Cytology and Cytology Gynecologic Laboratory Services

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General Information
The Cytopathology Laboratory provides diagnostic services to the clinicians of Memorial Health System, 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. In addition, Memorial Health System Pathologists are available to perform fine-needle aspirations as requested by the medical staff.

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.

Communication is facilitated by email, telephone, and departmental huddles. A hand off communication board is maintained at MHC to assure an appropriate level of communication between rotating staff members.

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 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, date and time of collection, and collector’s identification.

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 Millennium 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, 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.

In addition, Memorial Health System pathologists are available to perform fine-needle aspiration procedures. Contact the Cytopathology Laboratory at 719-364-3200 for further information and scheduling.

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’s computerized ordering system or may be obtained from the 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 72 hours after receipt. Reports will be available in PowerChart (inpatients) or Physician Link and also will be faxed to the office if on an outpatient.

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

**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. For conciseness, we have elected not to incorporate the optional element, General Categorization, into our report format. Rather, 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 cytologic 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
- Specimen
- Interpretation
- Comments
- Additional findings
- Microorganisms
- Specimen adequacy
- Educational note
  - An educational note is issued on all Pap test reports, which states: "The Pap test is a screening test used to detect cervical cancer and its precursors. False-negative and false-positive results occur due to sampling and interpretation limitations. Pap test results should be interpreted in the context of pertinent clinical information."

**Memorial Health System 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 endocervical cells, of undetermined significance
- Atypical endometrial cells
- Atypical cells present, consistent with radiation effect
- Atypical glandular cells of undetermined significance
- Squamous intraepithelial lesion (SIL):
  - Low grade SIL
  - High grade SIL (moderate dysplasia)
  - High grade SIL (severe dysplasia/CIS)
- Suspicious Findings:
  - Highly atypical glandular cells, favor neoplasia
  - Highly atypical endocervical cells, favor endocervical neoplasia
  - Suspicious for squamous cell carcinoma
  - Suspicious for adenocarcinoma
  - Suspicious for endometrial adenocarcinoma
  - Suspicious for endocervical adenocarcinoma
- Malignant Findings:
  - Squamous cell carcinoma
  - Endocervical adenocarcinoma in situ
  - Adenocarcinoma, endocervical
  - Adenocarcinoma, endometrial
  - Adenocarcinoma, extrauterine
  - Adenocarcinoma, not otherwise specified
  - Malignant melanoma
  - Malignant mixed mullerian tumor
  - Malignant cells present
  - Malignancy, not otherwise specified
- Microorganisms:
  - Shift in flora suggestive of bacterial vaginoses
  - Fungal organisms morphologically consistent with Candida species
  - Trichomonas vaginalis
  - Bacterial organisms morphologically consistent with Actinomyces species
  - Cellular changes consistent with HSV

<table>
<thead>
<tr>
<th>Glossary of Selected Terms</th>
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<tbody>
<tr>
<td><strong>Negative for intraepithelial lesion or malignancy</strong></td>
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<tr>
<td>No significant cellular alterations identified.</td>
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<tr>
<td><strong>Atrophic vaginitis</strong></td>
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<tr>
<td>A cellular pattern characterized by the presence of benign and</td>
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<tr>
<td>degenerated parabasal cells, inflammatory exudate, and necrotic</td>
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<tr>
<td>debris.</td>
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<tr>
<td><strong>Metaplasia</strong></td>
</tr>
<tr>
<td>Transformation of 1 adult cell type to another cell type.</td>
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<tr>
<td>Squamous metaplasia is commonly seen in Pap test specimens,</td>
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<tr>
<td>and is not reported except in cases of DES exposure. If</td>
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<tr>
<td>abnormal squamous metaplasia is identified on a Pap test, it is</td>
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<td>reported as ASCUS or ASCUS-H.</td>
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<tr>
<td><strong>Parakeratosis</strong></td>
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<tr>
<td>Epithelial surface reaction characterized by the presence of</td>
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<tr>
<td>miniature polygonal squamous cells with dense orangeophilic</td>
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<tr>
<td>cytoplasm and small pyknotic nuclei.</td>
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<tr>
<td><strong>Atypical parakeratosis</strong></td>
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<tr>
<td>Parakeratotic cells that demonstrate cellular pleomorphism and/or</td>
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<tr>
<td>nuclear enlargement and hyperchromasia. These cells may</td>
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<tr>
<td>indicate the presence of HPV, dysplasia, or carcinoma.</td>
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<tr>
<td>Following the Bethesda System guidelines, these changes are</td>
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<tr>
<td>reported as ASCUS.</td>
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<tr>
<td><strong>Repair</strong></td>
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<tr>
<td>A reactive change of epithelium characterized by sheets of</td>
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<tr>
<td>enlarged cells with prominent nuclear features. Frequently</td>
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<tr>
<td>seen in patients with extensive inflammation, infection, and</td>
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<tr>
<td>following trauma, or instrumentation.</td>
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<td><strong>Radiation effect</strong></td>
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<td>The effects of irradiation vary and may include some or all of</td>
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<tr>
<td>the following changes: vacuolization, macrocytosis, nuclear</td>
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<tr>
<td>enlargement, multinucleation, bizarre shapes, and altered</td>
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<tr>
<td>cytoplasmic staining. Dependent upon the severity of the changes,</td>
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<td>the findings will be classified cytologically as reactive or</td>
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<tr>
<td>atypical.</td>
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<tr>
<td><strong>Reactive endocervical cells</strong></td>
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<tr>
<td>Reactive/reparative changes in endocervical cells, characterized</td>
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<tr>
<td>by enlarged cells with prominent nuclear features, including</td>
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<tr>
<td>nucleoli. Considered to be a benign reactive change and not</td>
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<tr>
<td>routinely reported.</td>
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<tr>
<td>Glossary of Selected Terms</td>
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<tr>
<td>---------------------------</td>
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<tr>
<td>Reactive/atypical changes associated with an IUD</td>
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<tr>
<td>Atypical squamous cells of undetermined significance (ASCUS)</td>
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<tr>
<td>ASCUS cannot rule out HGSIL</td>
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<tr>
<td>Squamous intraepithelial lesion (SIL)</td>
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<tr>
<td>Human papilloma virus (HPV)</td>
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<tr>
<td>Dysplasia</td>
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<tr>
<td>Carcinoma in situ</td>
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<tr>
<td>Invasive carcinoma</td>
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<tr>
<td>Atypical glandular cells</td>
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</table>
### Glossary of Selected Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Atypical endocervical cells</td>
<td>Abnormal endocervical cells characterized by enlarged irregular nuclei, altered chromatin, and/or abnormal cellular arrangements. This lesion may be related to infection/instrumentation, may reflect endocervical involvement from a squamous dysplasia, or may arise distinctively as a neoplastic precursor of endocervical adenocarcinoma. Colposcopy, with endocervical sampling, is recommended in these patients. Endometrial sampling should also be considered in patients &gt;35 years of age, or in patients with abnormal bleeding. HPV testing may be of value.</td>
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<tr>
<td>Atypical endometrial cells</td>
<td>Abnormal endometrial cells characterized by macrocytosis, enlarged and irregular nuclei, irregular chromatin, and the presence of nucleoli. Cells are most frequently identified in clusters. Correlation with clinical information and findings on physical examination is essential. Endometrial sampling is recommended.</td>
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<tr>
<td>Adenocarcinoma in situ</td>
<td>A malignant transformation of the epithelial lining of the endocervical glands, without stromal invasion. Also known as pre-invasive adenocarcinoma.</td>
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<tr>
<td>Adenocarcinoma</td>
<td>A malignant neoplasm of the endocervix or endometrium, which demonstrates cytologic and/or histologic evidence of stromal infiltration/invasion.</td>
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### Non-Gynecologic Terminology

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.
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.

Cervista High Risk HPV™ and Cervista HPV 16/18 Genotyping™ is available on ThinPrep® specimens.

High risk HPV testing is recommended in the following circumstances:

- Initial triage management for women ≥21 years with a Pap test result of ASCUS. Women with ASCUS who test positive for high-risk HPV DNA positive can have Cervista HPV 16/18 performed and should be referred to colposcopy. Women with ASCUS who test negative for the HPV DNA can be followed with repeat cytology testing at 12 months.
- Initial triage management of postmenopausal women with a Pap test result of low-grade SIL.
- Post-colposcopy management of women of any age with an initial Pap test result of atypical glandular cells or atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASCUS-H), when the initial workup does not identify a high grade lesion.
- Post-colposcopy management of women aged ≥21 with an initial Pap test result of ASCUS or low-grade SIL (LGSIL), when the initial colposcopy does not identify a high grade lesion.
- Post-treatment surveillance.

High risk HPV testing is generally not appropriate in the following situations:

- Routine cervical cancer screening in women aged ::20 years.
- Initial triage or management of adolescents (aged ::20 years) with any abnormal cytologic result. If HPV testing is performed in this subset of patients, the results should not be used to influence patient management.
- Initial triage of LGSIL, except for postmenopausal women.
- Initial triage of atypical squamous cells, cannot exclude ASCUS-H, high-grade squamous intraepithelial lesion (HGSIL), or adenocarcinoma in situ.

Colposcopic examination is recommended following a Pap test diagnosis of LGSIL. Colposcopy with endocervical assessment is recommended for management of women with HGSIL.

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.

Quality Assurance, Accreditation, and Turnaround Time

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.
Gynecologic specimen results are usually available 48 hours after receipt. Non-gynecologic specimen results are generally reported within 48 hours after specimen receipt. All reports of unexpected malignancies are faxed to the requesting physician. The final written report is faxed to the appropriate record center at 12:30 p.m. or 12:30 a.m., following the time it was verified. For clinicians without fax capability, the final report is mailed or sent by courier the following working morning.

Implementation of a comprehensive quality assurance program is essential for good cytology laboratory practice, and is a requirement of accreditation and licensure agencies. An extensive quality assurance program is in place in the Memorial Health System Cytology Laboratory. Practices have been developed to exceed the requirements of regulatory bodies.

References
Articles:
Braly P: HPV Screening and Treatment. OB/GYN, Spring 1999, 11-13


Books:

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


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

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

Specimen Collection
Cytology laboratory tests ordered on the hospital computer system will generate a request in the PowerPath computer system.

• 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

Gynecologic Testing Options
In an effort to enhance the quality of Cytopathology Services being offered to our patients, we offer some of the newest, FDA-approved testing options, including ThinPrep® Pap tests, Human Papillomavirus (HPV) DNA testing, 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, are now available 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 together or individually, 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.
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.

**Gynecologic Patient Instructions**
Good patient preparation contributes to effective representative and interpretable testing. Patients should be instructed:

- Not to schedule an appointment for a Pap test during time of active menstrual bleeding
  
  **Note:** Patients experiencing excessive bleeding, or bleeding out of cycle are encouraged to see their physician.
- Not to douche or use intravaginal medications 48 hours prior to Pap testing
- To refrain from sexual intercourse for 48 hours prior to Pap testing

**Physician Instructions for Gynecologic Testing**
General requirements for optimal cytologic 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.**

**General 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 un lubricated 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.

<table>
<thead>
<tr>
<th>Selection of Pap Tests Available</th>
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<tbody>
<tr>
<td><strong>Type of Pap Test</strong></td>
</tr>
<tr>
<td>ThinPrep® - 2 Sampler Method</td>
</tr>
<tr>
<td>ThinPrep® - 1 Sampler Method</td>
</tr>
<tr>
<td>Conventional Pap Test - 2</td>
</tr>
<tr>
<td>Conventional Pap Test - 1</td>
</tr>
<tr>
<td>Evaluation of Vaginal Adenosis (DES)</td>
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*Cytology brushes are not recommended for use in pregnant patients.