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**PURPOSE:**

The purpose of this SOP is to offer written instructions for ordering Pap smears as cytology specimens.

**SCOPE:**

Processing Department

**RESPONSIBILITY:**

The Medical or Section Director is responsible for ensuring that the procedure is in compliance with CAP and CLIA regulations. The Director must review and approve this procedure at appropriate intervals. The Medical Director may delegate some of the responsibilities to other CLIA/CAP qualified personnel.

The Processing Supervisor/Manager will have the overall responsibility for implementing this procedure. The supervisor/manager is responsible for ensuring that the procedure is followed accurately and that competency documentation is appropriate.

All processors performing this procedure are required to have appropriate training and competency approved. They are responsible for reading, understanding and competently performing this procedure without deviation.

**EQUIPMENT:**

Zebra GX4301 Barcode printer, Zebra TLP2824 Barcode printer  
Tomcat Racks include white for Surepath specimens and black for Thinprep specimens


**SUPPLIES:**

Green Labeled Aptima Gen-Probe

**PROCEDURE:**

**Surepath and Thinprep Ordering**

- A. BBPL receives both Surepath (SP) and Thinprep (TP) pap specimens
  - 1. The Thinprep specimens will come in a white top container and are the more common of the two sample types
  - 2. The Surepath specimens are in a green top container, which is much smaller than the TP
- B. Most Paps are ordered in L4 (See L4 Order Entry SOP) with the exception of those that require specimen receipt (see Specimen Receipt Verification SOP)

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C. **There will also be a few (approx. 8-10 per week) Conventional Pap smears received.**

D. Tomcat Racks include white for Surepath specimens and black for Thinprep specimens. Samples are placed in the back first working towards the front (the front being the part of the rack with the handle).

## Order Entry

A. Remove the specimen and requisition from the bag.


1. Verify that the name on the specimen and on the requisition match
2. Mark at the bottom 1 SP, 1 TP, etc and processor number
  - i. Some requisitions will have an area to check SP or TP, others will not
3. Follow procedure for Exceptions if necessary

**B. NOTE: Label an Aptima tube along with the SP/TP if any testing other than a Pap alone is ordered**

C. **Scannable Requisitions** - These requisitions include a bar code that can be scanned to populate the fields in L4 (i.e. Women's Health Associates, web orders)

1. **Follow the L4 Order Entry SOP**

- i. Place cursor on Accession field in L4 and use bar code scanner to scan the barcode
- ii. Verify the BILL TO field and change to C for Client billed, P for patient billed and MC for Medicare or Medicaid
- iii. For Women's Health a HOLD GYN code will automatically populate under test codes (605000). This test code needs to be removed (click on remove)**
2. Click on the Women's Health requisition option in L4
3. Click on each test ordered which will add the appropriate test codes
4. Use the X at the upper right to exit out of the requisition sample page
5. If a CTNG or HPV is ordered, there will be a field that requests the MEDIA TYPE. Enter either S for Surepath or T for Thinprep, depending on the sample type
6. Be sure to order all **Clinical History**. This information is used by the Ctyo Techs.
  - i. If no client history is provided, click "No client history provided"
7. Click "FILE" and labels will be generated

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- i. All SP, TP and Aptima labels should have the accession letter at the cap end of the specimens (See Specimen Processing SOP)
  - ii. The small 1 inch label (GX4301 machine) is for the Surepath sample
  - iii. The 2 inch label (TLP2824) will be placed on the Aptima tube
  - iv. The ZEBRA labels are placed on the requisition and any attached paperwork or insurance forms
8. If a client orders an incorrect code, such as a TP for SP testing, it is an exception and a new order is requested .

**D. Manual Requisitions** - These requisitions are manually entered

1. **Follow the L4 Order Entry SOP**
2. In L4, skip the Accession field and go to Client # - Type in the Client number and TAB or select from the drop down box
3. Enter all other required fields
4. If there is any other information given (i.e. Soc. Sec.#) enter it
5. Manually type in the test code(s) provided by the client, or use the Women’s Health Requisition from the requisition examples in L4 to choose tests
6. Click “FILE” and labels will be generated
  - i. All SP, TP and Aptima labels should have the accession letter at the cap end of the specimens (See Specimen Processing SOP)
  - ii. The small 1 inch label (GX4301 machine) is for the Surepath sample
  - iii. The 2 inch label (TLP2824) will be placed on the Aptima tube
  - iv. The ZEBRA labels are placed on the requisition and any attached paperwork or insurance forms
7. If a client orders an incorrect code, such as a TP for SP testing, it is an exception and a new order is requested .

**E. Specimen Receipt/Verify Requisitions** - These requisitions require verification according to the number provided by the client

1. **Follow the Specimen Receipt Verification SOP**

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2. These requisitions cannot be ordered in L4, but must be receipted in Antrim.
3. When you specimen receipt an order in Antrim, the small bar codes for the specimen and the Aptima tubes will not print out
  - i. Access PRINT BARCODES section in L4 (Staff, Utilities, Print Barcodes) and use dropdown box to select "Both Accession and Slide Labels"
  - ii. Scan the barcode that was generated in Antrim. This will print the small 1 inch bar code for the specimen and the 2 inch bar code for the Aptima tubes.

**F. PAP ONLY TESTS** with no other testing are **not** placed on the Tomcat

1. The requisition will include a code **4546** or **604544** for Surepath tests **or** **4545** or **604545** for Thinprep tests
2. These should be ordered as usual and a sticker placed on the pap specimen (no Aptima tube)
3. Then they are scanned and placed directly into the clamshell for Histology.

**G. CONVENTIONAL PAPS:** Conventional pap smears will be received in slide form in a flat box

1. These will always be ordered with a **4015** test code
2. Place a label on the back of the pap slide box and label the requisition
3. Scan the requisition and place everything back in the plastic bag that it was received in
4. Take to Histology for processing

**H. TESTING WITH NO PAP (i.e. CTNG or HPV ONLY)**

1. CTNG and/or HPV only tests will mainly be seen on Thinprep orders
2. Order as usual, place on Tomcat, but the specimens with NO PAP are placed in a plastic container after processing on the Tomcat and Molecular will pick those up in the morning
3. **Histology does not receive the specimen when there is NO PAP ORDERED**


**Procedural Notes:**

- I. Specimen receipt/verify orders from certain Clients (mainly seen with Lake Regional and Bothwell THINPREPS) there will be 2-3 separate specimen receipt numbers, each with a different test code
  1. When you have a label with a PAP ONLY sticker, you will need to place 2 stickers on the specimen (the S number with the FLEX or CTNG testing first and then the M Access number with the PAP only TP-IG)

2. The Aptima tube will only include the S sticker with the FLEX or CTNG testing
  3. Histology must have the M Access number with the PAP ONLY order so they can process the pap slide
  4. Molecular must have the OTHER TESTING sticker on the Aptima tube for their information
  5. These orders will either have 2 test code labels or 3 test code labels
  6. For SurePath, label the SP with the CT/NG or other molecular accession number to run on the TomCat. Relabel with the PAP label after the specimen has run on the TomCat and take to histology.
- J. Some clients wrap stickers around the bottom of the Surepath samples. These interfere with the Tomcat processing and create problems, so make sure these removed from the bottom of the specimens.

### **TomCat**

- A. The labeled Aptima tube and labeled Pap sample are placed in the Tomcat rack (white rack for Surepaths, black rack for Thinpreps)
- B. Start placing samples in the back first, working toward the front (the front being the part of the rack that has the handle)
- C. Load each rack onto the Tomcat. The racks do not have to be completely filled when loading
- D. Each Surepath rack takes approximately 20-25 minutes to run and the Thinprep racks take approximately 10-15 minutes
  1. If a specimen fails (clot detected in input container, etc.) the Aptima tube will be replaced in the original input rack next to the specimen
  2. Failed specimens, Aptima tubes and requisitions are placed in the failed sample area on the counter
    - i. Molecular will pick these up throughout the day and manually aliquot each specimen
  3. The Aptima, once inoculated, is placed into the black output rack while the original specimen is returned to the input rack
  4. Once the Tomcat has completed all sample inoculations in a rack, the green light will go off and the rack can be removed.
  5. Remove each specimen and re-verify that the requisition matches each specimen done previously when ordering.
  6. Place the specimens in the plastic clamshells to be taken to Histology.
  7. The requisitions are scanned and checked for order entry verification by designee in Processing or Client Services

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- E. Throughout the day, remove the Aptima tubes from the output racks once filled and place in the racks according to the testing
1. Surepaths to the left and Thinprep to the right on each rack
  2. They are divided by REFLEX, CTNG, HPV and MULTI TESTS
  3. These will be picked up by Molecular the next morning and/or throughout the day, or taken upstairs by Processing

**REFERENCES:** N/A

**RELATED DOCUMENTS:** L4 Order Entry, Exception Handling SOP, Specimen Processing SOP.

**APPENDIXES:** N/A