Collection of ThinPrep HPV and GC Chlamydia Specimens (LTR32721)

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COLLECTION OF THINPREP HPV AND GC/CHLAMYDIA SPECIMENS

PRINCIPLE

Chlamydia is one of the most common sexually transmitted diseases in the United States. It is caused by the bacterium *Chlamydia trachomatis* and can result in irreversible damage to a woman's reproductive organs before any symptoms are recognized. *Neisseria gonorrhoeae* is the bacterium responsible for causing gonorrhea. In women, gonorrhea is a common cause of pelvic inflammatory disease (PID), which can damage the fallopian tubes and tissues in and near the uterus and ovaries.

In general, HPV testing is performed on ThinPrep sample vials from patients over 30 years of age and those with an abnormal Pap result (e.g. ASCUS). The test helps to identify those patients who are most likely to develop high grade dysplasia and cancer of the cervix. Women with high risk HPV types (i.e. 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, and 58) are at least ten times more likely to develop cervical disease. It is believed that just four HPV types (16, 18, 31, and 45) may be responsible for 70% of cervical cancers worldwide. Persistent HPV infection is the major risk factor for the development of high grade lesions and cervical carcinoma.

One advantage of the ThinPrep Pap Test is that HPV and/or GC/Chlamydia testing may be performed on the same sample vial from which the Pap smear is prepared. This eliminates the need for a follow up office visit to collect an additional sample from the patient.

POLICY

The purpose of HPV and GC/Chlamydia testing is to identify patients with high risk HPV types and/or with infection by *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae.* The following procedure provides guidelines for the proper collection, preservation, and transport of specimens to the Cytology Department for HPV and/or GC/Chlamydia testing.

SPECIMEN

Patient Preparation: Per attending Physician or authorized agent.

Type: ThinPrep Pap sample for HPV and/or GC/Chlamydia testing. If possible, samples should be collected at mid-cycle (menstrual smears are not preferred). The patient should be instructed not to douche for 24 hours before the sample is to be collected.

Handling Conditions:

1. For **HPV TESTING <u>ONLY</u>** from ThinPrep Pap specimens collected *within the BVH network*, use *<u>"orders +add"</u>* in the main menu of Power Chart. Enter *<u>HPV DNA</u>* in the search box and complete the required fields in yellow (i.e. collection priority and collection

date and time). When finished, be sure to sign the order by using the ***sign*** button in the bottom right corner of the screen. Retrieve the specimen label (if available) from the designated printer and place it on the ThinPrep Pap vial. If no specimen label is available, please write the following information on the ThinPrep vial: patient name, date of birth, date and time of collection, and the collector's initials. Also, please indicate the desired test (i.e. HPV DNA only) on the label to ensure that the specimen is not processed as a Pap smear. Please note that the preceding steps should also be used for *add-on* HPV orders for Pap smears (i.e. if HPV testing was desired but was accidentally missed in the original order).

For **GC/CHLAMYDIA TESTING ONLY** from ThinPrep Pap specimens collected *within the BVH network*, use *"orders +add"* in the main menu of Power Chart. Enter *GC/Chlamydia DNA* in the search box and complete the required specimen type field in yellow. For Thin Prep Pap specimens, select "***Liquid Prep***" from the drop-down menu. When finished, be sure to sign the order by using the *sign* button in the bottom right corner of the screen. Retrieve the specimen label (if available) from the designated printer and place it on the ThinPrep Pap vial. If no specimen label is available, please write the following information on the ThinPrep vial: patient name, date of birth, date and time of collection, and the collector's initials. Also, please indicate the desired test (i.e. GC/Chlamydia DNA only) on the label to ensure that the specimen is not processed as a Pap smear. Please note that the preceding steps should also be used for *add-on* GC/Chlamydia orders for Pap smears (i.e. if GC/Chlamydia testing was desired but was accidentally missed in the original order). However, it is very important to notify the laboratory *immediately* if a GC/Chlamydia request has been added to a Pap order to ensure proper specimen handling.

For **HPV AND/OR GC/CHLAMYDIA *AND* PAP CYTOLOGY TESTING** from ThinPrep Pap specimens collected *within the BVH network*, use *"orders +add"* in the main menu of Power Chart. Enter *Pathology Pap Smear Request* in the search box and complete the required fields in yellow (i.e. gyn specimen source, clinical information, LMP, hormones, routine screening or follow-up exam, pregnant, post-partum, hysterectomy, post-menopausal, and additional comments if applicable) at the bottom of the screen. The gyn specimen description drop-down menu allows the user to select from the following options for HPV and/or GC/Chlamydia + Pap testing: Liquid Prep with HPV, Liquid Prep with GC/Chlamydia, Liquid Prep with HPV and with GC/Chlamydia, and Liquid Prep reflex ASCUS and with GC/Chlamydia. Since GC/Chlamydia testing is included in the preceding list of options, there is no need to place a separate GC/Chlamydia order for testing from the ThinPrep Pap vial. When finished, be sure to sign the order by using the *sign* button in the bottom right corner of the screen. Retrieve the specimen label (if available) from the designated printer and place it on the ThinPrep Pap vial. If no specimen label is available, please write the following information on the ThinPrep vial: patient name, date of birth, date and time of collection, and the collector's initials.

2. For **HPV AND/OR GC/CHLAMYDIA DNA ONLY** Thin Prep specimens collected *outside of the BVH network* (e.g. non-BVH owned physician offices), a properly completed BVH lab requisition form must be sent to the Cytology Department before the Aptima HPV assay and/or the GC/Chlamydia DNA probe (Aptima combo 2 assay) can be performed. These tests may also be ordered *in addition* to a Pap by marking the appropriate line in the bottom left hand corner of the BVH Pap smear requisition form. Be sure to check that the specimen vial is labeled with the patient's name, date of birth, date and time of collection, and collector's initials. BVH lab requisition forms must include the signature of the ordering Physician and a diagnosis. Also, please include a copy of the patient's insurance information and/or insurance card whenever possible. If desired, orders may be faxed to the laboratory. The fax number is (419) 423-5125.

EQUIPMENT AND MATERIALS

Equipment: Per attending Physician or authorized agent

Materials: Available from the Cytology Department upon request. Vials of PreservCyt Solution for the ThinPrep Pap Test, plastic spatulas and endocervical brushes *or* plastic broom-like devices. *Please do not use a wooden cervical scraper or a cotton tip applicator to collect the specimen.*

PROCEDURE

Please refer to the collection procedure for ThinPrep Pap smears to view the steps that should be followed to obtain an optimal cervical sample. Please note that the Aptima HPV assay should be carried out within 30 days of specimen collection. Therefore, it is very important that the test be ordered as soon as possible. Also, please note that GC/Chlamydia testing should not be ordered *after* the Pap slide has been prepared due to the likelihood of cross-contamination of DNA between specimens.

REPORTING RESULTS

Results of the Aptima HPV assay and GC/Chlamydia DNA probe are usually available within three to five days from the test order date. The results will help to identify patients who are at risk for the development of pelvic infection and disease as well as cervical dysplasia and cancer. This information will help Physicians to determine the most appropriate course of treatment for their patients. If there are any questions, please feel free to call the Cytology Department at ext. 55814 and speak with a Cytotechnologist or a Pathologist regarding this procedure.

REFERENCES

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