MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid, or other federally funded programs, the following requirements apply.

- 1.Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
- 2.If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
- 3.Effective January 1, 1998, the ordering physician must provide an ICD-9 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
- 4.Organ or disease related panels should be billed only when all components of the panel are medically necessary.
- 5.Both JMC and client customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
- 6.Medicare National Limitation Amounts for CPT codes are available through HCFA or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

Questions concerning utilization of CPT codes should be addressed with your local carrier, as CPT codes may vary from one third-party payer to another.

At JMC we are *Making the Best Better* by keeping you informed of regulatory requirements and changes that pertain to the laboratory industry.

CLIENT INFORMATION SERVICES AND CONSULTANTS

CLIENT INFORMATION SERVICES

Service Commitment

At JMC Laboratory, we believe in working closely with our clients to ensure quality patient care as well as client satisfaction. Our primary goals are to offer superior testing and personalized service, and our corporate challenge is to continually improve our quality by "making the best better." By building professional relationships with our clients, we can define and exceed individual customer needs, while also supporting our clients in their own delivery of service.

Staff

The purpose of Client Information Services is to provide our clients with world-class customer service professionals who answer all inquiries in a timely, accurate, and friendly manner. Clients may call with questions ranging from routine test results, specimen requirements, STAT services and courier/supply services to technical information. Questions of a technical nature may be referred to the appropriate department personnel. Clients can consult directly with medical technologists, the laboratory medical director, and pathologists.

Problem Resolution Specialists

Problem resolution specialists are available at JMC to help clients with complex issues that require research and follow-up. Our specialists can assist clients with specimen location, shipments, troubleshooting, problem solving, test add-ons, specimen storage and retrieval, and quality control.

Message Center

The JMC Message Center ensures that all calls are answered by a personal representative. The Message Center is staffed Monday through Friday from 8:00 a.m. to 5:00 p.m. (561)743-5015. The Message Center operator can send reports, distribute messages to representatives, and transfer a client to a problem resolution specialist for critical calls.

Supply Orders

Collection tubes, forms and containers for the collection and transport of laboratory specimens to JMC are available to our clients as a part of our service. Contact a service representative to place orders; also you can fax or e-mail your requests.

Phone Numbers and Hours

Jupiter Medical Center Laboratory

Open 24 hours 365 days a year (561) 263-4430

Client Information Services (courier) direct line (561) 263-5015

JMC(MAIN NUMBER) (561)263-2234

SPECIAL COLLECTION INSTRUCTIONS

STOOL COLLECTIONS (24, 48, 72 HOUR)

Patient Preparation

Instruct the patient to eat a normal diet containing 50 to 150 g of fat per day for at least three days prior to beginning fecal collection. This diet should be maintained throughout the collection period. Ideally, no medications should be given immediately prior to and during the collection period. Exclude substances like castor oil and mineral oil from the diet.

URINE COLLECTION (24 HOUR)

Instructions to Collector

- 1. Give a collection container and detailed instructions to the patient. Record any medication that the patient is receiving on the test request form. Keep in mind that refrigeration and/or freezing is the most important part of specimen preservation.
- 2.If a urine preservative is required, the designated preservative may be put into the urine collection container prior to the start of the collection (obtained by request from JMC lab). The patient should be cautioned that the preservative may be toxic and caustic and that it should not be spilled or discarded. Alternatively, preservative may often be added by the laboratory after specimen collection, as long as the specimen has been refrigerated during collection and transport.
- 3. Make certain all lids are securely fasten.

Instructions to the Patient

- 1.Avoid alcoholic beverages and vitamins for at least 24 hours before specimen collection begins, and during the collection period. Do not discontinue medications unless instructed by your physician, but inform the laboratory which medications you are taking.
- 2.Do not exceed your normal intake of liquids or change your dietary habits during the day before and the day of your collection unless your physician gives you specific instructions to do otherwise.
- 3.On the day of collection, discard the first urine passed after arising (first morning void) and begin the collection after this time.
- 4.Collect <u>all</u> urine for the next 24 hours. The urine passed shortly after arising on the second morning is the final urine added to the collection.
- 5. Keep the urine refrigerated during collection and transport.
- 6. Preservative may have been added to the container. Please be careful not to spill any of the preservative, as it may be caustic and do not add urine directly to the container if it has preservative.

SENDING SAMPLES TO JMC

SPECIMEN TRANSPORT INSTRUCTIONS

Filling Out Test Requisition Forms & Labeling Specimens USE OF MANUAL TEST REQUISITION FORMS

- 1. Complete a separate Test Requisition Form for each patient, as outlined here.
- 2.Please use a black pen.
- 3. Fill in the patient I.D. and the lab test(s) to have them appear on the report.
- 4.Be sure to record the following:
- •Patient name, birthdate, sex, social security number, physician's signature, insurance information, and diagnosis(for each test).
- Collection date and time.
- •Type, temperature and collection duration of specimen submitted.
- •Source of specimen for microbiology analysis. or virology test(s), and other comments, in "Comments" box.
- 5.Mark box(es) [x] indicating the test(s) requested. If there is no box for a test you are requesting, write the **test number** and/or **test name** in the "Other" section.
- 6. Keep bottom copy of form for your records.
- 7. Write patient name, date, and time of collection *legibly* on specimen container.

Specimen Labeling Policy

To assure positive identification and optimum integrity of patient specimens from the time of collection until testing is completed and results reported, the client must label all specimens submitted to JMC for testing with the patient name, date of birth, date and time of collection, and collectors initials. Multiple samples from the same patient on the same day should also be labeled with the time of collection and pertinent information (ie trough, peak, pre, or post). Clients will be notified of inappropriately labeled specimens, and the specimen may be rejected for testing and returned to the client upon request.

Packing Specimen(s) For Transport USE OF MANUAL TEST REQUISITION FORMS

- 1. Place the specimen(s) in the ziplock portion of the specimen bag.
- 2.Fold completed requisition(s) in half, and place the form(s) in the outside sleeve of the specimen bag with patient name showing.
- 3. Mark the outside of the bag with the correct temperature for transport.

Caution: Be sure to tighten caps on tubes and cups and close bags securely.

Note: If submitting more than one specimen per patient, and specimens need to be stored and transported at different temperatures, use separate bags and Test Requisition Forms for each temperature type.

Specimen Containers

To ensure safe handling procedures, non-compromised specimens, and to provide quality patient care, including fast and accurate test results, we request that JMC clients use the following guidelines:

Acceptable containers (provided by JMC):

- •JMC Standardized Tubes
- Shipping containers(biohazard bags)
- •Sterile specimen containers
- Swabs
- •Transport media
- •O & P containers

Unacceptable containers/conditions:

The following will not be accepted by JMC because of safety and biological contamination issues and specific test requirements:

- •Glass tubes for frozen specimens
- •Leaking specimens that are not placed in a secured secondary container or leaking in such a way as to compromise testing
- Syringes with needles attached
- •Transfer tubes secured with parafilm or paraffin
- •Specimen not labeled or stored properly
- •Incorrect specimen type for test request

Minimum Acceptable Volumes

The JMC User's Guide defines minimum acceptable volumes. If there is insufficient volume for testing, attempts will be made to locate any additional sample at JMC which was collected at the same time or it should be recollected.

Diagnostic Specimens: Any human or animal material, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, *being sent for purposes of diagnosis*, but excluding live, infected animals.

Packing Requirements for Diagnostic Specimens

Specimens without specific information defining the specimen as infectious should be shipped as Diagnostic Specimens. Specimens must be kept from contact with each other. All specimens must be in leak-proof primary containers, and must be placed in leak-proof secondary containers. Couriers are not allowed to pick up specimens that are leaking or are not in secondary containers. All secondary plastic bags and tube racks must be marked as to correct holding and transport temperature. JMC Laboratories and couriers cannot be responsible for the handling of unmarked specimen bags.

JMC Specimen Transport Supplies

To reorder JMC supplies, call your Client Information Services Representative at (561) 263-4430. See section "Client Information Services and Consultants"

AMBER TUBE

The transport tube is also available in an amber color that is required for all light-sensitive tests. This tube has the same 5 mL capacity as the clear tube and must not be over filled. Covering specimen is sufficient also.

TEST STABILITY

Tests may have stability information listed for the convenience of the client. This information may be useful for determining if a sample already drawn on a patient is still appropriate for testing at JMC Laboratories.

The temperatures and times listed under stability do not indicate preferred transport conditions or temperatures. If a particular specimen fits the stability criteria for an assay, please refer to the transportation line on how to send the specimen to JMC Laboratories.

Contact our Client Information Services department for information regarding JMC's STAT policy, test menu and transport instructions.

REFERRAL TESTING

One of JMC Laboratory's service goals is to support clients by providing comprehensive service for all reference laboratory testing. To accomplish this goal, JMC has enhanced its in-house test menu of over 2,000 tests and test combinations by selecting primary vendors to perform additional tests not performed at JMC.

Primary vendors are selected based upon a corporate protocol that considers the aspects of service, quality, reliability, turnaround time, and price. The same criteria you want from JMC is what we expect from the labs we choose to serve you.

For JMC's established referral test vendors, test results are transmitted expediently to JMC, so you can receive your results by the fastest most error-free method possible. Due to JMC's relationship with these vendors, we prefer to send selected tests to these designated laboratories.

If a client requests that a test performed by JMC, or by one of our primary vendors, be performed by another laboratory, JMC will honor that request <u>if it is clearly indicated on the test requisition submitted at the time the test is ordered.</u>

For questions, please contact our Client Information Services at (561) 263-4430.

EXCEPTION HANDLING SPECIMEN REJECTION/TEST CANCELLATION

If a discrepancy is found with a specimen submission, it is forwarded to the Exception Handling department at JMC. These problems must be corrected before testing can be performed to ensure the best patient care possible. When a client receives a phone call from the Exception Handling department, it is very important that resolution be given as soon as possible to avoid any further result delays. Clients will be notified of specimen rejections and test cancellations as soon as possible. The Exception Handling department can be reached seven days a week from 7:30 a.m. to 6:30 p.m.EST. (561)263-4430.

Common reasons submissions go to Exception Handling and may result in specimen rejection and test cancellation include:

- 1. Samples shipped at an incorrect temperature.
- 2. Requisitions not filled out correctly; for example, testing not marked.
- 3. Paperwork received without a specimen.
- 4.Extra specimens received without an order for testing.
- 5. Specimens that have leaked in transit or are an insufficient volume for testing desired.
- 6.Inappropriate sample type sent for testing desired.
- 7.Name mismatch.
- 8. No identification on specimen.
- 9.No order or requisition for specimen received.
- 10.No source provided.
- 11. Specimen that has been sent in incorrect or expired transport media or tube.

To avoid delays and facilitate patient care on weekends, it is very important that JMC have a Saturday and Sunday client contact phone numbers. You can update your contact information through Client Information Services at (561)263-4430.

BILLING

BILLING PROCEDURES

General Billing

JMC Laboratory billing is concurrent with the generation of test results. Clients receive monthly itemized invoices for services.

Medicare/Medicaid/Third Party Billing

JMC bills and accepts assignment as payment in full from Medicare, Medicaid and selected third-party payors.

CREDIT AND COLLECTION PROCEDURES

All clients must complete a Customer Information Profile. JMC reserves the right to review credit reports from reporting agencies (Dunn & Bradstreet, TRW, etc.). All invoices are due in full upon receipt and must be paid within 30 days from the date billed. Any charges unpaid after 30 days are to be increased by 1.5% per month, both before and after judgment, and continuing each month until paid. Charges still outstanding after 90 days from invoice date are subject to collection, and all collection or arbitration expenses, attorney's fees, and court costs will be borne by the purchaser. All payments are payable in Jupiter, Florida, U.S.A. All claims, requests for adjustment, or notification of errors must be made within 30 days, or charges are considered accepted. No terms or conditions hereof may be changed except by written consent of JMC Laboratories. Please remit payment to Jupiter Medical Center Laboratory.

CLIENT BILLING SUMMARY

JMC clients may request a copy of their billing summary by calling (561)263-4430.

JMC TEST INFORMATION

GENERAL TEST INFORMATION

JMC provides comprehensive testing for more than 2,000 tests and test combinations. These tests are listed in the JMC User's Guide, which is available in print. Because laboratory medicine is a rapidly changing science, new test methods are frequently added and reference intervals and interpretive information may change as knowledge and experience increase. See JMC's web site at www.jupitermed.com for additional information, including an e-mail list of JMC staff, an introduction to JMC's executive staff and medical directors, JMC accreditation certificates from CAP and other agencies, and departmental information.

JMC is committed to remaining on the cutting-edge of automation, and will continue to identify new tests and processes that can be improved and directed to this purpose.

Our main priority is to remain flexible in order to meet the needs of our clients.

An appropriately completed JMC Laboratory's requisition or worksheet must accompany all specimens for laboratory testing.

JMC laboratory's requisitions can be customized to include testing based on the individual study or research project.

- •The patient's name, date of birth, and social security number or other unique identifier <u>must</u> be filled-in on the requisition.
- Each specimen <u>must</u> be labeled with the <u>exact</u> same patient name, and date of birth or other unique identifier.
- •The specific specimen information <u>must</u> be filled-in on the requisition, including date and time of collection.

Results are transmitted to clients in hard copy reports, as well as reports via fax.

For PFA use 21 gauge of larger needle, blood should be drawn directly into two light blue tubes, gentley invert the tubes 3 to 4 times. Discard the sample if there is a venous collapse or stoppage of blood flow during collection, hemolyzed samples can not be used. Do not chill or centrifuge the sample. Transport to lab, do not use lab tube system. Specimen is stable up to 4 hours at room temperature.

Note: Samples containing heparin should not be used for coagulation studies. If possible, stop heparin therapy before the draw to avoid contamination. Heparin interferes with most clotting assays.

C.Labeling

Microbiology and Virology specimens are not acceptable unless each specimen is appropriately labeled. The specimen must be identified by the patient name, collection date and time. If a separate label is used, the label must be affixed permanently to prevent loss of identity during transport. Labeling of slides for staining must not interfere with the staining process. Labeling of each individual slide submitted is required (labeling the outside slide container only is not acceptable), and should be performed on the same side of the slide inoculated with the specimen.

D.Requisitions

Microbiology and Virology specimens must be accompanied by a completed requisition slip and **the source of the specimen is required.** Information regarding the patient, collection time and date, clinical history, symptoms and diagnosis, antimicrobial therapy and any suspected organism(s) is essential for the optimal and appropriate processing of the specimen. If an organism is sent for identification, the suspected organism must also be indicated.

E.Transport

It is critical that all specimens are transported as quickly as possible. Prompt processing minimizes loss in viability of potential pathogens and insures a more accurate appraisal of the quantity of different flora present.

F.Result Reporting

Preliminary results are issued as soon as accurate data is available. Final results are generated at the completion of the culture. Preliminary results will be called to the physician or requesting lab (as indicated on the requisition slip) on any positive significant culture (e.g. blood, CSF, sterile body fluid and *Salmonella* or *Shigella* isolates) or stain. Other results will be called and faxed to the physician or requesting lab if, along with a telephone and fax number, it is indicated on the request slip. Results or interpretations of results may be obtained by calling the laboratory during the hours of operation or by calling JMC Client Information Services.

II. SPECIMEN - SPECIFIC COLLECTION GUIDELINES

The proper collection of a specimen for culture is the most important step in the recovery of pathogenic organisms responsible for infectious disease. A poorly collected specimen may lead to failure to isolate the causative organism(s) and result in the recovery and subsequent treatment of contaminating organisms.

A. Basic Concepts for Collection

- 1.Collect the specimen from the actual site of infection, avoiding contamination from adjacent tissues or secretions.
- 2.Collect the specimen at optimal times (for example, early morning sputum for AFB culture).
- 3. Collect a sufficient quantity of material.
- 4.Use appropriate collection devices: sterile, leak-proof specimen containers. Use appropriate transport media (i.e. anaerobe transport vials, aerobic transport vials, Viral transport media, genprobe media).
- 5. Whenever possible, collect specimens prior to administration of antibiotics or antivirals.
- 6.Properly label the specimen and complete the requisition slip. The source of specimen is required.
- 7. Minimize transport time. Maintain an appropriate environment between collection of specimens and delivery to the laboratory.
- 8. If appropriate, decontaminate the skin surface. Use 70-95% alcohol (ALC) and 1-2% tincture of iodine (TIO) to prepare the site. Allow a contact time of two minutes to maximize the antiseptic effect.

В.			
SPECIMEN	TESTS OR PROCEDURE	COLLECTION & SUBMISSION	SPECIAL COMMENTS
ABSCESS	A.Aerobic/Anaerobic Bacterial Culture and Gram stain B.Fungus Culture and Microscopic Examination C.Mycobacterial (AFB) Culture and Microscopic Examination	REQUIREMENTS A-C. Wipe the outer surface of the abscess with 70% alcohol followed with 2% tincture of iodine. Allow drying. If abscess is closed aspirate from the leading edge of the lesion with a sterile needle and syringe. If abscess is open aspirate the base of the lesion. Aspirate as much material as possible. Expel any air bubbles from the syringe and cap with a port protector. Discard needle in a sharps biohazard container. Transport and store ambient.	1)Do not sample surface pus or drainage. 2)If needle aspiration of the abscess is not possible, collect sample from the deep base of the lesion using Eswab. Collect one swab for each test request. Limitations should be noted and communicated to physician. 3)Unacceptable specimens: Any specimen received on formalin, fixative, or other preservative.
BIOPSY TISSUE	B.Fungus Culture and Microscopic Examination	A-D. Using aseptic technique transfer biopsy tissue to a sterile screw-cap container or tube. Add a few drops of sterile saline to prevent desiccation. Transport and store ambient. E. Tissue or tissue grindings for Viral Cultures ship cold (2-8°C) in viral transport media.	1)Tissue collection is an invasive procedure and/or requires surgery from a trained physician. 2)Include material form both the center and edge of the lesions. 3)Do not submit the specimen is formalin.
BONE MARROW	A. Aerobic/Anaerobic Bacterial Cutlure and Gram stain B. Fungus Culture and Microscopic Examination C. Mycobacterial (AFB) Culture and Microscopic Examination D. Viral Antigen Detection (PCR) E Pathology biopsy and clot in formalin and green top tube (Sodium Heparin) for Flow cytometry cytogenetics.	A-D. Prepare skin as for blood cultures. Drape the surrounding skin with sterile linen. Aspirate the marrow percutaneously using a sterile needle and syringe. Send bone marrow in capped syringe, Transport and store ambient. E) Refer to Reference Lab for send out procedure.	1)Do not submit syringe with needle attached. 2)Clotted specimens are not preferred but will be accepted. 3)Material submitted in formalin or any other preservative including anticoagulant reagents are not acceptable.
BLOOD Note: A total of 2-4 culture sets collected in a 24 hr period form separate venipuncture sites not less than 1/2-1 hour apart is generally recommended for optimal diagnostic evaluation. Note: For cases of acute sepsis in which antibiotics need to be administered ASAP, collect 2 sets of blood cultures 5 minutes apart from separate venipuncture sites	A. Aerobic/Anaerobic Bacterial Culture B.Mycobacteria (AFB) Culture C.Fungus Culture D.Legionella Culture and/or specialPathogens E.Leptospira Culture F. Viral Culture G. Viral PCR	A-C. Swab the top of blood culture bottle with a alcohol swab. Donot allow the alcohol to pool onthe top of blood culture bottles as it could as it could enter the system and kill organisms. A-G. Cleanse the skin on children >2 months old and adults using Cloraprep. Babies <2 months old use iodine prep pad. Apply a tourniquet proximal to the point of venous entry. The venipuncture site should not be palpated following disinfection unless sterile gloves are worn. Use a sterile needle and syringe or closed blood collection tubing system. Collect blood. The volume of blood collected is critical. Inoculate bottles without changing needles. Cleanse the iodine from the skin after collection.	bottle with 8-10 ml of blood. If less than 17 ml of blood is collected for 2 bottles, inoculate the aerobic bottle with 8 ml and the anaerobic bottle with the remainder.
BRONCHIAL BRUSHINGS	A.Gram Stain B.Fungus (KOH) C.Mycobacteria "AFB" Stain D. Smears in 95% alcohol for cytology.	A,C. Prepare a thin film of the specimen over a 1 cm square area of a clean glass slide. Prepare one slide for each stain procedure requested. Allow slide(s) to air-dry. B. Submit brush in saline. Use a sterile container and transport cold, 2-8°C	This technique is best performed by an experienced physician. Write patient name and specimen site on frostedend of slide. Submit slides in clean container, do not use cytofixative.

BRONCHIAL WASHINGS LAVAGE CATHETER TIP	& A.Aerobic Bacterial Culture and Gram stain. B.Fungus Culture and Microscopic Examination. C.Mycobacterial (AFB) Culture and Microscopic Examination D.Legionella Culture and DFA Microscopy E. Viral, Chlamydia, Mycoplasma Culture F. Cytology A.Aerobic Bacterial Culture	A.F. Collect as much material as possible in a sterile ET Suction Container. Store and transport cold, 2-8°C. C. For Acid Fast Cultures, a minimum of 5 ml is required. E. Transfer a portion of specimen to a Chlamydia/Viral Transport Medium tube. Store and transport cold (2-8°C) Disinfect the intravascular catheter insertion site	Bronchial washing and lavage specimens for anaerobic culture, are available by special request only. Urinary Foley catheter tips are
(INTRAVASCULAR CANNULAS)	B.Fungus Culture	with 70% alcohol followed with 2% TIO. Allow iodine to dry on skin. Withdraw catheter and snip off catheter tip above the site of skin contact using sterile scissors A-B. Submit clipped cannula in a sterile screw cap container	not accepted for culture.
CEREBROSPINAL FLUID (CSF)	A.Aerobic Bacterial Culture and Gram Stain B.Fungus Culture C.Cryptococcal Antigen Latex/India Ink D.Mycobacteria (AFB) Culture and stains E.Bacterial Antigen Profile F.Viral Culture/smears G. Cytology	A-G. Lumbar puncture: Prepare the needle puncture site as for blood cultures. The physician will aseptically perform percutaneous aspiration to obtain fluid. Insert a needle with stylet at the L3-L4,L4-L5 of L5-S1 interspace. When the subarachnoid space is reached, remove the stylet and spinal fluid will appear in the needle hub. Collect 3- 10 ml of CSF. Slowly drain the CSF into sterile leak-proof tubes. Generally, three tubes are required for Microbiology/Hematology/Chemistry. The second tube is optimal for Microbiology. It should be noted that, unless there is a traumatic tap, the most turbid tube should be sent to Microbiology. Brain abscess CSF: (90% of brain abscesses and their fluids will grow anaerobic bacteria) A physician aspirates material from the lesion and sends it to Microbiology utilizing the collection process noted above. If Bacterial Culture is to be performed, store and transport ambient. If not culture is ordered, store	This technique is best performed by an experienced physician. Delivered immediately without delay to laboratory and processed immediately within 1 hour of receipt
EAR	A.Aerobic Bacterial Culture B.Fungus Culture	Wipe the external Ear Canal with 70% alcohol and allow drying. A-B. For otitis Media carefully pass a minitip Eswab into the ear canal to sample drainage from eardrum. For Otitis external, vigorously swab the affected area. Submit one swab per test request. Store and transport ambient	Note: Ear cultures are processed as superficial wounds. If the diagnosis is Otitis Media, the specimen of choice is middle ear fluid collected by tympanocentesis. Collect according to current medial procedures.
EYE	A.Aerobic Bacterial Culture and Gram Stain B. Fungus Culture C. Viral/Chlamydia Culture	A-C. Conjunctivitis: Remove excess exudates from eye with sterile gauze. With a minitip culturette swab vigorously swab conjunctiva. Submit one swab per test request. Store and transport ambient. A-B. Keratitis: Obtain corneal scrapings with a sterile spatula. (This should be performed by an Ophthalmologist). Culture media (provided by Laboratory) should be inoculated at the patient's side. Store and transport immediately, ambient. A thin film of cellular material should be spread over a 1 cm square area on a clean microscope slide. Submit one smear for each test or procedure requested. Allow slides to air-dry (Do Not Fix) write patient name and specimen site on frosted-end of slide	Media for Keratitis (Aerobic Bacterial culture and Fungus culture) should include Chocolate agar, Sheep blood agar, Sab/Dex agar, and BHI Broth. C. Use Viral/Chlamydia transport media. Store and transport cold (2-8°C). A-C. Intraocular fluid: Collect fluid by surgical needle aspiration. Deliver immediately to Lab at ambient temperature or 2-8°C for Viral Cultures

FLUIDS: PLEURAL, PERITONEAL ,PERICARDIAL, SYNOVIAL (JOINT),SPINAL (SEE CSF)	A.Aerobic/Anaerobic Bacterial Culture and Gram stain B.Fungus Culture C.Mycobacteria (AFB) Culture and Microscopic Examination. D.Legionella Culture and Direct Immunofluorescence Microscopy. E.Viral Cultures and Stains F Cytology	A-F. Prepare the needle puncture site as for blood cultures. The physician will aseptically perform percutaneous aspiration to obtain fluids. Collect the fluid using a sterile needle and syringe. Expel any air bubbles from the syringe and slowly drain the fluid into sterile leak-proof tubs. Generally three tubes are required for Microbiology, Hematology and Chemistry testing. The second tube is optimal for Microbiology. It should be noted that the most turbid tube should be sent to Microbiology. Submit at least 10 ml of the specimen for analysis. Transport the specimen in a capped syringe if volume is low. Suggested volumes for Microbiology studies are as follows: 1. Routine culture – at least 2 ml 2. AFB culture – at least 1 ml 3. Fungal culture – at least 1 ml Transport and store ambient. D. Send 1 ml in sterile screw capped tube. Keep refrigerated. E. Transfer at least 1 ml of specimen to Chlamydia/Viral Transport Medium tube. Store and transport cold (2-8).	If tuberculosis or fungal infections are suspected, larger volumes may be required. This technique is best performed by an experienced physician. Unacceptable specimens: 1. Any specimen received in formalin, fixative or any other preservative. 2. Eswabs are acceptable only if the body fluid is not obtainable. Lab will accept the specimen, but limitations should be noted and communicated to the ordering physician.
GENITAL: ENDOMETRIUM, CULDOCENTESIS FLUID	A.Culture for Neisseria gonorrhea B.Culture for Chlamydia trachomatis C.Aerobic/Anaerobic Bacterial (includes G.C.) Culture and Gram Stain D.Culture for Mycoplasma – Ureaplasma E.Viral/Chlamydia Culture and Smears F.PCR for Chlamydia and Neisseria gonorrhea	A-F. Place the patient in the lithotomy position. Insert speculum and visualize the cervical os. Place a narrow-lumen catheter within the cervical os. Insert the tip of a Eswab through the catheter and collect the endometrial specimen. This method prevents touching cervical mucosa and reduces the chance for contamination A.Use routine Eswab and transport within several hours. Store and transport ambient. B.Use Viral/Chlamydia transport media. Store and transport cold (2-8°C) C.Submit Eswabs for culture requests. Submit aspirate when available. Store and transport ambient. D,E,F. Use Viral Transport Media. Store and transport cold (2-8°C)	
GENTIAL: CERVIX, VAGINAL	A. Culture for Neisseria gonorrhea B. Culture for S. aureus, and G. vaginalis C. Chlamydia trachomatis Direct Immunofluorescence microscopy and culture D. Culture for Mycoplasma – Ureaplasma E. Wet-Prep Microscopy for Trichomonas vaginalis, Candida spp. & Non-specific Vaginosis (Gardneralla) F. Viral Culture/Smears (Herpes Simplex) G. Chlamydia/ GC DNA probes H. Culture for Beta StrepGroup B.	Place the patient in the lithotomy Prepare the speculum, avoiding the sue of a lubricant other than warm water. Insert the speculum and visualize the cervical os. Remove excess mucous with a cotton ball. A-G. Insert a Dacron swab in the distal portion of the cervical os, rotate gently, and allow to remain for 10 to 30 seconds. Remove swab and place in transport sleeve. A-B. Store and transport ambient C-D. Use Viral/Chlamydia transport media. Store and transport cold (2-8°C). E. Place swab in a non-barrier white top tube filled with at last 3 ml of sterile saline. Send to the laboratory immediately at ambient temperature. F. Submit in Viral Transport Media. Store at transport cold (2-8°C) G. Use special female collection kit. Submit specimen in Genprobe transport tube. Store and transport (2-25°C) within 7 days of collection H. (Available to OB/GYN patients): Insert aerobic swab gently into vagina then rectum. Remove and place swab in transpot sleeve. Send to laboratory at ambient temperature.	Vaginal cultures, in general, do not produce meaningful results and are not recommended except for group B Streptococcal cultures and Staphylococcus aureus infection (Toxic Shock Syndrome). Beta Strep Group B culture should be collected from the vagina and rectum using the same swab.
GENTIAL: IUD	Aerobic/Anaerobic Bacterial Culture	Cut IUD into one of more segments using sterile scissors. Place one or more of the IUD segments in a sterile cup with screw cup lid. Transport ambient.	

GENITAL: PENIS, URETHRA	A.Culture for Neisseria gonorrhea B.Culture for Chlamydia trachomatis C.Culture for Mycoplasma/Ureaplasm a D.Culture for Haemophilus ducreyi E.Routine Culture and Gram Stain F. Chlamydia/GC DNA Probes	Urethral (Male) Swab Collection. 1. The patient must have urinated at least 1 hour prior to sampling. 2. If purulent discharge is present, collect discharge directly on Eswab. 3. If no discharge is present, insert a minitip Eswab 2-4 cm into the urethra. Rotate 3 to 5 seconds and withdraw A,E. Use routine minitip culture Eswab, transport within several hours. Store and transport ambient. B-C. Submit swab specimen in Viral/Chlamydia transport media. Store and transport cold (2-8°C) D. Submit minitip culture swab. Fluid aspirates may be sent in sterile tightly capped tube. Store and transport ambient. E. Prepare a thin film of urethral exudates on a clean glass slide. Allow to air dry (Do Not Fix). Write patient's name and specimen stie on frosted end of slide in pencil. Submit in slide mailer. F. Use special male collection kit. Submit specimen in Genprobe Transport tube. Store and transport (2-25°C) within 7 days of collection	
PINWORM		The specimen is collected from the skin of the perianal area first thing in the morning, before the patient has bathed or used the toilet. Place a strip of clear cellulose tape (adhesive side down) on a microscope slide as follows: Starting at 1.5 cm from one end, run the tape toward the same end , and wrap the tape around the slide to the opposite end. Tear the tape even with the end of the slide. Attach a label to the tape at the end torn flush with the slide. To obtain a sample from the perianal area peel back the tape by gripping the labeled end, and, with the tape looped (adhesive end outward) over a wooden tongue depressor that is held firmly against the slide and extended about 2.5 cm beyond it, press the tape firmly several times against the right and left perianal fold. Smooth the tape back on the slide, adhesive side	should be taken for at least 4 to 6 consecutive days with negative results before a patient is considered free of infection.
NASOPHARYNX	A.Aerobic Bacterial Culture B.Culture and Direct Immuno- fluorescence Microscopy for Bordetella pertusis C.Culture for Corynebacterium diphtheriae D.Fungus Culture E.Viral Culture and Smears F.RSV Antigen Detection	A,D.Submit one swab per test request. Store and transport ambient. B.Use two calcium alginate swabs in Modified Amies Charcoal Transport medium to collect the specimen. One swab is used to inoculate the transport medium.	Anterior nare cultures collected with a regular cotton swab, is an inappropriate specimen for anything other than assessment of staphylococcal or streptococcal colonization. B. Pertusis: Obtain swabs from Laboratory. Rayon or Cotton-Tipped swabs should be avoided since they contain fatty acids that are toxic to B. pertusis. C. Diptheriae: Both throat and nasopharyngeal specimens are required in cased of respiratory illness. If cutaneous diptheriae is suspected, collect skin, throat, and nasopharyngeal specimens.
RECTAL	Gonorrheal culture	Moisten a Eswab with sterile water and insert the swab into the anal canal just beyond the anal sphincter. Allow 10-30 seconds for absorption onto the swab. Withdraw swab gently and sent to Lab immediately. Store and transport ambient.	Stool is not an acceptable specimen for gonorrheal culture.

SPUTUM	A.Aerobic Bacterial Culture and Gram Stain B.Fungus Culture and Microscopic Examination C.Mycobacterial (AFB) Culture and Microscopic Examination D.Legionella Culture and Direct Immunofluoresence Microscopy E.Chlaymydia Mycoplasma or Viral Culture F. Cytology	A-F.First morning, deep cough sputum samples are preferred. Have patient rinse mouth and gargle twice with water. If patient wears dentures instruct patient to remove them prior to mouth rinse and collection of sputum. Instruct patient to cough deeply and expectorate sputum into a sterile screwcap container. Avoid collecting saliva and postnasal drainage. Specimen should be submitted to Laboratory immediately following collection. Refrigerate if delay in transport of more than 1-2 hours. E. Transfer a portion of sputum to a Chlamydia/Viral transport medium tube. Store and transport cold (2-8°C)	1.When a particular test is ordered X3 (e.g. AFB), submit one early morning specimen per day. 2. Pooled (24 hour) sputum specimens are not acceptable 3.Each sputum sample is evaluated microscopically. Specimens indicative of oropharyngeal secretions (e.g. saliva) will be rejected for culture. 4.For Acid Fast Cultures, a minimum of 5 ml is required.
STOOL	A.Routine Culture for Salmonella spp., Shigella spp., Aeromonas spp., and Campylobacter spp. B.Culture Yersinia spp. or Ecoli 0157- H7 C.Culture for Mycobacterium spp. (e.g. M. avium-intracellular) D.Ova and Parasites (OP) E.Cryptosporidium, Isospora, Cyclospora, Microsporidium F.Giardia Cryptosporidium Rapid Antigen G.Clostridium difficile DNA Amplification H.Viral Culture I.Rotavirus/Adenovirus Antigen	A-I. Collect specimen in a clean bedpan or use plastic wrap placed between the toilet seat and the bowl. Submit freshly passed stool in a clean, well sealed container and transport to Lab immediately. If a stool is unobtainable, a rectal swab inserted 1 inch into the anal canal is acceptable for routine culture only. D. Para-Pak Ecofix Preservative needed. F-I. Unpreserverd sample. Store and transport cold (2-8°C). G. Collect unformed stool indicative of C. difficile.	1. Do not submit stool contaminated with urine of toile water. 2. Stool Cultures: for optimal testing, submit 3 stool specimens, collected 1 per day 3. If patient is in-house for >3 days, reject specimens for O&P. Giardia and Cryptosporidium antigen will be performed. 4. O&P: performed if patient has been out of the USA in the last 2 weeks and/or is immunocompromised. 5. Giardia/Crypto-sporidium is the most common parasite in the USA, this immunoassay will be performed in place of the O&P unless patient meets above criteria. 6. Consider C. difficle testing if the patient has a history of antibiotic therapy. Do not order times three. 7. Only loose or diarrheal stools are recommended for routine bacterial cultures and C. difficile testing. No formed stools will be accepted for C. diff testing.
THROAT	B.Culture for Corynebacterium diphtheria	A-C.Carefully swab (culturette) the posterior pharynx, D.Use Viral transport media. Store and transport cold (2- 8°C) tonsillar fauces, and any ulcerations, exudates, lesions, or area of inflammation. Store and transport ambient.	

LIRINE	A Aerobic Bacterial Culture	Instructions for famala midstream collection. The	Straight catheter urine is useful
URINE	A.Aerobic Bacterial Culture B.Fungus Culture C.Mycobacteria (AFB) Culture D.Bacterial Antigen Profile E.Viral Culture (CMV) F.Leptospira Culture G.Legionella Antigen Assay H. Cytology	Instructions for female midstream collection: The person obtaining the specimen should wash hands with soap and water, rinse and dry. If the patient is collecting the specimen, she should be given detailed instructions, including diagrams. Clean the urethral opening and vaginal vestibule area with soapy water or a soap pad. Rinse the area well with sterile water or water soaked gauze pads. Hold labia apart while voiding. Allow a few millimeters of urine to pass. (Do not stop the flow of urine.) Collect the midstream portion of the urine in a sterile container. Instructions for male midstream collection: The person obtaining the specimen should wash hands with soap and water, rinse and dry. If the patient is collecting the specimen, he should be given detailed instructions, including diagrams. Cleanse the penis with soapy water, retract the foreskin (if not circumcised). Rinse the area well with sterile water. Collect the midstream	Straight catheter urine is useful when clean catch specimens cannot be obtained or when results from such specimens are equivocal and diagnosis is critical. Urine catheter tips are not acceptable for culture. Do not collect urine from drainage bag because growth of bacteria outside the catheter may have occurred at this side. Do not accept 24-hour urine collections. They are contaminated and dilute. Urines received in a sterile cup must be refrigerated immediately, for no longer than 24 hours before processing. If a BD Vacutainer
		portion of the urine in a sterile container. Straight catheter urine: Male and Female: Prior to catheterization, the patient should force fluids until the bladder is full. Clean the patient's urethral opening (and, in females, the vaginal vestibule) with soap and carefully cleanse with sterile technique pass a cather into the bladder. Collect an initial 15 to 30 ml of urine and discard. Collect a sample from the mid or latter flow of urine into a sterile container. Indwelling catheter urine: Male and Female: Clean the catheter with an alcohol pad. Aspirate at least 5 ml of urine and deliver directly to a sterile container or place a port protector on the syringe. Suprapubic urine: Urine specimens are acceptable for anaerobic culture. Male and Female: Before procedure, the patient should force fluids until the bladder is full. Shave and disinfect the suprapubic skin overlying the urine bladder.	containing a lyophilized urine maintenance formula is used to transport urine, it can be held are room temperature for 48 hours before processing (routine bacterial cultures only).
	URINE cont.	The physician will, by aseptic technique, make a small lance through the epidermis, just above the symphysis pubis. Aspirate urine, using a sterile needle and syringe, from the bladder. Aspirate at least 5 ml of urine and transfer to a sterile container or place a port protector on the syringe. Cytoscopy: Useful in determining the site of infection in the urinary tract. Male and Female: The patient should force fluids until the bladder is full. Clean the patient's urethral opening (and, in females, the vaginal vestibule) with soap and carefully cleanse with sterile water. Insert a cystoscope into the bladder. Using sterile technique, collect 5-10 ml of urine into a sterile container. A-G. Collect and submit urine in a sterile, tightly sealed, screw cap container. A volume of 2-10 ml is sufficient for any of the tests listed except for Mycobacterial culture. For AFB culture a first morning-voided sample of 50-100 ml is required. Transport specimens to the laboratory within 2 hours of collection. If the specimen cannot be transported immediately, the specimen should be refrigerated. (2-8°C)	

BULLAE, CELLULITIS, VESICLES (CLOSED WOUNDS	A.Aerobic Bacterial Culture and Gram Stain B.Aerobic/Anaerobic Bacterial Culture and Gram Stain C.Fungus Culture D.Mycobacteria (AFB) Culture and Microscopic Examination E.Viral Cultures and Stains	A-E.Cleanse the skin as for blood cultures. Aspirate the fluid/purulent material using a sterile needle and syringe. If an aspirate is obtained, send the syringe capped with a port protector.If no material is obtained, unroof vesicle or bullous lesion and use a swab to collect cells from the base of the lesion. Send aspirate or aerobic/anaerobic swabs to the laboratory immediately. Submit one swab per test or procedure requested. A-D.Transport and store ambient E.Use Viral Transport Media. Store and transport cold (2-8°C)	Cellulitis: Eswab and leading edge aspirates fail to yield etiologic agents in the majority of patients. If an unusal organism is suspected, a leading edge punch biopsy is the recommended specimen of choice. Eswabs are acceptable only if body fluid or tissue is not obtainable. Lab will accept the specimen, but limitations should be noted and communicated to the ordering physician.
WOUND (OPEN)	A.Aerobic Bacterial Culture and Gram Stain B.Aerobic/Anaerobic Bacterial Culture and Gram Stain C.Fungus Culture D.Mycobacteria (AFB) Cutlure and Microscopic Examination E.Viral Cultures and Stains	Wipe the surface of the wound with 70% alcohol to remove excess debris and colonizing flora. Allow to air dry. Pass the culturette swab as far as possible into the wound, being careful to avoid touching skin surface. Vigorously swab the base of the wound. Place swab in culturette transport tube. A,B. Culturette swab. Submit one swab per test or procedure requested. Store and transport ambient B.Anaerobic transport tube. Submit one swab per test or procedure requested. Store and transport ambient. C,D. Aerobic or anaerobic swabs are acceptable only if body fluid or tissue is not obtainable. Lab will accept the specimen, but limitations should be noted and communicated to the ordering physician. Submit one swab per test or procedure requested. Store and transport ambient. E.Use Viral Transport Media. Store and transport cold (2-8°C)	Do not submit cultures of superficial lesions for anaerobic culture. Biopsy of advancing margin of wound is preferred specimen for the following: anaerobes, fungi and mycobacteria. Immediately deliver to laboratory for processing

C. Bordetella pertussis Culture and DFA

- 1.Use two calcium alginate swabs on a flexible wire handle to collect the specimen. One swab is used to inoculate the transport medium. The other swab is used to prepare the smears. (Must call lab in advance for media).
- 2. Seat the patient comfortably. Tilt the head back.
- 3.If available, insert a nasal speculum. Press the swab through the nares until resistance is met due to contact with the nasopharynx.
- 4.Rotate the swab gently and allow the swab to maintain contact with the nasopharynx for 20-30 seconds or until coughing is induced.
- 5.Place the swabs into the transport medium.Gently roll second swab onto two microscope slides.Label the tube and slides with the patient's name and identification number. Leave the swab embedded in the tube during transport. Transport the specimens at ambient temperature.

D.Buffy Coat (virus only)

- 1.Cleanse the skin as for blood cultures.
- 2.Collect blood in a 5 mL EDTA (purple top) tube. Use the pediatric size (approximately 3 mL) only when absolutely necessary. Do not use pediatric tubes to collect from adults or children over 2 years of age.
- 3.Invert tubes several times after specimen collection.
- 4. Cleanse the iodine from the skin after collection of the specimen.

NOTE: Send specimens to the laboratory immediately. Do not refrigerate or attempt to separate the buffy coat from the whole blood sample.

E.Cutaneous (fungus only)

1.Hair

a.Scrape the scalp with a blunt scalpel.

b.Place specimen in a dry sterile container.

c.Send to the laboratory at ambient temperature.

d. The following specimens are also acceptable:

i.Hair stubs,

ii.Contents of plugged follicles,

iii.Skin scales,

iv. Hair plucked from the scalp with forceps.

e.Cut hair is not an acceptable specimen.

2.Nails

a.Cleanse the nail with 70-95% ALC.

b.Remove the outermost layer by scraping with a scalpel.

c.Place specimen in a dry, sterile container.

d.Send to the laboratory at ambient temperature.

e.The following specimens are also acceptable:

i.Clippings from any discolored or brittle parts of

ii.Deeper scrapings and debris under the edges of

the nail.

3.Skin

a.Cleanse the skin with 70 - 95% ALC.

b.Collect epidermal scales with a scalpel, at the active border of the lesion.

c.Place specimen in a dry sterile container.

d.Send to the laboratory at ambient temperature.

F.Nose

- 1.Collect anterior nares culture with a regular cotton swab. In small children, use a nasopharyngeal swab to facilitate collection.
- 2. Send the specimen to the laboratory at ambient temperature.

Note: This is an inappropriate specimen for anything other than assessment of staphylococcal or streptococcal colonization.

G.Prostate

- 1. Obtain prostate fluid by digital massage through the rectum.
- 2. Collect the specimen in a sterile container and send directly to the lab at ambient temperature

VIRAL TRANSPORT MEDIA (M4)

Some samples can be submitted without utilizing a transport media with a reasonable expectation of virus viability. Specimens in this category include, "sterile" fluids such as cerebrospinal fluid, pleural fluid, blood submitted in EDTA, urine, as well as some non-sterile specimens such as nasopharyngeal washings, sputum, bronchoalveolar lavage, and feces. Whenever there is a question of stability the specimen should be placed in a suitable virus transport media such as M4. Refer to a specific test in the alphabetical section of this Users Guide for more information.

CMV Antigenemia testing (includes CMV by PCR) – Collect 5 ml Blood (EDTA) or 1 ml Bone Marrow (EDTA). Transport in sealed biohazard bag to the lab within 2 hours of collection. Samples that exceed the time frame for optimal test sensitivity, or those samples with low cellularity will be rejected. If possible the specimen will be recollected. If it is not possible to recollect the specimen, a comment will be attached to the result noting the potential reduction in test reliability due to inappropriate sample storage and/or delay in processing.

- 1. **Tissue and biopsy material** can be placed directly into the M4 media. Each sample need not be more than 1-2 cm in diameter.
- 2. Abscess material, bullae, pustules, vesicles, lesions, skin scrapings can be collected on the swab and placed directly into M4. If the material has been aspirated, place no more than 3 mLs (equal to the amount of transport media) in the vial of M4.
- 3.CSF should be submitted in a sterile container. Do not add CSF to the M4 tube.
- 4. Urine should be submitted in a sterile container or no more than 3 mLs added to the M4 tube.
- 5. Bronchoalveolar washings, nasopharyngeal washings, sputums, and other sterile body fluids can be submitted in sterile containers or no more than 3 mLs placed in the M4 tube.
- 6.**Stool** should be submitted in a sterile container, or a small aliquot the size of a walnut can be placed in the M4 tube.
- 7.**Blood** should be submitted in an EDTA tube.

Viral transport media (M4) criteria is the same for other liquid viral transport media such as those available from Bartels, Syva, etc. labeled for viral/chlamydia transport. Swabs that are made of calcium aliginate are known to interfere with the recovery of some viruses. This can also act as a PCR inhibitor and is not appropriate for this type of testing.

STORAGE AND TRANSPORT:

Specimens should be delivered to the laboratory promptly, ideally within 2 hours of specimen collection, but at least within 1 day of collection. Specimens should be refrigerated within 1 hour of collection.

PATHOLOGY TESTING SERVICES

INTRODUCTION

The Histology and Pathology Department at Jupiter Medical Center provide routine and frozen section diagnostic pathology services and special stains as need as per protocol for all tissue specimens including bone marrows. Special studies which are not performed in-house are transported to a qualified reference laboratory selected by Jupiter Medical Center Laboratory (ie. Flow cytometry, DNA, chromosome, and genetic studies)

CONSULTATION SERVICES

Consultation services are available in many anatomic pathology specialties. Requests for consultation may be referred to the Pathology Department at (561)263-4487.

ROUTINE AP SERVICES

Routine surgical pathology slide preparation and special stains are available with or without consultation. Specimens must be submitted in 10% Neutral Buffered Formalin. Specimen containers must be securely tightened to eliminate leakage, and must display the OSHA required FORMALDEHYDE cautionary information.

CYTOLOGY

GENERAL INFORMATION

The Cytology Laboratory accessed to JMC provides routine screening and diagnostic cytology services for non-gynecologic, pulmonary (including bronchoalveolar lavage), gastrointestinal, body cavity fluid, cerebrospinal fluid, urologic, fine needle aspiration and ophthalmologic cytology. Special studies, including flow cytometry, immunocytochemical studies, and electron microscopy are forwarded to a qualified laboratory selected by Jupiter Medical Laboratory.

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CYTOLOGY REQUISITION

A JMC Cytology Requisition should be completed for all non-gynecological specimens. Include the following information on the request form for accurate specimen preparation, interpretation, result reporting, record keeping and billing. Exclusion of any of the following information may result in specimen rejection and/or processing delays.

- 1.Patient's complete name, other client specific unique patient identification numbers, date of birth and sex.
- 2.Date specimen collected.
- 3. Specimen type: Check the space next to the specimen type (e.g., cervical vaginal smear, gastric brush, bronchial wash, etc.).
- 4. Complete patient history:
- 5. Name of the physician: Clearly state the name of the physician and how that individual may be contacted if additional information is required or results need to be reported by phone.
- 6.Complete the patient billing information (or attach copy). The appropriate ICD-9 code (for medical necessity) and guarantor information are required as well as physician signature.

Cytology Order Form

Please contact Client Information Services for additional Cytology Order Forms at 561-263-4430.

SPECIMEN REJECTION

Specimens to which the following conditions apply will be rejected and returned to the originating site.

- 1. Specimen is submitted without a requisition.
- 2. Specimen is not labeled with the patient name.
- 3. The patient name (or other identifying information) on the specimen and requisition do not correspond.
- 4. The specimen is labeled appropriately but the requisition is not labeled.
- 5. The specimen slide(s) is (are) irreparably broken.
- 6. Specimen is submitted from an unauthorized source.

RESULT REPORTING

<u>Non-gynecologic Specimens</u> Results for non-gynecologic specimens will be available within 48 hours following receipt within the laboratory unless additional studies are required.

Pulmonary Specimens

The adequacy of a sputum specimen is determined primarily by the presence of alveolar macrophages indicating that the specimen obtained is a deep cough specimen producing material from the lower airways. In addition, the specimen should not be obscured by oral or upper airway contaminants. Adequate bronchial brushing and washing specimens should contain large numbers of well-preserved bronchial lining cells with as little contaminating oral and upper airway material as possible. Bronchoalveolar lavage specimens should contain abundant well-preserved alveolar macrophages with as little contaminating upper airway material as possible.

Sputum

Indications: For the detection and characterization of premalignant/malignant pulmonary lesions. Specimen Required: 5 mL (about one teaspoon) or more if possible, of sputum obtained from a deep cough specimen.

Supplies: 120 mL clean plastic specimen container.

Collection Procedure: When clinically feasible, sputum specimens should be obtained as follows. The optimum time for specimen collection is within 15 to 30 minutes after waking and before eating breakfast. Brushing of teeth or rinsing of the mouth thoroughly with water will reduce contamination by saliva. Instruct the patient to inhale and exhale deeply, forcing air from the lungs using the diaphragm. Repeat until the patient coughs and is able to produce a sputum specimen. Collect the specimen in the container, attempting to obtain at least one teaspoon of sputum. Specimen should be a deep cough specimen and not saliva. Saliva is of no diagnostic value.

Transport to the lab immediately. Greater diagnostic yield may be obtained if specimens are submitted on three to five successive mornings. Label the container with correct patient information and submit the specimen, along with the completed cytology request form, to Jupiter Medical Center Laboratory.

Note: If a good specimen is not obtainable by this method, or if the patient is unable to comply, obtain an induced sputum or tracheal aspirate.

Post-Bronchoscopy Sputum

Collect <u>one</u> good, deep cough specimen at any time during the 24-hour period following bronchoscopy, as outlined above. Submit the specimen to the Laboratory, along with the completed cytology request form.

Bronchial Brushings

Indications: For the detection and characterization of bronchoscopically visible premalignant/ malignant pulmonary lesions; for the identification of some microbiologic pathogens (primarily viral and fungal). Specimen Required: Bronchoscopically-directed brushing of the identified lesion.

Supplies:Standard bronchoscopy equipment. One (or more if necessary) 5 to 10 mL sterile container, slides should be placed in 95% ethyl alcohol container.

Collection Precedure: Using standard bronchoscopy technique, identify the lesion in question and obtain a brushing sample of the lesion. Upon withdrawing the brush, agitate the brush vigorously in a 5 to 10 mL vial of sterile saline. If possible, detach the brush and leave it in the vial. If physician makes slides place immediately into 95% alcohol. Label the vial with correct patient information and submit the specimen along with the completed cytology request form to the Laboratory.

Bronchial Washings

Indications: For the detection and characterization of bronchoscopically ill-defined or invisible premalignant/malignant pulmonary lesions; for the identification of some microbiologic pathogens (primarily viral or *Pneumocystis carinii*).

Specimen Required: Bronchoscopically-obtained washing (preferably at least 10 mL) of the bronchi in the region of the suspected lesion.

Supplies: Standard bronchoscopy equipment. 120 mL clean plastic specimen container(s).

Collection Procedure: Using standard bronchoscopy technique, lavage the distribution of the bronchus to be sampled. Collect the wash in a clean container. Label the container with correct patient information and submit the specimen, along with the completed cytology request form to the lab.

Bronchoalveolar Lavage

Indications: For the detection and characterization of microbiologic pathogens (primarily *Pneumocystis carinii*, viral, fungal and bacterial) in immunocompromised patients; for detection and characterization of malignancy.

Specimen Required: Bronchoscopically-obtained lavage (preferably at least 20 mL) of the distal airways and alveoli in the distribution of the suspected lesion.

Supplies: Standard bronchoscopy equipment. 120 mL clean plastic specimen containers.

Collection Procedure: Using standard bronchoscopy BAL technique, lavage the lung distribution in question with normal saline (or other physiologic solution). Collect the lavage specimen in a clean specimen container. Label the container with the correct patient information and submit the specimen, along with the completed cytology request form, to the Laboratory.

Note: For the interpretation of BAL specimens, relevant clinical information must be provided. The primary diagnosis of *P. carinii* is made on Pap stained material. GMS stains, performed on all BAL specimens, are used as confirmatory tests only.

Gastrointestinal Specimens

The adequacy of a gastrointestinal specimen is determined primarily by the presence of well-preserved epithelial cells indicative of the type of epithelium present at the gastrointestinal site sampled. All GI specimens will tend to deteriorate rapidly due to enzymatic activity which is present throughout much of the GI tract. In addition, these specimens are easily contaminated by epithelia from sites proximal to that being sampled.

General Information for all Gastrointestinal Specimens

As all GI specimens will rapidly deteriorate in the fresh state bring to laboratory immediately.

Brushings (Esophageal, GI Junction, Gastric, Duodenal, Bile Duct, Other)

Indications: For detection and characterization of endoscopically visible gastrointestinal lesions; for the identification of some microbiologic pathogens (primarily Herpes, CMV and Candida).

Specimen Required: Endoscopically-directed brushing sample of the identified lesion.

Supplies:Standard endoscopy equipment. One (or more if necessary) 5 to 10 mL vial or tube of sterile normal saline.

Collection Procedure: Instruct the patient to fast overnight or for a minimum of six hours prior to the procedure. Using standard endoscopy technique, identify the lesion in question and obtain a brushing sample of the lesion.

Note: It is important to brush the edges of an ulcer, as well as the floor, in order to obtain diagnostic material.

Upon withdrawing the brush, agitate the brush vigorously in a 5 to 10 mL vial of saline. If possible, detach the brush and leave it in the vial. If slides are made place immediately into 95% alcohol. Label the vial with correct patient information and submit the specimen along with the completed cytology request form to the Cytology Laboratory.

Washings (Esophageal, Gastric, Other)

Indications: For detection and characterization of endoscopically ill-defined or invisible gastrointestinal lesions; for the identification of some microbiologic pathogens (primarily Herpes, CMV, and Candida). Specimen Endoscopically obtained washing (preferably at least 10 mL) of the region of the suspected lesion.

Supplies: Standard endoscopy equipment. 120 mL clean plastic specimen container(s).

Collection Procedure: Instruct the patient to fast overnight or for a minimum of six hours prior to the procedure. Using standard endoscopy technique, lavage the area of interest using a physiologic solution. Aspirate the solution and place in a clean specimen container. Label the container with the correct patient information and submit the specimen and the completed cytology request form to the Lab.

Bile Drainage

Indications: For the detection of malignant cells arising within the hepatobiliary system.

Specimen 10 mL or more of collected bile drainage.

Supplies: Standard transcutaneous or endoscopic biliary drainage equipment. Clean plastic specimen container of an appropriate size.

Collection Procedure: Using appropriate sterile technique collect as much bile drainage through the drainage apparatus as possible, into a clean plastic specimen container. Label the container with the correct patient information and submit the specimen and the completed cytology request form to the Laboratory.

Note: Bile specimens will degenerate very rapidly due to enzymatic activity and bile salts. Therefore, a 24-hour bile collection is not suitable for cytologic evaluation.

Body Cavity Fluid Specimens

Body cavity fluids are commonly evaluated for the presence of malignant cells from metastatic disease. Body cavity fluids in general are relatively easy to obtain and are relatively difficult to compromise. However, in some instances, due to a large number of inflammatory cells, specimens may degenerate rapidly. In addition, if large amounts of protein are present, the specimen may clot, trapping diagnostic cells within the clot.

Collection of Body Cavity Fluids

Indications: Detection and characterization of malignant cells in body cavity fluids.

Specimen 10 mL (or more) of fluid obtained from an appropriately performed paracentesis.

Supplies: Standard paracentesis equipment. Clean collection container of appropriate size.

Collection Procedure: Using standard paracentesis technique, obtain a fluid specimen from the desired body cavity. If necessary, move the patient into multiple positions to suspend cellular material in the fluid. A minimum of 10 mL of specimen is desirable for optimal cytologic evaluation. If other studies are required, withdraw a fraction of the specimen and submit it to the appropriate laboratory separately, following their guidelines for specimen collection. Heparin may be added to the specimen to reduce clotting, use a heparinized tube for collection. Rinse the paracentesis instrument with a small amount of heparin to prevent clotting of specimen before it is put into the collection container. Add specimen to the heparinized container. Gently agitate to thoroughly mix the specimen and heparin. Submit the specimen to the Laboratory along with the completed cytology request form.

CSF Specimens / Vitreous Fluid

In cytology, cerebrospinal and vitreous fluids are most commonly evaluated to detect and characterize malignancy which may have gained access to the central nervous system or the eye, respectively. While in most individuals CSF specimens are relatively easy to obtain, in some individuals collection may require radiographic guidance. Vitreous fluid specimens require special collection procedures under the direction of an ophthalmologist. In addition, due to lack of nutrients in most of these fluids, cells may rapidly degenerate rendering morphologic evaluation less than optimal if adequate care is not taken.

Collection of Cerebrospinal/Vitreous Fluids

Indications: Detection and characterization of malignant cells in the central nervous system or eye. Specimen Required: Minimum of 3 mL cerebrospinal fluid. For vitreous fluids, there is no minimum amount but collect as much as possible. (10 mL CSF minimum required for immunologic marker studies.) Supplies:Standard cerebrospinal fluid collection equipment or standard vitreous aspiration equipment. Clean, clear 10 mL collection container for CSF. Standard vitreous aspirate collection container for vitreous fluid.

Collection Procedure: Using standard CSF or vitreous collection procedures, collect 3 mL of CSF or an appropriate amount of viteous fluid. In general, morphology of cells within the CSF or vitreous fluid can be adequately maintained with prompt refrigeration for 24 hours. Fresh specimen is required. Submit the specimen to the laboratory along with the completed cytology request form.

Note: Specimens submitted for immunocytochemical testing must be submitted fresh. If necessary, on-call personnel can be utilized during the evenings or on weekends for processing of urgent specimens or those which need to be processed rapidly to avoid degeneration.

Urologic Specimens

Urine is commonly evaluated cytologically for the presence of malignant cells in the detection of urologic malignancies. Urine may also be evaluated cytologically in the detection and characterization of some renal diseases. Method of specimen collection as well as time of collection will affect the cytologic evaluation in many instances.

Voided/Catheterized Urine

Indications: Detection and characterization of malignant cells and other urologic abnormalities in symptomatic (usually hematuria) patients; screening for malignancy in selected individuals at high risk for the development of urologic malignancy; detection and characterization of some non-neoplastic renal diseases in symptomatic (usually hematuria) patients.

Specimen Required: 50 mL of an appropriately-collected voided or catheterized urine specimen. Supplies:Clean collection container of appropriate size. Standard catheterization equipment (for catheterized urine).

Collection Procedure: For purposes of obtaining the greatest yield of diagnostic material, a second morning voided urine specimen should be obtained, if possible. A midstream, clean-catch specimen is recommend to avoid vaginal contamination in female patients. A midstream specimen, not necessarily clean catch, is recommend for male patients. If the patient must be catheterized to obtain the specimen, this should be noted on the specimen requisition as catheterization can lead to artifacts which may be misinterpreted without the knowledge that the specimen was catheterized. Submit the specimen to the Laboratory along with the completed cytology request form indicating whether specimen is voided or catheterized.

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Other Urologic Specimens

Indications: Detection of suspected malignancy utilizing lavage specimens obtained cystoscopically (bladder washing, ureteral washing); staging of urologic malignancies.

Specimen Requied: 10 mL (or more) of an appropriately-collected, cystoscopically-derived specimen.

Supplies: Standard cystoscopy equipment. Clean collection container of appropriate size.

Collection Procedure: Using standard cystoscopy technique, obtain washing specimens, carefully denoting specific specimen sites for each specimen on the requisition. Submit the specimen fresh to the Laboratory along with the completed cytology request form.

Fine Needle Aspiration Specimens

Fine needle aspiration of mass lesions is commonly utilized in the detection and characterization of a variety of malignant diseases. Obtaining an adequate specimen requires attention to good aspiration technique as well as to processing of material obtained. It is highly desirable that several direct smears be prepared (preferably air-dried) for all fine needle aspiration specimens submitted to the laboratory.

Collection of FNA Specimens

Indications: To determine benignity or malignancy of mass lesions, and to characterize the type of malignancy or benign disease, which are present.

Specimen Required: Adequate cellular material for cytologic evaluation obtained from an appropriately performed fine needle aspiration. This will depend on the specimen site and character of the lesion being aspirated. In general, this requires that there be enough material for the examiner to at least determine that the aspirating needle sampled a mass lesion.

Supplies: 3, 5, 10 or 20 mL syringe. Syringe pistol (optional). 22 to 25 gauge needle of appropriate length. Single-end frosted glass slides (for preparation of direct smears). 95% alcohol is 95% ethyl alcohol. Collection Procedure: Please note that the following collection procedure is a suggested guideline. Aspiration techiques vary widely based on personal preferences, and specific clinical circumstances must be taken into account when deciding on the method of aspiration utilized.

Breast Nipple Secretions

Indications: Detection of malignant cells in nipple discharge specimens.

Specimen Direct smear of nipple discharge.

Supplies: Two clean glass slides (single-end frosted), 95% ethanol, request form.

Collection Procedure: Label the two slides with the patient name. Collect a small amount of nipple secretion directly onto one of the slides. Oppose a second glass slide onto the first, allowing the collected material to provide surface tension between the two slides, and then gently and quickly pull the two slides apart in a horizontal motion to distribute the material in a thin film over both slides. The smears should be placed immediately into 95% ethyl alcohol to prevent air-drying. Submit the specimen and the completed request form to the Laboratory.

Conjunctival Scrapings

Indications: Detection and characterization of inflammatory/infectious processes of the conjunctiva. Specimen Required: Direct smear of material collected from the conjunctival surface.

Supplies:Two clean glass slides (fully frosted), 95% ethyl alcohol, conjunctival scraping spatula, request form.

Collection Procedure:Label the slides with the patient's name and place in a container filled with 95% alcohol so that the slides are completely covered. Gently scrape the area of abnormality. Remove one of the slides from the 95% alcohol. Quickly and evenly smear the collected material on one of the glass slides. Immediately re-immerse the slide in 95% alcohol. Repeat the process with the second slide, if necessary, for better diagnostic yield. Submit the specimen and the completed request form to the Laboratory.

Oral Scrapings

Indications: Detection and characterization of malignancy and infectious processes in the oral cavity.

Specimen Required: Direct smear of material collected from the oral mucosa.

Supplies: Two (or more) clean glass slides (fully frosted), 95% alcohol, oral scraping spatula, request form.

Collection Procedure: Label the slides with the patient's name and place in a container filled with 95% alcohol so that the slides are completely covered. Gently scrape the area of abnormality. Remove one of the slides from the 95% alcohol. Quickly and evenly smear the collected material on one of the glass slides. Immediately re-immerse the slide in 95% alcohol. Repeat the process with the second slide if necessary for better diagnostic yield. Repeat the process for additional areas if necessary. Submit the specimen and the completed request form to the Laboratory.

Skin Scrapings / Smear

Indications: Detection and characterization of inflammatory/infectious processes of the skin, especially herpetic infections.

Specimen Required:Direct smear of material collected from a skin lesion, usually a vesicle. Supplies: Two (or more) clean glass slides (fully frosted), 95% alcohol, skin scraping spatula, request form.

Collection Procedure: Label the slides with the patient's name and place in a container filled with 95% alcohol so the slides are completely covered. Gently scrape the area of abnormality. If the abnormality is a vesicle, remove the covering and scrape both at the base of the vesicle and around the rim. Remove one of the slides from the 95%alcohol. Quickly and evenly smear the collected material on one of the glass slides. Immediately re-immerse the slide in 95%alcohol. Repeat the process with the second slide, if necessary, for better diagnostic yield. Repeat the process for additional areas if necessary. Submit the specimen and the completed request form to the Laboratory.

ROUTINE VAGINAL SMEAR - 1 OR MORE SLIDES

Indications: Evaluation of inflammatory/infectious or benign proliferative conditions; screening of unsuspected or confirmation of suspected atypia, premalignant, or malignant changes; follow-up of patients with known and/or treated premalignant or malignant lesions (can be used in conjunction with routine cervical/endocervical smears in individuals with a uterus, or alone in hysterectomized patients).

Specimen Required: Lateral vaginal wall smear or smear of sample from a clinically concerning area.

Supplies: Vaginal speculum, one or more wooden cervical spatulas, 95% ethyl alcohol, one or more clean glass slides (single-end frosted), black lab pencil, request form, spatulas, slides, 95% alcohol, and cardboard slide folders may be obtained from customer service, (561-263-4430). Collection Procedure: If only a routine lateral vaginal wall sample will be obtained, label one slide with the patient name. If vaginal sample will be obtained in conjunction with a cervical and endocervical component, make sure that the slides are also appropriately labeled according to site. If smears from separate vaginal areas are also to be obtained, label the sites accordingly as to specific site (e.g., left lateral vaginal wall, posterior vaginal wall, etc.). Obtain specimens prior to bimanual evaluation. Use an unlubricated speculum (saline or warm water may be used). Scrape the desired region of the vaginal mucosa with the spatula. Withdraw the spatula and spread the material quickly and evenly onto the glass slide (if cervical/endocervical smears are also obtained, or smears from other areas of the vagina are obtained, make certain that each smear is performed on the correspondingly labeled slide). Fix immediately (drop slide into 95% alcohol.) Scrape additional areas of the vagina that appear abnormal and spread and fix as above. Complete the cytology request form, including relevant history. Submit the specimen to the Cytopathology Laboratory.

Tests Available

8209701	Body Cavity Fluid	8100200	Pap Slide
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8209700	Breast Nipple Secretion	8100211	ThinPrep [®] Pap Test
8280000	Bronchoalveolar Lavage 1	8200200	Bladder Tumor Associated
			Antigen™
8280005	Bronchoalveolar Lavage 2	8209702	Pulmonary
8209713	Conjunctival Scraping	8209703	Cerebrospinal Fluid
8209706	Fine Needle Aspirate	8209704	Urologic
8209709	Gastrointestinal	8209712	Skin Scraping
8209710	Oral Scraping	8209715	Vitreous Fluid