Centrex Clinical Laboratories, Inc.
28 Campion Road
New Hartford, New York 13413
(315) 624-5900

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General Disclaimer

Every effort is made to maintain the accuracy of information included in this publication. Occasionally modifications are made to new procedures, obsolete procedures, turn around times, patient service center hours, etc., that may not be reflected in this edition of the Directory of Service Manual.

This new edition of the Directory of Services contains numerous modification, updates, and revisions. In the interest of full CPT disclosure, the CPT codes are consistent with the 2010 edition of *Current Procedural Terminology,* a publication of the American Medical Association (AMA)

Medicare Compliance – Medical Necessity

The Medicare program in the United States is administered by the Centers for Medicare and Medicaid Services (CMS); formerly known as (HCFA). In order to comply with services reimbursed by Medicare, medical necessity regulations have been implemented in the Centrex Clinical Laboratories, Inc., billing procedures. HCFA has required medical necessity documentation associated with laboratory testing services. These documentation requirements are referred to as local medical review policies (LMRP) or limited coverage tests.

Medicare requires ICD-9 diagnosis codes on all laboratory orders in order to pay for services deemed medically necessary. Most physicians currently use ICD-9 codes to diagnose patient conditions. It is essential that this practice be included when ordering laboratory tests and that the same diagnosis is being evaluated. The diagnosis code in the patient's medical record must match the diagnosis code provided to the laboratory for services on the same date.

Advanced Beneficiary Notice (ABN)

Orders without a valid ICD-9 code may not be paid by Medicare or third party payers, therefore patients will be asked to sign a waiver of liability. This waiver verifies that payment responsibility will be met by the patient in the event it is not an approved/covered service by Medicare. The ABN provided to the patient will include the name of the laboratory test, the reason payment may be denied, and describes the patient's payment responsibilities. A patient has the right to refuse to sign the ABN, however, specimens will not be collected.

Compliance

Federal regulations require physicians to provide certain information to laboratories prior to any diagnostic testing which indicates the medical reason why the tests are being ordered. In order to comply with all state, federal and local laws, Centrex Clinical Laboratories, Inc., requires all laboratory requisitions to have an authorized physician's signature, ICD-9 code and a signed ABN (if necessary) to perform laboratory testing. Requisitions will be reviewed at the time of service at each patient collection center for required information prior to any specimen collection.

Mission Statement

"The mission of Centrex Clinical Laboratories, inc., is to provide a full spectrum of diagnostic and patient status information for physicians, hospitals, and other qualified individuals, thus benefiting patients and improving the health care of the communities we serve."

We shall accomplish this by utilizing the following standards:

1. Establish a culture of corporate compliance.
2. Comply with all laws and regulations governing the laboratory industry.
3. Provide high-quality health care to all physicians.
4. Pursue excellence in the performance of all work.
5. Operate in a safe manner.
6. Provide quality care at reasonable fees.

Facilities

Centrex Clinical Laboratories, Inc., Corporate Office is located at 28 Campion Road, New Hartford, NY. The corporate office includes Administration, Human Resources, Accounts Payable, Billing, Information Technology, Supplies, Special Testing Services, and Transportation. Parking and the entrance are located at the back of the building.

Centrex Clinical Laboratories, Inc.'s core laboratory is located on the St. Luke's Campus of Faxton-St. Luke's Healthcare, 1656 Champlin Avenue, Utica, NY. The first floor of the Professional Office Building is the location for the Chemistry, Hematology, Special Chemistry, Immunology, Microbiology and Blood Bank services. Pathology and Cytology are on the ground floor of the hospital. This site performs laboratory services for the hospital in which it is located as well as routine and esoteric testing for clients throughout the Centrex service area.

The Faxton- St. Luke's Healthcare Laboratory at 1676 Sunset Avenue, Utica, NY provides essential services at the Faxton campus. The laboratory is located in the first floor of the hospital adjacent to the cafeteria.

Patient Service Centers

New Hartford/Utica Area

- 95 Genesee Street, New Hartford 315-797-6896
- 37 Main Street, Whitesboro 315-768-6115
- 1656 Champlin Avenue, Utica 315-797-0790
- 1904 Genesee Street, Utica 315-797-1082

Syracuse/Rome Area

- 4989 Brittonfield Parkway, East Syracuse 315-434-9821
- 604 Seneca Street, Oneida 315-361-1334
- 1614 North James Street, Rome 315-339-6019
- 91 Perimeter Road, Rome 315-339-2989

Valley/North Country/South Central

- 201 East State Street, Herkimer 315-717-0167
- 175 West Main Street, Little Falls 315-508-5027
- 7980 State Route 12, Barneveld 315-896-4226
- Town Of Web Professional Building, Old Forge 315-369-2402
- 161 Clinton Street, Suite 106, Watertown 315-788-2833

Hours of operation vary at each site. Please call the center for hours or directions.

Telephone Extensions

Area Code 315

Corporate Office **28 Campion Rd**	**800-753-8653** **624-5900**	**Central Laboratory** **1656 Champlin Ave**	**800-562-1550** **797-0790**
Fax Number	624-0500	Fax Number	797-1884
Department	**Extension**	**Department**	**Extension**
Administration	5918	Operator	8221
Billing	5979	Clinical Office/Results	8224
Drug Testing	5924	Cytology	8260
		Patient Service Center	8247
Information Technology	5922	Technical Support	8237, 8232, 8254
Supplies	5917	Pathology	8244
Sales	5940	Pathology Fax	624-8206
Transportation	5903	Reference Testing	8287, 8289, 8280
House Call Department	792-8090		
Faxton Laboratory **1676 Sunset Ave**	**624-5261**	**Syracuse Office** **4939 Brittonfield Pkwy**	**800-564-8882** **434-9821**
Fax Number	797-3696	Fax Number	434-9825
Department		**Department**	**Extension**
Clinical Office	624-5261	Clinical Office/Results	5981
		Transportation	5983
		Housecalls	5984

Departmental Services

Materials Management –(315) 624-5917 Fax (315) 797-2780

Ordering supplies – Complete the "Request for Supplies" order form (found in the forms section of this directory). Include the account name and address. Fax the request to (315) 797-2780. Follow up with a call to the Materials Management Department at (315) 624-5917 to confirm receipt of your request.

Orders will be filled and delivered within four days of receipt of your request. If your order cannot be filled for any reason, you will be notified within three days. Centrex will maintain an internal tracking for the ordering and delivery of supplies. Supply orders that exceed monthly specimen submissions will be flagged and investigated by Centrex.

Due to the limited shelf life of many specimen-collection supplies, a regular review of supplies is encouraged. Never use outdated collection supplies. Since quality assurance variations have been traced to specimen-collection lot numbers, Centrex recommends documenting the date implemented for each new lot number of collection supplies. Only supplies necessary for the collection, transportation, and performance of testing at Centrex Clinical Laboratories, Inc., can be provided.

Materials Management Compliance Information

Federal and State Laws and Regulations allow Centrex Clinical Laboratories, Inc., to provide supplies to clients solely for the purpose of collecting, transporting and processing laboratory specimens at Centrex laboratory sites. The United Stated Department of Health and Human Services Office of Inspector General (OIG) interprets this to include only those supplies which have little, if any, independent value to clients. Centrex Clinical Laboratories, Inc., is also limited by law to providing supplies only in those amounts that are reasonable and necessary to accomplish collection, transport and processing. Violation of the federal anti-kickback law and physician self-referral ("Stark") law (released January 4, 2001) could result if these restrictions are not adhered to.

In addition, the Centers for Medicare and Medicaid Services (CMS) (formerly known as HCFA), specifically stated that laboratories may provide items such as vials, specimen cups, and single use needles and may not provide biopsy needles, reusable aspiration and injection needles, or other supplies that are reusable or have independent value to laboratory clients.

Centrex Clinical Laboratories, Inc., is committed to conducting business in full compliance with state and federal laws and as part of our compliance program we will be communicating our policy on the provision of supplies. Centrex will not provide any item that is reusable or has a clear and independent value to a client or for which the client is in any fashion reimbursed.

Centrex Clinical Laboratories, Inc., is confident that you share our desire to fully comply with the intent of the federal regulations and we will continue to provide our clients with excellent service.

Transportation –(315) 624-5903

Specimen Pick-up Procedure – Centrex Route Service Couriers will come to your facility prepared to properly package the specimens for transport to the laboratory to maintain specimen integrity for any frozen specimen. The courier will also ensure integrity of room-temperature and refrigerated specimens by properly packaging the specimens for transportation to the laboratory. Whenever possible, lock boxes will be provided for after-hour pick-ups.

Centrex Route Service Couriers perform Double Check – a customer service program that improves the quality and efficiency of laboratory testing and services for all Centrex customers. The benefits of this program include: reduced follow-up calls to your office, adheres to medical necessity regulations, provides better billing services to patients, and enhances client/patient satisfaction. Couriers review the laboratory requisitions for accuracy, completeness, and compliance at your office. Specimen labeling is also checked. Occasionally, the courier will ask your staff for additional information or clarification regarding mislabeled specimens, patient demographics or missing diagnosis codes or for an authorized signature.

STAT testing pick-up arrangements can also be requested by calling the Transportation Department at (315) 624-5903.

Results Reporting –(315) 624- 8224.

Reporting/Requesting Results – Centrex will provide timely, accurate laboratory test results in a concise format while maintaining patient confidentiality. Reports can be provided in a variety of ways, including courier delivery, remote printer, fax machine, or web-enabled automated processing system.

Outpatient physician's requests for the phoning of test results will be honored. In addition, STATs, corrected reports, critical and panic values will be phoned to the appropriate physician. (See Panic Values in Section 5).

After-hour panics, critical and STAT results will be called to the on-call physician. If the on-call physician does not call back within an appropriate length of time, it will be necessary to initiate a second call.

When a physician asks not to be called after a certain time of day, regardless of the test result, a signed written statement must be provided to the laboratory. The statement will be valid for one year.

Inpatient panics, critical, and STAT results will be called to the nursing personnel on the patient unit.

Laboratory results are available twenty-four hours a day, seven days a week by calling (315) 797-0790.

Technical Support –(315) 624- 8237

Laboratory Technology Assistance – The Centrex Technical Support Department is a vital key to our customer service success. The staff includes Medical Technologists who have been working in the laboratory industry for years and will provide your office with the latest information involving laboratory technology, quality reporting, and problem solving. Call Technical Support for information on: Turn-around-times, result ranges, new tests, specimen requirements, and add-on testing.

Laboratory Claims Billing –(315) 624-5979

In-house billing - is performed by the Centrex Billing Representatives with an extensive background/experience in medical billing, claim review, CPT4 and ICD-9 coding skills. Centrex is one of the largest participating providers in our industry. We submit laboratory claims directly to the insurance carriers below.

Participating Insurance Carriers

AARP
Acordia National
Aetna Life and Casualty
APA Association Plan Administrators
CDPHP
Champus/Tricare
Cigna
Compensation Claims
Empire BC/BS
Empire Plan
Excellus
Fidelis
GHI
Great West
Guardian
HealthNow
John Hancock Mutual Life Insurance
Mailhandlers
Medicaid
Medicare
MVP
No Fault Auto Insurance
POMCO
Principal Mutual Life Insurance
RMSCO
Unicare Life and Health
United Health Care
Univera/PHP
Veteran's Administration

* We also submit to many Medicare Managed Care

Test Ordering and Processing

Laboratory Requisitions

Ordering tests – Clearly mark each test you wish to order on the laboratory requisition. Tests that you would like performed that are not pre-printed on the requisition should be clearly indicated by writing the complete test name. Please make sure that any special instructions (eg, fax results, call doctor, copy results to) are clearly indicated in the appropriate area of the requisition.

Patient Identification - Legibly print the following information on all Centrex Test requisitions: Name of Patient, Date of Birth, Sex, Social Security Number, Collection Date and Time, and the Ordering Physician. Accurate specimen identification is in the best interest of the patient and you, our client. Laboratory regulations and good laboratory practice require proper identification of all specimens.

Patient Information - Centrex will send a bill to the patient or to the patient's insurance company provided it is a participating provider. The following information must be included on the requisition for billing purposes: Subscriber/Insured Person's name, address, telephone number, relationship to the insured, patient social security number, insurance company name, insurance identification number/policy/group number, ordering physician's signature, and the ICD-9 codes for all tests ordered for the date of service.

Advanced Beneficiary Notice (ABN) – The Medicare Advanced Beneficiary Notice should be signed by the patient with the knowledge that the patient agrees to be responsible for payment of the tests indicated does not meet Medicare Medical Necessity Regulations.

Specimen Review – Prior to packaging for transport to the lab, the specimens and test requisition should be reviewed for accuracy. The patient information must be identical to the specimen label. Check specimens for proper sample preparation, temperature, adequate volume, and lack of hemolysis or lipemia (see page 9).

Add-On Testing – Additional tests may be ordered through Centrex's Technical Support Department as long as the specimen is available and specimen integrity has not been compromised. Written authorization from the ordering physician and diagnosis codes are required for all add-on testing.

HIV Testing – The following information must be provided on the requisition for proper identification and release of confidential HIV reports: Date and time specimen was collected, Patient name in full (No numerical identifiers), Sex, Date of Birth, Ethnic Race, County, State, and Zip Code of patient, Diagnostic or Prognostic test requested, and billing information.

Lead Testing – New York State requires the following information to process specimens for Lead Testing: Date and time of specimen collection, Ethnic Race, Initial or Repeat testing, Source of Sample (fingerstick or venous), Patient Name, Sex, Date of Birth, Patient's full address, Ordering physician's signature and ICD-9 code for all Medicaid Patients.

Ordering physician's signature and ICD-9 codes are required for all Medicaid Patients.

Specimen Integrity

Factors That Compromise Specimens/Assays

Hemolysis – Hemolysis occurs when the erythrocytes are ruptured and release their contents into the serum or plasma. Visibly the hemolyzed serum or plasma will be light pink to bright red. Hemolysis, even in small amounts, may alter test results markedly, particularly potassium and LDH. Grossly or moderately hemolyzed specimens may be rejected.

Causes of Hemolysis may be – a small needle used to collect specimen, difficult phlebotomy draw, placing red top tubes in the refrigerator without allowing 30 minutes at room temperature for complete clotting, vigorously shaking specimen, or storage in a refrigerator that is too cold.

Quantity Not Sufficient – Each assay requires a minimum amount of specimen to perform accurate testing. You will be contacted if the minimum volume requirement is not received.

Lipemia – Excessive lipids in the blood produce a cloudy or milky specimen. Moderately to grossly lipemic specimens may invalidate many test results. Lipemic specimens may be the result of a recent meal prior to the blood collection.

Hyperbilirubinemia – Icteric serum or plasma will appear dark to bright yellow. Icterus may affect some results. To insure quality we may suggest that another specimen be collected for analysis.

Identification of Specimens – Crucial to the quality process, specimens must have proper identification on both the requisition and the accompanying specimen(s). Name, date and time of collection, date of birth, and sex are imperative to insure that the correct normal range is reported. Specimens arriving at the laboratory unlabeled or mislabeled may be rejected. If a significant disparity is noted between the name on the requisition and the name on the tube, the specimen may also be rejected. All specimens must be labeled with patient's first and last name, date and time of collection, initials of person collecting the specimen. In addition - One of the following unique identifiers must be included on the specimen label and requisition (date of birth OR Social Security Number OR Medical Record Number).

Specimen Rejection – Specimens received in expired collection or transport tubes will be rejected. To provide the highest quality lab results with the least possible inconvenience for your patients, Centrex Clinical Laboratories has a Specimen Rejection Policy. Specimens may be rejected if they are mislabeled or unlabeled, or if the specimen integrity is such that the specimen will not provide accurate results for the particular test ordered. For example, marked hemolysis may impact the potassium level, but the specimen may still be acceptable for other tests not affected by hemolysis. In this case, a markedly hemolyzed sample would be rejected and recollected if potassium is ordered. In every case, Centrex personnel shall review all specimens received in an effort to complete testing on acceptable samples that may already be in the laboratory.

To comply with New York State Department of Health and CLIA guidelines, if testing is performed on a suboptimal specimen at your request, the laboratory report will clearly indicate this as well as the type of specimen integrity issue identified. For example: the specimen submitted does not meet the laboratory's criteria for acceptability, specimen hemolyzed, Testing from sub-optimal specimen performed at client request.

Mislabeled/Unlabeled Specimens - In cases where a specimen is mislabeled, we have identified two categories of discrepancies: minor and major. For minor discrepancies, our staff will contact you for verbal confirmation of the correct name. An example of this might be a specimen labeled *Johnny Smith* sent with a requisition labeled *John Smith*.

For major discrepancies and specimens which are unlabeled, the specimens shall be rejected and the specimens recollected.

If the physician or authorized designee requires the test to be performed on this mislabeled or unlabeled specimen, a Specimen ID Confirmation form must be completed and faxed to our laboratory.

In these cases, the lab results report will state:

Sample received unlabeled or with a name discrepancy.

The Physician/Clinician or authorized designee has authorized the release of results.

The Physician/Clinician or authorized designee agrees to assume responsibility for sample identification.

Specimen Preparation Guidelines – Special Instructions

Centrifuge Procedure

Blood specimens drawn for serum must be properly centrifuged. Faulty test results may occur if this is not performed properly.

Therefore, the following procedure is to be adhered to strictly:

1. After filling the SST tube with blood, gently invert 5-6 times. This process allows the blood to mix with the clot activators found in the gel layer.
2. Allow the SST tube to clot in an upright position for a minimum of 30 minutes to insure adequate clotting, but no longer than 2 hours.
3. If using a fixed angle centrifuge, i.e., an Octafuge, spin the tube for 15 minutes; decreasing the time may result in poor barrier formation, allowing red cells to migrate into the serum. The horizontal, swing bucket, type of centrifuges, i.e., the TJ6, are to be spun for 10 minutes, again, decreasing the time will result in poor barrier formation.
4. If the serum needs to be re-centrifuged, i.e., because there is fibrin, the serum is to be transferred to another test tube. Do NOT Re-spin an SST tube.

When using plastic collection tubes remember to use a plastic tube as a balance when centrifuging.

Transport Bag

Specimens must be transported in specimen transport bags to the laboratory. Clear specimen bags should be used for routine specimens, red bags for STATs.

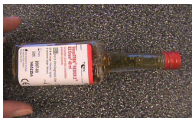
Specimen bags have two pockets - The front pocket is for the completed test requisition and the back pocket is for the specimens. Place the "Laboratory Copy" of the test requisition in the pocket of the transport bag so that the patient information is viewable. Place the specimens in the second pocket of the bag and seal. A test requisition is required.

Temperature Requirements - If specimen is frozen place a "Frozen Specimen" label on the bag. If specimens should be left at room temperature please place "Do Not Refrigerate" label on the bag. If specimen is to be transported on ice, place labeled specimen on ice in the specimen bag – **DO NOT** use "Frozen Specimen" labels on transport on ice specimens.

Blood Collection Tubes Order of Draw

The following "**Order of Draw**", is the approved order as established by NCCLS
Blood cultures ALWAYS need to be drawn first, when ordered, to maintain the aseptic field that is needed.

- Each colored stopper has specific uses in the Laboratory. Following the order of draw is necessary to insure the integrity of each specimen. Carry-over from an additive tube can affect results.
- Gently invert all tubes 5-6 times after filling.

	**Blood Culture:** - **(BCC**) Use one aerobic (purple top) and one anaerobic (red top) culture bottle.
	**Aerobic and Anaerobic Blood Cultures or Yellow Tube SPS:** **Note:** Yellow top (SPS) tubes can be used in place of aerobic/anaerobic blood culture bottles.
	**Light Blue Stopper (plasma): (BLU)** Contains sodium citrate as anticoagulant.
	**Red Stopper (serum): (RED, RRE)** No Additives. Usually used for Chemistry and Reference Lab
	**SST or Gold Stopper (serum): (SST, RST, SXT)**
	**Green Stopper (plasma): (GLI, GNR)** Contains **lithium heparin** **Light Green tube: (PST)** Plasma separator tube. Contains **lithium heparin**.
	**Green Stopper (plasma): (RGR)** Contains **Sodium heparin**. Used for DNA studies.
	**Tan Top Tube: (TAN)** Reference testing.
	**Lavender stopper (plasma): (LAV, PUR, RLV. RLA)** Contains K2EDTA.
	**Pink Top Tube: (PRP)** Used for ABO-RH, Antibody Screen, Type and Screen.
	**Pearl or White Top Tube: (RPT, RWT)** Contains K2EDTA with gel. Molecular testing, PCR Amplification
	**Gray Stopper (plasma): (G1T, GFT, GRY)** Used for Reference testing, Blood Drug Testing, Glucose Tolerance Test.
	**Yellow Tube ACD: Solution A and B: (YLW)** Reference testing. HLA Tissue Typing, Paternity, DNA studies
	**Royal Blue (plasma or serum): (NVY)** Reference testing. Used for Aluminum, Heavy metals, RBC Minerals testing.

Centrex Clinical Laboratories, Inc.
Microbiology Collection and Transport Devices

Urines for Culture and Routine Outpatient Urinalysis

Boritex Container

- Collect specimens in a sterile container, via the clean catch method.
- Transfer the urine to the Boritex container, being sure to fill to the line marked on the container (approximately 20 ml.).
- Specimens transported in the Boritex container remain viable for testing for 48 hours from the time of collection.

If 10 ml of specimen cannot be obtained, please send in a sterile cup.

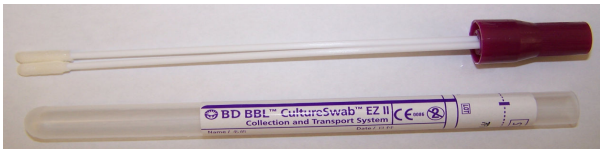
Culture only short specimens—a BD Vacutainer (gray top) urine tube may be used. It must be filled to the minimum line on the tube (4ml.)

All Aerobic and Anaerobic Cultures and MRSA PCR

- Peel back plastic packaging
- Remove and discard cap from tube
- Collect specimen with swab
- Insert the swab in the collection tube

NOTE: Single swab device may be used if Stat Gram Stain is NOT ordered

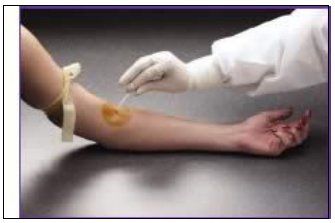
Throat or Strep A Antigens



- Peel back plastic packaging
- Pull out the swab
- Collect the sample
- Return the swab to the collection tube
- Can also use double swab liquid Stuart's

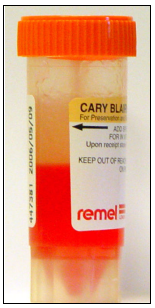
NOTE: Strep A Antigen can NOT be performed from Amies Gel Swabs

Blood Culture Collection



- Use one aerobic (purple top) and one anaerobic (red top) blood culture bottle.
- Cleanse surface of rubber stoppers with 70% alcohol followed by surface sterilization with chloraprep.
- Sterilize patient's venipuncture site by crushing chloraprep ampule and apply in a circular motion.
- View the blood entering the bottle and fill until the blood flow slows to a drip.
- **Do not put more than 5ml into each bottle**
- Effect patient hemostatis and remove any residual blood from rubber top of bottles

Stool Culture with Shiga Toxin or Stool for Lacto Ferrin



- Open the vial(s) carefully.
- Using the collection spoon attached to the cap, add enough specimen until the liquid reaches the ARROW on the label.
- Fill only one vial at a time and replace the cap onto the same vial.
- DO NOT mix caps.
- ***If you are using an empty vial, fill to one-half full with stool specimen.***

IMPORTANT: Collect areas of the stool which appear bloody, mucoid, or watery. If the stool is hard, sample from each end and the middle of the specimen.

Giardia/Crypto Antigen or Concentrated Microscopic O&P

- Collect stool using the collection spoons provided in the cap of the container.
- Sufficient stool is added to each container to bring the liquid level up to the "fill here" line.
- Agitate each specimen with the spoon along the sides of the container
- Tighten the cap and shake firmly to insure that the specimen is adequately mixed.
- When mixing is complete, the specimen should appear homogenous.

Stool for C-diff Toxin

- Collect the stool specimen in a wide mouth container, bedpan, or on a clean newspaper or plastic bag placed over the toilet seat opening. **(C-diff testing can only be performed on unpreserved stool samples)**
- **DO NOT** pass the specimen into the toilet or directly into the collection container. Specimens can not be mixed with urine or water. Secure the cap tightly on the container.

Pinworm

- Hold the paddle by the cap and remove it from the tube
- Separate the buttocks
- Press the tacky surface against several areas of the perianal region.
- Replace the paddle in the tube for transport to the lab.

Viral Transport

Specimens must be transported Cold to the Lab

- Collect specimen as early as possible following the onset of symptoms
- Aseptically remove cap from vial
- Insert swab into medium
- Break swab shaft evenly at the second line
- Replace cap to vial and close tightly

All specimens must be labeled with:

- The patient's first and last name
- Date and time of collection
- Date of birth (or social security number or medical record number)
- The initials of the person collecting the specimen (if other than patient)

Specimens must be submitted with the physician's laboratory order slip.

If at any time you have questions regarding the collection or transport procedures please contact the Microbiology Department at 624-8226 or the Technical Support Department at 624-8237.

Laboratory Postings and Patient Collection Instructions

Fecal Fat Collection Instructions

1. Place the white container in the toilet so that the straight end is facing forward
2. As you sit, align yourself so that your stool goes into the container. **Please note**: **urine cannot** be mixed with the stool at anytime.
3. Specimen should be kept cool throughout collection period to reduce production of gas in the container. After each bowel movement seal container with both the steel can top and white plastic seal for the rim.
4. When all collections are complete, seal can properly and submit can in a large plastic bag.
5. Specimen should be submitted to the lab on the day of your last collection.

White Plastic Container

Fecal Fat Container

STOOL OCCULT BLOOD

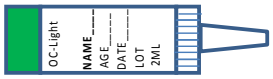
Patient Instruction Sheet

Sample Deposit

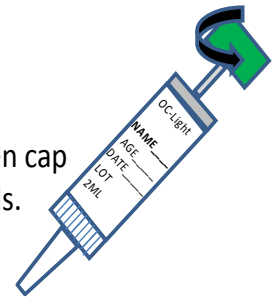
1. Place supplied collection paper inside toilet bowl on top of water
2. Deposit stool sample on top of collection paper.
3. Collect sample from stool before paper sinks and stool sample touches water.
4. Flush. Collection paper is biodegradable and will not harm septic systems.

Sample Collection

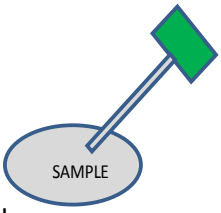
1. Fill in all required information on the sampling bottle.



2. Unscrew green cap and pull upwards.

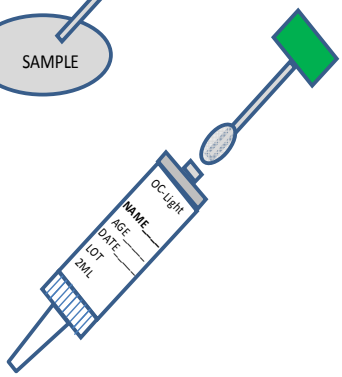


3. Scrape the surface of the fecal sample with the sample probe.

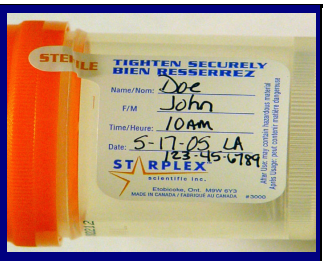


4. Cover the grooved portion of the sample probe completely with stool sample.

5. Close sampling bottle by inserting the sample probe and screwing cap on tightly to the right. Do not reopen.



6. Return the sample device to your doctor or laboratory.



Sterile Collection Container

Stool Specimen Collection Instructions

Read entire instructions carefully before beginning stool collection.

The collection kit consists of one, two or three different vials. The vials may or may not have liquid in them. **DO NOT drink**. **Keep out of reach of children and pets.**

Collect the stool specimen in a wide mouth container, bedpan, or on a clean newspaper or plastic bag placed over the toilet seat opening. DO NOT pass the specimen into the toilet or directly into the collection container. DO NOT mix urine or water with the sample.

Secure the cap tightly on the container. Label the specimen with patient name, date and time of collection, and return to the laboratory with the physician's laboratory order slip.

Transport the sample to Centrex Clinical Laboratories, Inc., located at the St. Luke's Campus Professional Office Building, 1656 Champlin Avenue, Utica, New York within 2 hours of collection.

If the stool sample cannot be transported to the clinical laboratory within 2 hours of collection, collect the sample in the Cary Blair container and follow the instructions below.

Cary Blair Collection Vial

Cary Blair Collection Instructions:

Open the vial(s) carefully. Using the collection spoon attached to the cap, add enough specimen until the liquid reaches the ARROW on the label. Fill only one vial at a time and replace the cap onto the same vial. DO NOT mix caps.

If you are using an empty vial, fill to one-half full with stool specimen.

IMPORTANT: Collect areas of the stool which appear bloody, slim, or watery. If the stool is hard, sample from each end and the middle of the specimen.

Label the specimen with patient name, date and time of collection, and return to the laboratory with the physician's laboratory order slip.

Stool samples should be brought to the laboratory as soon as possible after collection but no longer than 24 hours.

If at any time you have questions regarding the collection or transport procedures please contact Centrex Clinical Laboratories, Inc., at 315-797-0790.

Centrex Clinical Laboratories, Inc.
Working to give you *Results*

28 Campion Road
New Hartford, NY 13413

Seminal Fluid Collection

1. Patient must abstain from sexual intercourse for four to seven days.
2. Collection of fluid must be made without the use of a contraceptive.
3. Collection of fluid should be made directly into a clean container.
4. Fluid should be delivered to the laboratory within one hour of collection. Please note time of collection on the specimen container.
5. Collection must be kept warm (near body temperature).
6. If semen analysis and culture is requested, a sterile container must be used and may be obtained from the laboratory.
7. Centrex Clinical Laboratories, Inc., will perform this testing daily, Monday through Friday from 8 am to 12 noon ONLY. Deliver your specimen at these times only.
8. All specimens are to be delivered directly to the laboratory located at the Professional Office Building, 1656 Champlin Avenue at St. Luke's Hospital.
9. A physician's order must accompany the specimen when submitted to the laboratory. If the specimen is for a post-vasectomy screen, this must be indicated on the order.
10. Please inform the clerk if you have insurance and present your card. Billing information will be requested at that time.
11. If any additional information is needed, please call the laboratory at (315)-797-0790.

Urine, Clean Catch Collection

Please read the following instructions carefully before starting the collection

1. In the bathroom, wash and dry your hands and prepare the materials you will need. This includes the sterile container and towelette provided by the laboratory.
2. Remove the cover from the container without touching the inside of the cap.
3. Open the first towelette and use it to cleanse the urinary entrance and the area around it thoroughly. Women must wipe from front to back.
4. Throw away the first towelette and repeat the cleaning with the second one. Discard this towelette also.
5. Holding the open container in one hand, start to urinate into the toilet.
6. After the flow of urine has been established and without letting the container touch the genital area, put the container into the flow of urine and fill it at least half full.
7. Replace the cap and close the container tightly without touching the side.
8. Wipe the outside of the container with a paper towel and give the specimen to the technician.
9. If you collect the specimen at home, refrigerate it and bring it to the laboratory as soon as possible after collection during regular office hours.
10. Please be sure the patient's name, date and time of collection, and date of birth are written on the container.

Urine, 24-Hour Collection

Many chemical analyses performed on urine specimens require 24-hour urine collections. This 24-hour collection eliminates the variability of urine analyte peak excretion times, which exhibit diurnal variation, and allows for standard units for reporting results (ie., units/24 hours).

Collection of the specimen according to this protocol requires the cooperation of the patient and the laboratory staff.

1. At the beginning of the collection period the patient should empty the bladder and discard this specimen, and the time and date should be noted on the requisition slip.

2. For the next 24 hours, the patient collects all urine in a clean container and transfers it to the collection jug.

3. The patient makes the final collection 24 hours after the initial starting time and notes the time and date.

4. If possible, all 24-hour collection bottles should be refrigerated during collection. It is the responsibility of the clinical chemistry laboratory to assure that the proper preservative is added.

5. Label the specimen with patient name, date and time of collection, and return to the laboratory with the physician's laboratory order slip.

6. Transport the container to Centrex Clinical Laboratories, Inc., located at the St. Luke's Campus Professional Office Building, 1656 Champlin Avenue, Utica, New York

NOTE: Some procedures may require the collection of specimens for time intervals other than 24 hours, eg., 2 hours or 12 hours. For those cases, the above procedure for collecting the specimen should be followed for the time interval specified for the ordered test.

Clinical & Microbiology Specimen Collection Procedures

Fungal Specimen Collection

Skin Scrapings

1. Cleanse the affected area with 70% alcohol using a gauze pad (NOT cotton balls).
2. Gently scrape the surface of the skin at the ACTIVE or PERIPHERAL margin of the lesion with a sterile scalpel blade.
3. NEVER collect a scraping from the central margin of the lesion.
4. Place sufficient (the more the better) skin scraping sample into a clean container for transport to the laboratory.
5. Complete the requisition and order "Fungal smear and Fungus culture."
6. Label the specimen container with patient name, date and time of collection, date of birth and return to the laboratory with the physician's laboratory order slip.
7. Transport to Centrex Clinical Laboratories, Inc., located at the St. Luke's Campus Professional Office Building, 1656 Champlin Avenue, Utica, New York

NOTE: Positive smears provide for early diagnosis and, importantly, the laboratory diagnosis of tinea versicolor can only be established by smear exam.

Nail Samples

1. Wipe nail with 70% alcohol using gauze (NOT cotton balls). The use of cotton may result in false positive smear exams.
2. From the UNDERSIDE and END of the nail, scrape away nail material and debris.
3. Place collected material (the more the better) and/or debris in a clean container for transport to the laboratory.
4. NOTE: Nail parings and clipping are NOT recommended for culture because they are difficult to process in the laboratory.
5. Label the specimen container with patient name, date and time of collection, date of birth and return to the laboratory with the physician's laboratory order slip.
6. Transport to Centrex Clinical Laboratories, Inc., located at the St. Luke's Campus Professional Office Building, 1656 Champlin Avenue, Utica, New York

Complete the requisition and order "Fungal smear and Fungus culture."

Glucose Tolerance Tests (2, 3, 4, and 5-hour)

Introduction:

Patients with mild or diet-controlled diabetes mellitus may have fasting blood glucose levels within the normal range, but be unable to produce sufficient insulin for prompt metabolism of ingested carbohydrates. As a result, blood glucose rises to abnormally high levels and the return to normal is delayed. In other words, the patient has decreased tolerance for glucose. Therefore, glucose tolerance tests are most helpful in establishing a diagnosis of a mild case of diabetes mellitus.

A three-hour test is usually adequate for routine evaluation of impaired glucose tolerance. If hypoglycemia is suspected by the provider, additional specimens may be taken at four and five hours.

Patients should be instructed at the time of scheduling that they must remain on-site for the duration of the test. Any mobility that the patient engages in will alter the test results and render the test invalid, as will smoking and the ingestion of caffeine.

If patients object to these instructions, the test should not be performed, and they should discuss the matter further with their physician.

Procedure:

1. A fasting glucose will be obtained from the patient and tested. If the glucose is >140 mg/dl or <60 mg/dl, the physician will be contacted to give his/her permission to proceed with the test.

2. The patient will be given the Glucola beverage and asked to finish it within 10 minutes.

3. Blood glucose will be collected hourly from the time the patient finishes the Glucola.

4. Some patients may become ill during the test. If for any reason the patient vomits the glucola solution, the test is to be canceled. Be certain the patient feels well enough to leave the laboratory. Do not allow any patient to leave if he/she feels faint.

50 Gram Push

1. A fasting specimen is not routinely required. Physicians orders should indicate if the specimen should be collected fasting.

2. The patient will be given 50 gm of Glucola to drink.

3. A blood glucose will be collected one hour after the patient finishes the Glucola.

References:

1. Tietz Textbook of Clinical Chemistry, Second Edition, WB Saunders Company. Philadelphia PA. 1994

2. Clinical Diagnosis & Management by Laboratory Methods. 16th Edition. WB Saunders Company. Philadelphia PA. 1979.

Lactose Tolerance Testing

Lactose is a disaccharide composed of glucose and galactose. It is found in milk and milk products. Lactose is digested by the villi of the small intestine after being split into the sugars glucose and galactose by the disaccharide lactase. It is these simple sugars, glucose and galactose that are absorbed in the small intestine and enter into the blood stream.

The absorption of these sugars, glucose and galactose is the basis for the lactose tolerance test. By assessing the rise of serum glucose after the ingestion of lactose, a determination of the degree of digestion and subsequent absorption of lactose and its component sugars can be made. The Lactose Tolerance test indirectly measures the amount of lactase present in the small intestine. If lactose is not digested and absorbed, it enters the colon. There fecal bacteria will degrade the lactose into small-chain fatty acids which are irritating to the colon. This may produce the clinical complaints of constipation, flatulence, borborygmus, diarrhea, or bloating.

The Lactose Tolerance test can also assess the degree of lactose intolerance and since milk is the major source of lactose, the Lactose Tolerance test is indicated for evaluating milk tolerance.

Patient Preparation:

Patients need to be in a fasting state, typically 12 to 14 hours with no food except water prior to administration of this test.

Procedure:

1. A fasting sample is drawn.

2. An oral dose of LAC-TOL solution is administered to the patient, stressing the importance of ingestion of the complete lactose solution.

3. Following the ingestion of the LAC-TOL solution, blood glucose samples will be collected at intervals of one-half hour, one hour, one and one-half hours, and two hours.

Expected Results:

A peak maximal rise of 25 mg/dl in the venous blood glucose value signifies normal lactase activity. A peak rise less than 20 mg/dl is strongly indicative of lactase deficiency.

References:

1. Tietz Textbook of Clinical Chemistry, Second Edition, W.B. Saunders Company, Philadelphia, PA, 1994.

2. Clinical Diagnosis & Management by Laboratory Methods, 19th edition, W.B. Saunders Company, Philadelphia, PA, 1996.

LAC-TOL Package Insert, ENDOVATIONS, INC., READING, PA.

Respiratory Syncytial Virus Specimen Collection

Acceptable specimens for RSV antigen detection are: nasopharyngeal washes, nasopharyngeal aspirates, or nasopharyngeal swabs, with aspirates and washes being preferable to swab samples. To collect a nasopharyngeal aspirate or wash, pass appropriate-sized tubing or catheter into the nasopharynx. Aspirate material with a small syringe, and place in approximately 2.5 mL of sterile saline OR sterile PBS (phosphate-buffed saline). If material cannot be aspirated, tilt the patient's head back about 70 degrees and instill 3-7mL of sterile saline or PBS until it occludes the nostril, then re-aspirate and place the wash material into a sterile tube or container. To collect a nasopharyngeal swab, pass a flexible mini-tipped swab (cotton, Dacron, or rayon) into the nasopharynx. Allow secretions to absorb for 5 seconds, and then carefully removed the swab and place it immediately in 2.5 mL of sterile PBS or saline. **Collection of a nasopharyngeal specimen is an invasive procedure and must be performed by a physician or a nurse. This procedure CANNOT be performed by any Centrex staff.**

NOTE: Specimens for RSV antigen detection must be kept cold and transported to the laboratory promptly, ideally on wet ice.

Viral culture backups are not automatically performed on negative RSV antigen tests. However, backup culture is recommended when there is a strong suspicion of RSV infection, because there are documented cases of positive RSV cultures where the antigen test was negative. If viral culture backup is desired, it must be specifically ordered along with the RSV antigen test.

Influenza A&B Antigen

The specimen of choice for Influenza A & B antigen testing is a nasopharyngeal wash or nasopharyngeal aspirate in sterile saline (ref to collection procedures under "RSV" above). Alternately a nasopharyngeal or pharyngeal swab can be collected, but such specimens are only about 70% reliable in detecting positives. Swab samples must be placed in 1-2 mL of sterile saline or M5 Viral Transport immediately after collection. Specimens must be kept cold and submitted promptly to the laboratory, ideally on wet ice.

Specimens will be batch tested Monday through Sunday. All positive test results will be called to your office followed by a printed hard copy.

Please Note: Unless otherwise specifically requested, our laboratory will perform a rapid respiratory viral culture on specimens that have negative Influenza Antigen results. Such back-up culture is recommended by the manufacturer of our antigen detection kit; and our own in-house studies have indicated a relatively large number of Influenza positive specimens exhibited negative antigen results. Please specifically note if you DO NOT want a rapid respiratory culture.

Specimen Collection and Transport

1. Collect one nasopharyngeal swab, place swab in a special transport medium provided by Centrex.
2. Label specimen with the patient's name, date of collection, and date of birth. Transport all specimens with a cool pack and send to the laboratory as soon as possible.
3. Contact the Centrex transportation department at 315-797-0791 extension 5903.
4. **IMPORTANT**: The nasopharyngeal swabs provided by Centrex must be stored in a refrigerator. To request swabs please call 315-797-0790 extension 8280 or 8251.

Therapeutic Drug Monitoring Peak Collection Times

Peak concentration is measured after the drug distribution phase is complete, to assure that it is within the therapeutic range and not above it.

Test	Peak Collection Times
Acetaminophen (Tylenol)	Draw sample at least 4 hours after drug ingestion.
Amikacin (Amikin)	IM: 60 minutes after injection. IV: 30 minutes after end of 30 minute infusion; immediately after end of 60 minute infusion.
Carbamazepine (Tegretol)	3-4 hours after oral dose.
Digoxin (Lanoxin)	6-8 hours after oral dose.
Ethosuximide (Zarontin)	2-4 hours after oral dose.
Gentamicin (Garamycin)	IM: 60 minutes after injection. IV: 30 minutes after end of 30-minute infusion; 15 minutes after end of 60-minute infusion
Phenobarbital	Any time; however, for comparative measurements, the sampling times should be consistent.
Phenytoin (Dilantin)	3-9 hours after oral dose.
Primidone (Mysoline)	IV: 2-4 hours after loading dose. Oral: Immediately prior to next oral dose.
Procainamide (Pronestyl)	1-4 hours after oral dose.
Quinidine	Quinidine Sulfate: 1-2 hours after oral dose. Quinidine Gluconate: 4-6 hours after oral dose.
Theophylline (Amminophyline)	IV: Prior to IV infusion (if patient has history of theophylline ingestion). 4-6 hours after beginning the infusion. Oral: 2 hours after oral dose of solution or solid dosage form with rapid dissolution. 4 hours after slow-release preparation eg, Slo-Phyllin Gyrocap 3-7 hours after Theo-Dur dose.
Tobramycin	IM: 60 minutes after injection. IV: 30 minutes after end of 30 minute infusion. 15 minutes after end of 60 minute infusion.
Valproic Acid (Depakene)	1-3 hours after oral dose.
Vancomycin	IV: 30-60 minutes after infusion.

All trough levels should be collected immediately prior to next dose.

Throat Culture, Rapid Strep Screens and Strep Screens (plated)
Collection and Preparation

Principle:

The culturette system is used as a sterile disposable culture collection and transport system. It consists of a polystyrene tube containing a transport medium and a swab. It incorporates a Dacron-tipped, plastic soft swab for throat specimens. An ampule of modified Stuarts medium prolongs the survival of microorganisms when a significant delay occurs between collection and culturing. The culturette will transport and maintain aerobes and facultative anaerobes that are pathogenic for up to 72 hours.

Specimens should be transported to the laboratory and cultured as quickly as possible.

Procedure:

1. Peel the sterile package partially open.
2. Remove the swab, taking precaution to avoid contamination.
3. Obtain the specimen using a depressor to restrain the tongue, insert the swab to the back of the throat.
4. Throat culture procedure: rub the swab over each tonsillar area and posterior pharynx. Any areas of white patches should also be touched.
5. Return the swab to the culturette.
6. If a Culture has been ordered crush the transport ampule. If a Rapid Strep Screen has been ordered DO NOT break the ampule.
7. Label the culturette with the patient's full name and date of collection and date of birth.
8. Send to the laboratory for processing.
9. In the case of a Rapid Strep Screen, package as a STAT. Call for a STAT courier.
10. When a Rapid or Quick Strep Screen is ordered: obtain two (2) specimens
11. When a Rapid Strep Screen and a Throat Culture are ordered: obtain two (2) specimens.
12. When a Strep Screen is ordered and no designation is made for rapid or quick: obtain one (1) specimen.

Virology Testing

The Virology section of Microbiology at Centrex Clinical Laboratories performs direct specimen antigen testing for influenza A/B viruses, RSV, and rotavirus as well as the cultural isolation and identification of most viruses associated with common human diseases. The Virology Laboratory's hours of operation are Monday through Saturday from 7am to 3pm for cultural isolation (set up only on Saturdays), and 24 hours a day, 7 days a week, for direct antigen testing. Specimens for viral culture received after 2pm will be processed the next working day.

Specimen Requirements

1. Specimen source ***MUST*** be included in the order.
2. "Swab" specimens (i.e., throat, rectal, lesions, etc.) must be collected using viral transport medium. Keep refrigerated until used and check that the transport medium is in date.
3. Other specimens (i.e., body fluids, urines, sputum, nasal washes, and tissue samples) should be placed in a sterile container.
4. ***All viral specimens must be transported COLD to the laboratory, preferably on wet ice.***
5. Specimens must be properly labeled with patient's full name and a second identifier (date of birth, MRN), the date of collection, ***and the specimen source indicated***.
6. Reasons for rejection: specimen received warm, specimen received in inappropriate transport container, specimen received unlabeled or inadequately labeled, or specimen source not indicated.

Cultures Available

1. Respiratory Viral Culture includes Influenza A and B, Respiratory Syncytial Virus (RSV), Parainfluenza viruses, and Adenovirus. Specimens submitted include throat swabs, nasal washings, sputum, bronchial washings, or other samples originating from the respiratory tract.
2. Herpes Only Viral Culture screens for Herpes simplex viruses type I or II, primarily from genital cultures. Specimens submitted include swab samples from lesions or aspirates of vesicle fluid which are rinsed into viral transport medium.
3. Varicella Zoster Virus (VZV) Culture. Cutaneous lesions can be submitted to the laboratory for the cultural isolation of VZV and Herpes Simplex Virus (HSV). Collect lesion samples using a swab which is then placed in viral transport medium. Alternatively, vesicles may be aspirated using a needle and syringe, and rinsed into viral transport medium.
4. The "General Viral Culture" test request screens for the presence of a variety of different viruses that can cause human infection. Importantly, since viruses demonstrate such remarkable tissue tropisms, the type of specimen collected determines the viruses that are routinely cultured for. As such, it is of critical importance to indicate the specimen source when collecting the sample. The following represents the various viruses that are cultured from specific specimen types.

   Bronchial Washings: CMV, Herpes, Respiratory Viruses
   CSF: Enterovirus
   Pleural Fluid: Enterovirus
   Pericardial Fluid: Enterovirus
   NP/Rectal (or Throat/Rectal): Enterovirus
   Eye: Adenovirus, Herpes
   Rectal/Stool: Adenovirus, Enterovirus
   Tissue (lung): CMV, Respiratory viruses, Herpes
   Tissue (kidney): CMV
   Tissue (other): consult supervisor
   Urine: CMV

NOTE: If additional viruses are sought due to special circumstances (i.e., unusual history of patient travel, animal exposure, etc.), please contact the Microbiology laboratory and special arrangements may be made to screen for the presence of extremely unusual or uncommon viruses.

Additional Notes:

1. If a viral culture is positive, an additional charge may be billed for identifying the virus present.
2. Influenza A/B and RSV antigen detection tests will continue to be offered. Negative Influenza A/B antigens will still have a viral respiratory culture performed UNLESS the physician requests otherwise. Negative RSV antigens do not require a culture, but studies indicate that negative antigen screens sometimes yield positive results when cultured. If you want a culture when the RSV antigen test is negative, you must order it. It will NOT be done automatically.

Virology Tests

Test Name	Requirements	Instructions	CPT4
RSV Antigen	Nasopharyngeal aspirate or washing	Submit on ice. Although backup viral culture is not required for negative RSV Antigen tests, it is recommended if there is a strong suspicion of viral infection.	87420
Influenza A&B Antigen	Nasopharyngeal aspirate or washing, on ice; or nasopharyngeal swab or vigorous throat swab in approximately 1mL sterile saline On Ice or in M5 Viral Transport.	A second specimen in M5 Viral Transport Medium, also on ice, must accompany saline specimen to laboratory in case backup culture is needed.	87400 x2
Rotavirus Antigen	Stool in sterile container.	Refrigerate until transported. Must reach laboratory within 24 hours.	87425
Viral Culture, General or Viral Culture, Respiratory	"Swab" specimens (throat, rectal, lesion, etc): immerse swab in Viral Transport Medium. Other specimens (body fluids, urine, sputum, nasal washes, tissues): place in sterile container.	All viral specimens must be submitted to the laboratory promptly and keep cold.	87252, General Culture 87254x2 for Respiratory Specimens
Viral Culture, Herpes only or Viral Culture, Herpes with Typing	Swab from lesion or aspirate of vesicle fluid in Viral Transport Medium	Send to laboratory on ice.	87255
Viral Culture Herpes and VZV	Swab from lesion or aspirate of vesicle fluid in Viral Transport Medium	Send to laboratory on ice.	87254

Cytology & Pathology Specimen Collection Procedures

All Medical Cytology specimens must be accompanied by a completed Medical Cytology requisition form. The clinical history, source and method of obtaining the specimen are crucial to rendering an accurate diagnosis.

Test Name	Specimen Requirements	Special Instructions
Urine for Cytology (voided or catheterized)	Minimum: 10 mL Maximum: 60 mL Patient must be hydrated. If voided specimen is submitted, collect second morning specimen in nonsterile specimen container labeled with 2 unique patient identifiers.	Must be received on day of collection. Refrigerate specimen if delay in transportation to laboratory is expected. 24-hour specimens are not accepted due to cellular degeneration.
Bladder Washings for Cytology	Collect in urine container labeled with 2 unique patient identifiers.	Transport to laboratory as soon as possible after collection. Refrigerate specimen if delay in transportation is expected.
Body Fluid for Cytology (pleural, peritoneal, pelvic, cerebrospinal, abdominal, pericardial, etc.)	Minimum: 5 mL Maximum: 100 mL* *Pleurovac and similar large vacuum collection devices are unacceptable. Remove an aliquot of fluid and submit in smaller container labeled with 2 unique patient identifiers.	Transport to laboratory as soon as possible after collection. Refrigerate specimen if delay in transportation or processing is expected.
Sputum for Cytology	Minimum: 5 mL Maximum: 30 mL Container must be labeled with 2 unique patient identifiers.	Transport to laboratory as soon as possible after collection. Refrigerate specimen if delay in transportation or processing is expected.
Nipple Secretion for Cytology	Submit prepared slides labeled with two unique patient identifiers. Indicate right or left breast on slides. Smear fluid secretions thinly on slide(s). Spray immediately with cytology fixative.	Transport to laboratory as soon as possible after collection.
Lung Washing (Bronchial Washing)	Container must be labeled with 2 unique patient identifiers.	Transport to laboratory as soon as possible after collection. Refrigerate specimen if delay in transportation or processing is expected.
Scrapings/Tzanck Smear	Submit prepared slides labeled with 2 unique patient identifiers. Indicate site of scrapings on cytology request form. Smear scrapings thinly on slides. Spray slides immediately with cytology fixative. Air dry remaining slide. Label each slide appropriately.	
Brushings (esophageal, gastric, bronchial, or other)	Obtain CytoLyt solution by calling Centrex pathology (315) 624-8297. Place brush immediately into labeled CytoLyt solution container. Label with 2 unique patient identifiers.	
Gastric or Biliary Fluid Aspirate for Biliary Pigment/Cholesterol Crystals	Submit fresh in container labeled with 2 unique identifiers. On requisition specify study requested and exact location of aspirate.	Refrigerate specimen if delay in transportation to lab is expected.

Fine Needle Aspiration (FNA) Specimens

Cytology Preparation of Fine Needle Aspiration Specimens

Materials Needed

- Small gauge (18-25 gauge) needles, per physician's preference.
- 5 or 10 cc syringes, per physician's preference.
- Positively Charged Glass slides.
- Marking pen.
- Spray fixative.
- Non-gynecologic cytology request form.
- 30 ml tubes of CytoLyt Solution, a preservative fluid.**

NOTE: At least 2 glass slides and one CytoLyt tube are needed per each organ or each quadrant or each side of the same organ that is being aspirated separately, as indicated clinically. Those separate tubes and slides should be labeled differently as parts A, B, C, etc…according to corresponding anatomic sites. If indicated, a 2nd pass from the same nodule could be performed and labeled accordingly; e.g. #1, #2, etc…

Procedure

A. Prior to the start of this procedure, match the patient's name and account number on the order sheet/request form to the patient's name band or ask the patient to state his/her name and date of birth.
B. Label the specimen(s), four glass slides and one tube of CytoLyt Solution (see note below) with the patient's last name and first initial.
C. Express a drop or two of the cellular and non-bloody aspirate onto one slide and gently smear the material between two glass slides. Immediately spray fix 1 or 2 smears with a spray fixative or put the smears in the CytoLyt tube. In addition, allow 1 or 2 slides to air-dry. Label smears; "fixed" of "air dried"
D. Express the remainder of the aspirate into the tube of CytoLyt Solution and rinse the needle and syringe with the preservative fluid. A thin layer slide as well as a cell block (if the specimen is cellular enough) will be made from the rinsings.
E. Rinsings into the same tube of CytoLyt Solution can be performed as long as the same site is aspirated, according to the physician's instructions.
F. Core tissue biopsies should be placed in formalin.
G. Complete the cytology requisition form, including:
    1. The time and date of procedure with initials of person performing procedure.
    2. The site, and quadrant, or lobe and side, of the aspirated lesion when applicable.
    3. Any pertinent history and any known primary malignancy, site and differentiation (attach a copy of previous pathology or cytology report or accession numbers).
    4. Previous biopsy, radiation and/or chemotherapy.
H. Deliver the slides and tightly capped tube of CytoLyt and the requisition to the Laboratory if within the hospitals. Outpatient specimens should be packaged using a slide holder with all specimens and the requisition placed in a specimen bag for courier pick-up.

Note

A. If a lymphoma is suspected or to be ruled out, a separate sample should be submitted in RPMI** for Flow Cytometry Analysis and request form marked accordingly. A STAT courier should be called preferably before 3:00 pm.
B. In case of FNA of Fat Pad is performed to rule out Amyloidosis, it is recommended that 4 aspirates with 18 gauge needle on both sides of the umbilicus are performed to accumulate at least 30 mg of fat tissue, which will be submitted in CytoLyt for Thin Prep slides, a cell block preparation and possible immunohistochemical studies.
C. In cases of thyroid nodule(s), which are usually heterogeneous, it is recommended to do at least 2 passes and no more than 4 passes per nodule to avoid excess bleeding. A very thin needle is also recommended (25 gauge).
D. ** Tubes of Cytolyt Solution or RPMI can be obtained by calling the Anatomic Pathology Department at St. Luke's site at (315) 624-8297 or (315) 624-8298

Gyn Specimen Acceptance and Adequacy

Unsatisfactory/Inadequate Gynecological Specimen or Pap Smear

A Pap smear or Thin Prep specimen shall not result in a diagnostic report if:

- The apparent condition of the specimen indicates that it is unsatisfactory for testing, or that it is inappropriate for the test requested.
- The requisition and/or slide lack patient identification.
- It has been collected, labeled, preserved, or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.
- It contains insufficient cells, that is, scant epithelial cells spread over less than 10% of the slide(s).
- For a conventional smear,more than approximately 75% of the cells are uninterpretable due to obscuring blood, inflammation, thick areas, foreign material, poor fixation, and air-drying artifact.
- A Thin Prep slide should be considered unsatisfactory when less than 40% of the area of the 20 mm cell deposit contains well-preserved and well-visualized squamous epithelial cells.

Satisfactory for Evaluation

The presence or absence of endocervical transformation zone and any other quality indicators, e.g., partially obscuring blood, inflammation, etc., are described. Adequate numbers of well-preserved cells from both the ectocervical and the endocervical areas, including the transformation zone, may not be present. An adequate transformation zone sample for both conventional and Thin Prep smears is defined as at least 10 well-preserved endocervical cells and/or squamous metaplastic cells, singly or in clusters. This applies to non-atrophic smears from pre and post menopausal patients with a cervix.

Thin Prep samples should have a minimum of 5000 epithelial cells and conventional smears should have a minimum of 8000 to 12000 epithelial cells to be reported as Satisfactory for Evaluation. Professional judgment is needed when applying numerical criteria to certain cases, e.g., atrophy.

NOTE: Specimen adequacy including sampling of endocervical transformation zone is evaluated in all cases. However, any epithelial abnormality is of paramount importance and must be reported regardless of compromised specimen adequacy. **If abnormal cells are detected, the specimen is never categorized as "Unsatisfactory".**

References:

- The Bethesda System for Reporting Cervical Cytology, Definitions, Criteria and Explanatory Notes;2nd ed..Diane Solomon & Rita Nayar, 2004, Springer- Verlag Inc., N.Y.
- Thin Prep Morphology Reference Manual, Kurt L Douglass, CT(ASCP), 1994, Cytyc Corporation, Boxborough, MA.
- Bethesda2001.cancer.gov; jama.ama-assn.org/issues/v287n16ffull/jst10013.html.

Human Papilloma Virus Specimen Collection (HPV)

Specimen Types/Collection:
The types of cervical samples recommended for use in the HPV test are listed below. Specimens collected in other sampling devices or transported to the laboratory in other transport media do not qualify for testing with this HPV assay.

Cervical specimens must be collected prior to the application of acetic acid or iodine if colposcopy is being performed.

Cervical Specimens in Cytyc PreservCyt Solution
Specimens are collected using a broom-type or brush collection device and placed in Cytyc PreservCyt Solution for use in making Thin Prep PAP test slides as well as performing the HPV test. Physicians may order the HPV test on such cervical samples as a routine screen OR as a "reflex" test if ASCUS (Atypical Squamous Cells of Undetermined Significance) is seen on the PAP by checking the appropriate box on the gynecologic cytology requisition. Cytyc PreservCyt Solution specimens may be stored for up to three weeks at 4-37 degrees C prior to processing for the HPV test.

Cervical Brush Samples
Cervical brush samples may be collected and transported to the laboratory by using the Digene Cervical Sampler (Digene Cervical Brush and Transport Medium). Specimens may be stored in this transport container for up to two weeks at room temperature before specimen processing.

Pap Test – ThinPrep Method

Requirements, Collection and Handling

Test Name: **Pap Smear, ThinPrep Method**

Specimen Requirements:
Specimens should be taken before the bimanual examination and before the other tests, eg., gonococcus and Chlamydia.

1. Instruct patient not to use vaginal medication, vaginal lubricants, vaginal contraceptives or douches during the 48 hours before the exam.

2. Use speculum lubricated only with warm water.

3. Cervix and adjacent vagina should be well-visualized.

4. Sample endocervix and ectocervix separately.
   Cervix: Rotate plastic spatula with good pressure over entire ectocervix OR insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

5. Rinse the spatula or the broom into the PreservCyt Solution vial by swirling the spatula or broom vigorously in the vial 10 times. Swirl the broom vigorously to further release material. Discard the collection device.
   Endocervix: Recommend endocervical brush, slowly rotate ¼ to ½ turn in one direction. DO NOT OVER-ROTATE.

6. Rinse the brush as quickly as possible in the PreservCyt Solution by vigorously rotating it 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

7. Tighten the cap so that the torque line on the cap passes the torque line on the vial.

8. Record the patient's name and second unique identifier (ex, Date of birth) on the vial. Record the patient information and clinical history on the GYN cytology requisition.

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

10. If Human Papilloma Virus testing is requested, please refer to HPV specimen collection information.

Reference:
Cytyc Corporation, ThinPrep Pap Test Quick Reference Guide, 2007.

Surgical Pathology

All specimen containers must be labeled with the patient's name, date of birth, age and type of specimen. This must be accompanied with a legible and completed surgical pathology requisition form with the appropriate ICD-9 code and the name of the surgeon and additional copies to.

Test	Performed	Specimen	Comments
Biopsy, special e.g., skin, GI, GU, prostate, etc.	Monday - Friday	Submit in 10% neutral buffered formalin.	
Lymph node, or spleen for suspected lymphoid malignancy	Monday – Friday	Wrap in saline soaked gauze and transport immediately to Surgical Pathology.	Inpatient and Ambulatory surgery
Nerve Biopsy	Monday – Thursday 8am to 4pm	Submit fresh. Sent to Mayo Clinic.	Inpatient Only. 24-hour notice required. Contact Histology
Muscle Biopsy	Monday – Thursday 8am to 4pm	Submit fresh. Sent to Mayo Clinic. Biochem sent to Athena Diagnostics.	Inpatient Only. 24-hour notice required. Contact Histology
Renal Biopsy	Monday – Friday	Sent to Columbia Presbyterian.	Renal kit provided on request.
Intraoperative Consultation (IOC) Frozen Sections (FS) Tissue Consultation (TC)	All Times	Call pathology or on-call pathologist after hours or weekends. Make arrangements with pathologist ahead of time if not on the surgery schedule.	Inpatient Only
Bone Marrows	Monday – Friday	**Peripheral Blood** – Collect lavender top tube, Invert gently 5-6 times. **Core Biopsy** – Submit 4 touch preps. Place biopsy in B5 fixative. Mix at the time of procedure. **Aspirate** – Submit 8-10 smears, depending on availability of particles in aspirate. Submit clot in 10% Neutral Buffered Formalin. For flow cytometry and/or cytogenetics studies, an aspirate pass should be placed in a green top/heaprinized.	

Sample Requisitions and Forms

REQUEST FOR COPIES OF LABORATORY RESULTS

TO ADDITIONAL PHYSICIANS

To comply with HIPAA Regulations and assure delivery of laboratory results to only those authorized to receive them, the first and last name and address of physicians who are to receive copies of lab reports must be received prior to release of those copies.

PATIENT NAME: _____ DOB: _____

Copies of Lab Results to be Released: _____
(Tests / Dates of Service)

Copy To:

REQUIRED

PHYSICIAN NAME
_____
First Name Last Name

Address _____

_____

Telephone No. _____

Fax No. _____

REQUIRED

PHYSICIAN NAME
_____
First Name Last Name

Address _____

_____

Telephone No. _____

Fax No. _____

REQUIRED

PHYSICIAN NAME
_____
First Name Last Name

Address _____

_____

Telephone No. _____

Fax No. _____

_____ _____
SIGNATURE (PHYSICIAN OR DESIGNEE) DATE

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Test Menu

Every effort is made to maintain the accuracy of information included in this publication. Occasionally modifications are made to new procedures, obsolete procedures, turn around times, patient service center hours, etc., that may not be reflected in this edition of the Directory of Service Manual.

This new edition of the Directory of Services contains numerous modification, updates, and revisions. In the interest of full CPT disclosure, the CPT codes are consistent with the 2010 edition of *Current Procedural Terminology,* a publication of the American Medical Association (AMA)