Hospital Client Manual

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CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
MAWD PATHOLOGY GROUP, PA
9705 LENEXA DR
LENEXA, KS 66215

CLIA ID NUMBER
17D2154812

EFFECTIVE DATE
11/28/2018

LABORATORY DIRECTOR
PABLO J HERNANDEZ-RIOS M.D.

EXPIRATION DATE
11/27/2020

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown herein (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Karen W. Dyer
Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

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FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER. PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.
93449.234 Muscle Biopsy

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed 5/31/2018
Next Periodic Review Needed On or Before 5/31/2020
Effective Date 5/31/2018

Author
KML

Comments for version 1.0
Initial uploaded version

Approval and Periodic Review Signatures

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Controlled Copy of a Manual ID 19554
Location Saint Lukes Main Lab
Organization MAWD Pathology Group, P.A.

Muscle Biopsy | Version: 1.0 | Document Number: 93449.234
MUSCLE BIOPSY

Note: Time is of the essence!

Principle
A muscle biopsy is performed to assess muscle disease.

Specimens
Biopsy a section of the muscle that is involved in the disease process, but has not reached "end-stage" atrophy. This test is best for biopsies from elderly patients and/or those suspected to have an inflammatory myopathy.

Quality Control
Detailed clinical information is required. The following information must be provided with the samples (use the requisition supplied in the kit or provide separate documentation):
- Patient age and sex
- Working/suspected clinical diagnosis
- Pertinent current and prior clinical history
- Medications
- Referring physician and contact information
- Site of biopsy
- Date of biopsy
- Physician ordering
- Patient information including address and insurance

Reagents and Supplies
1. Muscle/Nerve biopsy kit from Arkana
   - Neutral buffered formalin container
   - Glutaraldehyde fixative container
   - Water-tight container
   - Arkana Requisition

Procedure
1. Schedule muscle biopsies early in the morning, Monday through Thursday, to preserve specimen integrity and prevent testing delays.
2. The MUSCLE/NERVE BIOPSY kit must be obtained from MAWD prior to collection.
3. Preferred Collection Method:
   a. Separate fresh tissue specimen into 3 parts:
      i. Wrap an intact portion of the tissue (nice belly of muscle) in gauze or telfa that has been barely dampened with saline solution and place in the water-tight container. Tightly seal the container and place on cool packs.
      ii. Place the second section of tissue in the formalin vial (tightly seal).
      iii. Place the last section of tissue in the glutaraldehyde vial (tightly seal).
4. **If a kit is not available:** Wrap the specimen in gauze or telfa that has been barely dampened with saline solution and place in a tightly closed water-tight container.
5. Store container(s) on cold packs or keep refrigerated until the courier picks up the kit.
6. The MAWD Sendout department will send the specimen to Arkana laboratories for testing.

References
1. MAWD Pathology Group, 2750 Clay Edwards Drive, Ste. 420, North Kansas City, MO. 64116; (816) 241-3338.
2. Arkana Laboratories, 10810 Executive Center Drive, Suite 100, Little Rock, AR 72211; (501)604-2695

Author / Source
KML 2/8/2018; HJY Reformat 5/9/2018
93449.235 Nerve Biopsy

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed: 6/1/2018
Next Periodic Review Needed On or Before: 6/1/2020
Effective Date: 6/1/2018

Comments for version 1.0
Initial uploaded version

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Nerve Biopsy | Version: 1.0 | Document Number: 93449.235
NERVE BIOPSY

Note: Time is of the essence! See Procedure Notes.

Principle
A nerve biopsy is performed to assess nerve deterioration and pathology.

Specimens
Section of peripheral nerve.

Quality Control
Detailed clinical information is required. The following information must be provided with the samples (use the requisition supplied in the kit or provide separate documentation):
- Patient age and sex
- Working/suspected clinical diagnosis
- Pertinent current and prior clinical history
- Medications
- Referring physician and contact information
- Site of biopsy
- Date of biopsy
- Physician ordering
- Patient information including address and insurance

Reagents and Supplies
1. Muscle/Nerve biopsy kit from Arkana
   a. Neutral buffered formalin container
   b. Glutaraldehyde fixative container
   c. Water-tight container
   d. Arkana Requisition

Procedure
1. Schedule nerve biopsies early in the morning, Monday through Thursday, to preserve specimen integrity and prevent testing delays.
2. The MUSCLE/NERVE BIOPSY kit must be obtained from MAWD prior to collection.
3. Preferred Collection Method:
   - Separate fresh tissue specimen into 3 parts:
     a. Wrap an intact portion of the tissue (nice belly of muscle) in gauze or telfa that has been barely dampened with saline solution and place in the water-tight container. Tightly seal the container and place on cool packs.
     b. Place the second section of tissue in the formalin vial (tightly seal).
     c. Place the last section of tissue in the glutaraldehyde vial (tightly seal).
4. If a kit is not available: Wrap the specimen in gauze or telfa that has been barely dampened with saline solution and place in a tightly closed water-tight container.
5. Store container(s) on cold packs or keep refrigerated until the courier picks up the kit.
6. The MAWD Sendout department will send the specimen to Arkana laboratories for testing.

References
1. MAWD Pathology Group, 2750 Clay Edwards Drive, Ste. 420, North Kansas City, MO, 64116; (816) 241-3338.
2. Arkana Laboratories, 10810 Executive Center Drive, Suite 100, Little Rock, AR 72211; (501)604-2695

Author / Source
KML 2/8/2018; HJY Reformat 5/9/2018
93449.236 Renal Biopsy

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed 5/31/2018
Next Periodic Review Needed On or Before 5/31/2020
Effective Date 5/31/2018

Author KML

Comments for version 1.0
Initial uploaded version

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Renal Biopsy  | Version: 1.0  | Document Number: 93449.236
RENNAL BIOPSY

NOTE 1: Time is of the essence! It is crucial that the specimen is processed and packaged for shipping immediately (same day as collection).

NOTE 2: See below for special instructions for biopsies collected on a Friday.

Principle
Renal biopsies are performed to diagnose renal function or other medical problems.

Specimens
If electron, immunofluorescence, and light microscopy are all desired, the optimum specimen is 2 needle core biopsies.

Reagents and Supplies

The RENAL BIOPSY kit must be obtained from MAWD prior to collection

1. The kit includes:
   - 10% Neutral Buffered Formalin, White Top (Light Microscopy and EM Studies).
   - Michel's Fixative, Blue Top (Zeus fixative) (Immunofluorescent).
   - Directions for biopsy requirements are in the supply box.
   - Copy of completed Arkana Paperwork (Patient Information Sheet and Clinical Data Form).
   - Shipping Box with Clinical Pak and Pre-paid, pre-addressed FedEx mailer.
2. Face sheet or photocopy of both sides of the patient's insurance card.

Procedure
1. Email Kathy Little with every Renal Biopsy sent out.
2. MAWD Client will send a copy of all completed paperwork including the requisition to MAWD Sendout Department with the next available courier.
3. MAWD Secretaries will enter the Renal Biopsy in the CoPath System as a Card Case for tracking. When the Report is available, the Secretaries will scan the report into Copath and file it with the paperwork in the file.

Procedure for Saturday Delivery for Rush Cases Only
1. MAWD Pathology Group will call Arkana on Friday by 5:00 pm at 866-736-2529.
2. Arkana will need the on-call Nephrologist's contact number(s).
3. The Saturday Delivery box will have to be checked on the FedEx airbill.

Reporting
1. Reports will be faxed to MAWD Pathology Group and the ordering physician. The reports will be scanned into Copath.
2. Reports are also available online at Arkana for the Hospital/Pathologist and ordering Nephrologist. The instructions and passwords are included with the first report.
Limitations / Interferences
1. Contamination of the tissue preserved in Michel’s solution by formalin (even a small amount on a forceps) instantly renders the tissue unsuitable for Immunofluorescence.
2. Specimen tracking will be done by the MAWD Sendout Department.
3. Patient or Patient’s Insurance will be billed in all cases.

References
1. Arkana, 10810 Executive Center Drive, Suite 100, Little Rock, AR 72211, 866-736-2529, arkanalabs.com
2. Emergency After Hours Number 501-837-7416

Author / Source
KML 8/26/13, rev 12/26/17; Reformat 5/9/18HJY
93449.237 Additional Test Request Form (CYT.550)

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed 5/25/2018
Next Periodic Review Needed On or Before 5/25/2020
Effective Date 5/25/2018

Author TDW

Comments for version 1.0
Initial version

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Linked Documents

- 93449.265 Handling Requests for Additional Testing (CYT.550)

Additional Test Request Form (CYT.550) | Version: 1.0 | Document Number: 93449.237
Additional Test Request (CYT.550)

Date of Request: ______/_____/_____

Patient Name (print): ________________________________________________

Patient DOB: ______/_____/_____

Patient Case #: ______________________________________________________

Physician (print): ____________________________________________________

Called in by (print): ___________________________ Fax #: __________________

We received a verbal request to add the following test(s) to the patient (listed above):

- HPV, High risk  (ICD10: _________)
- HPV 16/18 Genotyping

- Chlamydia & Gonorrhea (from ThinPrep Vial)**  (ICD10: _________)
- Chlamydia Only (from ThinPrep Vial)**  (ICD10: _________)
- Gonorrhea Only (from ThinPrep Vial)**  (ICD10: _________)

**If adding CT/NG testing after the ThinPrep has been processed there may be an increased risk of false positive results due to cross contamination from other ThinPrep samples.

- Other (specify): ___________________________  (ICD10: _________)

Please sign and date below to confirm the addition of the test(s) and then fax this form to: (816) 241-6531, Attn (print): ______________________________________

Print Name ___________________________ Signature ___________________________ Date ___________

If you have questions, please call ______________ at (816) ______________

CYT.550 Form A
93449.238 Chromosome Study - Fetal

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed: 7/7/2018
Next Periodic Review Needed On or Before: 7/7/2020
Effective Date: 7/7/2018

Author: KML

Controlled Copy of a Manual ID 19554
Location: Saint Lukes Main Lab
Organization: MAWD Pathology Group, P.A.

Comments for version 1.0
Initial uploaded version

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CYTOGENETICS/CHROMOSOME ANALYSIS-FETAL

Principle
The purpose of this procedure is to define the process for sampling and submitting fetal tissue for cytogenetics/chromosome studies.

Specimens
- Cord blood: 2-5 ml in sodium heparin (green top)
- Fresh tissue: multiple 2-3 mm pieces of tissue in RPMI transport media

Reagents and Supplies
- Sodium Heparin blood collection tube (green top – if submitting fetal blood)
- RPMI transport media- if submitting cord blood
- Requisition ordering Cytogenetics
- Patient’s insurance information

Procedure
1. **Time is of the essence.**
2. Label RPMI transport media with the infant (or mother’s) name and DOB, date and time collected, and specimen type, "skin left arm".
3. Label a sodium heparin blood collection tube (green top) with the infant (or mother’s) name and DOB, date and time collected, and specimen type, “cord blood”.
4. Place all containers in a MAWD Pathology specimen bag.
5. Insert requisition and face sheet/patient insurance information into the requisition pouch of the specimen bag.
6. Place the sealed specimen bag in the MAWD Pathology courier pickup area. If pick up will be delayed store in refrigerator.

Limitations / Interferences
1. Long delays in collection of specimen may result in nonviable cells.
2. Non-refrigerated specimens may result in non-viable cells.
3. Specimens preserved in formalin are unacceptable.

References
1. CSI Laboratory Specimen Requirements

Author / Source
KMP/ 061107, Rev. 10/10/17, Reformat HJY 5/25/18
93449.239 Collection and Submission of Pathology

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Collection and Submission of Pathology | Version: 1.0 | Document Number: 93449.239
PROCEDURE FOR COLLECTION AND SUBMISSION OF
SURGICAL PATHOLOGY SPECIMENS

Principle
Surgical tissue specimens are submitted for gross and microscopic analysis to determine if the tissue contains malignant, abnormal, or normal tissue.

Specimens
The specimen can be any fixed (in zinc/neutral buffered formalin) tissue unless specifically prohibited in the “Reagents and Supplies” section.

Quality Control
- Specimen labeling is matched to the paperwork requesting testing.
- The pathologist considers clinical information provided, age and sex of the patient as part of the diagnostic process.
- The pathologist confers with the physician if microscopic findings are not expected based on the patient information.

Reagents and Supplies
1. Tissue samples for pathology only:
   - Plastic specimen cup with tightly fitting lid, zinc/neutral buffered formalin-filled
   - Patient identification device, either an adhesive label or permanent marker
   - Face sheet and copy of patient insurance card
   - MAWD Pathology Group requisition with patient information
   - MAWD Pathology Group specimen transport bag

Procedure
1. Select the appropriate container(s).
2. All plastic specimen container(s) must be labeled with 2 patient identifiers (see list below):
   - Patient Name
   - Date of Birth
   - Medical Record Number
   - Unique Identification Number
3. In addition to the 2 patient identifiers all containers need to be labeled with the following information:
   - Date of Specimen Collection
   - Physician Name
   - Specimen Source, e.g. “Left tonsil” or “Right ovary/fallopian tube”
4. Complete the appropriate laboratory requisition with the following information:
   - Patient Name
   - Date of Birth
   - Date of Specimen Collection
   - Patient ID Number/unique identification number
   - Physician Name
• Specimen Source, e.g. "Left tonsil" or "Right ovary/fallopian tube"
• If submitting more than one specimen, write the description of each to correspond with the specimen containers.
• Clinical history/reason for biopsy
• Special instructions

5. Place the specimen(s) in the appropriate, labeled containers.
6. Tightly seal all containers.
7. Place the specimens in the plastic MAWD Pathology Group specimen transport bag.
8. Place the requisition, face sheet and copy of the patient insurance card in the requisition pouch in the MAWD Pathology Group specimen transport bag. **Do not staple the paperwork.** Please place the requisition in the pouch so that the MAWD logo is apparent.
9. Place the sealed MAWD Pathology Group specimen transport bag in the designated area (room temperature). The MAWD Pathology Group courier will pick up the specimens and deliver them to MAWD Pathology Group.

**Hazards**
1. Formalin is a carcinogen. Intense and prolonged exposure over a long period of time (years) may cause cancer.
2. Fresh tissue (unfixed, not in formalin) is a potential biohazard. Body fluids may contain infectious agents such as bacteria, viruses like HIV and Hepatitis, and prion-like diseases, such as Creutzfeldt - Jakob disease. Use Universal Precautions at all times when handling tissue, fixed or unfixed.

**Limitations / Interferences**
1. Unpreserved tissue must be tested immediately. If not delivered immediately to the pathologist for testing, contact the pathologist to assess specimen viability.
2. Tissues preserved in formalin (or any other preservative) cannot be submitted for Bacterial Culture. MAWD Pathology Group does not perform cultures of any kind.

**References**
MAWD Pathology Group, Inc.; 2750 Clay Edwards Drive, # 420, NKC, MO. 64116. (816) 241-3200.

**Author / Source**
TLM/1/25/02; Rev KML 09/11/17; Reformatted HJY 5/18/18
# ADDENDUM: Pathology Specimen Collection and Submission Guidelines

It is **REQUIRED** that all specimen containers submitted be properly labeled with patient name and a second identifier (e.g. DOB) and specimen source. All specimens must be accompanied with appropriate paperwork containing tests ordered, patient history, demographics, and billing information.

<table>
<thead>
<tr>
<th>Test Requested</th>
<th>Submission Requirements</th>
<th>Preservative Requirement</th>
<th>Special Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cytogenetics</strong></td>
<td>• 5 ml peripheral blood in sodium heparin</td>
<td>• Green top tube of blood, bone marrow</td>
<td><strong>Time is of essence!</strong> For best results, specimen should be received the same day as collected. Keep refrigerated.</td>
</tr>
<tr>
<td></td>
<td>• 2-3 ml bone aspirate in sodium heparin</td>
<td>• RPMI for fresh tissue</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 2-5 ml cord blood in sodium heparin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Multiple 2-3 mm pieces of tissue in RPMI transport media</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct Immunofluorescence</td>
<td>Biopsy of Affected Skin</td>
<td>Michel's Fixative</td>
<td></td>
</tr>
<tr>
<td><strong>FISH</strong></td>
<td>• 3 ml of peripheral blood in sodium heparin</td>
<td>• Green top tube of blood or bone marrow</td>
<td><strong>Time is of essence!</strong> Must be received 24 hours from time of collection! <strong>Must submit tissue for routine Pathology!</strong></td>
</tr>
<tr>
<td></td>
<td>• 1-2 ml of bone marrow aspirate in sodium heparin</td>
<td>• RPMI for fresh tissue</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Multiple 2-3 mm pieces in RPMI transport media</td>
<td>• FFPE</td>
<td></td>
</tr>
<tr>
<td><strong>Flow Cytometry</strong></td>
<td>• 3 ml of peripheral blood in sodium heparin</td>
<td>• Green top tube of blood, bone marrow</td>
<td><strong>Time is of essence!</strong></td>
</tr>
<tr>
<td></td>
<td>• 1-2 ml of bone marrow aspirate in sodium heparin</td>
<td>• RPMI for fresh tissue</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Multiple 2-3 mm pieces in RPMI transport media</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HER 2</strong></td>
<td>Breast Carcinoma</td>
<td>Paraffin Block</td>
<td></td>
</tr>
<tr>
<td><strong>HPV</strong></td>
<td>Biopsy Suspicious for Human Papilloma Virus</td>
<td>Paraffin Block</td>
<td></td>
</tr>
<tr>
<td><strong>Muscle Biopsy</strong></td>
<td>Biopsy of muscle from familiar muscle group that has not reached &quot;end-stage&quot; atrophy</td>
<td>See Muscle Bx procedure (need kit)</td>
<td><strong>Time is of essence!</strong></td>
</tr>
<tr>
<td><strong>Nerve Biopsy</strong></td>
<td>Section of peripheral nerve</td>
<td>See Nerve Bx procedure (need kit)</td>
<td><strong>Time is of essence!</strong></td>
</tr>
<tr>
<td><strong>PCR</strong></td>
<td>• 5 ml of peripheral blood in EDTA</td>
<td>• Purple top tube of blood, bone marrow</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 1-2 ml of bone marrow aspirate in EDTA</td>
<td>• Paraffin block</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• FFPE</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quant Iron/Copper</strong></td>
<td>Biopsy of Liver</td>
<td>Paraffin Block</td>
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<tr>
<td><strong>Renal Biopsy</strong></td>
<td>2 Renal Core Biopsies to diagnose Renal Function (need kit)</td>
<td>• 1 core in 10% Buffered Formalin</td>
<td><strong>Time is of essence!</strong></td>
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<tr>
<td></td>
<td></td>
<td>• 1 core in Michel's Fixative</td>
<td></td>
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<tr>
<td><strong>Routine Biopsy</strong></td>
<td>Biopsy for Routine Pathology.</td>
<td>Zinc Formalin</td>
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<tr>
<td><strong>T Cell Gene Rearrangement</strong></td>
<td>Dermatologist suspects: CTCL; Mycosis Fungoides; Other Cutaneous Lymphoma</td>
<td>• 1 Skin Biopsy in Formalin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 1 Skin Biopsy in RPMI</td>
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93449.245 Cytology Specimen Collection CYT.100

Copy of version 1.0 (approved and current)

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Periodic Review Completed 7/22/2018

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Needed On or Before 7/22/2020

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Comments for version 1.0
Initial uploaded version

Approval and Periodic Review Signatures

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<td>7/22/2018</td>
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<td>Pablo Hernandez-Rios</td>
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<td>Tonya Warrmeyer</td>
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Controlled Copy of a Manual ID 19554
Location Saint Lukes Main Lab
Organization MAWD Pathology Group, P.A.

Cytology Specimen Collection CYT.100 | Version: 1.0 | Document Number: 93449.245
CYTOLOGY SPECIMEN COLLECTION (CYT.100)

CYTOLOGY SPECIMENS

Non-Gynecological Cytology Specimens
- Body Cavity Fluids and Washings
- Urine
- Sputum
- Cerebrospinal Fluid (CSF)
- Breast Fluids / Nipple Secretions
- Breast Cyst Aspirations
- Bronchial Washing
- Bronchial Brushing
- Fine Needle Aspiration (FNA) Biopsy

Gynecological (Cervical/Vaginal) Cytology Specimens
- ThinPrep Pap specimens
- SurePath Pap specimens
- Molecular tests
  - CTNG
  - Group B Strep
  - Vaginosis Panel

SPECIMEN LABELING

Always verify the identification of the patient by asking their name. If there are multiple specimens, place each specimen in a separate container and clearly note the specimen type/source in addition to the patient’s name. All specimens should be labeled at the time of collection with at least two patient identifiers.
1. The patient’s name (full last name, then full first name or initial) OR a unique ID code is always required.
2. The second patient identifier may be one of the following:
   - Date of birth (month/date/year)
   - Other unique patient identifier that is also on the test requisition, e.g. hospital or office ID code or file number.

REQUISITIONS

Each specimen submitted must be accompanied by an MAWD Pathology requisition form. We know that proper and timely billing of your patients is one of your concerns. In order for us to accomplish this task, we must have accurate patient information from you, which must be legibly written on the requisition form accompanying the specimen. (A separate patient information sheet may be attached to the requisition.) Please include the following:
• Complete patient name as it appears on the primary insurance card.
• Complete address of the patient.
• Patient’s date of birth.
• Guarantor’s name and date of birth if other than patient.
• Complete insurance information. It is best to attach a copy of patient’s insurance card(s), front and back, to the requisition.
• Appropriate ICD-10 code.
• Patient’s clinical history. This is a regulatory requirement because of its importance in rendering an accurate diagnosis.
• Requesting physician’s first and last name. Circle the appropriate choice if multiple physician names appear on the requisition.
• Specimen type and source.
• Specimen collection date.
• The procedures or special tests desired.

If the above information is not complete and legible, processing of the specimen may be delayed while we contact your office by phone or fax to obtain the required information.

SPECIMEN PACKAGING

Use only approved well-constructed containers and packaging materials. Secure container lids so that there is no leaking and seal the container into a biohazard bag. Place the requisition in the outer pocket of the bag. Place only one patient’s sample(s) in a biohazard bag.

SPECIMEN REJECTION POLICY

1. All requisitions must have the patient’s name, a second identifier such as a date of birth or patient ID number, tissue type and all pertinent available clinical history.
2. All specimen containers must be labeled with the patient’s name, a second patient identifier and type of specimen.
3. All slides and smears must be received labeled with 2 patient identifiers (e.g. name and date of birth or second unique identifier). Note: Slides or smears labeled with 1 unique patient identifier are acceptable if the outside container is labeled with at least 2 identifiers.
   • If specimens are received without a secondary identifier, a letter will be sent to the client of the requirements for specimen submission. If there continues to be secondary labeling issues the specimen(s) will be returned to the client.
4. Additionally, specimens will be rejected when slides are broken beyond repair, a specimen is received in a syringe with an intact needle, or the names on the specimen and requisition do not match.

VERBAL ORDERS

Verbal requests for additional testing must be followed up with a written ADD ON TEST form prior to the additional testing being performed. The ADD ON TEST form may be faxed to 816-241-6531.
NON-GYNECOLOGICAL CYTOLOGY SPECIMEN SUBMISSION

All cytology specimens should be submitted to the laboratory as soon as possible after collection. Delay will result in deterioration of unfixed specimens. If a delay is unavoidable (more than 1 hour), please refrigerate specimens until they are picked up.

All requests for cytologic examination must be submitted on MAWD Pathology requisition forms. Fluid and mucoid cytology specimens are processed with the ThinPrep® Technique. All cytology specimens should be submitted fresh or in CytoLyt® preservative.

The laboratory does not accept syringe needles. Flush the barrel of the needle into the specimen container, using the proper preservative and dispose of the needle into a sharps container.

If questions arise as to how a cytology specimen should be handled that are not answered in this manual, call 816-241-3338.

BODY CAVITY FLUIDS AND WASHINGS; PLEURAL, PERICARDIAL, PERITONEAL, AND PELVIC:

Supplies:
- Clean container (such as a sterile urine container)
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient's name, a second unique identifier and the source of the specimen.

Procedure:
1. Perform tap.
2. Place sample in clean specimen container or heparinized glass bottle.
3. Have specimen delivered immediately to the laboratory. If there is a delay, add 30 ml CytoLyt® to small volume samples or refrigerate larger volume samples. Please note on the container if CytoLyt® has been added.
4. If the specimen cellularity is adequate a cell block will be made.

CPT Code(s):
- 88112 - ThinPrep Non-gyn
- 88305 - Cell block

URINE:

Supplies:
- Clean container such as a sterile urine container or Cytolyt container
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient's name, a second unique identifier and the source of the specimen.

Procedural Notes:
1. A voided urine specimen should be obtained after the patient has been well hydrated and approximately three hours after the last void.
2. Do NOT submit the first morning void for cytology.
3. Clean catch samples are necessary. Female patients should be instructed to spread the labia during collection, then pass and discard a small amount of urine. Collect the remainder. Males should be instructed to pass and discard a small amount of urine and collect the remainder.
4. If the patient is unable to cooperate satisfactorily, a catheterized specimen should be obtained. Note the method of collection on the requisition form.

5. Do not submit 24-hour collection specimens for cytology. These are unsatisfactory due to cellular degeneration.

Procedure:
1. Provide patient with clean container and instructions.
2. Submit approximately 50 ml of urine to ensure a sufficient sample.
3. Have specimen delivered to the laboratory immediately. If there is a delay, add 30 ml CytoLyt® or refrigerate. Please note on the container if CytoLyt® has been added.

CPT Code: 88112 – ThinPrep Non-gyn

SPUTUM

Supplies:
- Wide mouth plastic container
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient’s name, a second unique identifier and the source of the specimen.

Procedure:
1. Instruct patient to collect specimen as soon as they wake up.
2. Instruct patient to rinse mouth with water, then cough deeply into container.
3. Inform patient that several coughs over a period of 2 to 3 hours may be necessary to produce a sufficient sample.
4. Have specimen delivered to the laboratory immediately. If there is a delay, add 30 ml CytoLyt® solution and mix well. Please note on the container if CytoLyt® has been added.
5. If three consecutive specimens are to be collected, all three specimens can be delivered on the third day of collection, provided the earlier specimens are fixed with CytoLyt®.

CPT Code:
- 88112 – ThinPrep Non-gyn
- 88305 – Cell block

CEREBROSPINAL FLUID (CSF)

Supplies:
- Clean container
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient’s name, a second unique identifier and the source of the specimen.

Procedural Notes:
1. Submit the largest volume of fluid possible.
2. DO NOT add CytoLyt® to this specimen.

Procedure:
1. Perform spinal tap.
2. Place sample in clean container.
3. Have the specimen delivered to the laboratory immediately.

CPT Code: 88112 – ThinPrep Non-gyn
BREAST FLUIDS: NIPPLE SECRETIONS

Supplies:
- Glass slides
- 95% alcohol or spray fixative
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient’s name, a second unique identifier and the source of the specimen.

Procedural Notes:
1. If secretion appears when pressure is applied to a particular area, it is advisable to note this on the requisition form and prepare a specifically identified slide from this material. This may be helpful in guiding future biopsy.
2. Cellularity tends to increase with each expression and multiple slides should be made if possible.

Procedure:
1. Label glass slides with patient’s first and last name and specimen source and date of birth or a second unique identifier.
2. Express material from nipple by gentle compression of the areolar area between thumb and forefinger directly onto glass slide.
3. Gently spread material over surface of slide.
4. Immediately fix specimen by dropping slide into 95% alcohol or spray with fixative. Do NOT allow specimen to air dry.

CPT Code: 88104 -smear and interpretation.

BREAST CYST ASPIRATIONS

Supplies:
- Clean container
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient’s name, a second unique identifier and the source of the specimen.

Procedural Notes:
1. Most breast cyst fluids do not need cytologic examination and can be discarded.
2. Submit the cyst fluid if:
   a. the cyst is recurrent
   b. the fluid appears bloody (brownish fluid suggestive of old bleeding, not fresh blood due to the procedure)
   c. the patient is postmenopausal and not on hormone replacement therapy

Procedure:
1. Perform aspiration.
2. Place specimen in clean container.
3. Have specimen delivered to the laboratory immediately. If there is a delay, add an equal volume of CytoLyt® or refrigerate. Please note on the container if CytoLyt® has been added.

CPT Code:
- 88112 – ThinPrep Non-gyn
- 88305 - Cell block
Respiratory Specimens
Note: If clinical laboratory testing is required please submit a separate specimen to the clinical laboratory or submit to clinical laboratory prior to submitting specimen for Cytology testing.

Bronchial Washing or BAL
Supplies:
- Clean container or bronchial trap.
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient's name, a second unique identifier and the source of the specimen.

Procedure:
1. Perform bronchoscopy.
2. Place sample in bronchial trap or clean specimen container.
3. Have specimen delivered to the laboratory immediately. If there is a delay, add an equal volume of CytoLyt® or refrigerate. Please note on the container if CytoLyt® has been added.

CPT Code:
- 88112 – ThinPrep Non-gyn
- 88305 - Cell block

Bronchial Brushing
Supplies:
- Clean container or bronchial trap.
- Glass slides
- 95% alcohol slide transport tubes
- MAWD Pathology Cytology requisition

NOTE: Specimens and requisition must be labeled with the patient's name, a second unique identifier and the source of the specimen.

Procedure:
1. Perform bronchoscopy.
2. If brush smears are performed
   a. Label a slide or multiple slides with patient’s last name, first initial, date of birth and site/source indicator. Use pencil or alcohol resistant ink.
   b. Smear the brush down the slide with enough pressure to leave specimen behind. Use a single swipe, do not re-smear over the same area of slide.
   c. Immediately spray fix or place slide in 95% alcohol transport tube.
3. Cut brush, leaving 1 inch stem and place in bronchial trap or clean specimen container, or Cytolyt tube. If sending fresh cover with enough saline to cover the brush.
4. Have specimen delivered to the laboratory immediately. If there is a delay, add an equal volume of CytoLyt® or refrigerate. Please note on the container if CytoLyt® has been added.

CPT Code:
- 88112 – ThinPrep Non-gyn
- 88104 – Nongyn smears
- 88305 - Cell block
FINE NEEDLE ASPIRATION

Specimens
Fine needle aspiration biopsy may be performed on any body site that can be reached with a fine needle. A fine or thin needle is defined as 22 or higher gauge. These specimens may be from the thyroid, salivary gland, or lymph node, lung, breast or other pertinent body site.

Reagents and Supplies
- Centrifuge tube containing Cytolyt preservative
- Spray fixative or Coplin Jar containing 95% Ethanol or other sealable container with 95% EtOH
- Glass slides
- Pencil or alcohol resistant marker for labeling slides
- MAWD Pathology Group specimen bag, cardboard slide folder.
- MAWD Pathology Group Cytology requisition with patient information

Importance of Clinical Information
- Identify the specific source of specimen along with clinical impression and history.
- Specify whether the specimen is a cyst, nodule, tumor, mass, and if the patient has a history of malignancy. All detailed information available is helpful.
- This information is a crucial part of the pathologist's ability to accurately interpret a specimen. Lack of complete history and impression can result in misdiagnosed or unsatisfactory specimens.

Procedure
1. Label the centrifuge tube containing Cytolyt with the following information:
   - Patient Name
   - Specimen Source, e.g. “FNA - Thyroid”
   - Patient date of birth or other unique identifier
2. Label the Coplin Jar or prefilled 95% alcohol slide holder with patient name and date of birth.
3. Label 4 to 6 microscope slides with the patient name, date of birth, and whether or not the slide will be fixed (fx) or air dried (AD). Use alcohol resistant ink or pencil.
4. Collect the specimen and express one or two drops of the cellular material onto one slide and smear with a second slide. Immediately, spray fix or place one of the slides into the alcohol and air dry the other.
5. Rinse syringe in the centrifuge tube containing Cytolyt fixative.
6. Repeat step 4 as needed to ensure good sampling. Multiple passes from the same site can be combined into one Centrifuge tube of Cytolyt.
7. Each different, clinically significant site requires proper labeling of glass slides and a new centrifuge tube containing Cytolyt for rinsing the needle.
8. Complete the MAWD Pathology Group Cytology requisition with the following information:
   - Patient Name
   - Date of Birth
   - Date of Collection
   - Performing Clinicians Name
   - Admitting Diagnosis
   - ICD-10 code
   - Specimen Source, e.g. “1- FNA - Right Thyroid” and “2- FNA - Left Thyroid”
9. Place air dried slides in the provided cardboard transport folders, the alcohol slide transport tubes, and the CytoLyt centrifuge tube in the plastic specimen bag along with the completed requisition, for transport to the laboratory.
10. Place the specimen bag in the tray for pickup by the MAWD Pathology Group courier. Room temperature storage is adequate.

Any questions or requests for supplies can be directed to the MAWD Pathology Group cytology department at: 1-816-936-8110

Duties of Pathologist or Cytotechnologist assisting on FNA or EUS/EBUS procedures

1. Before collecting any specimens the Pathologist and/or Cytotechnologist should participate in a time out procedure. The patient’s name, date of birth and procedure being performed should be announced and verified with any paperwork or patient labels provided.
2. Slides prepared by Pathology during the procedure must be labeled with the patient’s last name, first initial and date of birth. If multiple specimens are collected the slides should also include a site designation that corresponds to the site on the requisition.
3. All specimen containers and CytoLyt tubes should be labeled with the provided patient labels or if no labels are available, with name, date of birth, and collection site, prior to leaving procedure room.
4. If the Pathologist provides an adequacy assessment or preliminary interpretation the interpretation should be written on the specimen requisition along with the Pathologist’s initials and date. If the Pathologist recommends additional testing at the time of the procedure, that information should also be written on the requisition. The information will also be transcribed into CoPath.

CPT Code:
- 88172 - specimen adequacy evaluation when performed
- 88173 – Interpretation and report
- 88305 – Cell block
GYNECOLOGICAL (CERVICAL/VAGINAL) CYTOLOGY SPECIMEN SUBMISSION

The adequacy of Pap test collection is determined by:
1. Accurate patient and specimen identification
2. The presence of an adequate squamous component
3. The presence of an adequate endocervical component (in premenopausal females with a cervix)
4. Adequate cellular preservation
5. Pertinent clinical history (see below). Because of the importance of the patient's clinical history in interpreting the Pap test, be sure to note any relevant information such as:

- Cigarette Smoker
- Previous GYN Malignancy
- Total hysterectomy
- History of HPV or dysplasia
- Supracervical hysterectomy
- Immuno-compromised
- Pregnant (weeks)
- Abnormal GYN Exam (HPV, Cervical lesion)
- Postpartum (weeks)
- Abnormal Pap/BX within last 3 yrs
- Postmenopausal (year)
- Family Hx Cervical Cancer
- Estrogen Replacement therapy
- Early onset of sexual activity
- IUD
- Multiple sexual partners
- Post-coital bleeding
- Birth control pills
- Postmenopausal bleeding
- History of STD's
- Routine examination
- Pelvic radiation
- Repeat Pap

Pap test results are typically reported within 5 to 7 business days following receipt into the laboratory.

Procedural Notes for Pap test collection:
1. To ensure an adequate specimen:
   - Samples from both the ectocervix and endocervix including the transformation zone are essential.
   - The patient should be instructed not to use vaginal medications, spermicide or douches 24 hours prior to collection of the Pap test.
   - Patient should refrain from intercourse for 24 hours prior to collection.
   - Vaginal discharge or secretion (when present in large amounts) should be removed before obtaining the cervical sample.
   - It is preferred that lubricant NOT be used when obtaining a pap specimen.
2. If testing for sexually transmitted diseases is indicated, the cervical cytology sample should be taken first.
3. If a suspicious area is visualized, a separate sample from the area may be obtained and appropriately designated separate collection.
4. Complete the requisition form as previously instructed and include ALL of the following information:
   - specimen source (i.e. cervical/endocervical or vaginal)
   - relevant clinical history (as noted above)
   - last menstrual period (LMP)
   - collection date
5. No refrigeration is necessary.
Unacceptable Specimens
- No or illegible patient identification on the specimen container or the test requisition
- Mismatch between name of patient on specimen and name on test requisition
- Leakage of sample during transport
- Expired liquid-based preservative/vial
- SurePath Pap Test (blue vial) without a collection device

Imaged THINPREP™ PAP
ThinPrep™ Pap test is a liquid-based cell preparation system, collected in PreservCyt® solution and processed using the Hologic instrumentation. Monolayer preparations are screened by cytotechnologists using computer assisted imaging technology, with pathologist review of all abnormal cases.
Supplies:
- Un lubricated speculum (warm water or saline may be used)
- PreservCyt® solution vial
- Endocervical brush/spatula or Broom-like device
- Requisition

Cervical/ Endocervical Brush/Spatula Procedure
Obtain cellular material as per Hologic's instructions from the cervix using a spatula or endocervical brush:

ThinPrep Brush/Spatula
1. Insert vaginal speculum WITHOUT any lubricant. The use of lubricant has been known to interfere with the ThinPrep™ process, resulting in unsatisfactory for evaluation Paps due to low cellularity.
2. Obtain an adequate sampling from the ectocervix using a plastic spatula.
3. Rinse the spatula into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
4. 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 a quarter or half turn in one direction. Do NOT over-rotate.
5. IMMEDIATELY rinse the brush 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.
6. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
7. Label the vial with the patient's first and last name and 2nd identifier.

Broom-like Device Procedure
Obtain cellular material per Hologic's instructions from the cervix using a broom device:

ThinPrep/Broom-like Device
1. Insert vaginal speculum WITHOUT any lubricant. The use of lubricant has been known to interfere with the ThinPrep™ process, resulting in unsatisfactory for evaluation Paps due to low cellularity.
2. Obtain an adequate sample 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 5 times.
3. IMMEDIATELY rinse the broom 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.
4. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
5. Label the vial with the patient’s first and last name and 2nd identifier.

Additional Testing Available From ThinPrep™® Specimens
- High Risk HPV
- HPV Genotyping 16/18
- Chlamydia
- Gonorrhea

SurePath™® Pap without Imaging
The SurePath™® Pap test is a liquid based thin layer cell preparation system, collected in SurePath™® Preservative Fluid and processed using the PrepStain™ System. Slides are manually screened by cytotechnologists, with pathologist review of all abnormal cases.

Supplies:
- Unlubricated speculum (warm water or saline may be used)
- Brush (Rovers Cervex-Brush)
- SurePath™® Preservative Vial
- Requisition

Procedure:
Obtain cellular material as per instructions from the cervix using a Cervex device:
Surepath
1. Label the SurePath™® vial with the patient first and last name and 2nd identifier.
2. After visualization of the cervix is completed, use the Rovers Cervex-Brush to collect an adequate sample.
3. Insert the central long tines into the cervical/endocervical canal applying gentle pressure.
4. As these are being inserted, the device should be twisted slowly. Maintaining gentle pressure, hold the stem between the thumb and forefinger then rotate the brush five times in a clockwise direction. Do not alter the direction of the brush during sampling.
5. Transfer the entire sample by placing your thumb against the back of the brush pad, simply disconnect the entire brush from the stem into the SurePath™® preservative vial.
6. Recap the vial and tighten. **NOTE:** SurePath™® Pap specimens submitted without the collection devices in the vial are not compliant with the FDA approved Pap testing methodology and will be rejected for testing.

Additional Testing Available From SurePath™® Pap Specimens
- High Risk HPV
- HPV Genotyping 16/18
- Chlamydia
- Gonorrhea
**Women’s Health testing available at MAWD Molecular Laboratory**

- Roche swab and urine collection kits for CT/NG
- BD Max collection kit for Bacterial Vaginosis panel/Candida/Trichomonas
- E swab collection kit for Group B Strep

**Cobas® PCR Female Swab Sample Kit for CTNG**

**Supplies:**

- Cobas® PCR Female Swab Sample Kit
- The kit includes one vial of PCR media and one swab packet with 2 female collection swabs.

**Procedure: For Endocervical Swab Specimen collection**

1. **DO NOT** Pre-wet swab in PCR Media
2. Use one of the swabs to remove excess mucus from the cervical os and surrounding mucosa.
3. Discard swab
4. Insert the other clean swab into the endocervical canal. Gently rotate the swab 5 times in one direction in the endocervical canal. Do not over-rotate.
5. Carefully withdraw the swab avoiding contact with the vaginal mucosa.
6. Remove the cap from the cobas PCR media tube and lower the swab into the tube until the visible dark line on the swab is aligned with the tube rim. The tip of the swab should be just above the media surface near the Roche logo.
7. Carefully leverage the swab against the rim to break the swab shaft at the dark line. Discard the top portion of the swab.
8. Tightly re-cap the PCR media tube.
9. Label the PCR tube with patient name and date of birth.
10. Send specimen with appropriate order(s) and requisition to MAWD molecular laboratory.

**Procedure: For Vaginal Swab Specimen Collection**

1. **DO NOT** Pre-wet swab in PCR media.
2. Insert one swab (discard the second swab) about 5cm or 2 inches into the vaginal opening.
3. Gently turn the swab for about 30 seconds while rubbing the swab against the walls of the vagina.
4. Withdraw the swab carefully without touching any surface prior to placing into collection tube.
5. Remove the cap from the cobas® PCR media tube and lower the swab into the tube until the visible dark line on the swab is aligned with the tube rim. The tip of the swab should be just above the media surface near the Roche logo.
6. Carefully leverage the swab against the rim to break the swab shaft at the dark line. Discard the top portion of the swab.
7. Tightly re-cap the PCR media tube.
8. Label the PCR tube with patient name and date of birth.
9. Send specimen with appropriate order(s) and requisition to MAWD molecular laboratory.
Cobas® PCR Urine Sample Kit for CTNG

Supplies:
- One cobas®PCR urine sample kit which includes a cobas® PCR media tube and a disposable pipette.
- A urine collection cup (not provided)

Procedure:
1. Prior to sampling the patient should not have urinated for at least one hour.
2. Have patient provide first catch urine, approx. 10-50 mL of the initial urine stream into the urine collection cup.
3. Use pipette to immediately transfer urine into the PCR media provided.
4. Enough urine has been transferred when the fluid level is between the two black lines on the tube label.
5. Note if urine cannot be immediately transferred it can be stored at 2°C to 30°C for up to 24 hours.
6. Tightly re-cap the PCR media tube.
7. Invert the tube 5 times to mix.
8. Label the PCR tube with patient name and date of birth.
9. Send specimen with appropriate order(s) and requisition to MAWD molecular laboratory.

ESwab for Group B Strep testing

Supplies:
- ESwab collection kit.

Procedure:
1. Open the ESwab sample collection kit and remove the tube and swab.
2. Collect the sample form the patient.
3. Unscrew and remove the cap from ESwab tube making sure not to spill the medium.
4. Break the swab off into the tube as follows:
   a. With the other hand grasp the swab shaft at the very end with the thumb and first finger.
   b. Lean the part of the shaft with the breaking point against the rim of the tube.
   c. Bend the swab shaft at 180 degrees angle to break it off at the colored ink breakpoint mark. If needed, gently rotate the swab shaft to complete the breakage and take away the upper part of the swab shaft.
   d. Dispose of upper shaft in an approved medical waste container.
5. Replace cap on the tube and secure lightly.
6. Label the tube with patient name and date of birth.
7. Send specimen with appropriate order(s) and requisition to MAWD molecular laboratory.
BD MAX™ UVE Specimen

Orderable tests from BD Max™

1. Bacterial Vaginosis
   a. *Lactobacillus species* (*L. crispatus* and *L. jensenii*)
   b. *Gardnerella vaginalis*
   c. *Atopobium vaginae*
   d. *Bacterial vaginosis associated bacteria-2 (BVAB-2)*
   e. *Megasphaera-1 Bacterial vaginosis.*

2. Candidiasis
   b. *C. glabrata*
   c. *C. krusei*

3. Trichomonas vaginalis
   a. *T. vaginalis*

Supplies:

- BD MAX™ UVE Specimen collection kit

NOTE: Collected swabs must be transferred immediately (preferred) or within 2 hours after collection to the BD max sample buffer tube. Samples in buffer tubes should be kept between 2° and 30°C during transport and can be stored for up to 8 days at 2-30°C or 14 days at 2°-8°C. Do not expose to excessive heat.

Procedure: Endocervical swab specimen collection

1. Remove the sterile swab from its sheath taking care not to contaminate the tip or shaft. Do not use contaminated swabs.
2. Holding the swab by the white cap, insert it into the cervical canal and rotate for 15-30 secs
3. Withdraw the swab carefully, avoiding contact with the vaginal mucosa.
4. Uncap the BD Max™ UVE sample buffer tube and fully insert the swab into the tube so that the tip is at the bottom.
5. Grasping the swab by the cap, carefully break the swab shaft at the score mark. Use caution to avoid splashing or contamination of the tube contents.
6. Tighten the cap securely. In the event that the swab is too long to allow closing the tube securely, perform specimen collection with a new swab.
7. Label the BD Max buffer tube with patient name, date of birth and date/time collected. Be careful not to obscure the barcodes on the tubes.
8. Send specimen with appropriate order(s) and requisition to MAWD molecular laboratory.

Procedure: Vaginal swab collection

1. Remove the sterile swab from its sheath taking care not to contaminate the tip or shaft. Do not use contaminated swabs.
2. Hold the swab by the white cap.
3. Gently slide the swab no more than 2 inches into the vagina. If the swab does not slide easily, gently rotate the swab while it is pushed. Make sure the swab touches the walls of the vagina so the moisture is absorbed by the swab.
4. Rotate the swab for 10-15 seconds.
5. Withdraw the swab carefully, avoiding contact with the skin.
6. Uncap the BD Max™ UVE sample buffer tube and fully insert the swab into the tube so that the tip is at the bottom.
7. Grasping the swab by the cap, carefully break the swab shaft at the score mark. Use caution to avoid splashing or contamination of the tube contents.
8. Tighten the cap securely. In the event that the swab is too long to allow closing the tube securely, perform specimen collection with a new swab.
9. Label the BD Max buffer tube with patient name, date of birth and date/time collected. Be careful not to obscure the barcodes on the tubes.
10. Send specimen with appropriate order(s) and requisition to MAWD molecular laboratory.

References

Author/Source
CYT100. KR12/30/03; TW Rev 10/02/17; Format change HJY 4/7/18
93449.247 Quality Assurance Plan Pathology

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Effective Date 6/26/2019

Controlled Copy of a Manual ID 19554
Location Saint Lukes Main Lab
Organization MAWD Pathology Group, P.A.

Author KML

Comments for version 2.0 (last major revision)
This is edited to update the Saint Lukes thresholds.

Comments for version 2.1 (this revision)
Removed NKC address

Approval and Periodic Review Signatures

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Quality Assurance Plan Pathology | Version: 2.1 | Document Number: 93449.247
QUALITY ASSURANCE PLAN

GOAL:

The purpose of the Pathology Quality Assurance Program is to monitor and evaluate the department's efforts to provide the Medical Staff with high quality diagnostic data and to assist them in the treatment of their patients.

The four principal areas of pathology performance are:
1. Routine diagnoses, including tissue, blood, and bone marrow;
2. Frozen section;
3. Cytology; and
4. Evaluation of small biopsy specimens.

Pathology is frequently almost the last word in the diagnostic process, the true last word being the clinical course of the patient. In order that this clinical course is optimally impacted by the health care process, the pathology diagnosis must be accurate. Therefore, thresholds are set for accuracy and concurrence, so that each deviation from perfect performances are evaluated for impact on patient care, examined to find the cause of the problem, and reported in a departmental summary, tracked by individual pathologists to support the credentialing process.

INDICATORS:

1. 3% of all cases require peer review by one or more pathologists within the group. These cases include all new malignant diagnoses. NOTE: Whenever cases are evaluated by more than one pathologist, documentation will be made of their diagnoses.
2. When cases are shown to pathologists outside the department, as in a consultation, the outside diagnosis that is rendered should concur with the original diagnosis rendered within the department (threshold 99%).
3. When a frozen section is performed, the diagnosis rendered at frozen section should agree with the final pathology diagnosis rendered on paraffin embedded material (threshold 98% major variance).
4. When a frozen section is performed, the turnaround time shall have a 98% threshold for turnaround in 20 minutes from time of specimen reaching lab to notification of diagnosis. NOTE: This threshold is for cases only requiring 1 block, when more than 1 block is required this threshold is not valid. The times for turnaround will be documented on all frozen section cases.
5. When a diagnosis is made on a cytology specimen from an area from which a tissue specimen is subsequently obtained, the cytologic and histologic diagnoses should agree (threshold 95%).
6. When a biopsy specimen is followed by resection of the area from which the biopsy was taken, the biopsy and subsequent resection specimen diagnoses should agree (threshold 97%).
7. When a diagnosis is issued and a correction is required, there is 99% threshold for significant changes and a 95% threshold for insignificant changes. **NOTE:** Significant Changes: affect the diagnosis as in changes it (i.e. cancer staging, malignant to benign) and signs the report out with a total different patient than what was on the requisition. **Insignificant Changes:** do not affect the diagnosis and the case has to be opened up to change.

8. Turnaround time shall have a 90% threshold for the following:
   - Surgical- 48 hours for routine specimens
   - Non-Gyn- 48 hours
   - Gyn-120 hours
   - Autopsy-
     - Preliminary reports- 48 hours
     - Final reports- 60 days

**STUDY TOPIC/SELECTION PROCESS:**

Data regarding each indicator is maintained and summarized. Variances/deficiencies identified through an analysis of the data are addressed in periodic narrative reports, and used to identify areas for in-depth study or corrective action. Additional problems or issues for review are also identified through incident reports, inspections, employee concerns or other sources.

**IMPLEMENTATION PLAN:**

Based on a review of the statistical and narrative analysis, areas of concern are prioritized and a plan developed to ensure that identified problems are addressed. All identified problems are addressed and monitored through to resolution.

**REPORT:**

Quarterly reports are given to the Quality Assurance Coordinator that include a summary of gathered data, conclusions drawn from the data, actions taken, and evaluation of the effectiveness of the actions taken.

**ANNUAL REVIEW:**

The effectiveness of this Quality Assurance Plan is reviewed on an annual basis. This review considers the validity and usefulness of selected indicators, and the quality and timeliness of problem resolution activities.

**References**
MAWD Pathology Group

**Author / Source**
TLM 12/05/05; Reformat HJY 5/18/18; Rev KML 8/19/18
Fetal Autopsy (Physician Requested)

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Next Periodic Review Needed On or Before 7/7/2020
Effective Date 7/7/2018

Author K Little

Comments for version 1.0
Initial uploaded version

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<td>Section Supervisor</td>
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Controlled Copy of a Manual ID 19554
Location Saint Lukes Main Lab
Organization MAWD Pathology Group, P.A.
PHYSICIAN REQUESTED FETAL AUTOPSY

 Principle
 The purpose of this procedure is to ensure proper handling of fetal specimens for the purpose of autopsy when requested by a physician. If a family is requesting a fetal autopsy, see Family Requested Autopsy Procedure.

 Specimens
 The specimen consists of all fetuses greater than 350 grams and has a gestational age greater than 20 weeks. When fetuses are less than 350 grams and have a gestational age less than 20 weeks see Fetal Specimen Grossing Procedure.

 Quality Control
 Fetal specimens with the above qualifications and signed Autopsy Permit are to be sent to Dr. Michael Handler at Frontier Forensics, 913-299-1533.

 Reagents and Supplies
 1 Fetal Remains weighing greater than 350 grams and gestational age greater than 20 weeks
 2 Signed Autopsy Permit
 3 Written Physician Orders, requesting that an autopsy be performed
 4 Signed Funeral Home Release Form

 Procedure
 1. Verify that all forms and fetus are labeled with the patient’s name.
 2. Call Frontier Forensics at (913)299-1533 and tell them you are faxing (913)299-4931 an Autopsy Request form and permit. The Frontier Forensics telephone is answered daily (seven days per week), from 7:00 a.m. to 5:30 p.m. After these hours, leave the information on the answering machine. It is not necessary to contact them directly after hours unless there are extenuating circumstances.
 3. Contact First Call Removal at (913)262-2633 to arrange for transport of the body to Frontier Forensics. After the autopsy, Frontier Forensics will coordinate transport of the body to the designated funeral home. MAWD Pathology Group will pay First Call Removal Service for transport charges from the facility to Frontier Forensics.

 Reference
 Missouri State Statute Chapter 193

 Author / Source
 KMP 080207; Revised KML 072209; Revised KML 022111; Revised KML 061915; Format change HJY 031518
93449.267 Autopsy-Physician Request, Hospital

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Effective Date 7/7/2018

Author KML

Comments for version 1.0
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Controlled Copy of a Manual ID 19554
Location Saint Lukes Main Lab
Organization MAWD Pathology Group, P.A.
PHYSICIAN OR HOSPITAL REQUESTED AUTOPSY PROCEDURE

Principle
All autopsies are performed by board certified pathologists employed by Frontier Forensics Midwest.

Required Documentation/Information
1. Autopsy Permit authorized by next-of-kin
2. Medical Chart
   a. Facesheet
   b. Admitting history
   c. Progress notes
   d. Death summary
3. Detailed patient information:
   a. Name of deceased
   b. Date of birth
   c. Date and time of hospital admission
   d. Date and time of death
   e. Name and phone number of the physician requesting the autopsy
   f. “What is the question the autopsy is to answer?”
   g. Any other important clinical information relevant to the autopsy
   h. Funeral home name and number
   i. Responsible family member’s name and number

Procedure

Regular business hours, Monday–Friday, 7:00 a.m.–5:30 p.m.
Nursing Supervisor:
1. Fax the MAWD Medical Secretaries the signed autopsy permit. Call the MAWD Medical Secretaries at (816)241-3200 to verify receipt of the fax.
2. Fax the signed autopsy permit to Frontier Forensics Midwest (913)299-4931 and call (913)299-1533 to verify receipt of the fax. Please have the detailed information listed in "Required Documentation/Information" ready to give the staff member at Frontier Forensics Midwest.
3. Send the requested information from the medical chart to fax (913)912-1388. When the body is in the hospital holding area ready for transport call First Call Removal (913)262-2633 for transport to the morgue. MAWD Pathology Group is billed for transport to the morgue only.
4. After the autopsy, Frontier Forensics Midwest will coordinate transport of the body to the designated funeral home.
After hours

Nursing Supervisor:
1. Fax the MAWD Medical Secretaries the signed autopsy permit. Call the MAWD Medical Secretaries at (816)241-3200 to verify receipt of the fax.
2. Fax the signed autopsy permit to the Frontier Forensics Midwest at (913) 299-4931 and call (913)299-1533 to verify receipt of the fax.
3. Contact Frontier Forensics at (913)299-1533 and provide the detailed information listed in “Required Documentation/Information”. If you receive the recorded message when you call, you may leave the information on the answering machine. It is not necessary to contact Frontier Forensics personnel directly (eg, call their pager or cell phone) after hours unless there are extenuating circumstances.
4. Send the requested information from the medical chart to fax (913)912-1388. When the body is in the hospital holding area ready for transport call First Call Removal (913)262-2633 for transport to the morgue. MAWD Pathology Group is billed for transport to the morgue only.
5. After the autopsy, Frontier Forensics will coordinate transport of the body to the designated funeral home.

Important Numbers
1. MAWD Medical Secretaries: Phone (816)241-3200; Fax: (816)241-6531
2. Frontier Forensics: Phone (913)299-1533; Fax for signed permit (913)299-4931; Fax for medical records (913)912-1388
3. First Call Removal: Phone (913)262-2633

References
1. Chris Berry, Frontier Forensics Midwest Operations Manager
2. Missouri Revised Statutes, Chapter 194, “Death-Disposition of Dead Bodies”; Section 194.115

Author / Source
TLM 2/20/04; revised KML 12/28/17; Reformat 5/1/18HJY
93449.278 Critical Results

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Author HJY

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Organization MAWD Pathology Group, P.A.

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Initial version

Comments for version 1.1 (this revision)
Removed cytotech from responsible individual for calling criticals to match current practice; minor revision (no procedural change)

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Critical Results | Version: 1.1 | Document Number: 93449.278
REPORTING CRITICAL RESULTS NOTIFICATION AND DOCUMENTATION

Principle
The purpose of this procedure is to define critical results, whether diagnosed in our facility or at a reference laboratory chosen by MAWD Pathology Group that will prompt a telephone call to attending physician and be documented in patient's records.

Critical Elements
1. Cytology:
   a. Adenocarcinoma.
   b. Squamous cell carcinoma.
   c. Specific clinician request to call results.
2. Pathology:
   a. Any diagnosis where there is a specific discrepancy between the clinical and pathologic diagnoses.
   b. Specific clinician request to call results.
   c. Melanoma.

Procedure
1. Cytology, Non-Gynecologic and Pathology:
   a. The pathologist responsible for diagnosing a critical result or reviewing a critical result form an outside reference laboratory report will call the attending physician. *Note: The telephone number for the attending physician is printed in the working draft.*

   b. Verify patient identification and then give the critical result(s) to the clinician.

   c. After speaking with the clinician, the Pathologist will dictate the date, time and person contacted of the critical result(s).

   d. The medical secretaries will transcribe the diagnosis and call documentation in the patient record.

2. Gynecologic
   a. The pathologist responsible for diagnosing a critical result or reviewing a critical result from an outside consult or reference laboratory report will call the attending physician. *Note: The telephone number for the attending physician is printed in the working draft.*

   b. Verify patient identification and then give the critical result(s) to the clinician.

   c. The pathologist will record the date, time and person contacted of the critical result(s) on the working draft to be entered in the patient record. The Cytotechnologist will enter the call documentation in the patient record if recorded on the working draft.

Reference
MAWD Pathology Group, Inc.

Author/Source KML/NB 10/7/2015, HJY Reformat 8/6/2018
# Hospital Supplies Order Form

Client Name: ____________________________  Client #: ____________________________

Ordered by: ____________________________ Date: ____________________________

Phone Number: ____________________________

**PLEASE ALLOW 72 HOURS FOR DELIVERY**

<table>
<thead>
<tr>
<th>Quantity Ordered</th>
<th>Item Description</th>
<th>Quantity Filled</th>
</tr>
</thead>
<tbody>
<tr>
<td>½ oz. (20ml) Tissue Container – prefilled</td>
<td>24 / Box</td>
<td></td>
</tr>
<tr>
<td>1 oz. (40ml) Tissue Container – prefilled</td>
<td>24 / Box</td>
<td></td>
</tr>
<tr>
<td>2 oz. (60ml) Tissue Container – prefilled</td>
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<td></td>
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<td>24 / Box</td>
<td></td>
</tr>
<tr>
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<td>Individual</td>
<td></td>
</tr>
<tr>
<td>Cytolyt Solution</td>
<td>25 / Tray</td>
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<tr>
<td>RPMI Media</td>
<td>Individual</td>
<td></td>
</tr>
<tr>
<td>95% Ethanol Fixative - Slide Transport Tubes</td>
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<tr>
<td>Pap Holders - Cardboards</td>
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<tr>
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<tr>
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<td>Formalin Labels</td>
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</tr>
<tr>
<td>Specimen Bags – Small, Medium, Large Sizes</td>
<td>25/ 50/ 100/ Other</td>
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</tr>
<tr>
<td>MAWD Comb Cyto/Pathology Requisitions (Green Print)</td>
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<tr>
<td>MAWD Tissue Pathology Requisitions (Lavender Print)</td>
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<tr>
<td>MAWD Non-Gyn Requisitions (Dark Purple Print)</td>
<td>25/ 50/ 100/ Other</td>
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</tbody>
</table>

*** Please fax supply order form to 913-495-9759. Thank you! ***

Other: ________________________________________________________________

Date Order Filled: ____________________________  By: ____________________________