0%)
Positive Agreement	100.0%	(94.4% - 100.0%)
Negative Agreement	100.0%	(92.9% - 100.0%)

Table 5. Detection Characteristics for Contrived Nasopharyngeal Swab Specimens

	Aptima Specimen Transfer Sample Workflow						Specimen Lysis Tube Sample Workflow					
Target Conc.	n Valid	n Positive	% Positive	Average kRLU	St Dev kRLU	%CV	n Valid	n Positive	% Positive	Average kRLU	St Dev kRLU	%CV
Neg	50	0	0	299	9.7	3.2	50	0	0	300	9.3	3.1
0.5x LoD	10	10	100	1050	208.5	19.9	10	10	100	1153	113.0	9.8
1.0x LoD	10	10	100	1176	102.1	8.7	10	10	100	1205	24.3	2.0
1.5x LoD	10	10	100	1222	31.6	2.6	10	10	100	1223	21.9	1.8
2.0x LoD	10	10	100	1225	22.6	1.8	10	10	100	1237	26.0	2.1
3.0x LoD	10	10	100	1228	13.6	1.1	10	10	100	1215	25.5	2.1
4.0x LoD	5	5	100	1238	16.7	1.4	5	5	100	1212	12.5	1.0
5.0x LoD	10	10	100	1237	18.2	1.5	10	10	100	1246	28.3	2.3

Clinical Performance with Natural Infected Positive Specimens

The clinical performance of the Aptima SARS-CoV-2 assay using the Aptima Specimen Transfer tube specimen preparation workflow was evaluated in comparison to the Specimen Lysis Tube workflow tested with both the Aptima and Panther Fusion SARS-CoV-2 assays. For the study, three dilutions of 15 unique SARS-CoV-2 positive nasopharyngeal swab specimens were prepared and processed using both workflows. SARS-CoV-2 samples were previously determined to be positive using a non-Hologic molecular assay.

The positive percent agreement between the Aptima SARS-CoV-2 Assay using the Aptima Specimen Transfer tube and the Specimen Lysis Tube workflows were 97.6% (87.4% – 99.6%) and 97.5% (87.1% - 99.6%), respectively, when compared to the Panther Fusion SARS-CoV-2 assay using the Specimen Lysis Tube workflow as reference. The positive percent agreement of the Aptima Specimen Transfer tube workflow was 97.4% (86.8% - 99.5%) when compared to the Specimen Lysis Tube workflow as reference.

What is Required

Ensure that appropriate personnel (laboratory, clinic, supply chain/inventory, purchasing, accounting and ordering physicians) are notified of the information documented in this CTB.

If there are any questions or concerns regarding this communication, please contact your local Hologic support representative. In the U.S., Hologic Technical Support may be reached at +1 888 484 4747 or +1 858 410 8511, or by e-mail at molecularsupport@hologic.com.

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