

Aptima Cervical Specimen Collection and Transport Kit

For *in vitro* diagnostic use

For U.S. Export Only

Contents

50 Cervical Specimen Collection and Transport Kits. Each kit contains:

- One Cervical Specimen Collection Device
- One Female Cleaning Swab
- One Tube Containing Aptima Specimen Transport Medium (4.3 mL)

Warnings and Precautions

- A. Specimens collected with this kit may be tested with the Aptima HPV Assay and the Aptima HPV 16 18/45 Genotype Assay. Refer to the appropriate assay package insert.
- B. Performance has not been established with other products.
- C. Do not apply the transport medium directly to skin or mucous membranes or take internally.

Kit Storage requirements

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

Specimen Collection and Handling

Note: *Samples are to be collected by Clinicians.*

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.



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502013EN Rev. 002
2017-05