



DTEX

INDICATIONS:

The Cervical DNA Dtex test uses fluorescent in-situ hybridization (FISH) technology to identify the irreversible DNA damage to cervical cells as defined by multiple copies of 3q26 and 5p15. Used in conjunction with Pap and HPV testing, the Cervical DNA Dtex test can assist physicians in identifying which LSIL and ASCUS HPV+ patients may be at risk of progressing to severe dysplasia. This allows the clinician to optimize patient care and healthcare resources.

Thin Prep® Liquid Based pap test. One specimen will be used to provide samples for both the Pap test and/or the Dtex test.

SUPPLIES:

1. Vaginal speculum
2. Thin Prep® Collection Kit (which includes plastic spatula and brush or broom device and PreservCyt® Solution vial)
3. Your lab's gynecologic cytology requisition form
4. Biohazard bag for specimen transport

COLLECTION PROCEDURE:

Please note the following Thin Prep® Pap Test™ important information:

- Wooden spatulas cannot be used for the Thin Prep® Pap Test™. The wood is porous and cellular material will stick to the collection device and not be transferred to the collection vial. The Thin Prep® Pap Test™ is only FDA approved for use with the plastic spatula device, brush or broom device.
- Caution: PreservCyt® solution contains methanol, which is poisonous and may be fatal or cause blindness if swallowed. Vapor is harmful if inhaled. This solution causes eye and skin irritation. PreservCyt® is flammable: keep away from fire, heat, sparks and flame. Other solutions must not be substituted for PreservCyt® solution. PreservCyt® should be stored and disposed of in accordance with local, state and federal regulations. Check the expiration date on the vial prior to use. The laboratory cannot accept samples in expired PreservCyt® solution.

In premenopausal patients, obtain specimen during second half of menstrual cycle (if possible) to avoid obscuring blood. Instruct the patient not to douche or engage in sexual intercourse within 24 hours of the procedure.

1. Print the patient's name (last, first) on the PreservCyt® solution vial. The laboratory CANNOT accept unlabeled specimens. Check the expiration date to be sure the solution has not expired. The laboratory CANNOT accept specimens in expired solution vials.



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2. Place the patient in the lithotomy position. Using a speculum lubricated with warm water, expose the cervix as fully as possible. DO NOT use lubricant as this will interfere with the cytologic evaluation.
3. If excess mucus, exudates or blood is present at the cervical os, remove with a folded gauze pad or large cotton-tipped swab.
4. SPATULA/BRUSH TECHNIQUE: Obtain an adequate sample from the ectocervix (and transition zone if visible) by rotating the plastic spatula device five times around the circumference of the cervix. Rinse the spatula in the PreservCyt® solution vial by swirling the spatula vigorously 10 times in the vial. Discard the spatula. Obtain an adequate sample from the endocervix by inserting the brush device into the cervix until only the bottom most fibers are exposed. Slowly rotate ¼ to ½ turn in one direction. DO NOT OVER ROTATE. Rinse the brush in the PreservCyt® solution by rotating the device in the solution while pushing against the wall of the vial. Rotate 10 times. As a final step, swirl the brush vigorously to further release material. Discard the brush. BROOM TECHNIQUE: Obtain an adequate sample from both the ectocervix and endocervix simultaneously by inserting the center of the device into the cervical os until gentle resistance is felt and the outer-most tips of the broom are flat on the ectocervix. Push gently and rotate the broom five times, in a clockwise direction, 360 degrees around the os. Rinse the broom in the PreservCyt® solution vial by rotating the device in the solution 10 times, pushing the bristles of the broom against the bottom and edges of the vial (like rinsing a paint brush) to dislodge the material. Discard the broom. DO NOT cut off the end of the collection device and leave in the vial. The cellular material will harden onto the device and not effectively transfer to the solution.
5. Tighten the cap on the PreservCyt® solution vial so the torque line on the cap passes the torque line on the vial.
6. Use the specimen collection biohazard bags provided by your lab. Place the completed requisition in the outside pocket and the properly labeled PreservCyt® solution vial in the zip lock portion of the bag. Send to your lab for processing. The laboratory CANNOT accept unlabeled vials or specimens without a properly filled out requisition form.

If additional educational materials are desired on the proper collection technique used for the Thin Prep® Pap Test™, please contact your lab.

Submit all patient information following the procedure for "Completing a Gynecologic Cytology Requisition."

Complete test requisition including last and first name of patient, patient's date of birth and social security number, body site and source of specimen collected. Label specimen container (using the labels provided on the requisition) with patient's first name and last name, and body site/source. The container must have at least two (2) unique identifiers. Examples of unique identifiers: patient name, DOB, unique bar code, etc.



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Include pertinent clinical information, i.e., previous malignancy, radiation therapy, drugs, etc. Place container in a specimen bag with a biohazard label. Place the requisition in the side pocket of the specimen bag.

SPECIMEN:

1. Thin Prep® Based Pap Test
2. Aptima Swab Collection (Vaginal)
3. Aptima Swab Collection (Endocervical / Male Urethra)
4. Urine

SUPPLIES:

1. Cervical sampling:
 - CytoBrush & Spatula or Broom in Thin Prep or Sure Path Liquid Based Collection Vial [Adjunct to Pap]
2. Vaginal sampling:
 - APTIMA vaginal specimen collection swab and tube
3. Unisex sampling:
 - APTIMA unisex specimen collection swab and tube
4. Urine sampling:
 - APTIMA urine specimen collection tube
5. Specimen Requisition
6. Specimen Bag with a biohazard label

COLLECTION:

Thin Prep® Liquid Based Pap Test:

One specimen will be used to provide samples for both the Pap test and/or the Neisseria gonorrhoeae (NG) test. Follow the appropriate Pap collection instructions for testing of NG. This test can be performed adjunctively from the Pap vial.

APTIMA Vaginal Swab Collection [Separate from Pap]:

1. Partially peel-open the swab package. 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 Aptima Vaginal Swab Specimen Collection Kit.
2. Remove the swab.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft.



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- Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
- Withdraw the swab without touching the skin.
- 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 Aptima Vaginal Swab Specimen Collection Kit.
- Immediately place the swab into the transport tube so that the tip of the swab is visible below the tube label.
- Carefully break the swab shaft at the score-line against the side of the tube and discard the top portion of the swab shaft. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Vaginal Swab Specimen Collection Kit.
- Tightly screw the cap onto the tube.

APTIMA Endocervical / Male Urethra Swab Collection [Separate from Pap]:

Endocervical swab specimens:

- 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.
- Insert the specimen collection swab (blue shaft swab in the package with the green printing) into the endocervical canal.
- Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
- Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- Carefully break the swab shaft against the side of the tube at the score-line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- Re-cap the swab specimen transport tube tightly.

Male urethral swab specimens:

- The patient should not have urinated for at least 1 hour prior to sample collection.
- Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
- Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
- Withdraw the swab carefully.



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5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft against the side of the tube at the score-line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
7. Re-cap the swab specimen transport tube tightly.

Urine Collection:

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in rRNA target dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
3. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
4. Re-cap the urine specimen transport tube tightly. The specimen is now known as the processed urine specimen.

STORAGE REQUIREMENTS:

Cervicovaginal – Thin Prep® / Sure Path liquid based Pap vial at 2 to 30 degrees C.

Vaginal – APTIMA swab specimen transport tube at 2 to 30 degrees C.

Endocervical – APTIMA swab specimen transport tube at 2 to 30 degrees C.

Urine – APTIMA urine specimen transport tube at 2 to 30 degrees C.

STABILITY REQUIREMENTS:

Cervicovaginal, Vaginal, & Endocervical – APTIMA swab specimen transport tube or liquid based Pap preservative vial – 3 weeks from collection.

Urine – APTIMA urine specimen transport tube – 3 weeks from collection.

Note: Urine samples that are still in the primary collection container must be transported to the lab and transferred into the APTIMA urine specimen transport tube within 24 hours of collection.

STORAGE REQUIREMENTS – Room Temperature



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STABILITY REQUIREMENTS – 72 hours

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Complete test requisition including last and first name of patient, patient’s date of birth and social security number, body site and source of specimen collected. Label specimen container (using the labels provided on the requisition) with patient’s first name and last name, and body site/source. The container must have at least two (2) unique identifiers. Examples of unique identifiers: patient name, DOB, unique bar code, etc. Include pertinent clinical information, i.e., previous malignancy, radiation therapy, drugs, etc. Place container in a specimen bag with a biohazard label. Place the requisition in the side pocket of the specimen bag.