Policies and Procedures—Little Company of Mary Hospital and Health Care Centers

The laboratory provides full services to meet our patients needs. Emergency laboratory services are available 24 hours per day, 7 days per week.

Analytical Methods

Changes in methods described in laboratory procedure manuals may not be made unless authorized by the laboratory or section director. These manuals are open to inspection by all medical staff members.

Charges and Credits

Charges for laboratory tests are approved by the Board of Directors. Discounts must be approved by the Director of Finance or the Chief Executive Officer.

Clinical Information

At times, additional information is needed to proceed with the test ordered or to interpret the result. It might be a statement about specimen source, patient's drug intake, clinical diagnosis, etc. If this kind of information is not included on requisition slip or made known to a departmental medical staff member, then performance or reporting of test may be delayed.

Confidentiality and Release of Patient Information

The Department of Laboratory Medicine and Pathology at Little Company of Mary Hospital and Healthcare Centers will use and disclose protected health information to carry out treatment, payment, and/or healthcare operations and for those purposes permitted by law. The laboratory will abide by the terms of the US Department of Health and Human Services Office for Civil Rights Standards for Privacy of Individually Identifiable Health Information (45CFR Parts 160-164) as applicable to the laboratory.

Patient results/reports will be disclosed to practitioners who ordered them and/or to alternates authorized by them. For practical purposes, physician office personnel and nursing personnel are authorized alternates, as are certain hospital contract physicians, house physicians, and residents who may have assumed responsibility for the patient. Report information will include patient demographics.

Fasting Specimens

Reference to a "fasting specimen" or "fast" usually means no food ingested for 8 hours, but no less than 2 to 3 hours before specimen is obtained. Unless specifically prohibited in the procedure, normal water intake is permitted. Tests involving measurement of triglycerides and lipoproteins require strictly

observed fasts of 12 to 14 hours.

Medical-Legal Testing

The laboratory does not perform tests or examinations for forensic purposes.

Ordering Tests

The laboratory accepts requests for tests from practitioners currently licensed in Illinois under the Medical, Dental, or Podiatry Practice Act, or from others who are authorized to order laboratory tests by the Departmental Chairman or Vice President of Medical Affairs according to policies approved by the medical staff and Board of Directors (Ref. Hospital Licensing Requirements Rule (3-3) (b), Illinois Department of Public Health). An order must be written or electronic, signed, and dated by the physician initiating it and the original kept in the electronic chart, medical chart or laboratory file. When a test not listed in the test manual is needed, consult a departmental medical staff member or supervisor.

NOTICE TO PHYSICIANS: When ordering tests for which Medicare reimbursement will be sought, physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of the patient, and not for screening.

Laboratory testing is deemed Medically Necessary by Medicare if the test is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Any other use of laboratory testing is considered screening. Screening does not always denote that the ordered test is unnecessary or poor medical practice. Screening tests cannot be directly linked to an established diagnosis, sign, or symptom.

In order to establish Medical Necessity, the test order must be accompanied by the appropriate diagnostic information that justifies the test order. This information should be submitted in the form of an ICD-9 code or narrative diagnosis.

Reference Laboratories

Only those reference laboratories specifically approved by the medical staff and Board of Directors may be utilized. These reference laboratories have been approved for use: Coagulation Consultants, Quest Diagnostics, Mayo Medical Laboratory, Heartland Blood Centers, Illinois Department of Public Health, Neogenomics, Bostwick Lab, Agendia, Genomic Health, Myriad Genetics, and Response Genetics. When a requested referral test is available at 1 of these approved referral labs, the test must be performed at approved laboratory, regardless of special requests. When a specialized test is requested that is *not* available from any of the approved laboratories, efforts will be made to obtain testing. In all other cases of directed requests or "research" requests, it is the responsibility of ordering physician to arrange for specimen transport and payment.

Reflex Testing

The Department of Laboratory Medicine and Pathology at Little Company of Mary Hospital and Health Care Centers will perform reflex tests automatically when the initial test result meets the criteria for prompting a reflex test.

The Department of Laboratory Medicine and Pathology will bill the reflex tests it performs using CPT-4 code(s). The physician has the option of ordering the initial test without the reflex test. Whenever an initial test is subject to a reflex test, please consider whether the reflex test is medically necessary for that particular patient. If reflex test is unnecessary, please order on initial test and indicate that reflex test should NOT be performed. Please be advised that the Office of the Inspector General of the Department of Health and Human Services takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties.

Reports

Laboratory tests are routinely reported via computer or printed report. All printed reports will include at least patient identifying information received with specimen, result, date and time received and reported, and, if necessary, units or reference values, interpretations, and pertinent comments.

A physician or licensed caregiver will be notified immediately by telephone, if possible, under the following circumstances:

- Result of a test is critical as defined in "Critical Test Values," or if results are considered very unusual
- Physician has requested to be informed at once
- Specimen cannot be obtained
- Patient's preparation was not satisfactory
- Report will be unexpectedly delayed

Research Projects

The laboratory does not participate in research programs initiated outside the department.

Routine Admission Orders

Currently, no routine (ie, automatic) admission laboratory test order protocols are in effect.

Specimen Identification

Every specimen delivered to the laboratory must be in a tightlyclosed container. Every specimen must be labeled at time of collection. The label must have 2 forms of patient identification. All specimens must have a legible, completed requisition form. The requisition must include patient's full name, age/dob, sex, location, date and time specimen was obtained, the test required, diagnosis and signature of physician authorizing it.

Specimen Quality

Only fresh and properly preserved specimens will be accepted for analysis and examination. The laboratory assumes that the method of collection and patient preparation was correct for each specimen received, ie, performed according to policies and procedures published in the departmental test catalog. General criteria for rejecting a blood specimen submitted for testing are:

- Duplicate specimens with respect to patient name, test, and time collected
- Severe lipemia or hemolysis
- Clots in anticoagulated blood
- Insufficient quantity (multiply amount of serum or plasma needed by 2.5 to estimate amount of whole blood required)
- Improper container or preservative
- Improper specimen collection or storage
- Improperly labeled specimen (ie, tubes with no name, no test ordered, not double identified, etc.)

Specimen Sources

Only tissue, blood, fluid, and other material removed from or excreted by human beings will be accepted for analysis with the exception of material examined for the Infection Control and Quality Assurance Programs.

Specimen Transport

In accordance with CLIA '88 regulations, all specimens sent to the laboratory, including specimens from doctor's offices, care stations, radiology, etc., must be transported in closed, plastic BIOHAZARD bags. An accompanying requisition form must be firmly attached to the external surface of the bag.

Pathology

Autopsy

<u>General Policies</u>: A request for an autopsy will generally be accepted if the following conditions are met:

- The deceased was admitted to Little Company of Mary Hospital at time of death
- Investigation of cause of death *does not* fall under jurisdiction of the Cook County Medical Examiner (see "Medical Examiner's Cases" below)
- A valid autopsy consent, as described below, has been received
- See "Patient Care Services, Expiration Procedure" for additional information.

<u>Selection of Cases for Autopsy</u>: The medical staff at Little Company of Mary Hospital believes that autopsies are useful to improve and enhance patient care. In general, autopsies may be helpful to:

- Find the probable cause of death
- · Corroborate or correct antemortem clinical diagnoses
- Help reconstruct the sequence of major pathophysiological events leading to death
- Inform and educate staff physicians concerned with care of deceased patient
- Provide data for hospital Performance Improvement and Medical Education Programs

As approved by the Medical Executive Committee, a postmortem examination should be encouraged in the following specific circumstances:

- Unexpected or unexplained deaths that are apparently natural and *not* subject to the jurisdiction of the Medical Examiner's Office and cause of death is not known with reasonable certainty on clinical grounds
- Deaths in which autopsy may help to explain unknown and unanticipated medical complications
- Deaths in which autopsy may help to allay concerns of and provide reassurance to the family or would disclose a known or suspected illness that may have a bearing on survivors or recipients of transplanted organs
- Deaths which are unexpected or unexplained during or following any dental, medical, or surgical diagnostic procedures and/or therapies
- Obstetric deaths
- Natural deaths on inpatients that are subject to, but waived by, Medical Examiner's Office, such as persons

dead on arrival at hospital; deaths occurring in hospital within 24 hours of admission or following a surgical procedure; and deaths in which patient sustained or apparently sustained an injury while hospitalized

<u>Medical Examiner's Cases</u>: Whenever a person dies of causes involving any degree of "accident, casualty, medical attention" while undergoing surgery or during anesthesia, the case must be referred to the office of Medical Examiner for disposition. This definition is very broad and places may deaths under the jurisdiction. A more detailed list of these cases is available on request. If Medical Examiner should choose not to have an autopsy done or investigate further the circumstances of death, the case technically remains within his jurisdiction.

<u>Permission</u>: Permission to perform an autopsy requires a properly completed consent form signed by next of kin with legal authority to grant permission *and* at least 1 witness. When permission is granted by telephone, 2 witnesses must attest by signature that they heard the person identified on the consent form as next of kin, give permission for the autopsy.

Only persons listed below, in the order of the listing, have power to authorize autopsy:

- Agent under a durable power of attorney for health care (unless power of attorney excludes autopsy permission) or other advance directive
- Surviving spouse (even if estranged or separated)
- Adult (> or =18 years of age) son or daughter
- Either parent
- Adult brother or sister
- Other adult relative
- Close friend by affidavit

Where 2 or more persons have an equal right to sign the consent, authorization of only 1 is required, provided that all are notified of decision and have reasonable opportunity to object. If, however, any 1 of the persons in this class objects to the autopsy, it may not be performed. If the deceased is known to have advance directives regarding disposition of his/her body or any of its parts which is in conflict with the autopsy, the autopsy should not be executed.

The power to authorize an autopsy on a child (minor) resides with *both* parents. If divorced, the power to authorize an autopsy resides with the parent who has legal custody. It is generally unwise to proceed with postmortem examination of a child without written consent from *both* parents. Any limitations to the autopsy should be clearly listed on the permission and will be strictly adhered to by the pathologist. All refusals to grant permission for an autopsy should be documented in the physician/nursing notes.

<u>Autopsies on Stillborn and Aborted Fetuses</u>: Examination of all fetuses that have a weight > or =500 g, are > or =28 cm long (crown- heel), and/or have a gestational age of > or =20 weeks is performed by postmortem examination. For fetuses <500 g, <28 cm long (crown-heel), or <20 weeks of gestational age, it is preferable to examine the body as a routine surgical specimen. Under these circumstances it is not necessary to have an autopsy permit. If there is a question, consult a pathologist.

<u>Rejection of a Request for Autopsy</u>: Request for an autopsy, in which a valid consent is obtained, *may* be rejected for the following reasons:

- The presence of certain infectious diseases in the body which are believed to present a significant threat to prosector and assistant (eg, suspected or known cases of HIV, tuberculosis, Jakob-Creutzfeldt disease, and undiagnosed encephalopathies), and for which inadequate protective facilities are available
- Recent premortem injection or deposit of therapeutic doses of radioisotopes

<u>Autopsies on Patients Who Die Outside of the Hospital</u>: It is the general policy of the hospital that autopsies are not done on patients who die outside the hospital except when patient had recently, previouslybeen treated at Little Company of Mary Hospital or was under the care of a member of the medical staff. In all cases, special permission must be obtained from a pathologist and the next of kin must provide a signed, witnessed consent form as outlined above. Additionally, appropriate clinical records and information must be provided.

<u>Time Schedules</u>: While every effort will be made to complete the autopsy in a timely manner and to accommodate the needs of deceased's family regarding funeral arrangements, some complex cases may require additional time. In general, once a properly executed permit is obtained, most autopsies will be completed within 48 hours, excluding weekends and holidays.

<u>Reports:</u> A report of preliminary diagnosis based on gross examination will be prepared for the medical record and attending physicians and issued within 24 to 48 hours after the autopsy is completed. Final reports will be issued 30 days after the autopsy is completed unless special circumstances require extended study. Copies of the autopsyreport for relatives of the deceased who granted permission to do the postmortem examination can be obtained by written request to the Medical Record Department at Little Company of Mary Hospital.

The autopsy findings will be incorporated into the hospitalwide Medical Performance Improvement and Continuing Medical Education Programs.

Cytopathology—Cervicovaginal (Pap) Smears The laboratory processes specimens submitted for the ThinPrep® Pap TestTM preparation technique. See the respective tests for individual details.

Cytopathology—Fine-Needle Aspiration (FNA) A staff pathologist is available to perform FNA biopsies on all superficial, palpable masses. Procedures requiring radiologic guidance should be arranged for through Radiology. Please call 708-229-5817 to schedule an appointment.

Intraoperative Consultation (Frozen Section)

When an intraoperative consultation on a specimen is required, tissue should be submitted to the laboratory fresh with accompanying requisition indicating a frozen section is requested. A pathologist is routinely available for intraoperative consultation and immediate examination of surgically removed tissue daily (Monday-Friday, excluding Holidays) from 7:30 a.m. to 4:30 p.m. At other times when it is anticipated a frozen section may be needed, the pathologist on call will respond to requests and should be contacted with as much advance notice as possible.

Outside Consultations

The Department of Laboratory Medicine and Pathology is the legal custodian of all material submitted for examination, including gross tissue, histologic and cytologic microscopic slides, and paraffin blocks. This material is retained for the time specified in the current *Test Catalog* (see "Record and Specimen Retention Guidelines" in "General Information"). Because this material is the primary source on which interpretations and diagnoses are based, the pathologists and the hospital have an equal interest in maintaining the integrity of this material. However, the patient has a right to "benefit" from this material. The following guidelines aim to fairly serve the interests of all concerned parties. <u>Consults Initiated by a Staff Pathologist</u>: A staff pathologist may ask for a consultation from an outside source primarily for diagnostic/confirmatory purposes and/or to augment diagnostic data with tests or procedures not available in the laboratory. The primary source of consultation is Mayo Medical Laboratories. The policy is in place to promote efficiency and reduce chance of error that might result from use of multiple consultants. Other consultants may be utilized, at the discretion of pathologist.

Consults Requested by Clinicians or Patients (Second

<u>Opinion</u>): If a clinician or patient wishes to obtain an outside consultation, a properly completed waiver (release) form must be completed and signed by patient or his/her guardian before reports or materials can be distributed. Name and address of the physician to whom material is to be sent are required. Material is generally not given directly to patient, but sent to physician designated in release form or, if under subpoena, to designated party.

In general, original materials (histologic and cytologic slides and paraffin blocks) are always retained in the laboratory. For histology specimens, recut slides are made and reviewed by the pathologist to confirm that they show the same features as the "original" slides. Material that cannot be duplicated (such as small biopsies, Pap smears, and other cytology specimens) is sent with a special letter reminding recipient to return material promptly. Allmaterial that is sent out is carefully monitored and followed-up so that integrity of laboratory's files is maintained.

Legally motivated requests are handled in a similar fashion, but attorneys for the hospital and the pathologists' insurance carrier are notified before any action is taken.

Routine Surgical Pathology

<u>General Policies</u>: All tissue (excluding some placentas, foreign bodies, medical devices, and calculi) surgically removed from hospital patients must be sent to Surgical Pathology with an appropriately completed surgical pathology requisition. When foreign bodies or medical devices are removed and not sent to Pathology, their removal and disposition must be clearly documented in the medical record. Special analyses are performed as required. The report and other information about every specimen received is archived within the computer system for quick retrieval and report generation.

Written reports are routinely issued within 24 hours of specimen receipt. Exceptions to this include those specimens received on Saturday, Sunday, the day before a holiday, or too late in the afternoon for adequate fixation to take place prior to processing. In those instances where consultation, additional sections, or special stains and/or studies are needed, at discretion of consulting pathologist, a preliminary report will be issued with an explanation for the delay.

<u>Fetus and Stillborn Examination</u>: Examination of fetuses that have a weight > or =500 grams and are > or =28 cm long (crown-heel), and/or have a gestational age of > or =20 weeks is performed by postmortem examination; in these circumstances, a valid autopsy consent must be provided, as outlined below. For fetuses <500 grams, <28 cm long (crownheel), or <20 weeks of gestational age, the body will be examined as a routine surgical specimen.

Fixation of Specimens: Routine pathology specimens should be placed in 10% neutral-buffered formalin, which is supplied. Volume of fixative should be at least 10 times the volume of specimen to be fixed. All fresh (unfixed) tissue should be clearly labeled as such on specimen requisition. For fresh specimens, see below. Specimens too big for available plastic containers should be placed into doubled biohazard bags before delivery to the laboratory. After double-bagging in biohazard bags, limbs and fetuses are put into the pathology designated refrigerator with requisition sent to laboratory.

<u>Fresh (Unfixed) Specimens:</u> Certain specimens should be sent to the laboratory immediately, unfixed. Any specimen submitted fresh should be clearly labeled as such. When specimen is submitted on gauze, only saline-moistened Telfa® pads should be used; dry gauze rapidly dehydrates tissue, seriously affecting histologic interpretation, and should never be used. These specimens include, but are not limited to the following:

- Tissue for possible frozen section examination
- Lymph nodes/thymus for diagnostic purposes
- Muscle and nerve biopsies
- Skin biopsies for immunofluorescence procedures (may also be submitted in special fixative supplied)
- Tissue for chromosome analysis
- Uteri removed for endometrial carcinoma

At the discretion of submitting physician, other circumstances may dictate fresh submission. Specimens should not be left unfixed overnight unless specifically directed to do so by a pathologist.

Special Surgical Pathology Procedures Certain procedures require notification of the pathology laboratory beforehand so that proper fixatives and other special transport requirements can be arranged. Since many of these procedures also require immediate transportation to the testing facility, all specimens should be received in the laboratory before 1:30 p.m. These procedures include:

- Muscle biopsy
- Kidney (renal) biopsy
- Nerve biopsy
- Skin samples for immunofluorescence study
- Tissue for electron microscopy
- Bone marrow for leukemia immunophenotyping (flow cytometry)
- Skin for leukocyte immunophenotyping (mycosis fungoides, etc.)

For additional instructions, refer to the *Test Catalog* under specific procedures or contact laboratory for additional information.

Microbiology

Antimicrobial Testing

Most routine antimicrobial susceptibility testing is done on the Vitek 2 System, which is a micro dilution system measuring growth at 2 to 3 antimicrobial concentrations for each antibiotic.

Reports are given as S (sensitive), I (intermediate), or R (resistant) based on MIC "break points" defined in the most recent CLSI publications. MIC values for susceptibility tests are also reported.

Criteria for Rejecting Specimens Submitted for Microbiological Tests

For general criteria for rejection of specimens see "Specimen Quality" in "Policies and Procedures" in "General Information."

Additional criteria for rejecting a microbiology specimen are;

- Specimens submitted beyond the maximum number allowed
- Specimen container not intact, properly closed, or contaminated on its external surface
- Requests for culture of anaerobes on material from sites known to be normally contaminated or colonized by anaerobes
- Lack of clinical information (eg, exact source of specimen, type of viral culture wanted, etc.)
- · Urinary catheter tips
- Inadequate quantity of specimen submitted
- · Specimens not submitted in required transport media
- Improperly labeled specimen

Direct Microscopy

A Gram stain is performed routinely on material submitted for culture from the lower respiratory tract, male genital tract, wounds, cerebrospinal fluid, and other fluids. A Gram stain is not routinely performed on urine, feces, catheter tip, female genital tract, and blood cultures.

^cThe laboratory must be notified that certain organisms are suspected clinically so that special stains and preparations will be selected appropriately (eg, acid-fast stains for mycobacteria, nocardia, cryptosporidia; KOH preparation for fungi; Giemsa and Wright stains for filaria and plasmodia; toluidine blue, Giemsa, silver methenamine for *Pneumocystis carinii*, etc.).

Darkfield examination is not offered.

Positive microscopy results on all cerebrospinal fluid and blood cultures are reported by telephone directly to the attending physician, consultant, or nursing staff.

General Instructions for Collection of Microbiology Specimens

Obtain specimen before antimicrobial therapy starts. Collect material most likely to contain the infecting organism.

Collect specimen at the proper disease stage, which us usually the acute phase.

Obtain a sufficient quantity of specimen. This will depend on the infection suspected. Recall that larger specimens and repeated sampling are usually required to isolate acid-fast bacilli and fungi.

Collect specimen at a time it can be processed at once and deliver it in the appropriate transport media without delay. Microbiology Laboratory processes initial routine culture procedures from 6:30 a.m. to 8 p.m., Monday through Friday, from 6:30 a.m. to 4 p.m., Saturday and Sunday.

Supply sufficient clinical data so that correct culture media and procedures are selected by the laboratory.

General Rules and Procedures for Interpreting Antibody Titers in Infectious Disease

Collect serum for antibody titers during the early (acute) phase of the disease and during the late (convalescent) phase, ie, 3 to 4 weeks after the first specimen. Specimens will be tested together and reported.

A 4-fold increase in titer of the second specimen over the first one is strong evidence of a recent active infection.

In suspected congenital infections, obtain acute and convalescent serum from the mother and the infant. Absence of antibodies to the organism tested generally rules out congenital infection because antibodies in the infant are passively acquired and normally decay over 2 to 3 months postpartum. Maintenance of or an increase in antibody titer to the organism tested suggests active infection. In almost all infections, a rise in the IgM component of the antibody response in 1 specimen strongly suggests recent infection with the organism against which the antibody is active.

Service Levels

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Bacteriology service is classified as a Type 5 (definitive identification of organisms to the extent required for diagnosis and assistance in selection of therapy).

Mycobacterial service is classified as a Type 2 (isolation of mycobacteria only with identification provided by the reference laboratory). Mycobacterial antimicrobial sensitivity is only offered through the reference laboratory.

Mycology service is classified as Type 2 (identification to species level) for yeasts and Type 1 (isolation with identification by a reference laboratory) for molds.

Parasitology service is classified as Type 2 (definitive identification of all parasites to the extent required for diagnosis and assistance in selection of therapy).

Selected viral antigen testing is provided by the laboratory. Viral cultures and most viral serology tests are not offered except through reference laboratories. See "Virology" in "Microbiology" in "Special Instructions" for general guidance.



General Laboratory Section

Services

Chemistry and Subsections

- Chemistry
- Blood Gases
- Toxicology and Therapeutic Drug Monitoring
- Immunology

Hematology and Subsections

- Hematology
- Coagulation
- Diagnostic Immunology

Clinical Microscopy and Subsections

- Body Fluid Examination
- Urinalysis

Specimens

For general criteria for rejection of specimens, see "Specimen Quality" in "Policies and Procedures" in "General Information."

Instructions to prepare the patient and collect the specimen are specified for each test under its listing.

Therapeutic Drug Monitoring and Toxicology

The laboratory is not National Institute on Drug Abuse (NIDA) approved and does not conduct chain-of-custody procedures for collecting specimens to be analyzed for drugs of abuse.

Pharmacokinetic data given with reports are generic and not specific for the case. For specific information, the Pharmacy Department should be consulted.

Toxic levels given with reports are intended to be generic guidelines and should not be used as absolute values without reference to the specific clinical state and circumstances of each case.

Only qualitative analyses for drugs of abuse are done; reports are given as positive or negative.

Specimen Collection and Preparation

Laboratory test results are dependent on the quality of the specimen submitted. It is important that all specimens and request forms be properly labeled with name of patient, date of birth, collection date, and origin (source) of specimen, when applicable.

If there is any doubt or question regarding the type of specimen that should be collected, it is imperative that the laboratory be called to clarify the order and specimen requirements.

Blood Collection

Most laboratory tests are performed on anticoagulated whole blood, plasma, or serum. Please see our individual test directory section for specific requirements.

- <u>*Plasma*</u>: Draw a sufficient amount of blood with the indicated anticoagulant to yield the necessary plasma volume. Gently mix the blood collection tube by gently inverting 6 to 10 times immediately after draw. If required, separate plasma from cells by centrifugation within 20 to 30 minutes.
- <u>Serum</u>: Draw a sufficient amount of blood to yield the necessary serum volume. Gently mix the blood collection tube by gently inverting 8 to 10 times immediately after draw. Separate serum from clot by centrifugation within 20 to 30 minutes. Caution: avoid hemolysis.
- <u>Whole Blood</u>: Draw a sufficient amount of blood with the indicated anticoagulant. Gently mix the blood collection tube by inverting 6 to 10 times immediately after draw.

Specimen Collection Tubes Available

The following is a list of tubes referred to in Little Company of Mary Hospital's specimen requirements:

- <u>Blue-Top (Sodium Citrate) Tube</u>: This tube contains sodium citrate as an anticoagulant—used for drawing blood for coagulation studies.
 - Note: It is imperative that the tube be completely filled. The ratio of blood to anticoagulant is critical for valid prothrombin time results. Immediately after draw, invert tube 6 to 10 times in order to activate the anticoagulant.
- <u>Brown-Top Tube</u>: This plastic tube contains a spraydried K2 EDTA—used for drawing blood in lead testing only.

- <u>Mint Green Top (Lithium Heparin gel)</u> <u>Tube</u>: This tube contains lithium heparin—used for drawing heparinized plasma or whole blood for special tests.
 Note: After tube has been filled with blood, immediately invert tube several times in order to prevent coagulation.
- <u>Green-Top (Sodium Heparin) Tube</u>: This tube contains sodium heparin-used for drawing heparinized plasma or whole blood for special tests.
- Note: After tube has been filled with blood, immediately invert tube several times in order to prevent coagulation.
- <u>Grev-Top (Potassium Oxalate/Sodium Fluoride) Tube:</u> This tube contains potassium oxalate as an anticoagulant and sodium fluoride as a preservative—used for some chemistry tests.
 - Note: After tube has been filled with blood, immediately invert tube several times in order to prevent coagulation.
- <u>Lavender-Top (EDTA) Tube</u>: This tube contains EDTA as an anticoagulant—used for most hematological procedures and several chemistry tests.
 - Note: After tube has been filled with blood, immediately invert tube several times in order to prevent coagulation.
- <u>Red-Top Tube:</u> This tube contains a clot activator used for serum determinations in chemistry, serology, and immunohematology. Invert 5 times to activate clotting.
- <u>Royal Blue-Top Tube</u>: There are 2 types of royal blue-top Monoject® tubes—1 with the anticoagulant EDTA and the other plain. These are used in drawing whole blood or serum for trace element analysis. Refer to

individual metals in individual test listings to determine tube type necessary.

• <u>Serum Gel Tube</u>: This tube contains a clot activator and serum gel separator—used for various laboratory tests. Note: Invert the tube 8 to 10 times to activate clotting;

> let stand for 20 to 30 minutes before centrifuging for 10 minutes. If frozen serum is required, pour off serum into plastic vial and freeze. Do not freeze VACUTAINER®.

• <u>Special Collection Tubes</u>: Some tests require specific tubes for proper analysis. Please contact the laboratory at 708-229-5085 prior to patient draw to obtain correct tubes for metal analysis or other tests as identified in individual test listings.

• <u>Yellow-Top (ACD) Tube</u>: This tube contains ACD used for drawing whole blood for special tests.

Requests/Reporting

Interfering Substances

The most common interfering substances are listed in the specimen requirement of the test listing. A more comprehensive listing is available in Young DS: Effects of Drugs on Clinical Laboratory Tests. 4th edition. Washington DC, AACC Press, 1995.

Reference Values

All reference values listed are for adult normals unless otherwise indicated.

Laboratory Requisition

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Slucose 2 hr post dose (non pregnant)	GTT2HR	Rh Immunoglobulin		RHIG		Harpes, PCR source:	HSVPCR
Separati B Surface Antigen*	HBSAG	Urinalysis (mkrosoc	(bexeller sig	UA		Strep Gp A Ag acroen Rapid	STREPA
łi¥•	HIV	Unnelysia (microsco	pic and culture reflexed)"	UA REX CAS	L	(culture reflexed H negative)	
nor/DBC*	FETIRC	Ufine drug screan	ILIG MONITORS	I UAU	-	C. difficile A/B, stool	CDIFF
actate Dehydrogenase (LDH)	LOH	Carbamazepine		CARBAM		Glardia/Cryptospondium Antigen, stool	GIARCRY
.98d	LEAD	Digoxin" Lait Dose	d Date Time	PHENY		Occult Blood, stool - anignostic	OCCELD
fagnesium*	MG	Tacrolimus		TACRO		Ova & Parasites, slool	OP
Phosphorus Polaszkan	PHOS	Theophylline	101	VANCOR		Stool WBC's	WBC
Protein, total	PROT	Valproic Acid	200	VALPRO	X	OE/GYNE	
Tranglerin"	TRANS	XI	ENDOCRINE	ESTRAD	-	Alpha Feloproteit Quad	CYSTICF
Jrda Narogen (BOH)	URIC	Folicie Stimulating	Hormona (FSH)	FSH	-	GC/Chiamydia DNA Probe (source):	CTGC
Atamin 812	VITB12	HCG Quantitative		HCG QUANT		Glucose 1 hr post dose (Gestational	GTT1HR
BC.	CBC	Paralhyroid Hormon	0 (LH)	PTM	-	Glucose Telerance 3 hr (Gestational)	GTT3HR
BC with Differentiat	CBCDIF	Progesiarona	parsing spann	PROGES	-	HCQ - sorum, Qualitative	HCG-U
iemociobio*	HCT	Testosterone, Total	& From	TESTE		Obstatric Panal	OB
Platelots"	PLT	Testosterone, Total	and the second second	TESTOS		(CBC & Diff, HBSA; (confirmation reflexed)	industration to the second
SA (Westergren)*	ESA BETIC	TSH*	de reliexad	THYROID		Strep Op B screen, vspinal/recial	STREPB
TUMOR MARKERS		Torr July on date				Is patient alleroic to Penicilin? Y N	1
EP*	AFP	X CHEMISTRY	ANELS TESTSLIST	TO AN BE	Dha		Laure
A19-9*	CA19-9	Function Panel	AST (SGOT)	mi, IZU, AUK	-108	, FIOIDITIOIEI, ACI(OUFI),	CHEM 8
A125'	CA-125	Fasic Metabolic	Panal_ (Na.K.	CL.CO.CI	niciui	n. Glucose. Urga. Creatinina)	CHEM.8
A21-29*	CEA	metabolic Panal	Protein total Alin	umin. Alk ph	Da, C	ALT (SGPD, AST (SGOD)	CHEM 1
SA Disonosic	PSA	Electrolytes	(Na. K. Ci. COz)	1014 45 -	10. 1	a landismatica milavadi LOUALI	HEPPAN
BA Screening"	PSA	Hepatitis Panel	Cholesterol Troban	Ides HOI	LISA DI	g (conternation reliexed)	LIPID
	10000	Renal Panel	Alpumin, Calcium, M	A, K, CI, CO	, CA	antining, Glucose, Phosphorus, Uron)	RENAL
Alexandra and a second		X AD	DITIONAL TESTS		1.16	AUDIMONAL TESTS	1
and the second se		11					
Tests	Physician	's Signature				Date	
Rifed					-		
						A CONTRACTOR OF	

Supplies

The following supplies are available for laboratory testing.

Bags

Bags, ambient Bags, freezer Bags, refrigerate

Blood Collection Equipment Needles Green 21 g

Black 22 g

Safety-Lok™ Butterfly System 21 g Green 23 g Light blue 25 g Dark blue Blue Luer Adapter (attachment for butterfly)

Blood Collection Vacuum Tubes Black/Tan Tiger Top - Call free DNA BCT-10mL Blue-top (sodium citrate), 1.8 mL Brown-top (potassium EDTA), 3 mL Catecholamine tube -EDT A-sodium metabisulfite solution -10 mL for catecholamine fractionation, plasma, free Green-top (sodium heparin), 4 mL Grey-top (potassium oxalate/sodium fluoride), 4 mL Lavender-top (EDTA), 3 mL Mint green-top (lithium heparin gel), 3.5 mL, 4.5 mL Quantiferon - TB Gold Kit Red-top (none), 4 mL, 6 mL Royal blue-top metal-free Monoject® tube (EDTA [#8881-307022]), 6 mL Royal blue-top metal-free Monoject® tube (no additive [#8881-307006]), 6 mL Serum marbled gel tube, 7.5 mL Serum gel tube 3.5 mL Yellow-top (ACD solution B), 6 mL Clear, no additive tube, 3.0 mL, 6.0 mL

<u>Capillary Blood Gas Collection (for baby heelsticks only)</u> Blood gas capillary - balance Heparin 100 µL Quickheel green lancet, 1 mm Quickheel lavender preemie lancet, 0.85 mm

<u>Capillary Blood Collection</u> Lavender MICROTAINER® (EDTA), 250 μL/500 μL Amber MICROTAINER® (gel), 400 μL, 600 μL Yellow MICROTAINER® (gel), 400 μL, 600 μL MICROTAINER® tube holder

Chromosome and/or Tissue Collection

Hank's balanced salt solution Metal-free specimen vial (blue label) for tissue metal collections Michels transport medium for cutaneous immunofluorescence, biopsy RPMI

Forms

Alpha-fetoprotein Maternal Screen Form Cytogenetics/AFP Congenital Disorders Request Form Cytopathology Requisition Form Dermatopathology/Immunodermatology Request Form Lead/Heavy Metals Reporting Form Surgical Pathology Request Form Thalassemia/Hemoglobinopathy Information Sheet

Microbiology

BBL[™] CultureSwab (2 swabs with liquid Stuart's transport medium for strep A antigen) BBL™ CultureSwab™ Plus (2 swabs with amies gel transport medium for anaerobes) BD ProbeTec™ET Male And Female Collection And Transport Kit BD Vacutainer® (no additive tube for RSV collection) Blood culture bottles: BACTEC[™] Mycolf Lytic culture bottle BACTEC[™] Peds Plus®/F culture bottles BACTEC[™] Plus Aerobic/F culture bottles BACTEC[™] Standard Anaerobic/F culture bottles Foam tip applicator and transport tube (for collection of nasopharyngeal specimens for influenza antigen) Hemoccult® slides Luki sterile aspirating tube (Luken's tube) 90-mL screw-capped, sterile specimen collection container Pinworm Test Kit—Falcon™ Protocol Fecal C&S Transport System (1 orange vial) Protocol Zn-PV A/Formalin Transport Kit (grey/pink vials) VACUTAINER® Brand Urine Collection Kit: Clean, voided, 4 mL Chloraprep 10% iodine

Miscellaneous

Alcohol prep 70% isopropyl Band-aid® coverlet 1 inch x 3 inches Breath Test Kit for H. pylori CytoLyt® fixative DiaSorin UBT[™] Breath Test Specimen Collection Kit Formalin preservative Formalin-Meridian 10% buffered neutral Gauze, 2 inches Latex-free tourniquets Latex tourniquets Liquid Aimes Swab (Bordetella Pertussis) Mailers, infectious material, large Omni heel warmers One use needle holders Para-Pak® ECOFIX™ vial Pharmaseal® lumbar puncture way Powder-free latex gloves, S-M-L Powder-free white vinyl gloves S-M-L Quintron Lactest mix, 25 g Salivette Tube Seratonin Tube Serum vial, (6 mL) white cap StabilCyte[™] Reagent Kit Stool container, large (24 hour) ThinPrep® Collection Kits Urine bottle (60 mL) Urine container, 24-hour graduated Urine container, catheter urine (15 mL) Uro Risk Container V-C-M Medium Yellow conical urine tube, 8 mL Zeus solution

Glucose Tolerance Beverages

50 g lemon lime 75 g orange 100 g fruit punch

Critical Test Values

This listing is for tests performed at Little Company of Mary Hospital. All critical test values that are verbally communicated required read back verification.

<u>Outpatients:</u> Each time a critical value is generated, it is reported directly to the patient's physician, his designate, or his office.

Inpatients: During a hospitalization, a critical value is reported for a particular test by telephone to the appropriate nursing station as soon as it is verified as well as reported via printed report.

Critical Test Values				
Test	Critical Low	Critical High		
Acetaminophen, Plasma or Serum		>150 µg/mL		
Activated partial Thromboplastin time (APTT), Plasma				
Anticoggulant therapy		≥120 seconds		
No Anticogaulant therapy		>50 seconds		
Amikacin, Serum	C Strengton and Com			
Peak		>30 µg/mL		
Trough		≥10 µg/mL		
Bilirubin, Total and Direct, Plasma or Serum	-			
Total:		ander partnammen einen einen einen der einen andere der einen		
0 days		> 7.0 mg/dL		
l day		> 11.0 mg/dL		
2 days		> 3.0 mg/dL		
3 days	-	> 15.0 mg/dL		
> 3 days - 1 month		> 15.0 mg/dL		
Calcium, Plasma or Serum	< 6 mg/dL	> 13.0 mg/dL		
Carbamazepine. Serum		> 15.0 µg/mL		
Carboxyhemoalobin		> 15%		
Cell Count and Gross Exam. Spinal Fluid				
Total Nucleated Cell Count		>1,000 / µL		
Chlamydia trachomatis & Neisseria gonorrhoege by				
Amplified DNA Probe	Positive (inpatients)			
Chlamydia trachomatis by Amplified DNA Probe	Positive (inpatients)			
Chlamydia trachomatis Smear	Positive (inpatients)			
Clostridium difficile Toxin A & B. Feces	Positive			
Complete Blood Count (CBC), Blood				
WBCs	< 1,500 / µL	>35,000 / µL		
Hemoglobin	< 7.0 g/dL	>20.0 g/dL		
Hematocrit	< 15%	>60%		
Platelets	< 30,000 / µL	>1,000,000 / µL		
Complete Blood Count (CBC) with Differential White				
Cell Count, Blood				
WBCs	≤ 1,500 / μL	≥35,000 / µL		
Hemoalobin	< 7.0 g/dL	≥20.0 g/dL		
Hematocrit	≤ 15%	≥60%		
Platelets	<u>≤ 30,000 / μĽ</u>			
Creatine Phosphokingse (CK) MB		>9.3 ng/mL (outpatients)		
Culture, Alloaraft	Positive			
Culture (any type)	Positive for ESBL producing organisms, KPC producing organisms, or inpatient			
Culture, Blood	Positive	streptococcus pneumonia		
Culture, Feces	Positive for Campyle	obacter, Escherichia coli		

Critical Test Values

Critical lest Values			
iesi	Critical Low		
	0157:H7, Salmonel	la, or Shigella	
Culture, Feces, Campylobacter	Positive for Campyl	obacter	
Culture, Feces, Escherichia coli U157:H/	Positive for Escherichia coli 0157:H7		
Culture, Feces, Salmonella and Shigella	Positive for Salmonella or Shigella		
Culture, Feces, Vibrio	Positive for Vibrio		
Culture, Feces, Yersinia	Positive for Yersinia		
Culture, Genilal	Positive for Weisser	ia gonorrhoeae (inpatien	
Culture, Mycobacteria Rene Marrow - Eluid	Positive		
Culture, MyCobacteria, Bone Marrow of Plula	Positive (innetioned)		
Culture, Neissella gonormoede	Positive (inpatients)		
	TOSILIVE	> 2 10 ma/ml	
Digoxin, Plasma or Serum		> 25.0 ug/mL	
Electrolytos (pH, Plasma es Serum and Veneus Plead			
Electrolytes/pri, Flastila or set util and verious blood		>160 mmal/	
Potassium			
	<3.0 mmal/T	>8 0 mmo1/1	
<u>> 20 days</u>	<u><3.0 mmol/L</u>	$\geq 6.0 \text{ mmol/L}$	
Carbon Dioxido Contont		$\geq 0.0 \text{ mmol/L}$	
		<u>240 IIMIIOUL</u>	
Electrolyton Planna - Serum	51.2	21.0	
	<120 mm al/I	>160	
Botacsium			
	-2.0 mmo1/1		
\geq 30 days		<u>>6.0 mmol/L</u>	
Carbon Dioxido Content		20.0 mmol/L	
Ethanol Plasma er Sorum		> 300 mg/dI	
Fibringgon / Functional Plasma	< 100 mg/dI		
Gases Arterial Blood			
ouses, Anena blood	< 7.21	> 7 59	
p(0)	< 20 mm Hg	> 70 mm Hg	
p <u>CO</u> 2			
Neonates	< 35 mm Hg		
Adults	< 40 mm Hg		
	< 50 mm Uz		
		> 20	
FICU3 (colculated)		2 39 mm rig	
	-7.21	>750	
рп	≤ 7.21	≥ 7.55 $\geq 70 \text{ mm Hz}$	
pc02			
Noongtos	< 35 mm Hg		
Actuales			
Adulis			
Arterial	\leq 50 mm Hg		
Capillary	\leq 35 mm Hg		
HCO3 (calculated)	≤ 11 mm Hg	\geq 39 mm Hg	
CO ₂	< 18%		
Gentamicin, Plasma or Serum			
Trough		> 2.0 μg/mL	
Peak		<u>≥ 10.0 μg/mL</u>	
Glucose, Plasma or Serum 17			

Critical Test Values

Critical lest Value	es Critical Loui	Critical Ulat	
lest	Critical Low	Critical High	
Children (<16 years)	$\leq 30 \text{ mg/dL}$	≥ 300 mg/dĽ	
Adults (≥16 years)	$\leq 40 \text{ mg/dL}$	≥ 500 mg/dL	
Gram Stain	Positive for spinal flu	id	
Hematocrit, Blood	≤15%	≥ 60%	
Hemoglobin, Blood	≤7.0 g/dL	≥20.0 g/dL	
Hepatitis Bs Antigen (HBsAg), Serum	Positive (confirmation	testing)	
HIV-1 Antibody B (HIV-QT), Plasma or Serum	Positive		
HIV Antibody, Plasma or Serum	Positive		
Influenza A & B Antigen	Positive (inpatients and	outpatients)	
Iron and Total Iron-Binding capacity, Plasma or Serum Iron, Total		≥500.0 μg/dL	
Iron, Plasma or Serum		≥500.0 µg/dL	
Ketones, Serum	Positive (newborns)		
lactic acid		>4mmol/L	
lead. Blood		(and a meriod to	
<15 vegs		>10 mcg/dL	
>15 years		>25 mcg/dL	
Lithium Serum		>2.0 mmol/L	
Magnesium Plasma or Serum	<1.4 mg/dL	>6.2 mg/dL	
Malarial Parasites Blood Smear			
MR(A Screen	Positive		
Mycobacterial Smear	Positive		
Neisseria genersheege tu Amplified DNA Brobe	Positive (inpatients)		
Osmolality Sorum	<pre>// Control (impatients)</pre>		
Osmoldily, Selom	2250 mosmol/kg water	2020 mosmorkg water	
Ova and Falasiles, reces	TOSITIVE	>10 ug/mI	
Phenobarbilai, Plasma er Serum			
Phospholos, Plasma or Selum	<1.0 mg/dL	>1 000 000 /t	
Pidleiels, Blood >15 years	<u></u>	21,000,0007μL	
rolassium, riasma or selum	<2.0	NO	
	$\leq 3.0 \text{ mmol/L}$		
	$\leq 2.8 \text{ mmol/L}$		
Prothrombin lime (PI), Plasma		>5.0	
International Normalized Katio		23.0	
Serum	Reactive (Labor inpatients)		
Respiratory Syncytial Virus (RSV) Antigen	Positive (inpatients and outpatients)		
Rotavirus Antigen, Feces	Positive		
Salicylate, Plasma or Serum		≥70 mg/dL	
Sodium, Plasma or Serum	≤120 mmol/L	≥160 mmol/L	
T4 (Thyrosine), Free, Plasma or Serum		≥20 ng/dL	
Theophylline, Plasma or Serum		≥20 µg/mL	
Tobramycin, Plasma or Serum			
Peak		≥15 μg/mL	
Trough	and a submitter of the state of the second	≥2.0 µg/mL	
Troponin T, Blood		≥0.10 ng/mL (indicativ of myocardial injury)	
Urea Nitrogen, Plasma or Serum		≥100 mg/dL	
Urinalysis, Macroscopic			
Total Reducing Substances	Positive (newborns)		
Glucose	≥1,000 mg/dL (patients	mg/dL (patients <13 years)	
	Positive (newborns)		

Test Values

Critical Test Values			
Test	Critical Low	Critical High	
Urinalysis with Reflex Culture			
Total Reducing Substances	Positive (newborns)		
Glucose	≥1,000 mg/dL (patients	≥1,000 mg/dL (patients <13 years)	
Ketones	Positive (newborns)	Positive (newborns)	
Valproic Acid, Plasma or Serum		≥120 μg/mL	
Vancomycin-Resistant Enterococci Screen	Positive (inpatients)		
Vancomycin, Serum			
Peak		>40 µg/mL	
Trough	<20 µg/mL		
VDRL Screen with Reflex Titer, Spinal Fluid	Reactive		
WBC, Blood	≤1,500 / μL	≥35,000 / µL	

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Record and Specimen Retention Guidelines

Autopsy Fixed Tissue 1 year Paraffin Blocks 10 years Microscopic Slides 10 years Patient Reports 10 years Cytopathology 2 Specimens 1 week after final reports Microscopic Slides GYN: 5 years Non-GYN: 10 years 0 years Patient Reports 10 years General Laboratory 2 Blood Films 2 years Blood Specimens 7 days Electrophoretic Strips 10 years Fluid Slides 5 years Body Fluids/Spinal Fluid 7 days Patient Reports 10 years Specimens for Acid-Fast/Bacteria/Fungus/Ova and Parasites 7 days Patient Reports 10 years Surgical Pathology 7 Fixed/Wet Tissue 14 days after final rep Paraffin Blocks 10 years Microbiology 10 years Support Service 10 years Microbiology 10 years Surgical Pathology 10 years Surgical Pathology 10 years	
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ABO/Rh, Antibody Screen, DAT 10 years	
Donor Deterral List Permanent	
Donor Deferral Notification Permanent	
Donor Records 10 years	the second s
Patient Problem Cards Permanent	
Cord Blood 7 days	1
Pretransfusion Specimen 7 days post transfus	ion
Rh Immune Globulin Records 10 years	
Therapeutic Phlebotomy Records 10 years	
Transfusion Reaction Reports Permanent	
Transfusion Records 10 years	
Transfusion Transmitted Diseases Records/Results 10 years	

RECORD AND SPECIMEN RETENTION



Department of Laboratory Medicine and Pathology STAT TEST LIST

Chemistry

(serum, unless otherwise specified)

Acetominophen Albumin Alkaline Phosphatase ALT Amikacin Ammonia Amvlase Arterial Blood Gas (ABG) AST **Basic Metabolic Panel** (Chem 8) B-HCG (Serum & Urine), Qualitative B-HCG (Serum), Quantitative Bilirubin, T/D, Bilirubin, CB

Hematology

CBC Fluid Cell Counts, Body, CSF Hematocrit Hemoglobin Platelets WBC WBC-differential

Blood Gas (CB) Calcium Carbamazepine CK-MB Carboxyhemoglobin Comprehensive Metabolic Panel (Chem 14) CPK Creatinine Digoxin Drugs of Abuse Electrolytes Ethanol Gentamicin Glucose, Serum Glucose, CSF HIV-rapid Iron Lactic Acid Lipase

Microbiology

Gram stain Influenza A/B Antigen Rapid Strep A Antigen RSV Antigen

Coagulation

ACT Fibrinogen D-Dimer PT PTT

Lithium Magnesium Methemoglobin Myoglobin, Plasma Osmolality, Serum Phenobarbital Phenvtoin Phosphorus Potassium Protein, Total Salicylate Sodium Theophylline Tobramycin Troponin T TSH Urea Nitrogen, S Uric Acid Valproic Acid Vancomycin Wet Mount for Trichomonas, yeast

Transfusion Service

All Blood Products Newborn Hemolytic Screen Type and Screen/Crossmatch

<u>Urinalysis</u>

UA