

I. Staffing and Hours of Operation

The laboratory is staffed 24 hrs per day, 365 days per year. MHC Outpatient Lab Hours are as follows: Monday – Friday 6:30am – 6:30 pm; Saturday 6:30am – 3pm and Sunday 7:00am – 1pm. The laboratory is headed by a pathologist medical director and is staffed with an administrative director, section supervisors, medical technologists that perform testing, and lab assistants (phlebotomists) that collect specimens. Medical technologists and technicians are degreed, licensed personnel that meet CLIA 88 standards for clinical laboratory testing personnel. Technical supervisors as well as the medical director are available for physician or nursing consultation and questions. See Appendices for listing of contact persons and phone numbers.

II. Laboratory Sections

The following sections are within the clinical laboratory, with a brief description of their function:

- A. Specimen Collection: Responsible for collecting patient specimens on inpatients and outpatients, processing outpatient orders, printing and charting results, faxing results on request.
- B. Hematology: This section primarily performs CBCs, (Complete Blood Count) and component tests on blood cells. WBC, RBC, Hgb, Hct, Platelet and Differential wbc counts. Associated tests include reticulocyte counts, cell counts on body fluids and CSF, tests for blood in stool and gastric specimens.
- C. Urinalysis: This section does urine dipstick and microscopic analysis. The dipstick is sometimes referred to as macroscopic analysis, as opposed to the microscopic exam for cells, bacteria, casts, etc done under the microscope.
- D. Microbiology: All cultures and gram stains are done in this section. Rapid tests for bacteria and viruses are also done in this section such as Influenza, RSV, Rapid Strep.
- E. Chemistry: Most testing done on blood with the exception of hematology is done in chemistry. Chemistry tests are usually done on serum or plasma, which is blood that has been separated from the cells by centrifugation. Basic and comprehensive metabolic panels, lipid, thyroid, liver, hepatitis panels and their component tests are all done in chemistry as well as cardiac markers, tumor markers, blood gases, and therapeutic drug levels.
- F. Coagulation: This section deals with the bloods ability to clot, and respond to anti-clotting medication, such as coumadin or heparin. Protimes, PTTs, Fibrinogen, FDPs and Plavix Inhibition are all done in this section.
- G. Serology: Immunological tests such as RPRs, Rheumatoid Arthritis, Mono, Rubella are done in this section.
- H. Blood Bank: Blood typing, antibody screens, crossmatches, transfusions and rhogam work ups are done in this section. Because blood bank testing is critical

to the life and safety of the patient, a separate secondary patient ID system is used in addition to the hospital ID band.

- I. Molecular: Allows for the testing of infectious disease antigens using the latest in amplification technology.
- J. Pathology: This section is for examination of tissue and fluids by a pathologist for tumors, malignancy and other abnormalities.

III. Ordering Laboratory Tests

A. Authorized Personnel:

- i. Authorized to Order: Any licensed physician, or other provider working under the direct supervision of a physician may order laboratory tests on their patients. Only medically necessary testing should be ordered. All orders should be in writing, and a diagnosis is required. Verbal/telephone orders may be accepted but they must be followed up with a written order within 30 days.
- ii. Authorized to Receive Orders: All laboratory staff work under the direction of the pathologist medical director and are assessed for competency initially and on an annual basis thereafter. Any laboratory employee that has been trained and competency assessed, may receive laboratory test orders. All verbal test orders are repeated back to the person placing the order to confirm accuracy. Any written order that is illegible or unclear is clarified with the ordering provider before proceeding with testing.

B. Acceptable Orders: An acceptable outpatient order must include the following:

- i. Patient first and last name
- ii. Patient birth date
- iii. Patient social security number (preferred, but optional)
- iv. Patient billing information
- v. Ordering provider name and signature
- vi. Tests requested
- vii. Patient diagnosis

Outpatient orders are preferred on laboratory requisitions, but will be accepted on prescription pads, or other order forms as long as the above information is present. Outpatients must first present at the Patient Intake desk to be registered before going to the lab for specimen collection.

Inpatient orders are written in the chart, or verbally given to an authorized person as defined in the Medical staff by-laws and transcribed into the chart. Pre-printed order forms are acceptable. Orders are placed into the hospital computer system by nursing personnel or unit secretaries. Orders cross into the lab information system and are printed in the lab. Laboratory phlebotomy staff are dispatched to collect all inpatient blood work unless otherwise specified.

C. Order Priority: Tests may be ordered with the following priority status:

S = Stat	R = Routine
T = Timed	U = Urgent

Stats and timed stats should be reserved for medical emergencies, or testing needed for real time clinical decisions. Stats are collected within 20 minutes of the time they are ordered and resulted within 60 minutes of receipt in the laboratory for tests that are available stat, see stat list in Appendix.

Timed tests are collected within 20 minutes before or after the time they are ordered for. The test is processed routine. All trough drug levels are run stat, so that results are communicated to the nursing unit before the next dose is given.

Cycling orders for specific times are handled the same as timed orders.

Daily routine labs are drawn between 0330 - 0600 every day, and every hour thereafter. Cycling daily orders should be put in for 0500 or 0600, they will be coordinated with other routine morning draws on that nursing unit.

D. Order Codes: Order Codes for placing test requests in the hospital computer are determined by the administrators of the Computerized Physician Order Entry system. Laboratory codes for those tests are listed in the appendix.

E. Canceling Orders: If a test is ordered in error, it should be canceled by the nursing unit and lab should be called and notified. If the nursing unit fails to call, it may result in an unnecessary venipuncture for the patient. If however, a test is accidentally ordered in duplicate it should not be cancelled. The lab system will automatically cancel any test ordered in duplicate within a two hour time frame. If the nursing unit would also cancel that test, both tests may be canceled.

F. Combination of Orders: Lab Employees have the authority to combine routine lab orders within the following parameters for tests ordered within a **2 hour time frame**. It is not necessary to request permission from the floor.

1) If blood has already been drawn within 2 hrs, and an order is received for a test, that test will be done off of the previously drawn blood unless it is a peak or trough level, or a test that is being done on a cycling order of Q2hrs or Q1hr.

2) For orders not yet drawn: Timed orders may be moved to combine with other timed orders, splitting the time difference between the orders. However if a peak, trough or PTT are one of the orders, they should be drawn at the time ordered, and the other test drawn with it.

3) Lipid profiles do not require a full 12 hour fast. Lipid profiles may be run on blood collected during morning rounds. If fast is less than 8 hrs, let tech know to put a comment on the result.

IV. **Patient Identification**

A. Inpatient/Outpatient: All hospital inpatients and outpatients are registered by Patient Intake and an identification band is affixed to their wrist. Laboratory

personnel check the patient ID band for patient name, medical record number, or Date of Birth against the barcode test label for the test they are drawing. If any discrepancies are noted, the test is not drawn and the discrepancy is resolved before proceeding.

- B. Standing Order Patients: These patients come directly to the lab to be drawn on a repetitive basis for scheduled standing order tests (ie; monthly protime). These patients are identified by asking them to state their name and birthdate.
- C. Newborns: ID bands are placed on the ankles of newborns in the delivery room. These should be checked for name and medical record number and handled the same as adult inpatients.
- D. Blood Bank Patients: Patients must have a secondary ID band with a unique set of blood bank specimen ID numbers before receiving packed red blood cells. The specimen and the blood product and the ID band have matching unique numbers that must be checked before transfusions are started. Any discrepancy results in immediate termination of the process and starting over.

V. **Specimen Collection**

- A. Lab Collected Specimens: The laboratory collects/processes the following specimens with a valid order:
 - Venipuncture
 - Capillary Puncture
 - Blood Culture
 - Glucose Tolerance Test
 - Blood Bank Testing

The laboratory does not perform arterial punctures, cannot access indwelling catheters, may not draw over an IV, and may not perform venipuncture anywhere other than the antecubital space, wrists or hands. A phlebotomist may draw from a foot vein with a physician's written order to do so. Phlebotomists are not to perform venipuncture on the same side as a mastectomy unless there is a written physician order to do so. A phlebotomist is not to perform venipuncture on arms with fistulas, or pending fistula placement. It is the responsibility of the nursing staff to post signs in patient rooms if the above conditions apply. All phlebotomists receive initial training and annual competency assessment.

- B. Nurse Collected Specimens: Nursing personnel that are trained and receive competency assessment may collect the following specimens with a valid order:
 - Venipuncture
 - Blood from an IV start
 - Arterial Line or Indwelling Catheter
 - Urine
 - Microbiology or Pathology Specimens (Body fluids, swabs, tissue)
 - Blood Bank Testing (in the presence of laboratory personnel)

All specimens must be collected in appropriate containers, labeled with patient first and last name, medical record number, time and date of collection and their

initials. There are special instructions for collection of sterile specimens, and specimens other than blood. See appropriate laboratory section.

C. Patient Collected Specimens: Outpatients are instructed on proper specimen collection for urine specimens that are collected when they present at the laboratory. Other specimens such as stool, sputum or semen may be collected by the patient at home, but must be properly preserved and brought to the lab within specified time limits. If the patient comes to the laboratory for a specimen container, they are instructed on specimen collection as well as receiving an instruction sheet. See appendices for patient specimen collection instructions.

VI. Unable to Collect

Each phlebotomist may attempt venipuncture a maximum of two times. If the first phlebotomist is unable to obtain the specimen, the nursing unit is notified of the delay and a second phlebotomist is dispatched. If that phlebotomist is also unable to obtain a specimen, the nursing unit is notified and documentation of notice placed in the EMR system. Test may be cancelled if directed by nurse or physician, documentation must be included in EMR.

VII. Result Reporting

- A. Stat Results: Results can be found in EMR upon completion. Results are not given verbally unless there are extenuating circumstances. Verbal results will be given to requester by Laboratory Technician/Technologist, the person receiving the results will be asked to repeat them back to the laboratory staff for clarification.
- B. Interim Reports: Inpatient only. When results are complete they will upload into the EMR. Reports no longer print to the units.
- C. Cumulative Reports: Cumulative reports download to the patients chart in Chartmaxx once patient is discharged.
- D. Outpatient Reports: Outside offices or facilities may opt to receive automated scheduled reports directly to their fax machine. It is also an option to receive results over the internet, or to receive hard copy printed reports through the mail.
- E. Final Reports: All inpatients, ER patients, Observation patients and same day procedure patients have final reports charted in Medical Records.

VIII. Critical Values

Critical values are approved by the laboratory medical director before they are instituted and approved by the medical staff on an annual basis thereafter. Physician specialists may be consulted about critical values before they are presented to medical staff, or any physician may make recommendations for change.

Refer to SIH policy #SY-AD-850 Critical Test Results/Values for complete critical value definitions and procedures.

IX. Down Time Orders

When EMR is down, usually both the OE system and laboratory system are both down, it is preferable that only stat and timed orders be processed if the computers are expected to be down for less than 2 hours. This minimizes the amount of rework that is required later. Manual requisitions should be used, and results will be printed directly off of the laboratory instruments, or handwritten on to the requisition if no print out is available. If the computers are anticipated to be down for more than 2 hours, routine labs that are needed should be put on manual requisitions. Requisitions need to be brought to the laboratory.

X. Referred Testing

About 5% of the testing that is ordered is not performed on site. Some esoteric and low volume testing is sent to reference labs to be processed. The reference laboratories used are CAP accredited and comply with all state and federal regulations regarding laboratory testing and reporting. The reference laboratories used are approved by the medical director.

XI. Specimen Transport

- A. Nursing Units: All specimens collected on nursing units should be brought to the laboratory immediately, and not longer than 2 hours. Specimens can be placed on the dumb waiter, and the laboratory called to pick it up. All specimens should be placed in a leak proof biohazard bag for transport. Specimens that are brought to the lab should be clocked in, and a lab person notified.
- B. Outreach: Outreach specimens are either picked up on a scheduled run by the couriers, or can be dropped off by the facility. The couriers make a circuitous run each day, and are available for stats and hospital runs on Saturday. Stats outside of courier runs are limited to existing clients, and tests that are on the stat list. Veterinary clients are charged for stat pick ups outside of scheduled courier times. Clients are free to drop off specimens any time to the main laboratory, but the specimen must be properly identified and accompanied by an acceptable written order. Couriers maintain leak proof biohazard coolers for transport, and will only accept specimens in leak proof biohazard bags or other approved containers.

XII. Employee Testing

Employee and Pre-employment testing is ordered on manual requisitions by employee health or human resources. These tests are not ordered in the LIS, and there are no charges generated. All employee testing is referred to a reference laboratory and results go directly to employee health or human resources to maintain employee confidentiality. HIV testing for needlesticks is done on site, as well as any testing deemed necessary by the employee health nurse or human resources, that is needed on an emergent basis.

XIII. Needlestick/Exposure Protocol

See Policy# MC-EH-166 *Bloodborne Pathogen Exposure*, for specific instruction on handling exposures. Briefly, the following steps are taken:

- 1) Employee flushes and disinfects the site and reports incident to immediate supervisor.

- 2) An employee accident report (supplied by the nursing supervisor) is completed, and the employee takes it with them to ER immediately.
- 3) ER completes paperwork in Exposure Folder obtained from Nursing Supervisor.
- 4) Lab is called to draw the employee.
- 5) The HIV on the source is drawn and performed stat.
- 6) The HIV results are then reported to Employee Health Nurse or Nursing supervisor (for evenings and nights).
- 7) Follow up testing is generally required and is done at the direction of the employee health nurse.

XI. Patient Billing

- A. Medical Necessity: Medicare requires, and it is good medical practice to only order those laboratory tests that are clinically relevant to the care of the patient. It is prudent to limit testing to single tests rather than profiles if that is all that is needed, and for repeat testing to monitor only those analytes that are needed, rather than reordering profiles. Medicare will not pay for more than one basic or comprehensive profile per day, and many tests are screened for relevant diagnoses before they are paid. It is also the physician's responsibility to provide a diagnosis, or patient signs and symptoms to justify the reason for the test.
- B. Advance Beneficiary Notice: Commonly referred to as an ABN, this is a notice to Medicare beneficiaries that the testing that was ordered for them may not be paid by Medicare, and that they would be responsible for payment if Medicare denied the claim. Claims are usually denied for lack of medical necessity documentation (ie; diagnoses won't support the test), frequency limits exceeded, or certain tests that are never covered, which are tests that are not FDA approved or for research and investigational use. All outpatient Medicare testing is screened for ABNs by a computer program. If the test/diagnoses combination does not pass, the patient is asked to sign the ABN form before testing is done.
- C. Medicare Secondary Payer Status (MSP): Medicare is not always the primary payer for lab tests depending on the patient's situation. Kidney patients, disabled patients or patients receiving veteran's benefits may not have Medicare as the primary payer. Sometimes other insurance companies are responsible for payment, as in the case of an employed spouse, auto accident or work related accident. There are also other circumstances for which Medicare may not be primary. All outpatients are asked a series of questions by Patient Intake, and a questionnaire is completed, to ascertain Medicare secondary payer status. The MSP questionnaire is not required for outreach patients that do not present at the hospital, however the outreach requisition includes payer information that does ascertain Medicare secondary payer status.
- D. Direct Billing: Certain tests that are referred to outside reference laboratories for which the cost of testing exceeds reimbursement are direct billed to Medicare for non-patients and Medicaid outpatients and non-patients. Non-patients are defined as those patients that present for laboratory services only, are not admitted to the hospital as inpatients and receive no other physician services at that time.

- E. Client Accounts: Clients may opt to be billed by the hospital for outreach services for patients that are not Medicare or Medicaid. These tests are on a discounted fee schedule. However, it is a federal requirement that the lab performing the test direct bill Medicare or Medicaid, with only a few specific exceptions that most clients don't meet. Other private insurance or self pay patients can be billed by the office, and charges marked up at the discretion of the client. Physician clients may only order testing on their own patients, and veterinarians are not authorized to order testing on human patients.

XII. Transfer Testing to Core Lab

Each of the other SIH facilities (Memorial Hospital, Herrin Hospital and St. Joseph's Memorial Hospital) have fully operational laboratories with a full menu of tests.

Currently microbiology specimens are plated at each facility, and sent to Memorial Hospital to be processed. Molecular Microbiology testing is performed at Herrin Hospital. Pathology is done at Memorial Hospital only, but frozen sections are available at all facilities.

XIII. Outreach Reference Laboratory Testing

Memorial Hospital laboratory performs reference laboratory testing for physician offices, clinics, nursing homes and other clients. This service line is referred to as Outreach Reference Laboratory Services. Outreach clients have the option of setting up a client account for laboratory services, or having all testing direct billed to their patients. Medicare and Medicaid require that all testing done on their patients be direct billed by the laboratory performing the test, but other payer types do not have this requirement.

Outreach clients are supplied with custom requisitions, specimen collection supplies, and are set up with a courier schedule and a reporting schedule. Reports are automatically scheduled through the lab computer system and can be set to meet the needs of the practice or nursing home. Reports can be sent to either fax machines or printers.

Outreach patients may be asked to sign Advance Beneficiary Notices, if the diagnosis provided does not meet Medicare medical necessity guidelines. If a specimen is submitted for which this occurs, the client will be notified. If the client cannot be reached, the specimen will be held until contact is made. In the case of specimens with limited stability, the test will be performed if it is done on site, and the results held, pending direction from the client.