UnityPoint Health
St. Luke's Hospital

Cedar Rapids, Iowa

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S T A N D A R D O P E R A T I N G P R O C E D U R E S

PATHOLOGY-LABORATORY SERVICES

SCOPE OF SERVICE

1. Laboratory Services under the direction of a Laboratory Director who is board certified in Anatomic and Clinical Pathology are available to all patients of all ages and include diagnostic testing, therapeutic monitoring, and emergency testing. Quality, accuracy, reliability and timeliness are central to the laboratory mission.

2. The Laboratory offers services seven days a week, 24 hours a day, to inpatients, outpatients, and contract clients of all ages. Non-emergent services are not necessarily available at all times.

3. The laboratory departments offer a full range of clinical testing and support services in each discipline, including:

PATHOLOGY	• surgical: frozen section diagnosis and diagnostic histopathology • autopsy • medical transcription/procedure scheduling services • interpretation of GYN and non-GYN cytology • interpretation of peripheral blood smears • perform and interpret bone marrow biopsies and aspirates • perform fine needle aspiration (FNA) of palpable lesions • provision of immediate on-site evaluation of FNA's and needle biopsies performed by physicians in St. Luke's Hospital • provides consultation to providers concerning selection and interpretation of lab tests • directorship, clinical consult and regulatory oversight of all testing activities at all lab locations
CORE LABS: BLOOD BANK HEMATOLOGY COAGULATION URINALYSIS CHEMISTRY POINT OF CARE	• compatibility testing • antibody detection and identification • blood product preparation, storage and modification • Identify Rh Immune candidates • Fetomaternal hemorrhage detection • routine and special hematological testing • bone marrow collection/analysis • coagulation studies • urinalysis: routine and special urine examination • routine and special analyte testing • therapeutic drug monitoring • blood gas analysis

	• thyroid function testing • endocrine assays • infectious disease marker testing • toxicology: emergency screening and routine identification
SPECIALTY LABS: MICROBIOLOGY HISTOLOGY CYTOLOGY	• bacterial culture and antibiotic susceptibility testing • parasitology • mycology • serology • virology • molecular diagnostic testing • autopsy and surgical processing • routine and special stains, including specialized immuno-histochemical staining • routine and special cytological exams from all body sites
CLIENT SUPPORT	• phlebotomy • specimen preparation and distribution • patient registration and orders • verification of medical necessity • client assistance with reports • telephone communications • referred specimen preparation and send-out
OUTREACH	• Phlebotomy • Sample processing, storage and transport • CLIA-inspected Physician Office Laboratories (MedLabs) provides limited waived and moderately complex testing at the point of service for UnityPoint Family Medicine, Pediatric and Urgent Care locations.
MLS/MEDICAL TECHNOLOGY PROGRAM	The Laboratory also includes a Medical Laboratory Science Program.

HOURS OF OPERATION

HOSPITAL OUTPATIENT HOURS:

Monday – Friday: 0700 – 1700 hours

The following tests are offered Monday-Friday by appointment only:

- bone marrow biopsy
- dark-field exams
- fine needle biopsies of palpable lesions
- ACTH stimulation test
- Glucose Tolerance Tests
- Blood collection requests outside business hours

PATHOLOGY OFFICE HOURS:

Monday – Friday: 0700—1700 hours

Nights, Weekends and Holidays: Pathologist on call

HISTOLOGY/CYTOLOGY DEPARTMENT HOURS:
Monday – Friday: 0700 - 1700 hours

INPATIENT/ED BLOOD COLLECTION AND TESTING:
Monday – Sunday 0000 – 2400 hours

MEDLABS:
Hours and locations are available by following this link:
https://www.unitypoint.org/cedarrapids/medlabs.aspx

POLICIES

1. Laboratory testing is performed in compliance with federal and state laws. Under Iowa law, only licensed providers (or authorized individuals) may order laboratory testing.

2. Requests for laboratory testing must be in writing and signed by the requesting provider (or authorized individuals) before services can be performed.

3. Requests for laboratory testing by providers (or authorized individuals) without medical staff privileges at St. Luke's Hospital will be reviewed by a Pathologist before services are performed.

4. Requests for laboratory testing must have supporting documentation of signs/symptoms or diagnosis codes specific and consistent with the medical necessity for the testing to be performed. This supporting documentation must be in the patient's chart or included with the order to assure proper coding to comply with third party payer rules for medical necessity.

5. Turnaround time for laboratory testing varies by test and where the testing is performed. Testing performed locally by automated methods can be available within minutes of specimen receipt. Other testing (e.g. cultures and reference send outs) may require days for processing and reporting. See Test Catalog for test menu and turnaround times https://stlukescedarrapids.testcatalog.org/

6. All inpatient STAT requests are to be phoned or paged to the laboratory in addition to being ordered in the computer. If it appears there will be an excessive delay in reporting results, a laboratory manager or designee will be notified and will determine whether notification of the nursing staff or provider is warranted. The nursing unit will be kept informed of undue delays.

7. A nurse, nursing technician, or nursing assistant will accompany and remain with the phlebotomist while specimens are collected from patients in the inpatient psychiatric units.

8. For other laboratory related policies, refer to
   - 7000-01 Requesting, Dispensing, and Administering Blood
   - 7000-06 Blood Alcohol (Ethanol) For Legal Purposes (Chemical Test for Intoxication)
   - 7000-07 Withdrawal Of Specimens For Law Enforcement Agencies
   - 7000-08 Alcohols, Legal Draw and Hold
   - 7000-09 Blood Collection For Non-Laboratory Personnel
   - 7000-10 Massive Transfusion
   - 7000-11 Point of Care Testing

BLOOD COLLECTION AND TESTING

The laboratory offers centralized blood collection and testing services. Blood collection and processing is based on first in, first out processing according to order priority. Blood testing and reporting is based on first in, first out processing for random-access automated testing platforms. Manual tests are performed less frequently. Laboratory results for morning provider rounds are available for critical care patients by 0700 and medical surgical patients by 0730

PATIENT ORDERS IN ELECTRONIC MEDICAL RECORD (EMR)

1. The request/order for clinical laboratory testing is entered into the EMR by provider or designee.

2. Enter the frequency and priority level as specified by the provider. See Table 1.

Table 1.

Rank	EMR Code	LIS Translation	Specimen Collection Definition/Goal
1	STAT*	S	Potentially life threatening. Specimen is collected within 10 minutes of order.
2	Timed	T	Time sensitive. Specimen is collected ±15 minutes of specified time.(e.g. trough medication level, HepXa, K+ bolus)
3	AM draw	RT	Routine draw. Specimen is collected during designated AM swarm : • 0500 for critical care units and med surg units 0600 for all other units (excluding behavioral health) • 0730 for behavioral health units
	Today-Next draw		If routine lab is ordered after AM swarm, it will be collected on the next sweep time. ** Sweep times: 10a,12p,14p,16p,18p
As Ordered	Add On		Lab will add on to previously drawn specimen if possible.

*All inpatient STAT requests are to be phoned or paged to the laboratory in addition to being ordered in the computer.

**Routine lab requests prior to sweep time (e.g. patient to be discharged) should be called to lab

SPECIMEN LABELING

1. To prepare for collection of a lab specimen, the order must be released from the EMR (HIS) by "Print Label and Collect Specimen". This is the action that will release the order to the LIS and generate the specimen label on the blaster printer.

2. Prior to any labeling, proper identification of the patient must be established

3. Following the collection of specimens and before leaving the patient's room or bedside, label the specimen(s). NEVER LEAVE THE PATIENT'S ROOM PRIOR TO LABELING (except as noted below).
   a. In most instances, the person collecting the specimen should label the specimen. Situations may occur (e.g. in the Emergency Department) when specimens are collected by someone (e.g. Paramedic or Provider) and handed to laboratory personnel to label. If the laboratory personnel have WITNESSED the collection, he/she may label the specimen. If not, the person collecting the specimen must label it him/herself.

b. Due to the fact that urine specimens are not always collected in the patient's room in the Emergency Department, those specimens are to be labeled immediately following the receipt of that **specimen in the presence of the patient**
   1) in the restroom
   2) in the patients room.

4. The LIS label should be used to label specimens unless there is no blaster label printer on your unit. Write the B band number on the specimen when applicable.

   NOTE: Accepting a specimen for pretransfusion testing with a deviation from this labeling protocol must be approved by a Manager/Lead/Charge and if needed a Pathologist. Complete an electronic event report to document the circumstances. See the Specimen Labeling and Rejection Policy

OUTPATIENT and NON-PATIENT ORDERS

1. Legibly complete an Outpatient Requisition to order laboratory testing for outpatients/non-patients, unless orderable in the HIS. The following information is required for processing the order in a timely manner:
   - Patient name
   - Date of Birth
   - Gender
   - Ordering provider's name printed
   - Ordering provider's signature or signature/initials of designee
   - Insurance information
   - ICD-10 code(s), list all that apply for each test ordered or reason(s) for ordering the test and supporting signs/symptoms/diagnosis specific for ICD10 coding translation

2. Standing orders, executed in connection with an extended course of treatment, must also include specific diagnostic information which is consistent with the information documented on the patient's chart supporting medical necessity and coding.

3. The following practices are prohibited:
   - Use of diagnostic information provided by the provider from earlier dates of service.
   - Use of "cheat sheets" that provide diagnostic information that has triggered reimbursement in the past.
   - Use of computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the provider.
   - Making up diagnostic information for claims submission purposes.

SPECIMEN LABELING, HANDLING, AND DELIVERY REQUIREMENTS

1. Each specimen container must be clearly labeled with:
   a. Patient's first and last name
   b. Medical Record number
   c. Time and date of collection
   d. Initials/code of the collector
   e. Test(s) ordered
   f. Specimen source, if other than blood

2. STANDARD Precautions for blood and body fluid must be adhered to for all patients and for all specimens. All specimens couriered to the laboratory by non-laboratory personnel must be

placed in a secondary container, e.g., a zip-lock plastic bag with requisition pouch, and considered a biohazard. All handlers of specimens must wear gloves for their protection.

3. Specimens are to be transported/delivered to the lab promptly! See SOP 8320-03 Tube System, Pneumatic for transport guidelines for laboratory specimens.

HISTOLOGY AND CYTOLOGY ORDERS AND SPECIMENS

1. Requests for histology and cytology testing are orderable in the computer (HIS) .This order must accompany the specimen to the laboratory. If EPIC is unavailable a completed requisition, including relevant clinical history and ordering provider's first/last name or six digit provider number, must accompany all properly labeled specimens. Histology requisitions are available by calling the department at extension #7911. Cytology requisitions are available on the UnityPoint Hub by searching for "Cytology requisition."

2. After comparison of specimen collected to corresponding order requisition for complete and accurate labeling, delivery of the specimen will be documented on the order requisition by time, date and initials of person delivering, and initials of staff receiving.

3. To maintain specimen integrity and assure timeliness of result reporting, all specimens are delivered to the laboratory promptly following collection. Do not send tissue or cytology specimens through the pneumatic tube system.

4. Select tissues should always be sent to the laboratory fresh (unfixed) and as soon as possible. See Table 2 for list of select tissues to be prepared fresh (unfixed) for laboratory evaluation.

Table 2. Select Tissue To Be Prepared Fresh (Unfixed)

- Axillary dissection
- Bladder cystectomy
- Breast
- Bowel resections
- Cervical cone biopsy
- Esophageal resections
- Kidney
- Limb amputation (except finger/toe)
- Liver biopsy (for Iron studies)
- Lung
- Lymph nodes
- Ovarian tumors or cysts
- Parotid gland
- Placenta
- Radical neck dissections
- Prostatectomy
- Salivary gland
- Spleen
- Stomach resection
- Submandibular gland
- Submaxillary gland
- Testicle
- Thyroid
- Uterus

5. Extremely large specimens may also be submitted fresh (unfixed) and must be promptly delivered to the laboratory. Cytology Specimens should always be submitted fresh. Brushing specimens should be submitted in Cytolyt fluid or sterile saline.

6. All other surgical specimens should be delivered in formalin (10 to 20 times the volume of the specimen).

SURGICAL SPECIMEN EXAMINATION

Routine surgical specimens are received and examined by a Pathologist until 1700 hours Monday through Friday. Emergency specimen examination(s): Pathologists are available on call 24 hours for frozen specimen examination.

CRITICAL TESTS

Critical tests are those tests which will always require rapid communication of the results, even if results are normal. The following procedures or tests have been defined as critical tests where all results will be called:

- Frozen Section
- Cytologic evaluation of sample adequacy for image guided biopsy or Fine Needle Aspiration Biopsy.
    - Routine evaluation samples will not be called to the provider unless requested

CRITICAL VALUES

1. Critical values are those findings (even from routine tests), which will always require rapid communication of the results.

2. Standard Laboratory Critical Values will be reviewed annually by a manager or designee. Periodic review of critical values will include researching the literature and standards for best practice. Change requests are submitted to St. Luke's Laboratory Director.

3. All critical values are phoned and read back to a nurse in the nursing unit (or at the provider's office for OP and NP) and documented in the logbooks and/or through computer entry. Point of Care results are managed as per individual point of care procedures and per POC 501_POCT Compliance Policy.

Table 3. Standard Laboratory Critical Values

Chemistry	Less than	Greater than
Acetaminophen (Tylenol)		or =150.0 mcg/mL
Arterial pO2 (age >2 years)	50 mmHg	200 mmHg
Arterial pO2 (age 0-23 mo)	50 mmHg	300 mmHg
Bilirubin, Total (neonatal)		16.0 mg/dL
Blood pH (age <30 days)	7.2	7.5
Blood pH (age >30 days)	7.2	7.6
Calcium (age >7 days)	6.0 mg/dL	13.0 mg/dL
Calcium (age 0-7 days)	6.0 mg/dL	12.0 mg/dL
Carbamazepine (tegretol)		or = 20.0 mcg/mL
Carbon Monoxide		20%
Digoxin		or =2.5 ng/mL
Ethanol		or =300 mg/dL
Gentamicin, peak		12.0 mcg/mL
Gentamicin, trough		2.0 mcg/mL
Glucose (ages >2 days)	59 mg/dL	400 mg/dL
Glucose (ages 0-2 days)	45 mg/dL	200 mg/dL
Lactic Acid		or = 4 mg/dL
Lithium		2.0 mmol/mL
Magnesium - w/ Mg therapy		8.0 mg/dL
Magnesium - w/o Mg therapy	1.0 mg/dL	4.7 mg/dL
Phenobarbitol		40.0 mcg/mL
Phenytoin (Dilantin)		20.0 mcg/mL
Phosphorus	1.0 mg/dL	9.0 mg/dL
Potassium (age >30 days)	or = 2.8 mmol/L	or =6.2 mmol/L
Potassium (age 0-30 days)	or = 3.0 mmol/L	7.0 mmol/L
Salicylate		30.0 mg/dL
Sodium (age >30 days)	120 mmol/L	160 mmol/L

Sodium (age 0-30 days)	125 mmol/L	150 mmol/L
Theophylline		25.0 mcg/mL
Troponin		or = 0.05 ng/mL
Valproic acid (Depakene)		200.0 mcg/mL
Valproic acid (Depakene) <18 yrs		150.0 mcg/mL
Vancomycin, peak		40.0 mcg/mL
Vancomycin, trough		20.0 mcg/mL
Hematology	**Less than**	**Greater than**
Hematocrit (age 0-14 days)	30.00%	70.00%
Hematocrit (age 15-30 days)	24.00%	70.00%
Hematocrit (age >30 days)	21.00%	60.00%
Hemoglobin (age 0-14 days)	10.0 gm/dL	25.0 gm/dL
Hemoglobin (age >14 days)	7.0 gm/dL	20.0 gm/dL
Platelet count	50 $x10^3/\mu L$	1000 $x10^3/\mu L$
WBC (age 0-30 days)	5.0 $x10^3/\mu L$	50.0 $x10^3/\mu L$
WBC (age >30 days)	2 $x10^3/\mu L$	40.0 $x10^3/\mu L$
Neutrophil (absolute)	0.5 $x10^3/\mu L$	
CSF WBC		10 /cumm
Coagulation	**Less than**	**Greater than**
INR age >16 years		or = 5
Fibrinogen	or = 100 mg/dL	
PTT-nonheparinized (age 0-29 days)		or = 78.0 sec
PTT-nonheparinized (age 1-11mo)		or = 68.0 sec
PTT-nonheparinized (age 1-16yr)		or = 58.0 sec
PTT-nonheparinized (age>17 years)		or =62.0 sec
Heparin Xa		or =1.04 IU/mL
LMW Heparin Xa		1.10 IU/mL
Dimer		500 ng/mL FEU
Microbiology/Serology		
Positive Blood Culture gram stain	Culture of Potential bioterrorism agents: 1. Bacillus anthracis 2. Francisella tularensis 3. Brucella 4. Yersinia Pestis 5. Coccidodes immitis 6. Burkholderia mallei or pseudomallei	Molecular detection of Stool Pathogens: 1. Salmonella spp. 2. Shigella spp. 3. Campylobacter spp 4. Yersinia spp. 5. Shiga-toxin producing E. Coli
Positive CSF gram stain or culture		
Positive sterile body fluid gram stain		
Positive malarial antigen		
Positive systemic fungus culture		
Positive Acid Fast Bacteria (AFB) stain/TB culture		
		Molecular detection of Bordetella Pertussis
Blood Bank/Transfusion		
Positive Newborn DAT	Transfusion Reaction Evaluation with positive gram stain	
Incompatible or problem crossmatch	Acute Hemolytic Transfusion Reaction	
Positive fetal bleed > 30 ml (whole blood)		

REFERENCES

1. St. Luke's Laboratory Management Team, 2019.
2. College of American Pathologists, Laboratory Accreditation Program General Checklist, 2018

Reviewed Date: 2/2019

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