

Aptima™ Cervical Specimen Collection and Transport Kit

Instructions for Use
For *in vitro* diagnostic use
For US Export Only

Intended Use

The Aptima™ Cervical Specimen Collection and Transport Kit is intended to be used for clinician collection and transport of cervical specimens for use with the Aptima HPV Assay and Aptima HPV 16 18/45 Genotype Assay. Refer to the appropriate assay package inserts for additional assay specific information related to the Aptima Cervical Specimen and Transport Kit.

Materials Provided

50 Cervical Specimen Collection and Transport Kits (Cat. No. 302657)

Each kit contains:

Component	Quantity	Description
Aptima Cervical Specimen Collection Device	1	Individually wrapped, sterile cervical specimen collection brush
Aptima Cleaning Swab (Female)	1	Individually wrapped, sterile swab
Aptima Cervical Specimen Transport Tube	1	Tube containing Specimen Transport Medium (STM) 4.3 mL

Warnings and Precautions

- A. Use the provided collection device only. Failure to use the provided collection device may invalidate test results.
- B. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- C. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- D. 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. Discard used materials without passing over the containers. If gloves come in contact with specimens, change gloves to avoid cross-contamination.
- E. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Cervical Specimen and Collection Kit. Failure to use a new kit may invalidate test results.

- F. 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.
- G. Do not use the kit after its expiration date to collect specimens.

Note: Hazard Communication reflects the EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicds.com.

Kit Storage Requirements

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

Aptima Cervical Specimen Collection and Transport Kit Specimen Performance

Assay performance characteristics using cervical specimens collected with the Aptima Cervical Specimen Collection and Transport kit are provided in the CE marked Aptima HPV Assay and Aptima HPV 16 18/45 Genotype Assay package inserts.

Specimen Collection and Handling

1. Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). Discard this swab.
Note: To remove excess mucus from the cervical os, a large-tipped swab (not provided) may be used.
2. Insert the cervical specimen collection device (blue shaft brush in the package with the black printing) into the endocervical canal.
3. Rotate the device clockwise three full turns to ensure adequate sampling.
4. Withdraw the device carefully; avoid any contact with the vaginal mucosa.
5. Remove the cap from the cervical specimen transport tube and immediately place the specimen collection device into the transport tube.
6. Rotate the shaft of the device between the thumb and forefinger three times to dislodge the cells from the device. Discard the device. Do not break the shaft in the transport tube.
7. Re-cap the cervical specimen transport tube tightly.

Specimen Transport and Storage

After collection, transport and store the cervical specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed with the Aptima HPV Assay or the Aptima HPV 16 18/45 Genotype Assay within 60 days of collection. If longer storage is needed, cervical specimen transport tubes may be stored at ≤ -20°C for up to 24 months after collection.

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

Limitations

- A. The presence of personal lubricants containing Polyquaternium 15 at concentrations greater than 0.025% may interfere with the performance of the assay.
- B. The presence of anti-fungal medication containing tioconazole at concentrations greater than 0.3% may interfere with the performance of the assay.
- C. Use this collection kit only with the CE marked Aptima HPV Assay and Aptima HPV16 18/45 Assay. Performance has not been established with other products.

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.

This product is intended for use only in the field of human *in vitro* diagnostics.

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

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Revision History	Date	Description
AW-26246-001 Rev. 001	May 2022	<ul style="list-style-type: none"> Created Aptima Cervical Specimen Collection and Transport Kit IFU AW-26246-001 Rev. 001 based on 502013EN Rev. 004 for regulatory compliance with IVDR Added Instructions for Use Updated contact information including: EC Rep, CE Mark, Australian Rep information, and technical support