

February 2, 2015

FDA APPROVED COLLECTION DEVICES FOR HPV TESTING

FDA approval for the Roche Cobas 4800 HPV method was done using the brush and spatula collection devices. Validation for the Roche Cobas 4800 HPV testing at Methodist Pathology Center was performed using various collection devices (brushes, spatulas, brooms). The brush and spatula devices will be furnished with your Pap supply orders.



Collection directions for using the brush and spatula devices:

- Obtain an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.
- Rinse the spatula as quickly as possible into the PreservCyt solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
- Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **DO NOT OVER-ROTATE.**
- Rinse the brush as quickly as possible in the PreservCyt solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.
- Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- Record the patient's name and ID number on the vial, and the patient information and medical history on the cytology requisition form.
- Place the vial and requisition in a specimen bag for transport to the laboratory.

For questions on the new collection devices, contact Methodist Cytology at 402-354-4326.