PROCEDURE MANUAL FOR PERFORMANCE AND SUBMISSION OF OUTPATIENT PATHOLOGY SPECIMENS

2013 EDITION
CONTENTS:

1. Tissue (biopsy) specimens, p. 3-6

2. Cytology Specimens, p. 7
   a. Gynecologic cytology (pap test) specimens, p. 7-8
   b. Non-Gynecology cytology specimens, p. 8-10
      i. Body fluids
      ii. Brushings
      iii. Cerebrospinal fluid
      iv. Fine needle aspirates
      v. Nipple discharge
      vi. Tzank preparation
      vii. Urine
      viii. Washings
   c. Non-Gynecologic Cytology request form, p. 11
   d. Acceptance criteria for cytologic specimens, p. 10-11

3. Contact information, p. 11

TISSUE SPECIMENS

Tissue specimens consist of material surgically removed or biopsied from a patient (skin, cervix, endometrium, etc.). The specimen requirements and directions for filling out the tissue slip are as follows:

MATERIALS (available from Cumberland Pathology Associates)
- Labeled specimen container with formalin
- Pathology Tissue Slip
- To request supplies, order online at cumberlandpathology.com, or fax a request to 931-502-1464, or call 931-502-1488

SPECIMEN PREPARATION
- Place specimen in a container of 10% formalin with 5 parts formalin to 1 part specimen (the specimen must be completely covered in formalin).
  - Tightly close the lid to prevent leakage of formalin
- Label the container with:
  - the patient’s full name
  - the specimen source (e.g., “right forearm”)
  - the date of collection
  - the physician's name
- Fill out Pathology Tissue Slip or order online at https://labworks.ael.com/.
  - See attachment 1 for details
- For specimens submitted with a Tissue Slip, the following information is required:
  - the patient’s full name (note: if labels/stickers are used, please place a label/sticker on each page of the form)
  - the patient’s date of birth
  - the patient’s social security number
  - the patient’s address
  - date of collection
  - ordering physician (include any other physicians who want a report, too)
  - specimens:
    - if there is more than one specimen, such as mole right cheek and mole left cheek, list separately under a letter.
    - EXAMPLE:
      SPECIMENS OBTAINED
      A) RIGHT CHEEK
      B) LEFT CHEEK
  - Pre-Op Diagnosis/History
    - Clinical impression and/or suspected diagnosis is required by payors for coding and reimbursement
    - include any previous history relevant to this biopsy (e.g., “previous history of basal carcinoma” or “previous LGSIL pap smear”)
• If the previous diagnosis was performed at another institution, please provide a copy of the report, if available
  o Post-Op Diagnosis/Findings –
    • this would include any findings noted during the procedure or unexpected findings
    • Example: “possible positive deep margin” or “possible neoplasm”
  o Place the Pathology Tissue Slip in the side pocket of the biohazard bag along with the insurance information sheet

• For specimens ordered online:

  1. Navigate to the AEL Labworks website: https://labworks.ael.com/

  2. Log in using assigned username and password

(continued on next page)
3. Search for patient using patient name or ID.

4. If this is a new patient, see instructions in Attachment 1 for entering patient information, then continue with the next step.

5. If patient is found, highlight patient and click New Order.

6. Verify patient Demographic and Insurance information. If changes are necessary click edit to update information. Otherwise, click continue.
7. Search for tests from the Test Menu or select tests for Short List.

8. Click continue once all tests have been selected.

9. Search for ICD-9 or select from Short List

10. Click continue
11. Some tests such as Pathology require Test Level Questions to be answered. Fill in Information fields and click continue.

- Place the specimen into a biohazard zipper lock bag
- Place the Pathology Tissue Slip in the side pocket of the biohazard bag along with the insurance information sheet or a copy of the insurance card

**CYTOLOGY SPECIMENS**
Cytology specimens consist of fluids or cells (thoracentesis, joint fluid, PAP test) collected for an examination for malignancy. Cytology specimens are divided into two categories, Gynecologic and Non-Gynecologic.

**GYNECOLOGIC CYTOLOGY SPECIMENS**
Gynecologic specimens, or “pap tests,” are collected from various sites in the female genital tract. The best source for the collection of a pap test is from the ectocervix and the endocervix. If a quantitative maturation index is requested, a portion of the specimen must be taken from the lateral vaginal wall and submitted separately from the cervical components. Conventional smears cannot be processed by Cumberland Pathology; all samples should be submitted for liquid-based cytology (ThinPrep®) to optimize disease detection and computerized imaging.

- Materials - To request supplies, order online at CumberlandPathology.com, or print a request and fax to 931-502-1464, or call 931-502-1488.
  - Liquid-Based cytology / ThinPrep®
    - ThinPrep® vial
    - Plastic spatula and endocervical brush OR cytobroom
    - Gynecologic Cytology Request Form (or order online)
- Patient preparation
  - the ideal sampling date is two (2) weeks after the first day of the last menstrual period
  - discourage sampling during normal menses
- avoid use of vaginal medication, vaginal contraceptives, or douches for 48 hours prior to examination

- Liquid-based collection (ThinPrep®)
  - label the liquid based (Thin Prep®) vial with the patient’s full name
  - using a collection device (broom, cytobrush) collect the cells to be examined
  - immediately rinse the collection device in the liquid media (do not leave the collection device in the vial)
  - place the cap on the vial securely to prevent leaking
  - place the vial in a biohazard bag and seal

- Gynecologic Cytology Request Form – order forms online, download and print forms from online, or call Cumberland Pathology for forms
  - Patient’s full name
  - Patient’s date of birth
  - Patient’s address
  - Patient’s social security number
  - Date the specimen was collected
  - Source of the specimen (cervix/endocervix, endocervix-ECB, lateral wall)
  - Indication (screening-high risk, screening-low risk, diagnostic)
    - Screening low risk = patient with standard likelihood of developing cervical dysplasia/carcinoma
    - Screening high risk = patient with early onset of intercourse, history of sexually transmitted disease,
  - History (previous abnormal PAP?, pregnant/postpartum, irregular menses, menopausal/postmen., hysterectomy, radiation treatment, birth control or hormone treatment)
  - Last menstrual period
  - Tests required
  - Physician signature
  - Date

- Attach a copy of the patient’s insurance card or billing information to the Request Form

- For specimens ordered online, use https://labworks.ael.com/ and follow the directions listed above for tissue specimens. See attachment 1 for additional details.

- Place the completed Gynecologic Cytology Request Form in the outside pocket of the biohazard zip lock bag containing the sample

- Advance Beneficiary Notice
  - All MEDICARE patients must complete an Advance Beneficiary Notice (ABN), to acknowledge responsibility for the bill if Medicare does not pay for the test
  - Copies of the ABN are available online at CumberlandPathology.com under the PathGuide tab.
NON-GYNECOLOGIC CYTOLOGY
Non-Gynecologic specimens are any fluids or cells collected from any site other than the female genital tract (plural fluid, spinal fluid, joint fluids). Fresh (unfixed) non-gynecologic specimens are preferable, but must come to the laboratory as soon as possible or be immediately refrigerated. Fresh or refrigerated specimens must be processed by the lab within 72 hours of collection if not placed in preservative/CytoLyt solution. Forms are available online for download, and can be ordered online at CumberlandPathology.com, or you can call the office to request forms (931-502-1488).

• Specimen types
  o Body Fluids
    - deliver to the laboratory promptly in a sterile container or refrigerate
    - no fixation is necessary
  o Brushings
    - smear directly on a glass slide and immediately fix in one of the following techniques:
      1) spraying with fixative spray ("Spray-Cyte" or comparable fixative)
        - within 30 seconds of completing the smear, hold the spray fixative 5-6 inches from the slide and using quick strokes, spray the slide until the specimen is covered
        - allow spray fixative to air dry for 5-7 minutes
        - place slide into slide holder for transportation
      2) submerging slide in 95% alcohol
        - seal the slide in the 95% alcohol fixative container for transportation
  o Cerebrospinal fluid (CSF)
    - never add fixatives to CSF
    - Refrigerate specimen until courier pick up
  o Fine Needle Aspirates (FNAs) – submit in one of the following methods:
    1. smear directly on a slide and fix with alcohol preservative via one of these techniques:
      a) spraying with fixative spray ("Spray-Cyte" or comparable fixative)
        ▪ within 30 seconds of completing the smear, hold the spray fixative 5-6 inches from the slide and using quick strokes, spray the slide until the specimen is covered
        ▪ allow spray fixative to air dry for 5-7 minutes
        ▪ place slide into slide holder for transportation
      b) submerging slide in 95% alcohol
        ▪ place the slide in the 95% alcohol fixative container and seal the lid for transportation
    2. for immediate alcohol fixation, express the specimen from the syringe directly into cytology fixative ("CytoLyt")
• for optimal results, rinse the solution back and forth into the syringe through the needle several times to enhance cell recovery

○ Nipple discharge
  - perform a touch-preparation or a smear of the discharge on a glass slide and fix the slide within 5 seconds in one of the following techniques:
    1) spraying with fixative spray ("Spray-Cyte" or comparable fixative)
      ▪ within 30 seconds of completing the smear, hold the spray fixative 5-6 inches from the slide and using quick strokes, spray the slide until the specimen is covered
      ▪ allow spray fixative to air dry for 5-7 minutes
      ▪ place slide into slide holder for transportation
    2) submerging slide in 95% alcohol
      seal the slide in the 95% alcohol fixative container for transportation

○ Tzanck preparation
  - smear material directly onto a labeled glass slide and fix within 5 seconds using one of the following methods:
    1) spraying with fixative spray ("Spray-Cyte" or comparable fixative)
      ▪ within 30 seconds of completing the smear, hold the spray fixative 5-6 inches from the slide and using quick strokes, spray the slide until the specimen is covered
      ▪ allow spray fixative to air dry for 5-7 minutes, place slide into slide holder for transportation
    2) submerging slide in 95% alcohol
      ▪ seal the slide in the 95% alcohol fixative container for transportation

○ Urine
  - send in a sterile container with no fixative
  - keep refrigerated until courier pick up

○ Washings
  - send in a sterile container with no fixative
  - keep refrigerated

• Complete a Non-gynecologic Cytology Request Form – available for download online at CumberlandPathology.com or request forms online or call 931-502-1488 to request additional forms. Complete the following sections of the form:
  ○ Patient’s full name
  ○ Patient’s date of birth
  ○ Patient’s address (can be omitted if included in copy of insurance information)
  ○ Physicians who need a copy of the results
  ○ Ordering physician’s signature
  ○ Date the specimen was collected
o Clinical history and a description of the lesion
o Previous relevant pathology or treatment (to include: malignancies, radiation, etc.)
o Specimen source / procedure
o Attach a copy of the insurance card or a copy of the insurance sheet from your office – place in the side pocket of the biohazard bag that contains the specimen.

• Ordering Online – go to https://labworks.ael.com/ and follow directions above as listed under Tissue Specimens. See attachment 1 for additional details.

• Acceptance Criteria for Cytology Specimens: Potential Reasons for Rejection:
o specimen not labeled or not labeled with patient’s full name
o specimen not labeled with source
o a discrepancy between the patient’s name and any demographics given (date of birth or social security number not matching that patient name)
o improper fixation
o discrepancy between request forms submitted and the label on the container
o slides received in a labeled carrier, but the slide is not labeled
o incorrect or incomplete billing information
o Cumberland Pathology will make every attempt to clarify missing or conflicting information before rejecting an irretrievable specimen.

CONTACT INFORMATION:
Office: 931-502-1488
Fax: 931-502-1464
Pathologist:
    During office hours 931-502-1488
    On call 931-801-3017
Email: info@cumberlandpathology.com
NEW PATIENT RECORD

Step 1: Verify that the Patient is New
1. Click Patient Search on the Patients menu.
2. Enter the patient’s name (LAST, FIRST) in the Patient field and then click Search.
3. If a record is not found, click the New Patient link to open a blank record.

Step 2: Enter Patient Detail Information
1. Select the Billing Type from the drop-down list. (This is defaulted to the requested billing type and normally is not changed when entering in a new patient)
2. Enter required information (highlighted fields) and other pertinent information about the patient.

Note: Formatting is not needed for Date of Birth or the Phone # fields.
Example:
DOB: 12131977 will automatically be formatted to 12/13/1977 when entered.
Phone #: 9010000000 will automatically be formatted to (901) 000-0000.

Step 3: Enter Patient Insurance Information
1. Click the Insurance tab.
2. Select Primary Insurance provider from the drop-down list.
3. Enter the policy number, Relationship and DOB. (If the Insured’s information is the same as the patient information, click the Copy Subscriber Information from Patient button)
4. Enter Secondary Insurance provider information if applicable.

5. Click the Guarantor Details link at the bottom left to add guarantor information. (If Guarantor information is the same as the patient information or the Insurer, click the Copy from Patient or Copy from Primary Insurer button in the Guarantor Information dialog box to transfer the information.)
6. Select OK.
7. Select Save.
   (If any required fields are missed, LabWorks will open a message stating what the error is and will prompt you to return to that portion of the New Patient Setup to resolve it.)
To place a New Lab Order, use the Patient Search feature to locate and select a patient (Step 1). Click the New Order button on the Patient Search screen or the link on the patient’s Demographics screen to open the New Lab Order screen. Click the Continue button on the New Lab Order screen to open subsequent tabs for test selection, ICD-9 coding, and to answer Questions.

**Step 1: Patient Search**

1. Click Patient Search on the menu to open the Patient Search screen.
2. Enter the patient’s last name and first name, separated by a comma, or the patient ID number in the Patient field. (Use the first few letters of a patient’s last name or the first few characters of the patient’s ID for a wide-range search.)
3. Click the Search button to display a list of matching records. (Refer to the New Patient Record section of this guide if the patient’s record cannot be located.)
4. Select the patient’s name on the list and then click the New Order button to open the Order Info tab of the New Lab Order screen.

**Step 2: Order Information**

Many of the fields on the Order Info tab are automatically populated with data from the patient’s record. Add or change information as needed and then click the Continue button to save the Order Information and open the Tests tab.

**Step 3: Tests**

Select a test to add to the order by clicking the check box next to the name of the test in the Test Short List section of the tab.

If a required test does not appear in the Test Short List section, search for and select a test from the All Tests drop-down list.

1. Choose a filter by option for the All Tests field.
2. Based on the option selected, enter the first few characters of the test Code, Name, or Mnemonic in the field.
3. Open the drop-down list to display tests that match the criteria entered.
4. Locate and click on the test Code, Name, or Mnemonic on the list to add it to the order.

5. Click the Continue button when test selection is complete. (If Questions and/or ICD-9 forms are not required for any of the selected tests, the order is automatically saved and the requisition and bar code label printing process begins. When the printing process is completed, the order is automatically queued for transmission to the lab.)

**Step 4: ICD-9s (If Applicable)**

The ICD tab opens whenever coding is required for at least one of the ordered tests. Select ICD-9 codes from the short list to apply the code to the selected tests, or follow the steps below to search for ICD-9 codes.

1. Select a test on the list.
2. Choose a filter by option for the ICD-9 field.
3. Based on the option selected, enter the first few characters of the ICD-9 Code, Name, or Mnemonic in the field.
4. Open the drop-down list to display ICD-9 codes that match the criteria entered.
5. Locate and click on the appropriate ICD-9 code to apply it to the test.
6. Click the Continue button when ICD-9 coding is complete. (If no other forms are required, the order is automatically saved, the requisition and bar code printing process starts, and the order is queued for transmission to the lab.)

**Test Fails LMRP**

If an ICD-9 code that is applied to an ordered test fails to meet LMRP (Local Medical Review Policy) rules, the list of tests will be re-displayed with the word “FAILED” in the LMRP column for each test that failed. The user will be prompted to select an option to proceed with or cancel the order.

**Step 5: Questions (If Applicable)**

If any selected tests require additional information, the Questions tab opens automatically. Select options or enter values for any questions and then click the Continue button to save the order, start the requisition and bar code printing process, and queue the order for transmission to the lab.
Use the Search Criteria Tab at the top to locate and review the details of any lab order in the database. After locating a lab order, the order requisition can also be reviewed and/or printed.

**Step 1: Lab Order Search**

1. Select **Order Search on the Orders** menu to open the Order Search screen.
2. Select the **Search Criteria** tab and use the Order Search Criteria fields and options to locate a specific lab order or group of orders.
3. Select an order on the list and then click one of the viewing or printing options below the list.

**Status Types:**
- **Incomplete** – Order has not been completed and will need to be completed or deleted. *Orders in this status can still be edited.*
- **Not Sent to Lab** – Order has not been transmitted yet and can still be edited.
- **Sent to Lab** – Orders have been electronically sent to the lab but not yet resulted.
- **Partial** – Some of the tests in the order have been resulted.
- **Final** – All tests in the order have been resulted and finalized.

**Step 2: Editing**

Any order can be edited or deleted as long as it has not yet been electronically sent to the lab.

1. Select the order needing edited.
2. Click on **Edit Order**.

Selecting Edit Order will open the original order and changes can now be made. Once all changes are made and the order is finished, a new requisition and specimen label(s) will print. These new copies will need to be included along with specimens and incorrect copies properly discarded.

Manifests are an important tool that can be used as a checks and balance system to have in lab work flow to ensure that all tests have been received for all specimens sent.

**Manifests**

If you know the number of the manifest that you want to review or print, enter the number in the Manifest Number field and then click **Search**.

If you know the approximate creation date of the manifest that you want to review or print, enter From and To dates in the date fields that include the approximate date, and then click **Search**.

*If AutoPrint is installed, the manifest will automatically print each time orders are transmitted to the lab.*
The procedure for creating a Standing Order is similar to creating a New Lab Order.

**Step 1: Locate and select the record of the patient for whom you want to create a Standing Order.**
1. Select **New Standing Order** from the Patients menu to display the Order Info tab of the New Standing Order screen.
2. Review, edit, or add information as required on the Order Info tab as you would for regular lab orders, and then click **Continue** to open the Tests tab.
3. Select the required tests and click **Continue** when test selection is complete.
4. Enter the ICD-9 codes if required and click **Continue**. When ICD-9 coding is complete, click **Continue** to answer any applicable test questions.
5. When the Recurrence tab opens, enter a **Start Date**, an **End Date** or a **Number of Orders**, and the **Occurrence Frequency**. After the Recurrence Pattern settings are complete, click **Continue** to close the New Standing Order screen and save the order as a Standing Order template. (After a template has been created it must be authorized before the test orders specified in the template will be generated.)

**Step 2: Authorize the Standing Order template**
1. Locate and select the record of the patient with the template that you want to authorize.
2. Select **Standing Order List** from the Patients menu to display all templates for the selected patient.
3. When the Standing Order List screen opens, select the template that needs to be authorized and then click the **Authorize Template** button.
4. When the Authorize Template dialog box opens, enter the authorization password (generally the user’s LabWorks password) and then click OK to generate the individual lab test orders.

To place an order, select a scheduled order on the list and click the **Perform Order** link to process the order and send it to the lab. (This is similar to the process for creating and sending new lab orders.)

**Step 1: Adding tests/ICD-9 codes**
1. Select **Short Lists** from the Master Files menu.
2. Select either **Test Short List** or **ICD-9 Short List**.
3. Click on **New Item**.
4. In the **Selected Test/Selected ICD-9** field, type in either the name of the Procedure that is being added or the ICD-9 code.
   
   **Example:** Complete Blood Count or V101.1

5. In the **Include** field, select to **Always Include**, **Never Include** or **Include Based on Usage**.

   **Note:**
   - **Always Include** items will always be included at the top of the Short List screen when completing a new order.
   - **Never Include** items will be prevented from being shown on the Short List.
   - **Include Based on Usage** items will appear on the Short List in order from most used to the least used under the Always Include items.

6. Select **Save Item**.
Step 1: Search Lab Reports
1. Click Reports on the Results menu.
2. Select a report on the list and then click the arrow to the right of the Report link to View or Print Report.

Step 2: Modifying Filter Criteria
1. Click on the Search Criteria tab at the top of screen.
2. Modify Search Criteria by changing or searching on any of the following fields or combination of fields:
   - Patient Name
   - Ordering Location
   - Reported Date Range
   - Ordering Physician
3. The reports are further filtered by the displaying criteria:
   - Read
   - Unread
   - Abnormal
   - Finalized
4. Click the Search button and results will be displayed based on the new criteria.

Step 2: Modifying Filter Criteria
1. Select Order Search from the Orders menu to open the Order Search.
2. Select an order on the list and then click one of the viewing or printing options below the list.
3. To reprint an entire set of labels for an order, click on the Specimen Labels at the bottom of the grid. If link is not available, click on the hexagon located below the SO (Standing Order) icon and customize grid to show specimen label link.

Users can change their own passwords at any time by selecting the Change Password option on the User menu. Passwords should be changed regularly to maintain the highest level of program and data security.
1. Click the Change Password option on the User menu.
2. Enter the Old Password in the first field on the Change Password screen. (Asterisks mask the actual characters as they are typed.)
3. Enter the new password. (Passwords are case sensitive.)
4. Re-enter the new password in the Confirm Password field.
5. Click Save New Password button to complete the change. (The password change takes effect at the next login.)
Use this feature to merge duplicate patient records into one record for the same patient.

Step 1: Select Merge Patients on the Master Files menu
1. Enter the patient’s name in the Patient field and then click Search to locate the duplicate records.
2. Select one of the patient’s records on the list and then click the Mark for Patient Merge link.
3. Select the duplicate patient record on the list and then click the Mark for Patient Merge link again.
4. A message box will indicate that the patient records have been marked for the merge process. Click OK to close the message box and continue. (Multiple sets of duplicate patient records can be marked for merge by repeating steps 1-4.)

Step 2: Click the Patient Merge List button to display a list of patient records that have been marked for merge.
1. Select the set of records to merge on the list and then click the Merge Patients link to start the merge process.
2. When the Merge Detail screen opens, review the demographics and results of the records to determine which record to merge into the other and then click the Merge 1 to 2 or Merge 2 to 1 button the merge the records.

For example, if demographic information appears to be complete and accurate in the first patient record, but demographic information is missing in the second record, merge the second record into the first record. The merge process will copy the results from the second record into the first record, and then suppress the view of the second record. **Merged records are not deleted from the database and can be reversed by Unmerging Patient records.**
Use this feature to chart patient results.

Step 1: Search for patient reports.
1. Enter the patient’s name in the Patient field and then click Search to locate the patient records.
2. Highlight patient’s name, and the click Patient Reports.

Step 2: Locate and select test.
1. Highlight report and then click the test to chart results.
2. Click the Chart Results link to open results selection dialog box. (The selected test will appear automatically on the list of Results to Chart.)

Step 3: Select second test to chart from drop box.
1. Click on drop box and scroll to select second test to chart.
2. When results selection is complete, click OK to display a graph of the results.
Use this feature to Auto Print Results & Manifests.

**Step 1:** Go to Start>Auto Print
(If the icon does not appear on the Start menu, it may alternately sometimes be found on the desktop or in the Startup Folder.)

If this has been completed correctly, the AP Icon will appear in the taskbar near the time and will change from Yellow to Green. You must wait for the color to change to Green to know that it has loaded completely.

After a few seconds, the Login Screen should appear.

After Auto Print has been loaded successfully, new reports will start printing in a few minutes. If the AP Icon does not appear or change to Green after a few moments, please contact AEL at 800-423-0504.

**Step 2:** Once this screen comes up, please type in your Auto Print User ID & Password. (If unsure of the username and password, it is usually the letters AP + the client code. For example Username: APCLIENTCODE, Password: APCLIENTCODE)

**Step 3:** Press Login.