MANUAL

Specimen Collection, Preservation, Transport

Phone  (301) 926 4707
Fax      (301) 926 4708
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**DIAGNOSTIC PATHOLOGY:** **SURGICAL PATHOLOGY**  
**FINE NEEDLE ASPIRATION BIOPSY**  
**CYTOLOGY**

- **Subspecialty Areas:** Surgical Pathology: GastroIntestinal  
  Gyn  
  ENT  
  Breast  
  Urology  
  Dermatopathology  
  Respiratory / lung  
  Soft tissue/bone pathology

  Fine Needle Aspiration: Performance (superficial, as requested), determination of adequacy, and interpretation

- **Reports:** Structured and clear:  
  - Diagnosis  
  - Photograph of pertinent findings  
  - Microscopic description as needed  
  - Gross description  
  - Clinical data  
  - Comparison with previous biopsies.  
  - Suggestions/recommendations  
  - Extramural consult for controversial/difficult cases, and as requested

  Tailored to practices’ needs upon request.

- **Communication:** Direct between Pathologist and referring physician for any consult/discussion of cases.

  Direct same day call/fax of all malignant cases.

  Reports faxed upon request.
- Transport: Courier pick-up scheduled from CBM Pathology.

  Procedure manual concerning specimen collection, specimen preservation and specimen transportation requirements is provided by CBM Pathology.

  Supplies provided by CBM Pathology.

- Turnaround time:
  - Routine (Biopsy, FNA): 24-48 hrs.
  - Routine (Gyn): 2-3 days
  - HPV Test (high-risk) 2-3 days
    - Reflex 16/18 Additional 2 days
  - FNA, preliminary Diagnosis: Normally within 4 hrs. of procedure
  - Frozen Section Diagnosis: same day

- Additional services

  - Same day second opinion for patients’ previous cases, when slides are available.

  - Review of interesting and difficult cases for treatment, education and QA purposes, scheduled as informal meetings or structured conferences, including microscopic and/or projecting slide tutorials.
IMPORTANT REQUIREMENTS

SPECIMEN LABELING
All specimen containers must be labeled with two patient identifiers at the time of collection. All slides must be labeled with two patient identifiers. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, medical record number. Specimens must be labeled and requisitions prepared in the room where the procedure is performed.

AUTHORIZED REQUESTOR:

THE LABORATORY CAN ONLY ACCEPT SPECIMENS FOR TESTING THAT HAVE BEEN REQUESTED BY: SUBMITTING PHYSICIAN

IF VERBAL AUTHORIZATION IS NEEDED, THE REQUESTING PHYSICIAN MUST SUBMIT A WRITTEN REQUEST VIA FAX/EMAIL OR REGULAR MAIL, AS SOON AS POSSIBLE (WITHIN 30 DAYS)
Surgical Biopsy

Synonyms:  Biopsy; Gross and Microscopic Pathology; Pathologic Examination; Surgical Pathology; Tissue examination

Applies to:  Gyn biopsy; Breast biopsy; Skin biopsy; Endoscopic biopsy; Soft tissue biopsy; Bronchial biopsy; Liver biopsy; other biopsies

Test Includes:  Gross and microscopic examination and diagnosis.  Imprints may be made if the tissue is fresh and unfixed and if indications for imprints exist.

Laboratory:  CBM PATH

Request Form:  Biopsy requisition including: operative diagnosis and source of specimen, clinical history, as well as patient’s name, date of birth, sex, collection date and time if appropriate, tests requested, name of surgeon, and names of other physicians who will need a copy of the pathology report.

Phone:  (301) 926 4707

Availability:  Mon-Fri, 10 AM – 6 PM

Turnaround Time:  24-72 hrs.  Delays are caused by the need for clinical information or special stains.

Special Instructions:  Surgical pathology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

Specimen:  Tissue fixed in 10% formalin or other appropriate fixative.  Each specimen container (not the lid) must be labeled to include source, patient’s name and a second patient identifier.  Each specimen from a different anatomic site must be placed in a separate, correctly labeled container, designated ‘left’, ‘right’, ‘proximal’, ‘distal’, ‘ventral’, ‘dorsal’ and so forth.  Tightly closed jars/containers from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form.  Each case (requisition form and all containers from the same patient obtained during the same procedure) must be placed in its own bag.

Container:  Jars of assorted sizes, containing 10% buffered formalin or another appropriate fixative; the neck of the container should not be smaller than its diameter.
(SURGICAL BIOPSY - continued)

**Collection:** Small biopsy specimens are to be placed immediately in fixative, unless special needs such as frozen section exist. Use approximately 5-20 times as much fixative solution as the bulk of the tissue. Small tissues such as those from bronchoscopic biopsy, bladder biopsy, and endometrium can be ruined in a very short time by drying out.

Breast biopsies should be placed within fixative as quickly as possible to minimize Cold Ischemic Time (CIT) which can impact any necessary ER/PR, HER2 test results. The time breast biopsy is removed and time placed in fixative should be less than 1 hour and documented on the requisition form.

**Storage Instructions:** Fixation in 10% formalin solution or other appropriate fixative.

**Patient Preparation:** It is essential that each specimen be accompanied by an adequate description of what it is thought to represent, as well as an appropriate clinical history.

**Causes for Rejection:** Mislabeled specimen container, unlabeled specimen, inadequate clinical information.

**Use:** Histopathologic diagnosis, evaluate extent of lesions and provision of classification and, when appropriate, grading in the case of tumors.

**Limitations:** Tissue fixed in formalin cannot be used for microbial culture, certain types of histochemistry, frozen sections, gene rearrangement, or optimal electron microscopy.

**Additional Information:** A major advantage of conventional tissue processing over frozen sections is that extensive sampling of the entire specimen can take place.

**Cultures:** of tissue are best taken in the O.R., where a sterile field exists. A piece of tissue (e.g., a curetting of a fistulous tract) should be placed in an appropriate sterile tube with requests for a smear, culture, anaerobic culture, AFB, and fungus culture if appropriate.
Frozen Section Surgical Biopsy

**Synonyms:** Frozen Section Diagnosis; Frozen Section Pathology; Rapid Diagnosis Consultation; Intraoperative Consultation

**Applies to:** Gyn biopsy; Breast biopsy; Skin biopsy; Endoscopic biopsy; Soft tissue biopsy; other biopsies

**Test Includes:** Gross evaluation, frozen section preparation, microscopic examination and frozen section diagnosis. Flow cytometry and touch imprints may be made if indications exist. Remaining tissue is submitted for conventional H&E processing for correlation and the final pathology report.

**Laboratory:** CBM PATH

**Request Form:** Biopsy requisition including: operative diagnosis and source of specimen, reason to request frozen section diagnosis, clinical history, as well as patient’s name, date of birth, sex, collection date and time, tests requested, name of surgeon, contact phone number.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10 AM – 6 PM

**Turnaround Time:** Verbal notification is 20-60 minutes from time receive sample depending on complexity of the case. Delays are caused by the need for more sections, clinical information. Delays from the time of procedure may be caused by transportation.

**Special Instructions:** Surgical pathology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

**Specimen:** Tissue must be fresh or stored in saline solution. Each specimen container (not the lid) must be labeled to include source, patient’s name and a second patient identifier. Each specimen from a different anatomic site must be placed in a separate, correctly labeled container, designated ‘left’, ‘right’, ‘proximal’, ‘distal’, ‘ventral’, ‘dorsal’ and so forth. Tightly closed jars/containers from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all containers from the same patient obtained during the same procedure) must be placed in its own bag.

**Container:** Jars of assorted sizes; the neck of the container should not be smaller than its diameter.
(FROZEN SECTION SURGICAL BIOPSY - continued)

**Collection:** Small biopsy specimens are to be placed immediately in saline. Use approximately 5-20 times as much saline solution as the bulk of the tissue. Small can be ruined in a very short time by drying out.

**Storage Instructions:** Saline solution only, the sample must not be fixed.

**Patient Preparation:** It is essential that each specimen be accompanied by an adequate description of what it is thought to represent, as well as an appropriate clinical history.

**Causes for Rejection:** Mislabeled specimen container, unlabeled specimen, inadequate clinical information.

**Use:** Rapid diagnosis when STAT reporting is needed.

**Limitations:** Tissue fixed in formalin cannot be used for frozen section pathology. Sampling and staining are diagnostic limitation compared to conventional tissue processing.

**Cultures:** of tissue are best taken in the O.R., where a sterile field exists. A piece of tissue (e.g., a curetting of a fistulous tract) should be placed in an appropriate sterile tube with requests for a smear, culture, anaerobic culture, AFB, and fungus culture if appropriate.
**Breast Smear, Nipple Secretion Cytology**

**Synonyms:** Breast Discharge Cytology; Nipple Discharge Cytology

**Test Includes:** Examination of stained slides

**Laboratory:** CBM PATH

**Request Form:** Cytology requisition form and billing form. The following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10 AM - 6 PM

**Turnaround Time:** 24-48 hours

**Special Instructions:** Specify nipple discharge. Include pertinent clinical data, history of carcinoma on the requisition. Cytology specimens must be labeled and requisitions prepared in the room where the procedure is performed.

**Specimen:** Nipple discharge

**Container:** Supplies and requisitions available in the Cytology laboratory.

**Collection:** Two to 6 sequentially numbered glass slides should be made and labeled with patient’s name, a second patient identifier, and source of specimen. Soak nipple with warm saline in cotton or gauze for 10-15 minutes, then gently strip subareolar area and nipple with thumb and forefinger. When secretion occurs, allow pea-sized drop to accumulate on apex of nipple. Place slide #1 upon nipple and slide across quickly. Air-dry or fix immediately by: spray, holding pump nozzle 5’ to 7’ (13-18 cm.) from slide, or placing in 95% ethyl alcohol fixative. Make all the slides by repeating the smear and fixation technique. The latter smears usually contain more abnormal cells. Label containers with patient’s name, and date. If smears are prepared from both breasts, label each slide as left (L) or right (R). Allow spray fixative to dry, place in cardboard holders and secure to completed requisition. All material from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all specimens from the same patient obtained during the same procedure) must be placed in its own bag.

**Storage Instructions:** Keep in dry place at room temperature until ready for transport.

*Updated 10/2016*
(BREAST SMEAR, NIPPLE SECRETION CYTOLOGY - continued)

**Causes for Rejection:** Improper labeling of specimen/slides, incomplete requisition form, improper fixation causing drying artifact which precludes evaluation of nuclear detail.

**Reference range:** Negative to abnormal cells diagnostic of neoplasm.

**Use:** To establish the presence of primary or metastatic neoplasm.

**Limitations:** If slides are fixed, drying of smear before fixation will render it unsatisfactory for evaluation. A negative result does not entirely exclude the presence of tumor.

**Additional information:** For patients with palpable mass, fine needle aspiration/needle biopsy are more productive procedures. Mammography should also be performed.
**Brushings Cytology**

**Applies to:** Bronchial Brushings Cytology; Colonic and Rectal Brushings Cytology; Esophageal Brushings Cytology; Gastric Brushings Cytology; Small Bowel Brushings Cytology; Tracheal Brushings Cytology; Urinary Tract Brushings Cytology

**Test Includes:** Routine examination of prepared smears or cytocentrifuge/ThinPrep preparations

**Laboratory:** CBMPATH

**Request Form:** Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10 AM - 6 PM

**Turnaround Time:** 24-48 hours

**Special Instructions:** Specify the site brushed and include pertinent clinical data (e.g., admitting diagnosis, history of carcinoma) on the requisition. Cytology specimens must be labeled and requisitions prepared in the room where the procedure is performed.

**Specimen:** Brush lesion area.

**Container:** Transport medium obtained from the Cytology laboratory.

**Collection:** If disposable brushes are used, rinse brush vigorously in transport medium, and cut off brush with 1 to 2” (3- 5 cm) of wire cable and place immediately into container holding 10-15 ml of transport medium. Reusable brushes should be briskly agitated in similar container. Label bottle with exact body site, patient’s name, second patient identifier and date. Place in refrigerator (4 – 6 C) until ready for transport. If slides are made, label frosted end with patient’s name, exact body site, and date. All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all the specimens from the same patient obtained during the same procedure) must be placed in its own bag.

**Causes for Rejection:** Improper labeling of specimen/slides, incomplete requisition form, Improper fixation causing drying artifact which precludes evaluation of nuclear detail.

**Reference Range:** Negative to abnormal cells diagnostic of malignant neoplasm
(BRUSHINGS CYTOLOGY - continued)

**Use:** Establish the presence of primary or metastatic neoplasms; diagnose certain infections with herpesvirus, cytomegalovirus, fungal diseases, *Pneumocystis carinii*, *Strongyloides*, *Echinococcus*, and *Paragonimus*.

**Limitations:** Allowing smears to dry before they are fixed or allowing the brushes to dry will render them *unsatisfactory* for cytologic evaluation. Cytologic samples are *not* cultured.

**Additional Information:** Special stains will be performed when appropriate.
Cervical/Vaginal Cytology

**Synonyms:** Cervical Smear; Cervicovaginal Cytology; Papanicolaou Smear; Pap Smear.

**Test Includes:** Evaluation of one to two slides of cervical and/or vaginal scrapings.

**Laboratory:** CBMPATH – Cytology.

**Request Form:** Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data (including LMP and history of previous abnormal Paps), source of sample, previous cases with diagnoses, and date collected.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10 AM - 6 PM

**Special Instructions:** Include pertinent clinical history (e.g., age, LMP, surgery, exogenous hormones, history of carcinoma, radiation, chemotherapy or abnormal vaginal bleeding, previous abnormal Paps) on the requisition. **Must include age and LMP** on requisition. Cytology specimens must be labeled and requisitions prepared in the room where the procedure is performed.

**Specimen:** Cervical scrape along with endocervical brushing is recommended in all cases. Aspiration of posterior vaginal fornix (vaginal pool) may also be used but is not a substitute for cervical specimens. Endometrial aspirations should be obtained if indicated. For lesions of the vagina, scrapings made directly from a lesion are desirable.

**Container:** Supplies and requisitions are available from the Cytology laboratory.

**Collection:**  
- **Fixatives:** Cytologic aerosol pump spray or 95% ethyl alcohol.  
- **Patient identification on specimen:** Each slide must be labeled with sample site, patient’s name, and a second patient identifier using graphite pencil on frosted end. Bottles (not tops) must be labeled with patient’s name, second patient identifier and date.  
- **Sampling:** Endocervix: cervical brushing of endocervical canal, always remove any mucus plug before sampling. Cervical brushing is obtained by inserting brush into cervical os and rotate. Place brush on slide and roll, spread evenly and **fix immediately.** Do not scrub brush on surface of slide.  
- **Ectocervical scrape:** With spatula scrape the entire ectocervix with emphasis on the squamocolumnar junction. Spread evenly onto labeled slide and fix immediately.  
- **Vaginal pool smear:** Obtain specimen by dipping the end of the spatula into the posterior fornix. Spread material evenly onto labeled slide and fix immediately. If maturation index is desired use procedure outlined under that test listing.  
- **Fixation:** Immediately spray fix the smears holding slides 5-7 inches (13-18 cm)
(CERVICAL/VAGINAL CYTOLOGY - continued)

from the pump nozzle. When several slides are immersed in fixative, attach a paper clip to each slide to separate and allow adequate fixation.

**Processing:** Place slides in cardboard holders (allow spray fixative to dry first) with all information (requisitions), to picked up by courier.

**Patient Preparation:** Patient should avoid douches 48-72 hours prior to the examination. Do not use lubricant on vaginal speculum if possible.

**Causes for Rejection:** Fixation in formalin, failure to indicate age and LMP on requisition, Other incomplete data on requisition slip, improper labeling.

**Reference Range:** Negative to abnormal cells diagnostic of malignant neoplasm.

**Use:** Establish the presence of primary or metastatic neoplasms, including precursor lesions of squamous carcinoma of the cervix; aid in the diagnosis of genital infections with herpesvirus, fungus, Trichomonas vaginalis, and Actinomyces; aid in the diagnosis of vaginal adenosis, Condyloma acuminatum; aid in evaluating hormonal function (maturation index).

**Limitations:** Failure to obtain adequate ectocervical, endocervical, or vaginal cell populations is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination. Air drying artifact due to improper/late fixation will make evaluation of cellular detail suboptimal. Collection of cytologic material following Schiller’s test or colposcopy will render sample unsatisfactory due to adverse effects caused by reagents used. Inflammatory reaction and *Trichomonas* precludes hormonal evaluation. A very significant proportion of adenocarcinomas of endometrium are not detected by this means. Occasionally, highly differentiated adenocarcinomas of endocervix can be missed. Occasional aggressive lesions of squamous epithelium of cervix can be missed, especially if the patient has only a single examination. A technically inadequate smear is not negative.
Cervical/Vaginal Cytology - Liquid Based Pap test (ThinPrep)

**Synonyms:** liquid-based Pap test; ThinPrep

**Test Includes:** Evaluation of one to two slides of cervical and/or vaginal scrapings.

**Laboratory:** CBM PATHOLOGY – Cytology.

**Request Form:** Cytology requisition form with billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data (including LMP and history of previous abnormal Paps), source of sample, previous cases with diagnoses, and date collected.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10 AM - 6 PM

**Special Instructions:** Include pertinent clinical history (e.g., age, LMP, surgery, exogenous hormones, history of carcinoma, radiation, chemotherapy or abnormal vaginal bleeding, previous abnormal Paps) on the requisition. **Must include age and LMP on requisition.** Cytology specimens must be labeled and requisitions prepared in the room where the procedure is performed.

**Specimen:** Cervical scrape along with endocervical brushing is recommended in all cases. Aspiration of posterior vaginal fornix (vaginal pool) may also be used but is not a substitute for cervical specimens. Endometrial aspirations should be obtained if indicated. For lesions of the vagina, scrapings made directly from a lesion are desirable.

**Container:** Supplies and requisitions are available from the Cytology laboratory.

**Collection:** ThinPrep vial containing PreservCyt® transport medium using a broom-type or cytobrush/spatula cervical sampling device.

**Sampling:**

I. **Brush/Spatula Protocol (See Figure A.1)**
   a. **Obtain** an adequate sampling from the ectocervix using a plastic spatula.
   b. **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.
   c. **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.
(CERVICAL/VAGINAL CYTOLOGY - LIQUID BASED PAP TEST – continued)

d. **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.

e. **Tighten** the cap so that the torque line on the cap passes the torque line on the vial.

f. **Record** the patient's name and second patient identifier on the vial (not tops). The patient information and medical history on the cytology requisition form.

g. **Place** the vial and requisition in a specimen bag for transport to the laboratory.

II. **Broom-Like Device Protocol (See Figure A.2)**

a. **Obtain** an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

b. **Rinse** the broom as quickly as possible into the PreservCyt® solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.

c. **Tighten** the cap so that the torque line on the cap passes the torque line on the vial.

d. **Record** the patient's name and second patient identifier on the vial. The patient information and medical history on the cytology requisition form.

e. **Place** the vial and requisition in a specimen bag for transport to the laboratory.

**Patient Preparation:** Patient should avoid douches 48-72 hours prior to the examination. Do not use lubricant on vaginal speculum if possible.

**Causes for Rejection:** Fixation in formalin; failure to indicate age and LMP on requisition; other incomplete data on requisition slip; improper labeling.

**Reference Range** Negative to abnormal cells diagnostic of malignant neoplasm. Inflammation/infection.

**Use:** Establish the presence of primary or metastatic neoplasms, including precursor lesions of squamous carcinoma of the cervix; aid in the diagnosis of genital infections with herpesvirus, fungus, Trichomonas vaginalis, and Actinomyces; aid in the diagnosis of vaginal adenosis, Condyloma acuminatum; aid in evaluating hormonal function (maturation index).
(CERVICAL/VAGINAL CYTOLOGY- LIQUID BASED PAP TEST – continued)

**Limitations:** Failure to obtain adequate ectocervical, endocervical, or vaginal cell populations is suboptimal for evaluation. *Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination.* Air drying artifact due to improper/late fixation will make evaluation of cellular detail suboptimal. Collection of cytologic material following Schiller’s test or colposcopy will render sample unsatisfactory due to adverse effects caused by reagents used. Inflammatory reaction and *Trichomonas* precludes hormonal evaluation. A very significant proportion of adenocarcinomas of endometrium are not detected by this means. Occasionally, highly differentiated adenocarcinomas of endocervix can be missed. Occasional aggressive lesions of squamous epithelium of cervix can be missed, especially if the patient has only a single examination.

A technically inadequate smear is **not** negative.
Anal Rectal Cytology / HPV-HR test on anal cytology samples

**Synonyms:** Anal Smear; anal Cytology; Anal Pap. HPV test for High risk HPV - Cervista

**Test Includes:** Evaluation of one to two slides of anal or ano-rectal scrapings. Liquid, Thin-layer Papanicolaou stain

**Laboratory:** CBMPATH – Cytology.

**Request Form:** Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data (including history of previous abnormal anal and cervical Paps), source of sample, previous cases with diagnoses, and date collected.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10 AM - 6 PM

**Special Instructions:** Cytology specimens must be labeled and requisitions prepared in the room where the procedure is performed.

**Specimen:** Sampling of cells from anal rectal area submitted in PreservCyt® collection fluid.

**Storage and transport:** Room temperature

**Container:** Supplies and requisitions are available from the Cytology laboratory.

**Collection:** Clinicians may use a tap water moistened Dacron swab, brush or broom. Insert into the anal canal until resistance is not met (approximately 5-6 cm) above the anal verge to distal rectum. Rotate/apply pressure to the walls of the canal while removing the sampling device (if a brush, lightly and only ¼ way. Agitate the sampling device in the vial of PreservCyt® collection fluid. Label the specimen vial with two patient identifiers and complete the cytology test requisition. All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all the specimens from the same patient obtained during the same procedure) must be placed in its own bag

**Causes for Rejection:** Fixation in formalin, incomplete data on requisition slip, improper labeling.

**Reference Range Results:**
- **Unsatisfactory:** Reported in specimens where there are less than 1 to 2 cells per high power field.
- **Negative:** Reported in specimens where only benign cells are seen.
- **Atypical:** ASC-US or ASC-H = Reported in specimens with cellular changes suspicious but not diagnostic of viral infection, suspicious but not diagnostic of ASIL, and in specimens where
(ANAL RECTAL CYTOLOGY / HPV-HR TEST - continued)

there are abnormal cells which are not conclusive for malignancy.

Positive: low grade ASIL, high grade ASIL, carcinoma = Reported in specimens where there are abnormal cells consistent with dysplasia or malignancy.

Note: Diagnostic reporting will follow the Bethesda System.

Use: The screening of cells from the anal rectal area for anal squamous intraepithelial lesions (ASIL) and squamous cell carcinoma is of value for the early diagnosis and treatment of squamous dysplasia/carcinoma of the anus. The incidence of squamous cell carcinoma in patients of high risk is similar to that of cervical cancer before the advent of the Pap smear. The anal rectal Pap smear looks for cells consistent with malignant, pre-malignant or infectious processes. By obtaining a blind sample of cells from the anal rectal area, one may determine if there are cellular changes that warrant further follow-up. Anal rectal cytology is only a screening test, and often may under-represent the grade of the anal disease. Any cellular atypia should be followed with high resolution anoscopy and biopsies. The anal rectal Pap test is a cost effective screening tool to determine if patients require further testing.

Please note: A technically inadequate smear is not negative.

HPV TEST

Currently there are no clear guidelines on HPV testing of anal samples. The test will be performed at the request of the submitting clinician. The test can be performed on the same cytology sample as the anal cytology. 2ml of cellular sample are required.


Sex Transm Infect 2008;84:94-96 doi:10.1136/sti.2007.027250 Clinical Abnormal anal cytology in high-risk human papilloma virus infection in HIV-infected Australians J Anderson1,2, J Hoy2,3, R Hillman4, C Gittleson5, G Hartel5, G Medley6, R Basser5

www.cap.org/apps/docs/.../0501_NewsPath_Anal-Rectal_Cytology.doc
Human Papillomavirus (HPV) Test for High-Risk HPV (Cervista™)

**Synonyms:** HPV HR DNA Probes, Cervista™ HPV Test

**Applies to:** Gyn cytology (ThinPrep®)

**Test Includes:** Qualitative detection of DNA from 14 designated high risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 in cervical specimens.

**Laboratory:** CBM PATH

**Methodology:** Invader Chemistry (Cervista™)

**Request From:** HR HPV can be ordered independently or as a reflex to ASC-US Gyn cytology results. Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data (including LMP and history of previous abnormal Paps), source of sample, previous cases with diagnoses, and date collected.

**Phone:** (301) 926 4707

**Availability:** Mon to Friday

**Turnaround Time:** 3-5 days.

**Specimen:** ThinPrep® Pap (refer to Gyn cytology, ThinPrep®)

**Volume:** 2 ml for the test

**Container:** ThinPrep® Pap specimen (Preservcyt).

**Collection:** Refer to Cytology, ThinPrep® Pap Test Specimen for specific collection guidelines.

**Storage Instructions:** Room temperature or refrigerated, 3 weeks. Frozen is unacceptable.

**Patient Preparation:** Females should avoid high concentrations of antifungal cream, contraceptive jelly, or douche at time of collection. Please do not use lubricant, as it may interfere with the test. Mid-cycle sampling yields better results.

**Causes for Rejection:** Mislabeled specimen container, unlabeled specimen, swabs or specimens in any other transport media.

Updated 10/2016
(HUMAN PAPILLOMAVIRUS (HPV) TEST FOR HIGH-RISK HPV - continued)

Use: In women with an ASCUS cervical cytology result, a concomitant negative high-risk HPV result suggests a low probability of finding a higher disease stage at colposcopy; cytology should be repeated in 12 months.
In women with an ASCUS cervical cytology result, a positive high-risk HPV DNA result suggests a low, but increased, probability of higher stage disease; colposcopy should be performed.
In women with cytology results >ASCUS, colposcopy should be performed regardless of the HPV result.

Limitations: Cross-reactions with other HPV genotypes may occur. False negative and false positive results may occur. Results should be correlated with cytologic/histologic findings. HPV DNA results must be interpreted in conjunction with other clinical and laboratory data. A “Not Detected” result is consistent with the absence of high-risk HPV DNA serotypes, a level of HPV DNA below the detection limit of the assay, or presence of a serotype other than those listed above. A “Detected” result indicates the presence of one or more of these high-risk HPV serotypes.

Additional Information: The Cervista™ HPV HR test is not intended for use as a screening device for women under age 30 with normal cervical cytology. The test is not intended to substitute for regular cervical cytology screening. Detection of HPV using the Cervista™ HPV HR test does not differentiate HPV types and cannot evaluate persistence of any one type. The use of this test has not been evaluated for the management of women with prior cytological or histological abnormalities, hysterectomy, who are pregnant, postmenopausal, or who have other risk factors (e.g. HIV+, immunocompromised, history of STI). The test is designed to enhance existing methods for the detection of cervical disease and should be used in conjunction with clinical information derived from other diagnostic and screening tests, physical examinations, and full medical history in accordance with appropriate patient management procedures. Cervista™ HPV HR test results should not be used as the sole basis for clinical assessment and treatment of patients.
HPV Human Papillomavirus, Genotypes 16 and 18 (Cervista™)

Synonyms: HPV 16 & 18 DNA Probes, Cervista™ HPV Test

Applies to: Gyn cytology (ThinPrep®)

Test Includes: Qualitative detection of DNA from HPV types 16 and 18, in cervical specimens.

Laboratory: CBM PATH

Methodology: Invader Chemistry (Cervista™)

Request Form: Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data (including LMP and history of previous abnormal Paps), source of sample, previous cases with diagnoses, and date collected.

Phone: (301) 926 4707

Availability: Mon to Friday

Turnaround Time: 3-5 days.

Specimen: ThinPrep® Pap (refer to Gyn cytology, ThinPrep®)

Volume: 2 ml for the test

Container: ThinPrep® Pap specimen (Preservcyt).

Collection: Refer to Cytology, ThinPrep® Pap Test Specimen for specific collection guidelines.

Storage Instructions: Room temperature or refrigerated, 3 weeks. Frozen is unacceptable.

Patient Preparation: Females should avoid high concentrations of antifungal cream, contraceptive jelly, or douche at time of collection. Please do not use lubricant, as it may interfere with the test. Mid-cycle sampling yields better results.

Causes for Rejection: Mislabeled specimen container, unlabeled specimen, swabs or specimens in any other transport media.

Use: Assess the risk of cervical cancer in women ≥30 years of age who have a negative Pap test and a positive high-risk HPV test, and/or assess risk of cervical cancer in women who have an ASC-US cervical cytology result and a positive high-risk HPV test.
(HPV HUMAN PAPILLOMAVIRUS, GENOTYPES 16 AND 18 – continued)

HPV infection causes the vast majority of all cervical cancers. Genital HPV types are categorized as low or high risk based on their oncogenic potential. Low-risk HPV types are typically associated with genital warts, whereas high-risk (HR) types are associated with invasive cervical cancer. Of the HR (oncogenic) HPV types, HPV 16 causes more than 50% of cervical cancers and HPV 18 causes 10% to 20%. The risk of developing cervical precancer (ie, grade 3 cervical intraepithelial neoplasia [CIN3]) or cancer is increased in women when they are infected with HPV 16 and/or 18. Based on these and other data, the American Society for Colposcopy and Cervical Pathology (ASCCP) recommends HPV 16 and 18 genotype testing for women ≥30 years old who have negative cytology and a positive HR HPV test. Although the ASCCP does not recommend HPV genotype testing for patients with atypical squamous cells of undetermined significance (ASC-US), the FDA has approved an HPV 16/18 genotyping test as an adjunct to guide management of these patients. Such management includes physician assessment of cervical cytology, HR HPV test results, and other risk factors.

Individuals Suitable for Testing
- Women 30 years and older who have negative cervical cytology and a positive HR HPV test
- Women who have ASC-US cervical cytology and a positive HR HPV test

Additional Information:
The ASCCP guidelines suggest the following actions for women 30 years and older with negative cervical cytology, positive HR HPV, and the genotype specified:
- HPV 16 and/or 18: refer for colposcopy
- No HPV 16 or 18: repeat both cytology and HR HPV testing in 12 months
- If repeat cytology negative and HR HPV positive, refer for colposcopy
- If repeat cytology and HR HPV both negative, repeat screening in 3 years
- If repeat cytology positive and any HR HPV result, manage per guidelines

Individuals who have ASC-US cervical cytology and HPV 16 and/or 18 have an increased risk of progression to ≥CIN2. The results of this test should not preclude women from proceeding to colposcopy.

HPV 16 and 18 genotype test results must be interpreted in conjunction with results from HR HPV testing and cervical cytology, and all other available clinical data.

Consult Cytology

Laboratory: CBMPATH

Request Form: Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, pathology report from forwarding institution and previous cases with diagnoses.

Phone: (301) 926 4707

Availability: Mon-Fri, 10 AM - 6 PM.

Turnaround time: 24-48 hrs.

Specimen: Prepared and stained glass slides.

Reference Range: Negative to abnormal cells diagnostic of malignant neoplasm.

Use: Establish the presence of primary or metastatic neoplasms; diagnose certain infections.

Limitations: Suboptimal cell preservation and slide preparation.
TRANSPORT TUBES FOR FNA, CYST FLUID AND OTHER NON-GYN CYTOLOGY SAMPLES

50 ml TUBES WITH 10 ml OF CYTOLYT PRESERVATIVE SOLUTION

INSTRUCTIONS:

Store tubes at room temperature.

Label the specimen tube with two patient identifiers.

For storage/transportation of cytology samples:

- FNA = After preparing direct smears (air-dried), rinse needle and syringe in tube by aspirating Cytolyt back and forth between tube and syringe/needle several times. The material obtained in Cytolyt will be processed in the laboratory as a cell block (if enough material) or as a ThinPrep.
- Cyst fluid = after preparing direct smears (air-dried) place the rest of the fluid in Cytolyt.
**Fine Needle Aspiration - Cytopathology**

**Synonyms:** ASP Cytology; FNA; Needle Aspiration Cytology; Thin Needle Aspiration

**Laboratory:** CBMPATH – Cytology.

**Request Form:** FNA requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, collection date and source of sample.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10AM - 6 PM.

**Turnaround Time:** 4 hrs. preliminary interpretation if appropriate; 24 – 72 hours for final result.

**Special Instructions:** Special problems may exist for each target lesion. All pertinent data (history, symptoms, signs, lab data, prior biopsies, diagnoses, surgery, and therapies) must be included to allow appropriate sampling, processing, and interpretation. Aspiration cytology service is also available to go to the patient’s site and perform fine needle aspiration. The referring physician will be called with preliminary interpretation within 4 hours after completion of the procedure. Cytology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

**Specimen:** Needle aspirate (any body site) using 22- to 25-gauge needles.

**Collection:** Schedule needle aspirate in advance by calling laboratory. Certain target lesions may yield less diagnostic material due to fibrosis and necrosis and require multiple samples. Rapid stains are available to help determine sample adequacy. Samples collected by referring physician: After preparing direct smears (air-dried), rinse needle and syringe in tube with Cytolyt by aspirating Cytolyt back and forth between tube and syringe/needle several times. The material obtained in Cytolyt will be processed as a cellblock (if enough material) or as a ThinPrep. All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all the specimens from the same patient obtained during the same procedure) must be placed in its own bag.

**Patient Preparation:** Skin cleansing.

**Causes for Rejection:** Improper fixation, air drying artifact, or lack of pertinent data on requisition

**Reference Range:** Negative to abnormal cells diagnostic of malignant neoplasm.
(FINE NEEDLE ASPIRATION – CYTOPATHOLOGY – continued)

**Use:** Establish the presence of primary or metastatic malignant neoplasms, benign tumors, inflammatory lesion that produce mass effect, cysts; aid in the diagnosis of infectious disease.

**Limitations:** Inadequate sampling or allowing a smear to dry before fixation will render it unsatisfactory for cytologic evaluation.

**Contraindications:** Diffuse swelling without a mass. The procedure should not be performed unless the physician is familiar with the method and has trained help in processing.
Oral Direct Smear

Synonyms: Oral Cytology; Oral Scraping Cytology; Pemphigus Smear.

Test Includes: Cytologic evaluation of prepared smears; tongue, gum, and mouth lesion smears for the detection of malignant cells.

Laboratory: CBMPATH – Cytology.

Request Form: Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, collection date and source of sample.

Phone: (301) 926 4707

Availability: Mon-Fri, 10 AM - 6 PM.

Turnaround Time: 24 – 72 hours.

Special Instructions: Information regarding age, physical findings, history of smoking, dentures, skin lesions, reverse smoking, and radiation or chemotherapy is essential to interpretation and should be received with specimen. Cytology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

Specimen: Direct scrape of oral lesion.

Container: Supplies include glass slides

Collection: Scrape lesion with spatula or tongue blade. Smear gently on labeled glass slide and fix immediately in 95% ethyl alcohol or with spray fixative. If multiple slides are prepared, do not allow them to stick together. Submit to the laboratory with completed requisition. All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form.

Patient Preparation: Patient should rinse mouth vigorously several times with water before making specimen slides.

Causes for Rejection: Improper fixation, air drying artifact

Reference Range: Negative to abnormal cells consistent with neoplasm.

Use: Diagnose dysplastic and malignant disease of the oral cavity; occasionally to diagnose neoplasms of minor palatal salivary glands; diagnose oral herpes, Candida.

Limitations: Drying of smear before fixation will render it unsatisfactory for evaluation.
**Sputum Cytology**

**Additional Information:** Biopsy is more sensitive than cytology, especially since some oral cancers show minimal cytologic atypia.

**Test Includes:** Three consecutive first morning sputum specimens for pulmonary diagnostic evaluation.

**Laboratory:** CBMPATH

**Request Form:** FNA requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, collection date and source of sample.

**Phone:** (301) 926 4707

**Availability:** Mon-Fri, 10AM - 6 PM.

**Turnaround Time:** 24 – 48 hours.

**Special Instructions:** Include clinical diagnosis and pertinent clinical history (e.g., history of carcinoma, exposure to carcinogen) on the requisition. Cytology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

**Specimen:** Expectorated sputum, *not saliva or nasal aspirates*.

**Volume:** Not less than 5 ml (1 teaspoon); between 5-20 ml. for induced sputum.

**Container:** Leak-proof container.

**Collection:** Collect specimen directly in container with Cytolyt. Label with patient’s name, DOB, collection date and time of collection. All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all the specimens from the same patient obtained during the same procedure) must be placed in its own bag.

**Storage Instructions:** Specimens must be placed in a refrigerator (but not allowed to freeze) and delivered as soon as possible via courier the same day. No anticoagulant or fixative is to be added.

**Patient Preparation:** The importance of a deep cough to obtain good quality diagnostic cells in sputum specimen should be explained.
(SPUTUM CYTOLOGY – continued)

**Causes for Rejection:** Improper saliva or nasal aspirates, improper labeling of specimen, incomplete requisition form.

**Reference Range:** Negative to abnormal cells diagnostic of malignant neoplasm

**Use:** Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of respiratory infections.

**Limitations:** If bronchial cells and/or dust-pigment macrophages are not identified, specimen will be reported as not entirely satisfactory for adequate evaluation.

**Additional Information:** When a pulmonary lesion is suspected, a complete sputum series should be examined. The complete sputum series consists of a fresh, early morning specimen each day for 3 days. A postbronchoscopy sputum should be included in the series. The complete sputum series increases the detection of primary bronchogenic carcinoma from 45% (one specimen) to 86% (three specimens). If only scanty sputum is produced, sputum should be induced with tap water aerosol.
Urine Cytology*
*See Washing Cytology for Cystoscopy Specimens

Test Includes Routine cytologic evaluation with cytocentrifuge or ThinPrep preparation.

Laboratory: CBMPATH

Request Form: FNA requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, collection date and source of sample.

Phone: (301) 926 4707

Availability: Mon-Fri, 10 AM - 6 PM.

Turnaround Time: 24 – 48 hours.

Special Instructions: Must specify collection method (voided or catheterized). Include pertinent clinical data (e.g., initial or working diagnosis, history of carcinoma, radiation or chemotherapy, etc) on the requisition. A first morning voided specimen is not suitable, because of cellular degeneration. Bladder washings should not be collected in a hypotonic solution. Cytology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

Specimen: Fresh voided or catheterized urine only; first morning urine is discouraged because of degeneration.

Volume: Not less than 25 ml, not more than 100 ml.

Container. Clean, capped, leak-proof container.

Collection: Fresh unfixed urine specimen must be kept refrigerated until courier pick-up. Label with patient’s name, a second patient identifier, time, date, and type of specimen (is, voided or catheterized). All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all the specimens from the same patient obtained during the same procedure) must be placed in its own bag.

Patient Preparation: It is important to hydrate the patient with one glass of water every 15-20 minutes for 2 hours prior to collection.

Causes for Rejection: Improper labeling of specimen, incomplete requisition form. 24-hour urine specimens are unacceptable.

Reference Range: Negative to abnormal cells diagnostic of malignant neoplasm.

Use: To establish the presence of primary or metastatic neoplasms; aid in the diagnosis of certain urinary tract infections and renal transplant rejection.
(URINE CYTOLOGY – continued)

**Contraindications:** Collection of urine at a time when it cannot be processed the same day.

**Additional Information:** Because of the severe degenerative effects of urine on cells, the use of fresh urine and its immediate (same day) processing cannot be overemphasized. Voided urine is much preferred over a catheterized sample due to atypical cell changes caused by trauma.
Washings Cytology

Synonyms: Lavage Cytology.

Applies to: Bronchial Washings; Colon and Rectal Washings; Esophageal Washings Cytology; Gastric Washings; Pelvic Wash Cytology; Sinus Washings; Tracheal Aspiration Cytology; Urinary Tract Washings Cytology.

Test Includes: Routine cytologic evaluation of smears with cell block and cytocentrifuge preparation if indicated.

Laboratory: CBMPATH.

Request Form: Cytology requisition form and billing form, the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, collection date and source of sample.

Phone: (301) 926 4707

Availability: Mon-Fri, 10 AM - 6 PM.

Turnaround Time: 24 – 48 hours.

Special Instructions: Include type of specimen and pertinent clinical information (e.g., previous carcinoma) on the requisition. Cytology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed.

Specimen: Obtained by physician. Collection using a balanced salt solution is preferable to normal saline.

Volume: Not less than 5 ml, not more than 100 ml.

Container: Sterile capped container.

Collection: Label bottle with patient name, second patient identifier, source of specimen and date. Keep refrigerated until same day courier pick-up. All specimens from one patient must be placed in a biohazard bag (provided by lab) with special pouch for requisition form. Each case (requisition form and all the specimens from the same patient obtained during the same procedure) must be placed in its own bag.
(WASHINGS CYTOLOGY - continued)

_Gastric washing:_ Evaluation for neoplasm: Collect resting gastric contents and discard. Then instill 300-500 ml normal saline through the gastric tube. Have patient then sit, lie on back, lie on stomach, lie on right side, and lie on left side. Aspirate as much of injected saline as possible and place in container packed in ice. Label with patient name, second patient identifier, source, physician name and date of collection.

_Peritoneal washings:_ Wash peritoneal site vigorously with several hundred ml of saline. Retrieve and submit, labeled by anatomic site.

_Storage Instructions:_ It **must** be refrigerated and submitted the same day to the laboratory (do not allow to freeze).

_Patient Preparation:_ For _gastric_ or _esophageal_ washings, patient must be fasting at least 12 hours prior to procedure (soft supper the night before, water ad-lib 1 hour before). For intubation, patient should be sitting upright. Dentures should be removed. _Colon washings_ specimens should be collected prior to barium examination. If this is not possible, wait 24 hours after the barium exam before attempting a cytologic study.

_Causes for Rejection:_ Improper labeling or improper preservation.

_Reference Range:_ Negative to abnormal cells diagnostic of malignant neoplasm.

_Use:_ Establish the presence of primary or metastatic neoplasm.

_Additional Information:_ Special stains will be performed when appropriate. Because of increased cell recovery and preservation with balanced salt solutions, they are preferred over normal saline. Lavage is not as sensitive or specific a test as endoscopically guided brushing and biopsy, which are to be preferred.
Ova and Parasites, Concentration and Stain

Synonyms: O and P, Comprehensive Ova and Parasite, Ova and Parasite, Parasites.

Methodology: Microscopic examination of concentrate and trichrome stain

Test Includes: Formalin concentrate and trichrome stain

Laboratory: CBM Path, referred to LabCorp/Quest - Microbiology Department.

Request Form: Biopsy requisition form (CBM), Microbiology requisition form (LabCorp), the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

Phone: (301) 926-4707

Availability: Mon-Fri, 10 AM- 6 PM

Setup Schedule: Set up 7 days a week (LabCorp)

Turnaround Time: Reports in 2 days from set-up.

Special Instructions: Do not use enteric bacteria transport medium. Do not submit unpreserved stools.

Preferred Specimen: 3-4 mL sputum or 5 mL feces. Minimum 3 mL. ParaPak™ Ova & Parasite Kit consists of a formalin vial and PVA vial. Recommended screening procedure is 3 random stool specimens, 1 a day for each of 3 days. Directions are provided with the collection kit.

Container: ParaPak Ova and Parasite Kit. Directions are provided with the collection kit.

Transport Temperature: Room temperature (up to a week).

Storage Instructions: Specimen placed immediately in formalin and PVA preservatives can be acceptably maintained up to 7 days for the recovery of ova and nonmotile trophozoites. Specimens should be transported in formalin and PVA transport containers.

Patient Prep: Specimens obtained with a warm saline enema or Fleet® Phospho®-Soda are acceptable. Specimens obtained with mineral oil, ismuth, iron, or magnesium compounds are unsatisfactory. Wait one week or more after barium procedures or barium laxatives before collecting stools for examination.

Causes for Rejection: Improper labeling of specimen, incomplete requisition form, unpreserved specimen, specimen in a diaper or tissue paper, insufficient specimen volume, specimen contaminated with urine and/or water, specimen contaminating outside of transport container,
(Ova and Parasites, Concentration and Stain- continued)

specimen containing interfering substances, e.g. castor oil, bismuth, Metamucil®, gallbladder dye, antimicrobial axerits or barium.

Reference Range: No ova or parasites seen in material examined

Use: Establish the diagnosis of parasitic infestation

Limitations: One negative result does not rule out the possibility of parasitic infestation; no more than two specimens should be submitted to the laboratory per day.

Additional information: Amoebas and certain other parasites cannot be seen in stools containing barium. Formed stools are more likely to contain amoebic cyst and helminth eggs. Soft or liquid stools (either normally passed or obtained by purgation) are more likely to contain trophozoites of the protozoa. Formalin will preserve protozoan cysts, and larvae and eggs of helminths. Used for concentration procedure. PVA (polyvinyl alcohol) will preserve the trophozoite stage of protozoa. A trichrome stain will be prepared from PVA fixed material. PVA cannot be concentrated, therefore, should always be accompanied by a portion of the specimen in formalin. Formed stools may be preserved in formalin.

Warning: Any stool collected by or from the patient may harbor pathogens which are immediately infective. Use extreme caution

Additional Tests: With the Ova and Parasites test, Giardia antigen detection can also be requested. Immunoassay will be performed along with the microscopy. Reports in 2 days.
C. Difficile Toxin A and B

Synonyms: Antibiotic Associated Colitis (AAC) Toxin Assay, Clostridium difficile Toxin Profile, Pseudomembranous Colitis Toxin Assay, C. Diff A&B, C. Diff Toxin, C. Diff (stool)

Methodology: Enzyme immunoassay (EIA) for C. diff toxins A and B

Test Includes: C. difficile A and B toxin screen

Laboratory: CBM Path, referred to LabCorp/Quest-Microbiology Department

Request Form: Biopsy requisition form (CBM), Microbiology requisition form (LabCorp), the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

Phone: (301) 926-4707

Availability: Mon-Fri, 10 AM- 6 PM

Setup Schedule: Set up 7 days a week (LabCorp)

Turnaround Time: Reports in 1 day

Preferred Specimen: 5 gms formed stool (walnut sized) or 5 mL liquid or semi-formed stool; minimum volume 0.5 g or 0.5 mL liquid stool

Container: Collect stool in clean plastic leak-proof container or stool transport (Para-Pak white clean vial)

Transport Temperature: Refrigerate and transport within 3 days

Causes for Rejection: Stool submitted with preservatives; stool submitted on swabs or mixed with urine; stool not refrigerated or frozen; specimen received after prolonged delay (usually more than 72 hours); leaking specimen.s

Reference Range: Not detected

Use: To determine the presence or absence of antibiotic-related colitis due to C. difficile

Limitations: Detection of toxins A and B by enzyme immunoassay has a sensitivity approaching 90%, so multiple specimens may need to be tested.

Additional information: Toxin-producing Clostridium difficile is a major cause of antibiotic-associated diarrhea and pseudomembranous colitis.
**Cultures, Salm/Shig/Campy, Stool**

**Synonyms:** Stool culture profile

**Methodology:** Aerobic culture on selective media; detection of EHEC Shiga-like toxins by enzyme immunoassay (EIA)

**Test Includes:** Salmonella, Shigella screen and Campylobacter culture. Identification and antibiotic sensitivities will be performed on aerobic pathogens isolated based on standards as defined by the National Committee for Clinical Laboratory Standards, at an additional charge (LabCorp).

**Laboratory:** CBM Path, referred to LabCorp/Quest -Microbiology Department.

**Request Form:** Biopsy requisition form (CBM), Microbiology requisition form (LabCorp), the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

**Phone:** (301) 926-4707

**Availability:** Mon-Fri, 10 AM- 6 PM

**Setup Schedule:** Monday to Friday (LabCorp)

**Turnaround Time:** 3 days

**Preferred Specimen:** 1 g, 1 mL, or one swab in stool C&S transport vial (usual bacterial swab is NOT acceptable although the swab may be used)

**Collection:** Portions of stool which contain pus, blood, or mucus should be transferred to transport medium. Rectal swab: Pass swab beyond anal sphincter, carefully rotate, and withdraw. Swabbing of lesions of the rectal wall or sigmoid colon during proctoscopy or sigmoidoscopy is preferred. Place swab in enteric transport medium.

**NOTE:** A single stool specimen cannot be used to rule out bacteria as a cause of diarrhea. It is recommended that two or three stool specimens, collected on separate days, be submitted to increase probability of isolating a bacterial pathogen.

**Transport Temperature:** Maintain specimen at room temperature

**Causes for Rejection:** Specimen in grossly leaking transport container, refrigerated specimen, specimen in phosphate buffered glycerol, saline, PVA, formalin or vial transport, frozen stool, dry rectal swabs, expired transport medium, received after prolonged delay in transport (usually more than 72 hrs), unlabeled specimen or name discrepancy

**Reference Range:** No Salmonella, Shigella, or Campylobacter isolated

**Use:** To determine the presence or absence of Salmonella, Shigella, or Campylobacter
Leukocytes, Stool

**Synonyms:** Stool for WBC, Fecal WBC, WBC smear, WBC (Feces), Fecal leukocyte stain, WBC (stool), White cells (stool)

**Methodology:** Simple stain

**Laboratory:** CBM Path, referred to LabCorp/Quest - Microbiology Department.

**Request Form:** Biopsy requisition form (CBM), Microbiology requisition form (LabCorp), the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

**Phone:** (301) 926-4707

**Availability:** Mon-Fri, 10 AM- 6 PM

**Setup Schedule:** Monday to Saturday (LabCorp)

**Turnaround Time:** One day from set up

**Preferred Specimen:** 1 g Stool or fecal pus in 2N-PVA fixative

**Transport Temperature:** Preserved (2N-PVA) room temperature (up to 24 hours), unpreserved refrigerated (up to 24 hours)

**Causes for Rejection:** Specimen contaminated with urine; quantity not sufficient for analysis; improper transport device; improper labeling; specimen received after prolonged delay

**Use:** Determine digestive processes; malabsorption syndrome; pancreatic exocrine function.
Culture, Aerobic & Anaerobic Bacteria with Gram stain

Methodology: Bacterial culture, aerobic, anaerobic, routine isolation and identification procedures with Gram stain microscopy. Antibiotic susceptibility testing when appropriate.

Test Includes: Aerobic culture, anaerobic culture and Gram stain.

Laboratory: CBM Path, referred to Labcorp/Quest- Microbiology Department

Request Form: Biopsy requisition form (CBM), Microbiology requisition form (Quest), the following information must be included: patient’s name, address, date of birth, insurance information, physician’s name, physician’s address, clinical data, source of sample, previous cases, and date collected.

Phone: (301) 926-4707

Availability: Mon-Fri, 10 AM- 6 PM

Setup Schedule: Set up 7 days a week (Quest)

Turnaround Time: Reports in 1 day

Preferred Specimen: Abscess or deep wound, tissue and sterile body fluid (other than urine, blood and CSF). Tissue and fluids are superior to a swab specimen. Tissue specimen should be placed on top of agar within transport container, do not press into agar. For larger samples, submit in sterile container and cover in saline. If swabs must be used, collect 2 anaerobic transport swabs, one for cultures and one for gram stain or submit one anaerobic transport swab with one air dried smear. Indicate source of specimen on both the requisition and specimen transport device.

Container: BD Port-A-Cul. For larger tissue specimens, sterile container with sterile saline.

Transport Temperature: Room temperature.

Causes for Rejection: Body sites with anaerobes as normal flora. Specimens not submitted in anaerobic transport media. Expired transport device and frozen specimens. Body sites inappropriate for anaerobic culture will be processed as aerobic culture only.

Reference Range: Not detected

Use: To determine the presence or absence of anaerobic and aerobic bacteria.

Limitations: The significance of any isolate(s), in pure or mixed culture, must be assessed with respect to the source cultured, the organism’s pathogenic potential, the possibility of colonization versus infection, and the number of other organisms recovered from the same culture.
Lymph Node for Flow Cytometry (Lymphoma Panel)

Transport media: RPMI (pinkish fluid in small tube). Provided from the laboratory before the surgical biopsy (1 day before). Keep frozen/refrigerated until needed. Then thaw to room temperature.

Specimen: Sterile fragment(s) of suspicious lymph node, cut very small – 1 mm cubes if possible. Alternatively, needle/core biopsy of suspicious lymph node. Do not contaminate (since the transport media contains nutrients to keep cells alive).

Transport: After specimen is in the transport media, label tube, fill requisition form, and keep all at room temperature. DO NOT REFRIGERATE ONCE SPECIMEN IS IN THE TUBE. Call laboratory for courier pick-up immediately.