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MercyOne – Laboratory 1410 North 4<sup>th</sup> Street Clinton IA 52732 LABORATORY HANDBOOK 2024

**Introduction**: Laboratories should provide accurate specimen collection, transport and storage information to all clinical professionals. This manual will provide necessary information but is not by any means comprehensive. Quality specimens and accurate test results provide important information for our patients and their providers.

The laboratory can help to ensure good samples by providing collection information to health care personnel at the collection site, making sure that appropriate containers and collection supplies are available, defining good labelling system and checking all samples carefully when they arrive in the laboratory.

#### **Contact Information:**

Title of Contact	Phone number
Pathologist Dr. Stan Eilers M.D./ Dr.	563-244-5653
Marta Van Straten M.D.	
General Lab Reception	563-244-5656
Laboratory Director	563-244-5666
Chemistry Section	563-244-5657
Hematology/POC/Coag	563-244-5663
Blood Bank	563-244-5658
Histology/Microbiology	563-244-5665
LIS/Billing	563-244-5660
Lab FAX	563-244-3943

**Hours of Operation:** Fully staffed laboratory 24/7/365. Pathologist on-sight approximately 0900-1400 Monday and Thursady and can be reached any time after hours.

**Outpatient Lab Hours:** Monday through Friday 07:00 am to 05:00 pm. Weekends scheduled appointments only.

**Medical Necessity and ABN:** Laboratories can submit claims to federally funded health programs only for services considered medically necessary. An ICD-10 code should be submitted with all orders substantiating the medical necessity of the testing. Additionally, Medicare frequency rules will also apply for testing such a INR, HgbA1C, Lipid, Thyroid and other lab tests. Mercy laboratory will run the Medicare Compliance Advisor to determine the coverage. Patients are made aware of the labs not covered and the reason for denial. ABN's signed before any testing ensues.

# Laboratory Accreditation:

- College of American Pathology (CAP) 1772501
- CLIA 16D0387650

Test Menu Index: http://www.mercyclinton.com/laboratory-services

- Follow this link to gain access to Mercy Laboratory Test Directory
- Microbiology Collection Manual
- Anatomic Pathology Collection Manual
- Critical (panic) Values

Note: The comprehensive test menu lists the specimen container, preservatives or anticoagulants and the required volume.

# **Test Requisitions:**

All specimens are accompanied by an adequate requisition. The requestor/provider must be authorized by evidence of the National Provider Identifier (NPI) from authorized individuals physicians, dentists, residents, podiatrists, chiropractors, physician assistants, advanced practice nurses including certified nurse midwife and public health agencies. Written lab requisitions accompany all outpatient lab services and are required to have the following information.

- OUTPATIENT: Requests for outpatients must be accompanied by a script or requisition from an authorized person (see above), which must include an appropriate ICD10 code or diagnosis. Any test orders that are unclear will be clarified with the physician prior to being entered into the laboratory information system. Medicare Traditional patients will be screened for medical necessity before labs are obtained.
- EMR ORDERING: All laboratory test requests should be appropriately ordered by the attending practitioner. If the provider has given verbal orders to nursing they can place the order and the provider must sign off on the order if they deem it acceptable.

- DOWNTIME: In the event of downtime paper DOWNTIME requisitions can be used to place orders. If possible the lab can then order the tests within the lab information system.
- ADD-ONS: Once a specimen has been collected, requests for add-on tests must be called directly to the appropriate Laboratory section PRIOR to ordering in in the electronic medical record (EMR). The laboratory scientists will then determine the suitability of the collected specimen for the requested test. It is then the responsibility of the requesting unit to order the test in the EMR.
- VERBAL ORDERS: To confirm the accuracy of verbal or phone orders for outpatients, and to clarify orders that may be unclear, the laboratorian must "read back" to the person originating the order. The actual order requisition must be provided to the lab within 24-72 hours that reflects the verbal order previously received. Use the verbal order log sheet for documentation and follow up. The laboratorian must gather the following information:
  - Patient name
  - Date of birth
  - Ordering provider
  - Diagnosis ICD10
  - Tests ordered

# **Patient Identification:**

Before performing any component of the phlebotomy procedure, the phlebotomist must properly verify the identity of the patient with the collection request using **two** distinct identifiers as follows:

- OUT PATIENT: Ask the patient to verbally state or spell their complete name and birth date. **Do not** ask the patient to confirm their identity by requesting a yes/no response. Compare this information with the name on the paperwork or the patient's identification band. Patients who are not capable of giving their name may be identified through verbal verification by another adult who can personally identify the patient. Each specimen label must then be compared to the paperwork prior to collection. Name and date of birth are to be verified. ED and SDS patients will have an identification band to check before any blood draws. Patients presenting to the outpatient lab may not have an identification band.
- IN PATIENT: Ask the patient to verbally state or spell their complete name and birth date. **Do not** ask the patient to confirm their identity by requesting a yes/no response. **All** patients before every blood draw encounter must have their identification band confirmed by the laboratorian. Compare this information with the name on the EMR issued barcodes. Patients who are not capable of giving their name may be identified through verbal verification by another adult who can personally identify the patient. Each specimen label

# **Specimen Collection:**

Check the collection requirements (type of tube, volume of specimen, timing of collection, preservation requirements such as specimen on ice, etc.) listed in the *Mercy Laboratory Test Directory*. The Laboratory Information System (LIS) barcodes also provide specimen collection requirements during the ordering process. Clarify any questions with the Laboratory prior to specimen collection.

Instructions with additional details for the collection of blood bank, finger sticks, heel sticks, blood cultures, etc. can be found in the "Phlebotomy Procedure" (Policy Tech unique number 2004).

# **Specimen Preservation:**

The comprehensive list of specimen preservation requirements is found in the *Mercy Laboratory Test Directory*, provided below are the requirements for some of the most common inquiries for testing add-ons.

- INR 24 hours at room temp
- PTT 4 hours at room temp
- BNP refrigerated 24 hours
- DDimer 4 hours at room temp
- ESR 4 hours at room temp or 12 hours refrigerated
- Reticulocyte 24 hours refrigerated
- Fibrinogen 24 hours at room temp
- PSA 24 hours refrigerated
- Troponin 24 hours refrigerated
- Vitamin B12 24 hours refrigerated
- Folate 8 hours refrigerated or frozen >8 hours
- HGB A1C 7 days refrigerated

## **Specimen Storage Post Testing**

- Chemistry serum/plasma stored refrigerated 72 hours
- Hematology EDTA stored refrigerated 24 hours
- Urinalysis specimens stored 24 hours
- Coagulation specimens stored 24 hours room temp
- Histology specimens have permanent preservation
- Microbiology specimens no post set up storage
- Blood bank specimens stored for 2 weeks for post transfusion reaction analysis

#### **Patient Preparation:**

- Phlebotomist will ensure proper handwashing or foaming and protective equipment is in place; gloves, masks, gown.
- Inform patient of the intended task of blood collection. Determine limitation such as mastectomies, surgeries, injuries etc.
- Position the patient.
- Apply the tourniquet.
- Palpate the vein of choice, to determine the necessary equipment for venipuncture.
- Cleanse the venipuncture sight with 70% alcohol unless special collection of blood cultures or blood alcohol has been requested.
- Consider the tube order of draw.
  - Blood culture vials
  - Sodium Citrate (light blue)
  - Serum tube (red, gold & tiger top plastic)
  - Heparin Sodium or Lithium (green)
  - EDTA (purple)
  - Royal blue (EDTA)
  - o Tan (EDTA)
  - o Fluoride (gray)
- Apply pressure to the venipuncture site and dress the venipuncture area.

For special collection methods such as capillary finger and heel refer to the policy titled "Phlebotomy Procedure" in Policy Tech.



#### **Special Collection:**

Blood Culture collection refer to the Microbiology Collection Manual.

Body Fluid (synovial, pleural, peritoneal & pericardial) collection refer to the *Microbiology Collection Manual* plus the quick reference can be found below.

- Collect body fluid in sterile fashion and place into each of the following ;sterile container, EDTA (lavender) tube and sodium heparin (green) tube.
- Invert the EDTA and heparin tube to ensure specimen doesn't clot.
- Label all collection devices with the five proper requirements must also include the specimen source.
- Transport to lab ASAP

24 Hour urine collection for tests such as Creatinine Clearance or Metanephrines should be clearly explained to the patient. Written instructions and the patient label are provided together as a sticker on the 24 container. Once you have explained the collection instructions use "Teach Back" to confirm that the patient or their caregiver understands.

- To complete a 24 hour period, start and end collection at approximately the same time in the morning.
- Do not void directly into container.
- Collect each specimen in a disposable clean plastic cup and carefully pour into the 24 hour container.
  - When adding a specimen to the container, add carefully to avoid splatter to skin and eyes and to be sure that there is nothing spilled.
- Refrigerate during and after all collections.
- **DAY 1:** Discard the first morning specimen and record time. Collect ALL specimens during the remainder of the day and night.
  - Record on label: START DATE AND TIME:
- Day 2: Collect the first morning specimen and then STOP collection.
  - Record on the label: STOP (FINISH) DATE AND TIME:
  - Tighten lid securely. Keep upright. Transport in a refrigerated container with requisition as soon as possible after completion.
  - If the amount of specimen exceeds capacity of the 24-hour urine container, use a similar sealable clean plastic container such as a clean and rinsed mild jug. Label as container number two and note on requisition that two containers submitted.

## **Other Special Timed Collections:**

Please refer to individual policies for timed testing such as renin, newborn metabolic screens, one hour glucose challenge, three hour glucose challenge, antibiotic trough levels and cortisol stimulation.

## **Specimen Labeling:**

All primary specimen labeling MUST be done in the presence of the patient. Primary specimen is defined as the innermost container that holds the original specimen prior to processing and testing. At least two patient specific identifiers must be on the innermost container. The following information must be legibly recorded on a label affixed in an irreversible fashion to the primary specimen container (specimen container examples can be a tube, cup, swab, slide or syringe):

- Patients full name (not a nickname)
- Date of birth
- Date of collection
- Time of collection
- Initials of collector

Barcoded pre-printed labels with accession numbers generated by an information system may be used. The date, time and collector initials must be recorded after the specimen has been drawn

and after verifying that the patient name and ID on the label agrees with that on the test requisition. This is the single most important factor in preventing errors in patient specimen identification.

- Use one label per specimen
- Transport specimens in leak proof sealed plastic biohazard bags designed for specimen transport.
- Place the labeled specimen in the bag. The label is affixed to the specimen container and not the bag.
- Place the matching requisition in the outside pouch of the bag. One patient per specimen bag (do not mix patients).
- Blood Bank testing requires additional labeling. Please refer to "Phlebotomy Procedure".

## **Specimen Date Received**

Outside specimen collection that is transported by medical personnel such as visiting nurses will have a specimen received time documented in one of the following places; packing slip or outpatient drop off log sheet. When orders are placed the LIS will capture the received time too.

# **Specimen Transport**

Inside hospital transport is either hand delivered by nursing, radiology or inside courier.

- Place the bagged specimen inside the laboratory door designated for specimen drop off. Turn on the red flashing light to indicate that a specimen has been placed in the drop off bin.
- Confirm that the specimen has been tasked off in Power Chart under Activities and Interventions.
- If the specimen requires and doesn't arrive on ice it will be rejected, such as lactic acid.

Outside hospital transport can be executed via outside courier, patient, individuals from nursing homes, home care or other medical clinics.

- Properly collected and labeled specimens should be wrapped in an absorbent material and placed inside a biohazard bag.
- Lab requisitions are required and must include provider name, diagnosis, tests, name of patient, patient date of birth and checked for specimen integrity.
- Outpatient lab reception has a log sheet for home care nurses and other medical clinics to write down the date and time of the specimen drop off. Patients are excluded from this process.
- Specimens collected in lithium heparin (green top) or red clot tube for chemistry analysis must be separated from cells (centrifuged) within two hours of collection or transported to lab within time limit.

#### **Specimen Rejection Criteria**

Specimens can be rejected for the following reasons (this is not comprehensive).

- Specimens may be rejected if labeling doesn't contain the five requirements of full patient name, date of birth, date of collection, time of collection and initials of collector.
- Specimens collected in lithium heparin (green top) or red clot tube for chemistry analysis must be separated from cells within two hours of collection.
- Specimens will be rejected if hemolysis occurs due to collection process.
- Specimens will be rejected if whole blood specimens are clotted.
- Specimens without enough quantity (QNS). For instance under filled sodium citrate tubes or neonatal metabolic screen without proper soaking onto the filter paper.
- Diluted specimens due to collection near IV access
- Expired collection containers such as tubes and swabs.
- Specimens not kept in the proper temperature requirements.
- Laboratory Scientists can make determinations on a case by case situation if specimens are appropriate for testing.

Documentation and notification of rejected specimens

- Notify the ordering provider or the attending nursing unit of the rejected specimen. Provide the reason for rejection and discuss recollection.
- Document the rejection by providing the following information onto the "Specimen Rejection" forms located in all departments. Outpatient and reference testing rejection forms are titled "Quality Management for Rejected Specimens".
  - Date, time and your initials
  - Who you notified regarding the rejection
  - o Patient name
  - $\circ$  Reason for rejection

The only exception is for specimens which are difficult/traumatic to obtain. Ex. CSF, bone marrow, or other irretrievable specimens.

#### Special Handling of Sub-Optimal Specimens (including specimen label correction)

- In all cases, the ordering physician or attending nurse must be notified when a specimen is rejected.
- The laboratory personnel will document into LIS the name of the person contacted and the reason for rejection. This will capture the date and time of entry. This will also be recorded on the laboratory rejection form and kept on file.
- In any case where the test cannot be reported, it will be cancelled. The patient will be credited for the procedure not performed.

- The test will need to be reordered and recollected at the decision of the physician or attending nurse.
- When a mislabeled specimen is one defined as "difficult/traumatic to obtain", the physician must be notified and he/she must validate the circumstances and assure that the specimen indeed belongs to the patient. The laboratorian must include a comment in the report stating that the "specimen was originally rejected due to mislabeling, but validated by (physician name)".
- Salvageable sub-optimal specimens that can be corrected include handwritten labels with minor spelling errors, missing date and time of collection that can be corrected by the collecting personnel and specimens that have inadequate information on the test requisitions.
  - Determine specimen is from correct patient by verification of patient identification.
  - Verify sample is correct specimen type.
  - Collector will return to the lab or the lab will take specimen to the collector for relabeling.
  - Document the correction of the label on the specimen rejection form in the department and within the LIS.

# **Turn Around Times (TAT)**

The turnaround time for laboratory tests represents the time period <u>from</u> specimen receipt in the laboratory <u>to</u> result availability. This does not include specimen collection time, but starts when the specimen actually arrives in the laboratory.

- STATS 60 minutes, this includes all basic emergency room tests such as urinalysis, chemistry profiles, hcg, CBC, coagulation, serology kit tests for mono, strep
- ASAP/Expedite 120 minutes
- Early am testing of Chem 8, CBC, INRPTT by 0700am if ordered as routine for early morning collection
- Routine in-house patient testing 4 to 8 hours
- Routine outpatient: Same day or 24 hours
- Reference laboratory testing: To be determined by the reference laboratory.
- Body fluid testing TAT approximately 90 minutes excluding crystal examination

## **Result Reporting**

- Inpatient results will populate the hospital EMR as soon as testing has been completed. If reference tests have been ordered that are not interfaced with the EMR the provider will receive a paper copy and this will be scanned into the patient chart.
- Outpatient results will generate a printed result that is auto-faxed via the lab information system (LIS). If the provider isn't built into the LIS then the outpatient lab assistant will manually fax results to the requesting provider.

• State of Iowa public reporting results are not yet interfaced with state hospitals, requiring paper results to be sent to providers. Microbiology lab scientists will also communicate positive results by calling the provider.

## **Critical Results**

To inform the requesting physician or care giver of any critical value within 30 minutes so that nurse/ physician may act accordingly. "Read-Back" will be used to prevent the possible occurrence of medical errors that result from the miscommunication of verbally reported results. A critical laboratory value is a value at such variance with normal as to represent a pathophysiologic state, which is life-threatening unless some action is taken in a very short time and for which an appropriate action is possible. It is a laboratory responsibility to communicate these values immediately and flawlessly to the responsible clinicians.

All critical values or results of certain laboratory tests should be reported to the physician requesting the laboratory test or the attending nurse within 30 minutes. Critical laboratory results when communicated verbally by phone or face to face will be read back and documented as such to confirm that the correct results were communicated.