



HUMAN PAPILLOMAVIRUS GENOTYPING

INDICATIONS:

HPV 16 and 18 are well known because they have been shown to significantly increase the risk of cervical cancer in women who have persistent infections with these two types. Many women with high-risk types of HPV infection never progress to more severe cervical cell changes or cancer. However, high-risk HPV types have been found in most women who are diagnosed with cervical cancer. HPV testing for high-risk types may help determine treatment for a woman with minor cervical cell changes. ThinPrep Liquid Based pap test. One specimen will be used to provide samples for both the Pap test and/or the High Risk (HR) HPV test and genotyping.

Sampling of the superficial cells of the cervix, endocervix and/or vagina to detect premalignant and malignant lesions of the uterine cervix and other abnormalities of the reproductive tract. The Thin Prep® Pap Test™ is intended as a replacement for the conventional method of Pap smear preparation. Studies have shown that this procedure decreases fixation artifacts, provides a more uniform specimen for microscopic evaluation and increases the yield of abnormal cells.

SUPPLIES:

1. Vaginal speculum
2. Thin Prep® Collection Kit (which includes plastic spatula and brush or broom device and PreservCyt® Solution vial)
3. CPA 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 CPA. 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 CPA 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 CPA.

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. 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.