# Hologic® Direct Load Capture Cap Collection Kit — FLOQSwabs®

**Instructions for Use**

**US: For Emergency Use Authorization (EUA) Only**

IVD

**Rx only**

## Intended Use

The Hologic® Direct Load Capture Cap Collection Kit – FLOQSwabs® is intended to be used for clinician collection of mid-turbinate nasal and nasopharyngeal (NP) swab specimens for testing with the Aptima SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of NP swab specimens for testing with the Aptima SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A) and/or influenza B virus (Flu B). The Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs has not been evaluated for home use.

## Materials Provided

**100 Hologic Direct Load Capture Cap Collection Kit—FLOQSwabs® (Cat. No. PRD-06952)**

Each kit contains:

| Component | Quantity | Description |
|---|---|---|
| Swab | 1 | Individually wrapped, sterile swab |
| Direct Load Capture Cap tube | 1 | Tube containing Specimen Transport Medium (STM), 2.9 mL |

## Warnings and Precautions

A. Wash hands with soap before opening collection kit.

B. Use the provided swab only. Failure to use the provided swab may invalidate the test results.

C. Do not use if the swab is visibly damaged (i.e., if the swab tip or shaft is broken, or pouch is damaged or open).

D. Do not bend or shape the swab before collection. Do not use excessive force, pressure or bending when collecting the specimen as this may result in accidental breakage of the swab.

E. Fiber adhesion to the shaft has been tested for instantaneous specimen collection: longer contact between the swab and the collection area may cause fiber detachment.

F. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.

G. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.

H. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

I. When used with the Aptima SARS-CoV-2 assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

J. When used with the Aptima SARS-CoV-2/Flu assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.

K. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.

L. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs. Failure to use a new kit may invalidate the test results.

M. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

N. Do not use the kit after its expiration date to collect specimens.

## Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

## Direct Load Capture Cap Collection Kit – FLOQSwabs® Performance

Assay performance characteristics for the types of specimens (e.g., NP swabs) collected with the Direct Load Capture Cap Collection Kit – FLOQSwabs is provided in the clinical performance section of the Aptima SARS-CoV-2 assay package insert. Performance of the Direct Load Capture Cap Collection Kit – FLOQSwabs with the Aptima SARS-CoV-2/Flu assay can be found in the Analytical Sensitivity section of the Aptima SARS-CoV-2/Flu assay package insert. Package inserts for both the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label includes a field to record each unique specimen source.

## Nasal Mid-Turbinate (NMT) Specimen Collection and Handling – Aptima SARS-CoV-2 Assay only

**Instructions for nasal mid-turbinate (NMT) swab specimen collection (clinician collection only):**

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the mid-turbinate region. Rotate the swab several times against nasal wall.
4. Remove swab, insert it into the other nostril and repeat the process.

5. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit. - FLOQSwabs.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
7. Carefully break the swab shaft at the score line against the side of the tube.
8. Immediately discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

## Nasopharyngeal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay and Aptima SARS-CoV-2/Flu Assay

**Instructions for nasopharyngeal swab specimen collection (clinician collection only):**

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Tilt patient's head back 70 degrees. Gently and slowly insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.[1]

   **Note:** Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit. – FLOQSwabs.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

## Specimen Transport and Storage

Swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Refer to the Aptima SARS-CoV-2 assay package insert and the Aptima SARS-CoV-2/Flu assay package insert for proper specimen storage conditions.

**Note:** Specimens must be shipped in accordance with applicable national and international regulations.

1 https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

## Limitations

A. Use this collection kit only with the Aptima SARS-CoV-2 assay and the Aptima SARS-CoV-2/Flu assay. Performance has not been established with other products.

B. Use appropriate personal protective equipment (PPE) when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).[2] Mid-Turbinate Swabs are authorized for use with the Aptima SARS-CoV-2 assay only

2 World Health Organization's (WHO) Laboratory biosafety guidance related to coronavirus disease (COVID-19): interim guidance. https://www.who.int/publications/i/item/laboratorybiosafety-guidance-related-to-coronavirus-disease-(covid-19).

# Contact Information and Revision History

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For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.



AW-26526-001 Rev. 001
2022-05

| Revision History | Date | Description |
|---|---|---|
| AW-26526-001 Rev. 001 | May 2022 | • Created Hologic Direct Load Capture Cap Collection Kit IFU AW-26526-001 Rev. 001 based on AW-20232-001 Rev. 004 for regulatory compliance with IVDR<br>• Added Instructions for Use on the first page<br>• Updated contact information including: EC Rep, Australian Rep information, and technical support |