

Hologic® Direct Load Capture Cap Collection Kit — FLOQSwabs™

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 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 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).
- 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. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2 and not for any other viruses or pathogens.
- J. 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.

- K. 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 Aptima SARS-CoV-2 package insert, which 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

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

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.*

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. Refer to the Aptima SARS-CoV-2 assay package insert for proper specimen storage conditions.

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

Limitations

- A. Use this collection kit only with the Aptima SARS-CoV-2 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).

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



Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA



Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium



UK Responsible Person:
Hologic Ltd.
Oaks Business Park, Crewe Road
Wythenshawe, Manchester, M23 9HZ
United Kingdom

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

Hologic, Aptima, and associated logos, are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries.

FLOQSwabs is a trademark of Copan Italia S.P.A.

All other trademarks that may appear in this package insert are the property of their respective owners.

This product may be covered by one or more U.S. patents identified at www.hologic.com/patents.

©2021 Hologic, Inc. All rights reserved.
AW-20232 Rev. 002
2021-05