**PROCEDURE: CORO MOLECULAR MICROBIOLOGY APTIMA HR HPV ASSAY ON**

**NON-CERVICAL SOURCES**

1. **PRINCIPLE**
   1. The APTIMA HPV Assay is an *in vitro* nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of human papillomavirus (HPV) in cervical specimens. The high-risk HPV types detected by the assay include: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. The APTIMA HPV Assay does not discriminate between the 14 high-risk types. This assay is not FDA approved to run on non-cervical sources. Validation of vaginal samples collected in ThinPrep solution was performed in lab. Certain non-cervical source samples will be run at the request of a Surgical Pathologist and reviewed by the Microbiology Lab Medical Director. A disclaimer will be added to the report.
2. **AVAILABILITY**
   1. Test is performed Tuesday and Thursdays with results available Wednesday and Friday. Specimens may be submitted 7 days/week, 24 hours/day.
3. **TEST CODE**
   1. HPV1
      1. Test is ordered in the Molecular Microbiology lab
      2. Under “Order Comment” add:

“Specimen Source:” \_\_\_\_\_\_\_\_\_\_\_ ex. Neck Fluid, Anal.

1. **SPECIMEN COLLECTION AND PROCESSING**
   1. Tissue or Fluid Specimen
      1. All requests should originate from Surgical Pathology.
      2. Molecular Microbiology lab should be notified of tissue/fluid HPV request by Surgical Pathology.
      3. Sample is added to Thin Prep Pap Test vials containing PreservCyt Solution by Pathologist and forwarded to Molecular Microbiology lab.
      4. Pathology report of Squamous Cell Carcinoma/ Atypical Squamous Cells must be received prior to running HPV assay.
      5. The ThinPrep Aliquot Removal procedure will be used where 1 ml of the PreservCyt Solution liquid cytology specimen will be removed and pipetted into an APTIMA Specimen Transfer Tube. Refer to Tomcat Operating Procedure and Checklist for directions.
   2. Vulvar, Rectal/Anal, etc. Specimens:
      1. Collect specimens in ThinPrep Pap Test vials containing PreservCyt Solution with broom-type or cytobrush/spatula collection devices according to the manufacturer’s directions.
      2. A comment noting the non-cervical source, ie. Vulvar, Anal must be placed in CoPath by the cytology tech or the pathologist.
      3. Cytology Tech will flag Non-Cervical Paps with a sticky note.
      4. Micro Tech will flag Aptima tube with colored tape labeled ie. Anal.
      5. If HPV/HPVG is ordered, an Order Comment will be added: Specimen Source: ex. Anal.
      6. Tape should stay attached to Aptima tube to alert the Panther Tech.
      7. Refer to Appendix A for complete lab workflow.
2. **TEST PROCEDURE**

Refer to HR HPV Assay for full Test Procedure/ Quality Control/ Interpretation.

* 1. Testing
     1. When HPV and HPVG task lists are made, a notation should be made on all non-cervical samples
     2. Run sample
     3. Save instrument printouts
     4. Recap with a hard cap and freeze at -80C for possible send out test comparison.
  2. Results
     1. Result as HPV Positive, HPV Negative, or HPV Indeterminate as determined by the assay
     2. Add the following canned comment: @SRCM:

Specimen source is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (add source)

This assay is not FDA approved for this specimen source. A negative result may

be due to insufficient amount of cellular material. Correlation of these results

with other pathology results is required.

* + 1. Print out final report for Dr. Chapin to review and sign.

1. **REVISIONS**
   1. March 2019. Deleted vaginal samples from procedure and added vaginal validation performed in lab.

**APPENDIX A**

**Processing Non-Cervical Samples for Validation**

1. Non-Cervical Thin Prep vials will be labeled by Cytology tech with a sticky note and an extra Aptima Sample Collection tube will be labeled with patient information.

**Note:** HPV requests on Anal/Rectal Thin Prep Vials will be performed if Cytology has also been requested. If Cytology has not been requested the Thin Prep Vial will be sent to the Send Out lab, APC 11 and sent to Quest.

1. Aliquot sample into 2 Aptima Collection tubes.

* Label each tube with orange tape/ source, ex. Anal

**Note: Place tape above LG# barcode**

* Process one tube as normal on Tomcat and add to daily rack
* The second tube will have 1 cytology label on it for ID but no barcode.
* Manually pipette the second tube and place in the rack labeled “Duplicate Non-Cervical Tubes” (located in rack in HPV area)

1. Process HPV/HPVG orders as requested.

* Add an Order Comment in Order Entry:

Specimen Source: ie. Anal

1. Tape should stay attached to Aptima tubes to alert the Panther tech
2. Make a notation on HPV and HPVG tasklists for any non-cervical sites.
3. Result test and add canned comment “@SRCM”

Specimen source is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (add source )

This assay is not FDA approved for this specimen source. A negative result may be due to insufficient amount of cellular material. Correlation of these results with other pathology results is required.

1. Print Instant Report and place in folder.
2. When all testing is complete and does not need to be held for any further testing save tube in -80 freezer labeled “Completed Non-Cervical HPVs”.

* Negatives can be put there right away
* Positives should go in “Positive” rack. Label top of tube with tape “Anal” +->-80

1. Place the duplicate tube for this order in the freezer rack with the tube that was tested.