Cytology and Cytology Gynecologic Laboratory Services

Laboratory Medical Director

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Cytopathology Medical Director

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General Information

The Cytopathology Laboratory provides diagnostic services to the clinicians of UCH South - Memorial, as well as offering cytology services locally. Diagnostic services include:

- Gynecologic
- Pulmonary
- Gastrointestinal
- Body cavity fluids
- Urinary
- Fine-needle aspiration cytology

Technical assistance and rapid onsite adequacy evaluation of fine-needle aspirations is also available.

Locations and Hours

Memorial North Cytopathology Lab
4050 Briargate Parkway, Room 1240
Phone (719) 364-3200
Fax (719) 364-3567

Memorial Central Cytopathology Lab
1400 E. Boulder Street, Room 0632
Phone (719) 365-6904
Fax (719) 365-5026

The hours for both locations are Monday through Friday from 7:30 a.m. to 4 p.m.

Primary cytology operations are located at MHN. A satellite cytology laboratory at MHC is staffed by 1 cytotechnologist whose primary role is assistance with fine-needle aspirations and specimen triage.

Submitting Specimens

During Cytopathology hours, specimens collected at MHC should be brought to the Cytopathology Specimen Receiving Area, Room 0632b, and placed in the refrigerator. Specimens collected at MHN should be brought to the Specimen Receiving Area in the clinical laboratory as soon as possible after collection. Fixed specimens (Pap tests) may be delivered at any time.

After Cytopathology hours, specimens collected at MHC should be delivered to Laboratory Support Services. Specimens collected at MHN should be delivered to Laboratory Specimen Receiving at MHN. Unfixed specimens collected after laboratory hours must be promptly refrigerated to preserve cellular morphology.

Specimen containers must be labeled with patient's name (first and last), medical record number, or date of birth, date and time of collection, and collector's identification. Courier (outreach) specimens must be labeled with patient name and date of birth.

Slides must be labeled with patient's name, date of birth or medical record number, in pencil on frosted end of slide.

- **Do not** label slides with pen or tape.
- **Do not** use slides with unfrosted ends.
- **Do not** label slide containers.

Unidentified or unlabeled specimens will be held, and the requesting office and physician will be notified. The requesting physician will be faxed a specimen identification form to complete and sign in order to continue processing of the specimen.

All orders should either be entered in Epic or on a paper requisition form and ordered by a physician or other authorized person. Adequate clinical information is necessary for accurate evaluation of the cytology specimen.
Note: STAT specimens should be approved by the Cytology Supervisor or a pathologist prior to delivery of specimen.

Technical Assistance

A cytotechnologist will assist the clinician for the purpose of obtaining optimal diagnostic specimens during fine-needle aspiration, endoscopic ultrasound, endobronchial ultrasound, and transbronchial needle aspiration. This service is available for both MHC and MHN for fine-needle aspirations of all body sites. Requests for assistance at other procedures will be considered. The cytology staff should be informed as soon as possible when and where a procedure is being performed.

Questions at any time concerning proper specimen collection will be welcomed by the Cytology laboratory staff.

Supplies

Supplies are available through the Memorial Health System computerized ordering system or may be obtained from the MHC Cytopathology Laboratory, Room 0632, or call MHC at 719-365-6904 or at MHN in Room 1240 or call 719-364-3200.

Report Turn Around Time

Non-gynecologic specimen results are generally reported within 48 hours after specimen receipt. Gynecologic specimen results are usually available 4 working days after receipt. Reports will be available in Epic (inpatients) and outpatient reports are faxed to the office.

Reports with unexpected malignancies and significant abnormalities are communicated to the requesting physician via phone, fax, personal meeting, or report comment. The final written report is sent as soon as it is completed to the appropriate record center.

Quality Assurance and Accreditation

Our goal is to provide accurate, consistent, and timely performance and reporting for all cytopathology specimens. All aspects of our service are closely monitored and evaluated through a comprehensive quality assurance program.

The Cytopathology Laboratory is inspected and accredited by the College of American Pathologists (CAP). All laboratory personnel participate in a program of continuing medical education, including nationally mandated gynecologic proficiency testing.

Terminology

The Cytology Laboratory at Memorial Health System utilizes the latest version of The Bethesda System of Terminology on all gynecologic reports. Reports are computer generated. Cytology reports reviewed by a pathologist include an electronic signature. Every effort is made to insure that each section of the report is comprehensive and accurate. Descriptive diagnostic statements are included under the heading **Interpretation**. In complicated cases or in those with unusual or suboptimal presentations, it may be necessary to modify the standardized terminology, or include additional comments. Questions regarding cytological diagnoses are welcomed by our pathologists and cytology staff.

If you should notice any errors, we ask that you contact the laboratory immediately.

The gynecologic report is organized in the following order:

- Patient demographics
- Clinical history
- Specimen source
- Specimen adequacy
- Interpretation
- Comments
- Additional findings
- Microorganisms
- High Risk and HPV 16/18 if applicable
- Educational note
  - —An educational note is issued on all Pap test reports, which states; **"The test is subject to both false-positive and false-negative results. Clinical correlation is recommended."**

UCH South Memorial Gynecologic Terminology for Cytology Report

- Unsatisfactory
- Negative for intraepithelial lesion or malignancy
- Negative for intraepithelial lesion or malignancy (reactive findings):
  - —Cellular changes consistent with herpes simplex virus (HSV)
  - —Reactive cellular changes associated with inflammation (repair)
  - —Reactive cellular changes associated with radiation
  - —Reactive cellular changes associated with intrauterine contraceptive device (IUD)
  - —Endometrial cells present, cytologically benign, in a pregnant patient
  - —Endometrial cells present, cytologically benign, in a peri/postmenopausal patient
- Atypical squamous cells of undetermined significance
- Atypical squamous cells of undetermined significance, cannot rule out HGSIL
- Negative for intraepithelial lesion or malignancy; glandular cells present in a vaginal sample
- Atypical glandular cells of undetermined significance (specify: NOS, endocervical or endometrial)
- Squamous intraepithelial lesion (SIL):
  - —Low grade SIL
  - —High grade SIL
- Suspicious Findings:
  - —Highly atypical glandular cells, favor neoplasia
  - —Highly atypical endocervical cells, favor endocervical neoplasia

- Malignant Findings:
  - —Squamous cell carcinoma
  - —Endocervical adenocarcinoma in situ
  - —Adenocarcinoma, endocervical
  - —Adenocarcinoma, endometrial
  - —Adenocarcinoma, not otherwise specified
  - —Malignant cells present, primary site undetermined
- Microorganisms:
  - — Bacterial vaginosis
  - —Fungal organisms morphologically consistent with *Candida* species
  - — *Trichomonas vaginalis*
  - —Bacterial organisms morphologically consistent with *Actinomyces* species
  - —Cellular changes consistent with HSV

Gynecological Recommendations

Specific recommendations are not routinely included on the diagnostic cytology report. Decisions regarding appropriate patient management are left to the discretion of the clinician. In cases where ASCUS is diagnosed and HPV reflex testing was not initially ordered, or in cases with an unusual or suboptimal presentation, recommendations may be included. Following screening intervals and HPV algorithm prescribed by the latest version of the American society for Colposcopy and Cervical Pathology (ASCCP) is recommended.

If you have questions regarding cytologic interpretation or suggested patient management, you are encouraged to contact any of our pathologists at 719-365-5808 or the Cytology Laboratory at 719-364-3200.

Gynecologic Testing Options

In an effort to enhance the quality of Cytopathology Services being offered to our patients, we offer, FDA- approved testing options, including ThinPrep® Pap tests, Human Papillomavirus (HPV) DNA testing, HPV 16/18 genotyping, and *Gonorrhoeae* and *Chlamydia* testing from the Pap test vial.

ThinPrep® Pap Test: This FDA-approved method has revolutionized the way Pap tests are collected. Check the appropriate box on the Gynecologic Cytology Request Form to utilize this technology.

Cervista™ High Risk HPV typing and Cervista™ HPV 16/18 Genotyping: This testing is performed in-house using the remaining fluid in the ThinPrep pap test vial. Inadequate specimen volume can interfere with our ability to provide HPV DNA testing. Vigorous sampling and transfer of material from samples to vial is critical in obtaining adequate cellularity for additional testing. The tests can be ordered by checking the appropriate box in the test requested section on the Memorial Health System Gynecologic Cytology Request Form. Pap test results are held in our computer until ancillary test results are completed.

Chlamydia and Gonorrhoeae DNA Testing: *Chlamydia* and *Gonorrhoeae* DNA tests, using GEN-PROBE® Aptima® technology, is performed as an in-house test from the ThinPrep® vial. This FDA-approved technology is exquisitely sensitive. In order to maintain testing accuracy, the tests must be ordered at the time of specimen collection, so an aliquot can be removed from the vial prior to ThinPrep® processing. The tests can be ordered by checking the appropriate box in the test requested section on the Memorial Health System Gynecologic Cytology Request Form. These ancillary results are available in a separate report.

Bacterial vaginosis panel is available as a sendout test from the ThinPrep® vial. This is a PCR test that checks for Candida sp. Trichomonas vaginalis, and Gardnerella vaginalis. This test can be requested by writing on the cytology requisition and must be requested at the time of order so that an aliquot may be removed prior to ThinPrep® processing. The results of this test will be reported directly to the physician's office.

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In most cases, it is **not** desirable to perform an immediate repeat Pap test following an abnormal. It has been reported that Pap tests collected at an interval of weeks or days may yield false-negative results.

Despite the proven value of cytology, it is essential that the clinician understand that his or her medical impressions must be a guide to dealing with the patient, and that the cytologic information is only adjunctive and/or substantiating. Therefore, the clinician is responsible for correlating the clinical information and arriving at a diagnosis consistent with both.

If you have questions regarding cytologic interpretation or suggested patient management, you are encouraged to contact any of our pathologists at 719-365-5808 or the Cytology Laboratory at 719-364-3200.

Physician Instructions for Gynecologic Testing

General requirements for optimal cytological evaluation of female genital tract specimens requires the following actions:

- Selection of appropriate sampling sites and type of Pap test
- Collection of adequate and representative cells
- Proper identification of the specimen
- Communication of relevant clinical information
- Compliance with specific preparation and fixation instructions

Completing the Request Form

Select the lavender and white Memorial Health System Gynecologic Cytology Request Form. Complete the Patient Information section including:

- Name
- Address
- Date of birth
- Social Security number
- Phone number
- Service date

  Note: It is essential that the laboratory have patient's **complete** and **correct** name and birth date for continuity of the medical record.

Include the names of both the nurse practitioner/physician assistant, **and** responsible physician, when appropriate. Indicate who is responsible for the bill, by checking Patient, Doctor/Clinic, or Insurance. Complete insurance information section, when appropriate, and attach a copy of the insurance card (front and back). Include subscriber's date of birth, Social Security number, and place of employment.

Complete the Advance Beneficiary Notice of Noncoverage (ABN) on the back of the Cytology Request form. Please include the following information:

- Patient name and Medicare number
- Type of service provided (ie, annual examination, to include Pap test, rectal examination, and breast examination)
- Choose option #1 or #2
- Patient signature and date
- Complete the Source by checking cervical, endocervical or vaginal, and/or other as applicable.

  Note: When submitting breast cytology specimens, complete the bottom section of the request form below the Breast Specimens banner.

For flexibility, test ordering is now done on a test by test basis. Indicate the test requested by checking the appropriate testing from the following choices:

- ThinPrep® Pap test
  - —No Pap (please check when ordering ancillary testing only)
- High Risk HPV, if ASCUS (Cervista™)
  - —This testing is only approved for patients ≥21 years of age
  - —16/18 genotyping if High Risk is positive
- High Risk HPV for patients ≥30 years of age (Cervista™)
  - —16/18 genotyping if High Risk is positive
- High Risk HPV on any diagnosis (Cervista™)
  - —This testing is only approved for patients ≥21 years of age
  - —16/18 genotyping if High Risk is positive
- *Chlamydia*
- *Gonorrhea*
- Conventional Pap test

Note: Chlamydia and Gonorrhea specimens must be removed before routine pap testing so it is essential that the orders be received at the time of processing.

Complete the Clinical Information section. Record LMP (first day of last menstrual period), and check additional boxes as appropriate. The latest version of the Gynecologic Request form has been designed to collect information that is needed for interpretation of the Pap test, while limiting the amount of time needed to complete the form. Additional space has been provided for communication of other pertinent information.

Complete the Risk Factors section. Check all boxes that apply. If the last Pap was abnormal, please provide a date (month/year) and result. If the patient is regarded as clinically high risk for any other reason, please specify.

Cytology Laboratories are required by Federal Regulations to seek pertinent clinical information prior to interpreting gynecologic cytology specimens.

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Gynecologic Specimen Collection Guidelines

ThinPrep® Pap Tests

- For best results in premenopausal patients, obtain specimens during midcycle or in the early second half of the menstrual cycle.
- Obtain all specimens prior to bimanual examination. **Use an unlubricated vaginal speculum (saline may be used).**
- Label the PreservCyt® vial with patient's name and birthdate using pen or marker.
- To assure that an adequate and representative specimen is submitted, vigorously swirl the samplers into the vial of fixative.
- It is preferable to obtain and fix the cervical specimen prior to obtaining the endocervical specimen. Collect the cervical specimen and place the material into the PreservCyt® vial and then collect the endocervical specimen; placing it into the same vial.

- Complete the Cytology Request form as instructed above.
- Cap the vial tightly and deliver with the request form to the Cytology Laboratory. Place in lock box or call Memorial Health System Laboratory Support Center to arrange for specimen transport at 719-365-5260.

Conventional Pap Tests

- For best results in premenopausal patients, obtain specimens during midcycle or in the early second half of the menstrual cycle.
- Obtain all specimens prior to bimanual examination. **Use an unlubricated vaginal speculum.**
- Label the slide(s) with patient's name and birthdate directly on the frosted end of the slide **in pencil**.
- It is preferable to obtain, spread, and fix the cervical specimen prior to obtaining the endocervical specimen.
- After collection, spread the specimen **quickly** and evenly onto a glass slide and **immediately** spray fix. **Spread and fix each specimen prior to obtaining additional specimens.**
- Complete the Cytology Request form as instructed above.
- Place slides in slide folder. Deliver slide and request form to the Cytology Laboratory. Place in lock box or call Memorial Health System Laboratory Support Center to arrange for specimen transport at 719-365-5260.

Non-gynecoligic Specimen Collection

Collect specimen per appropriate procedure. Submit all Cytology laboratory specimens with a test order requisition.

- Complete and submit request with the following:
  - —Specimen type
  - —Clinical information
  - —Date and time of collection
  - —Name of physician
- Label all specimen containers with the following:
  - —Patient's name
  - —Medical record number
  - —Date and time of collection
  - —Collector identification (initials)
- Label all slides with the following:
  - —Patient's name
  - —Medical record number

Non-Gynecologic Terminology and Reporting

Reports for non-gynecologic and fine-needle aspiration cases are generated using standardized cytologic terminology. The formats are as follows:

- Non-gynecologic cases
  - —Patient demographics
  - —Specimen
  - —Gross description
  - —Clinical information
  - —Diagnosis
  - —Microorganisms
  - —Comments
  - —Additional findings
- Fine-needle aspiration (FNA)
  - —Patient demographics
  - —Procedure
  - —Gross description
  - —Immediate evaluation
  - —Clinical information
  - —Diagnosis
  - —Microorganisms
  - —Comments
  - —Additional findings
  - —Microscopic description

In addition, the Bethesda system for reporting thyroid cytopathology is utilized for standardized diagnostic categories.

References

Articles:

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Solomon D, Schiffman M, Tarone R: Comparison of three management strategies for patients with atypical squamous cells of undetermined significance: Baseline results from a randomized trial. J Natl Cancer Inst 2001;93(4):293-299

Wright TC, Cox JT, Massad LS, et al: 2001 consensus guidelines for the management of women with cervical cytological abnormalities. JAMA 2002;287(16):2120-2129

2006 Consenus Guidelines for the management of women with abnormal cervical cancer screening tests, AJOG, October 2007, pp. 346-355.

Solomon D, Papillo JL, Davey DD (for the Cytopathology Education and Technology Consortium): Statement on human papillomavirus DNA test utilization. Cancer Cytopath, June 25, 2009, pp. 154-156.

Books:

Comprehensive Cytopathology. Edited by M Bibbo. Philadelphia, WB Saunders, 1991

Colon VF, Schumann GB: Clinician's Guide to Diagnostic Cytology. Chicago, Year Book, 1982

Demay R: The Art & Science of Cytopathology. Chicago, ASCP Press, 1996

Koss LG: Diagnostic Cytology and its Histopathologic Bases, 4th Edition. Philadelphia, JB Lippincott Company, 1992

Solomon D and Nayar R (Editors): The Bethesda System for Reporting Cervical Cytology, 2nd Edition. New York, Springer-Verlag, 2004.

Masood S: Cytopathology of the Breast. Chicago, ASCP Press, 1996

Meisels A, Morin C: Cytopathology of the Uterine Cervix. Chicago, ASCP, 1991

Patten SF Jr: Diagnostic Cytopathology of the Uterine Cervix. New York, S Karger, 1978

Package Inserts:

The ThinPrep® Pap Test Laboratory Implementation Kit. Cytyc Corporation 1997

GenFind™ package insert. 2009. Third Wave Technologies, Inc., Madison, WI

Cervista™ HPV 16-18 package insert. 2009. Third Wave Technologies, Inc., Madison, WI

Cervista™ HPV HR package insert. 2009. Third Wave Technologies, Inc., Madison, WI