University Hospitals
Elyria Medical Center

General Guidelines

Introduction:

UH Elyria Medical Center Laboratory offers comprehensive testing services in both Clinical and Anatomic Pathology. On-site testing is performed in the following diagnostic areas:

- Automated Chemistry
- Hematology
- Urinalysis
- Transfusion Medicine
- Cytology
- Autopsy Services
- Special Chemistry
- Coagulation
- Microbiology
- Molecular Diagnostics
- Histology

Our Laboratory is equipped with state-of-the-art instrumentation and information systems offering the newest and most advanced technologies, automated processes and robotics ensuing quality and integrity of results for best patient care. Extensive use of barcode technology ensures superior patient safety and a rapid turnaround. Hand-held computers with label printers are used by phlebotomists to scan patient information from their bar-coded wristbands. Labels are applied to specimen at the patient's bedside enhancing patient safely with positive sample ID.

Specimens are processed and analyzed as soon as they reach the laboratory. We strive to deliver results to physicians in the shortest time possible and offer solutions for transmitting lab results to physician's Electronic Medical Record (EMR) Systems.

Accreditation/Licensure:
Our Laboratories are currently accredited by CAP (College of American Pathologists) Laboratory Accreditation Program and are CLIA (Clinical Laboratory Improvement Amendments) certified. We also maintain current licenses, permits, and registrations required by state or local regulations. For copies of certificates click on the facility location (i.e. Elyria and Amherst) located on the main page.

Highly Trained Professionals:
Staffed with a team of highly skilled and extensively trained medical professionals, our employees are dedicated and committed to providing the highest level of service to patients, physicians and customers.

Test Directory users:
To ensure quality testing, it is important to adhere to the following guidelines when preparing a specimen for testing. Once a specimen is collected properly, it must be processed, stored and transported correctly or results may be compromised. If you are sending specimens to our

laboratory for analysis, make certain that your specimen collection, handling, and transportation procedures meet the guidelines set by our laboratory.

The test directory guide provides an alphabetical listing of most tests performed by UH Elyria Medical Center Laboratory or which may be referred to our contracted referral laboratories. Because clinical laboratory medicine is ever evolving and changing science there may be tests that are not currently in this listing. Please contact our Laboratory Client Response Center at 1-216-844-5227 for assistance if the testing you are looking for is not listed. Cytology Client Services call 216-844-1803 and Surgical Pathology Client Services call 216-844-1817.

Provider-Lab Consultation Line 216-286-9295 or email uhlabhelp@uhhospitals.org.
Questions about laboratory test interpretation and selection. Leave a detailed message or email, Medical Director or Technical staff member will investigate and respond a quickly as possible.

Note: the CPT-4 codes provided are for information purposes only. They are based upon AMA guidelines and our interpretation of CPT coding requirements. CPT coding is the sole responsibility of the billing party. We assume no responsibility for billing errors due to reliance on the CPT-4 codes listed in this test index.

Patient History forms
Some tests may be required for some testing this information is necessary to interpret patient results.

Patient Informed Consent Forms
Counseling and informed consent are recommended for some testing.

Health Insurance Portability and Accountability Act (HIPAA)
Our Laboratories are committed to complying with privacy and security standards set by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). UH Elyria Medical Center has implemented policies, processes and procedures designed to ensure compliance with these standards. Compliance is continuously monitored and audited for effectiveness.

Health and Safety Precautions:
Use universal precautions when handling specimens containing blood or other potentially infectious material. Work areas contaminated with blood or serum must be disinfected immediately with 10% bleach (hypochlorite at 0.5% final concentration) or other approved disinfectant. In the event of an exposure, administer first aid immediately, notify your manager or supervisor and seek prompt medical attention.

Specimens must be handled in a safe manner. Information on safe specimen handling may be obtained from the U.S. Occupational Safety and Health Administration (OSHA) and the Centers for Disease control.

Patient Identification:
All patients from whom clinical specimens are obtained must be positively identified prior to specimen collection. Positive identification is the responsibility of the person collecting the sample.

Patient Preparation:
Many test(s) require that the patient be prepared in some specific way to ensure useful results. The best analytical techniques provide results that are only as meaningful as the quality of the specimen that has been submitted for testing.

Fasting Requirements:
For most tests performed on serum, plasma or whole blood, a fasting specimen is preferred. Fasting is defined as no consumption of food or beverage, other than water, for 10 to 12 hours. Ask your doctor if you are allowed to take your regular medications before the test. Refrain from breath mints, cigarettes, and chewing gum during the fasting period. These can contain sugars or other active ingredients that may affect test results.

Collection kits and containers for patient use:
Collection kits for the following are available at any of the Patient Service Centers.

Urine Collections (Timed): 24 Hours, Stone Risk Profile, etc.
Fecal (Stool) Collections: Fecal Fat, Occult Blood, IFOBT, etc.
Urine (random, first morning) Collection kits: Urinalysis, Culture etc.

Collection and transport systems: used at University Hospitals Elyria Medical Center Laboratory and Amherst.
See supply section for ordering information for your location.

Provocation (challenge) Test(s):
Some test(s) require the patient to ingest a substance. The most common are the Glucose Tolerance Tests where the patient drinks a solution containing glucose, and a blood specimens are obtained before and at various times after the drink, to measure the concentration of glucose in the serum or plasma.

When ordering tests in a series (e.g. glucose tolerance, etc.):

1. Use one test requisition
2. Label each specimen with the Patient's full name, Date of birth, Collection date and time, sample number, or site (if applicable.)
3. Write the number of specimen on the test requisition.
4. Submit all specimens within a series together in one specimen bag.

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Proper Identification of Specimens:
Specimen Labels:
All specimens must be labeled at the time of collection in front of the patient.
Label must also include at least two identifiers.

1. Labels must include the Patient's full **legal** name or a unique ID code.
   The patient's name must be written exactly as it appears on the test requisition.
2. Date of birth (Month/Day/Year)
3. Date and time of collection
4. Site or source of collection if applicable
5. Number of sample if series test or multiples submitted.

When hand writing a label use a black ballpoint pen or fine line permanent marker.
If glass slides are submitted, use a pencil on the frosted end.

Test requisition:
Specimens must be accompanied by a paper requisition, prepared either by hand or printed electronic ordering system. The requisition must contain the following information:

- Patients full legal name.
- Patient demographics (address, telephone number, client patient I.D.)
- Patient Gender.
- Patient Date of birth.
- Ordering Physician Name, address, phone, fax and NPI number.
- Test(s) requested.
- Date of specimen collected, when appropriate.
- Source and type of specimen, and time of collection, when appropriate.
- Clinical Information, when appropriate
- Blood Bank request must include the signature of the person who positively identified the patient on the ordering requisition.

Some test(s) require scheduling. Refer to the individual test listing in the Test Directory or contact Laboratory Client Response Center at 1-216-844-5227..

Complete the *Patient Information* and *Insurance Information* sections of the requisition.
Provide an office face sheet that includes patient demographics, insurance information and a photocopy of insurance cards, if possible, when submitting a sample.
Select the tests to be performed. Legibly print patient information and indicate with a check mark which party will be responsible for payment in the "Bill to" section of the requisition. Enter the ICD diagnosis that reflects the patient's symptoms, condition, or diagnosis and prove medical justification for the tests ordered. Review test(s) ordered with the diagnosis indicated, verify you have a supporting diagnosis for each test indicated.

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Inappropriate Submissions
All specimens must be collected, labeled, transported and processed according to procedure. Review the appropriate container type, volume, and special handling requirements needed for analysis before the specimen is collected, If any of the guidelines are not met, the specimen maybe rejected, or the test may be canceled. The following list represents some possible causes for specimen rejection.

- **Compromised specimen (e.g., hemolyzed, lipemic or clotted specimens)**
- **Improper specimen transport**
- **Improperly labeled specimen**
- **Inappropriate specimen container**
- **Inappropriate specimen type**
- **Insufficient volume for analysis**
- **Specimen has been submitted in incorrect or expired media**
- **Specimen leaked in transit.**

Insurance:
For questions regarding your laboratory bill, call 1-800-931-6642.

Self pay by choice request:
Testing is offered at a reduced rate for those requesting self pay by choice.

Medicare Coverage:
When ordering laboratory test(s) that are billed to Medicare/Medicaid or other federally funded programs, the following requirements may apply.

Medicare only pays for test(s) which it considers medically necessary for the diagnosis and treatment of the patient. Medicare will not pay for a screening test for a disease when the patient displays no symptoms or evidence of a disease except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered research only. Ancillary services are expected to have on file, a diagnosis or complaint that shows a medical necessity. The ordering physician must provide an ICD diagnosis code, not a narrative description if required by the carrier.

Organ or disease oriented panels should be ordered only when all components of the panel are medically necessary.

If there is reason that Medicare will not pay for a test, the patient should sign an “Advance Beneficiary” (ABN) Form to acknowledge that they are responsible for the cost of the test if Medicare denies payment. The fact that Medicare may not pay a particular item or service does not mean that the physician should not order it. It does mean that Medicare probably will not pay for the laboratory tests.

The test(s) listed are for the following reasons:

- Medicare does not pay for these test(s) for your condition.
- Medicare does not pay for these test(s) as often as this (denied as too frequent).
- Medicare does not pay for experimental or research use test(s).

Adding on a test(s) request:
Add on test request are accepted when the specimen type allows and current sample condition warrants a valid result.
Regulations require that all tests must be confirmed by a written signed requisition within 30 days of the request. This includes standing orders, add on request, and verbal orders for all patients.

Panels and Reflex Testing:
UH Elyria Medical Center Laboratory offers group tests based on accepted clinical practice, as well as those defined by the American Medical Associations terminology (AMA CPT) Codes. Components of these panels may be ordered individually, unless otherwise indicated.

There are two types of reflex panels: Standard and Compulsory.
Standard: Allows the physician the option of ordering either the reflex test group or a single test.
Compulsory: Automatically generates a request for additional testing if the result of the initial test meets or falls outside set criteria. Microbiology and Blood Bank have predetermined panels based on specific medical criteria accepted as standard-of-care by the medical community. These panels are not available for ordering at the individual component level.

Chain of Custody:
Chain of custody documentation is not available. All test(s) performed at UH Elyria Medical Center Laboratory are designated for medical use only.

Transporting specimens:
Needles, Sharps or Medical Waste:
Do not send any needles or other sharp or breakable objects. Do not send medical waste as a diagnostic specimen since it may violate the lab policy and create a health and safety hazard. Properly discard used needles or other sharps prior to transport.
Sample collection using a syringe: the needle must be removed and the syringe capped before sending to the laboratory. Ensure there is no leakage or visible contamination outside the specimen container.

Transport specimens promptly: See specific test for collection, handling, and transport temperature requirements.

Specimens will not be accepted if the information on the specimen label does not match the information on the accompanying requisition.

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Test Turnaround Time:
Turnaround time is defined as the period of time from specimen receipt in the laboratory to the release of results. Testing schedules may change.

Availability of Results:
Specimens are processed as soon as they reach the laboratory. Routine testing is generally reported within 24 hours of receipt in the laboratory.
In some cases, owing the complexity of the test or when the test is not performed on a daily basis, a longer turnaround time may be indicated. (See individual Test Directory listings).

Result Reporting:
When verified and released, patient reports/results are available through a variety of mechanisms: electronically to physician EMR or Web Portal, also via courier, fax or mail.
Contact Laboratory Client Response Center at 216-844-5227
Option 1 Clinical lab results and specimen requirements.
Option 2 Cytology and Surgical Pathology results and questions

UH complies with state laws by reporting certain state defined reportable diseases and conditions to state departments of health. These reports include patient demographics and test information as required by each states regulations.

Telephone Reports:
Requests for telephoned or faxed reports should be indicated on the original test request.
Routine results are called or sent by fax within 10 business days.

Critical/Panic Values:
Critical/Panic values are defined as values that are outside the normal range to a degree that may constitute an immediate health risk to the individual or require immediate action on the part of the ordering physician. It is the policy of the laboratory to call critical values listed to a licensed provider as soon as completed and verified in the compliance with hospital policies approved by UH Elyria Medical Center directors. Read back of the critical values by the person receiving them to the person making the notification call is required.

Notification by the Laboratory of Critical (Panic) Values:

- The ordering physician's office will be called and the results communicated to an RN or MD.
- Documentation in the will be made of the call listing the first initial, last name, title of the person receiving the call and the time the call was make.
- For verification the person receiving the call will be asked to repeat the critical value back.
- If there is no answer, the physician's answering service or physician that is covering for the ordering physician will be called or paged.

Supplies:
Supplies can be provided for your location. Contact Laboratory Client Response Center 216-844-5227 Option 7. To initiate a new client relationship including a needs assessment. We will be happy to work with you to develop a supply order form customized to your needs.

Referral Testing
UH reserves the right to change vendors and test parameters for referral testing at any time.