

Policies – St. Luke’s Hospital Laboratory

Animal Specimens

We do accept animal specimens from veterinarians for laboratory testing.

Billing

Client—Each month you will receive an itemized invoice/statement which will indicate the date of service, patient name, CPT code, test name, and test charge. Payment terms are net 30 days. When making payment, please include our invoice number on your check to ensure proper credit to your account.

St. Luke’s Hospital Laboratory also routes a daily billing journal. If there are errors on this journal, return the journal with the correct billing information and diagnosis codes, so we can adjust the billing before the end of the month bill.

Patient—St. Luke’s Hospital Laboratory will bill the patient’s insurance, if requested. Please include the following required billing information: responsible party, patient’s name, current address, zip code, phone number, Social Security number, and diagnosis code. Providing this information will avoid additional correspondence to your office at some later date. Please advise your patients that they will receive a bill for laboratory services from St. Luke’s Hospital, and that they are personally responsible after insurance payment. Pathology specimens will also include a bill from Laboratory Medicine Specialist of Duluth for the physician component.

Billing - CPT Coding

It is your responsibility to determine correct CPT codes to use for billing. While this catalog lists CPT codes in an effort to provide some guidance, CPT codes listed only reflect our interpretation of CPT coding requirements and are not necessarily correct. Particularly, in the case of a test involving several component tests, this catalog attempts to provide a comprehensive list of CPT codes for all of the possible components of the test. Only a subset of component tests may be performed on your specimen. You should verify accuracy of codes listed. Where multiple codes are listed, you should select codes for tests actually performed on your specimen. **St. Luke’s Hospital Laboratory ASSUMES NO RESPONSIBILITY FOR BILLING ERRORS DUE TO RELIANCE ON CPT CODES LISTED IN THIS CATALOG.** For further reference, please consult the CPT Coding Manual published by the American Medical Association. If you have any questions regarding use of a code, please contact your local Medicare carrier.

Cancellation of Tests

Cancellations received prior to test setup will be honored at no charge. Requests received following test setup cannot be honored. A report will be issued automatically and charged appropriately.

Chain-of-Custody

Chain-of-custody, a record of disposition of a specimen to document who collected it, who handled it, and who performed the analysis, is necessary when results are to be used in a court of law. Mayo Medical Laboratories has developed packaging and shipping materials that satisfy legal requirements for chain-of-custody. This service is available to St. Luke’s Hospital Laboratory’s legal clients.

Compliance Policies

St. Luke’s Hospital Laboratory is committed to compliance with applicable laws and regulations such as the Clinical Laboratory Improvement Amendments (CLIA). Regulatory agencies that oversee our compliance include, but are not limited to, the Centers for Medicare and Medicaid Services (CMS), the U.S. Food and Drug Administration (FDA), and the Department of Transportation (DOT). St. Luke’s Hospital Laboratory develops, implements, and maintains policies, processes, and procedures throughout the organization which are designed to meet relevant requirements. In addition, St. Luke’s Hospital Laboratory has a robust internal and external audit and assessment program to monitor ongoing compliance. It is St. Luke’s Hospital Laboratory’s expectation that clients utilizing laboratory services will ensure their compliance with patient confidentiality, diagnosis coding, anti kick-back statutes, professional courtesy, CPT-4 coding, and other similar regulatory requirements.

Confidentiality of Results

St. Luke’s Hospital Laboratory is committed to maintaining confidentiality of patient information and Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance for appropriate release of patient results. Patient results will be released to the referring physician/client or to the patient on the request of the physician. Other requests will be referred to the hospital Medical Records Department.

We appreciate your assistance in helping St. Luke’s Hospital Laboratory preserve patient confidentiality. Provision of appropriate identifiers will greatly assist in prompt and accurate response to result inquiries and reporting.

Disclosures of Results

Under federal regulations, St. Luke's Hospital Laboratory is only authorized to release results to ordering physicians or other health care providers responsible for the individual patient's care. Third parties requesting results, including requests directly from the patient, are directed to the ordering facility.

Fee Changes

Fees are subject to change without notification. Specific client fees are available by calling St. Luke's Hospital Laboratory Client Service Department at 218-249-5200 or 866-794-1597 and asking for the Laboratory Outreach Manager or the Compliance Billing Coordinator.

Framework for Quality

"Framework for Quality" is the foundation for the development and implementation of the quality program for St. Luke's Hospital Laboratory. Our framework builds upon the concepts of quality control and quality assurance providing an opportunity to deliver consistent, high-quality, and cost-effective service to our clients. In addition, our quality program enhances our ability to meet and exceed the requirements of regulatory/accreditation agencies and provide quality service to our customers.

A core principle at St. Luke's Hospital Laboratory is the continuous improvement of all processes and services that support the care of patients. Our continuous improvement process focuses on meeting the needs of you, our client, to help you serve your patients.

"Framework for Quality" is composed of 12 "Quality System Essentials." The policies, processes, and procedures associated with the "Quality System Essentials" can be applied to all operations in the path of workflow (eg, pre-analytical, analytical, and post-analytical). Performance is measured through constant monitoring of activities in the path of workflow and comparing performance through benchmarking internal and external quality indicators and proficiency testing.

Data generated by quality indicators drives process improvement initiatives to seek resolutions to system-wide problems. St. Luke's Hospital Laboratory utilizes "LEAN," "Root Cause Analysis," and "Six Sigma" quality improvement tools to determine appropriate remedial, corrective, and preventive actions.

The review and analysis of indicator data is focused on recognizing and reducing variability in our processes, identifying systematic problems, and improving critical processes. The following metrics are just a few of the key performance indicators used to monitor performance and customer satisfaction:

- Pre-analytic
 - Lost specimens
 - On-time delivery
 - Specimen acceptability
 - Specimen identification
- Analytic
 - Turnaround time
 - Proficiency testing
- Post-analytic
 - Revised reports
 - Critical value notification
 - Test down/test delay
 - Customer service
 - Customer complaints
 - Customer satisfaction surveys

HIPAA Compliance

St. Luke's Hospital Laboratory is fully committed to compliance with all privacy, security, and electronic transaction code requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Although St. Luke's Hospital Laboratory cannot assure that individual clients will meet their own responsibilities under HIPAA, we are committed to sharing information and coordinating efforts toward that goal. All services provided by St. Luke's Hospital Laboratory that involve joint efforts will be done in a manner which enables our clients to be HIPAA compliant.

Infectious Material

The Centers for Disease Control (CDC) in its regulations of July 21, 1980, has listed organisms/diseases for which special packaging and labeling must be applied. Required special containers and packaging instructions can be obtained from St. Luke's Hospital Laboratory by completing a "Client Supply Requisition Form" (p. 1031).

Shipping regulations require that infectious substances affecting humans be shipped in a special manner. A copy of the regulations can be requested from the International Air Transport Association (IATA); they may be contacted by phone at 514-390-6770 or faxed at 514-874-2660.

Informed Consent Certification

Submission of an order for any tests contained in this catalog constitutes certification to St. Luke's Hospital Laboratory by ordering physician that: (1) ordering physician has obtained "Informed Consent" of subject patient as required by any applicable state or federal laws with respect to each test ordered; and (2) ordering physician has obtained from subject patient authorization permitting St. Luke's Hospital Laboratory to report results of each test ordered directly to ordering physician.

St. Luke's Hospital Laboratory on occasion forwards a specimen to an outside reference laboratory. State law where such reference laboratory is located may require written informed consent for certain tests. St. Luke's Hospital Laboratory will request that the ordering physician pursue and provide such consent. Test results may be delayed or denied if consent is not provided. Any costs incurred will remain the obligation of ordering party.

Parallel Testing

Parallel testing may be appropriate in some cases to re-establish patient baseline results when converting to a new methodology at St. Luke's Hospital Laboratory. Call your Regional Manager at 218-249-5200 or 866-794-1597 for further information.

Proficiency Testing

St. Luke's Hospital Laboratory is a College of American Pathologists (CAP)-accredited, Clinical Laboratory Improvement Amendments (CLIA)-licensed facility that voluntarily participates in CAP-approved proficiency testing programs.

St. Luke's Hospital Laboratory conducts internal assessments to ensure the accuracy and reliability of patient testing when interlaboratory comparison is not available or additional quality monitoring is desired.

Radioactive Specimens

Specimens from patients receiving radioactive tracers or material should be labeled as such. Specimens are not routinely tested for background radioactivity. This radioactivity may invalidate the results of radioimmunoassays.

Referral of Tests to Another Laboratory

Specimens shipped to St. Luke's Hospital Laboratory for referral to an outside laboratory should not be sent in a glass vial(s) due to restrictions set by many of the referral

laboratories. Specimen(s) should be poured off into a plastic, screw-capped vial(s) prior to freezing. A specimen received frozen in a glass vial(s) may be subject to cancellation at the performing laboratory's discretion.

For tests referred to another laboratory, a handling fee will be applied. St. Luke's Hospital Laboratory invoices for all testing referred to another laboratory at the price charged to St. Luke's Hospital Laboratory. These prices are subject to change, at the discretion of the referred to laboratory, without notification. In addition, St. Luke's Hospital Laboratory charges a per test administrative fee.

Reflex Testing

St. Luke's Hospital Laboratory identifies tests that reflex when medically appropriate. In many cases, St. Luke's Hospital Laboratory offers components of reflex tests individually as well as together. Clients should familiarize themselves with the test offerings and make a decision whether to order a reflex test or an individual component. Clients, who order a reflex test, will see the bill for the reflex test on their daily billing report which indicates the additional testing that has been performed.

Reportable Disease

St. Luke's Hospital Laboratory endeavors to comply with laboratory reporting requirements for each state health department regarding reportable diseases. St. Luke's Hospital Laboratory reports by fax, form, or phone depending upon your individual state health department regulations. In addition, St. Luke's Hospital Laboratory reports electronically where available. St. Luke's Hospital Laboratory reports to the appropriate state health department based upon the state listed in the patient address. We strive to cooperate with our clients so that we both comply with state regulations. If you need further information, please do not hesitate to contact St. Luke's Hospital Laboratory at 218-249-5555 or 866-794-1597.

Request for Physician Name and Number

St. Luke's Hospital Laboratory endeavors to provide high-quality, timely results so patients are able to receive appropriate care as quickly as possible. While providing esoteric reference testing, there are times when St. Luke's Hospital Laboratory needs to contact the ordering physician directly. The following are 2 examples:

- When necessary to the performance of a test, the ordering physician's name and phone number are requested as part of "Specimen Required." This information is needed to

allow our physicians to make timely consultations or seek clarification of requested services. If this information is not provided at the time of specimen receipt, St. Luke's Hospital Laboratory will call to obtain the information. By providing this information up front, delays in patient care are avoided.

- In some situations, additional information from the ordering physician is necessary to clarify or interpret a test result. At that time, we will request the physician's name and phone number so that 1 of our staff can consult with the physician.

St. Luke's Hospital Laboratory appreciates your rapid assistance in supplying the ordering physician's name and phone number, when we are required to call. Working together, we can provide your patients with the highest quality testing services in the shortest possible time.

Specimen Identification Policy

St. Luke's Hospital Laboratory policy states that all specimens received for testing must be correctly and adequately labeled to assure positive identification. Specimens must have 2 person-specific identifiers on the patient label. Person-specific identifiers may include: accession number, patient's first and last name, unique identifying number (eg, medical record number), or date of birth. Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and information accompanying the specimen (eg, computer system, requisition form, additional paperwork). When insufficient or inconsistent identification is submitted, we will recommend that a new specimen be obtained, if feasible.

Specimen Rejection

All tests are unique in their testing requirements. To avoid specimen rejection or delayed turnaround times, please check the "Specimen Required" field within each test. You will be notified of rejected or problem specimens upon receipt.

Please review the following conditions prior to submitting a specimen:

- Full 24 hours for timed urine collection
- pH of urine
- Lack of hemolysis/lipemia
- Specimen type (plasma, serum, whole blood, etc.)
- Specimen volume
- Patient information requested

- Patient/specimen properly identified
- Specimen container (metal-free, separation gel, appropriate preservative, etc.)
- Transport medium
- Temperature (ambient, frozen, refrigerated)

Specimen Volume

The "Specimen Required" section of each test includes the preferred volume for testing. Preferred volume has been established to optimize testing and allows the laboratory to quickly process specimen containers, present containers to instruments, perform test, and repeat test, if necessary. Many of our testing processes are fully automated. As a result, this volume allows hands-free testing and our quickest turnaround time (TAT). Since patient values are frequently abnormal, repeat testing, dilutions, or other specimen manipulations often are required to obtain a reliable, reportable result. Our preferred specimen requirements allow expeditious testing and reporting.

When venipuncture is technically difficult or the patient is at risk of complications from blood loss (eg, pediatric or intensive care patients), smaller volumes may be necessary. Specimen minimum volume is the amount required to perform an assay once, including instrument and container dead space.

When patient conditions do not mandate reduced collection volumes, we ask that our clients submit preferred volume to facilitate rapid, cost-effective, reliable test results. Submitting less than preferred volume may negatively impact quality of care by slowing TAT, increasing the hands-on personnel time (and therefore cost) required to perform test.

St. Luke's Hospital Laboratory makes every possible effort to successfully test the patient's specimen. If you have concerns about submitting a specimen for testing, please call St. Luke's Hospital Laboratory Client Service Department at 218-249-5200 or 866-794-1597. Our staff will discuss the test and specimen you have available. While in some cases specimens are obviously inadequate for desired test, in other cases, testing can be performed using alternative techniques.

Supplies

Shipping boxes, specimen vials, special specimen collection containers and kits, sterile vials, stool containers, and request forms are supplied without charge. Supplies can be requested using 1 of the following methods:

- Call St. Luke's Hospital Laboratory Client Service Department at 218-249-5200 or 866-794-1597
- Fax a "Client Supply Requisition Form" to 218-249-5542
- Go to labsupplies@slhduluth.com

Test Development Process

St. Luke's Hospital Laboratory serves patients and health care providers from St. Luke's Hospital and other health care providers in Minnesota and Wisconsin. We are dedicated to providing clinically-useful, cost-effective testing strategies for patient care. Development, validation, and implementation of new and improved laboratory methods are major components of that commitment.

Each assay utilized, whether developed onsite or by others, undergoes an extensive validation and performance documentation period before the test becomes available for clinical use. Validations follow a standard protocol that includes:

- Accuracy
- Precision
- Sensitivity
- Specificity and interferences
- Reportable range
- Linearity
- Specimen stability
- Specimen type comparisons
- Urine preservative studies
- Comparative evaluation: with current and potential methods
- Reference values
- Workload recording
- Limitations of the assay
- Clinical utility and interpretation

Test Result Call-Backs

Results will be phoned to a client when requested from the client.

Time-Sensitive Specimens (STATs)

Call St. Luke's Hospital Laboratory Client Service Department at 218-249-5200 or 866-794-1597 prior to sending a specimen for testing of a time-sensitive nature.

Turnaround Time (TAT)

St. Luke's Hospital Laboratory test menu reflects the needs of our own health care practice. We are committed to providing the most expedient TAT possible to improve diagnosis and treatment. St. Luke's Hospital Laboratory considers laboratory services as part of the patient care continuum wherein the needs of the patient are paramount. In that context, we strive to fulfill our service obligations. Our history of service and our quality metrics will document our ability to deliver on all areas of service including TAT.

Please call St. Luke's Hospital Laboratory Client Service Department at 218-249-5200 or 866-794-1597 regarding specific TATs.

Unlisted Tests

New procedures are developed throughout the year. Therefore, some tests are not listed in this catalog. Although we do not usually accept referred tests of a more routine type, special arrangements may be made to provide your laboratory with temporary support during times of special need such as sustained instrumentation failure. For information about unlisted tests, call St. Luke's Hospital Laboratory Client Service Department at 218-249-5200 or 866-794-1597.

Unsatisfactory Analytic Results

If St. Luke's Hospital Laboratory is unable to obtain a satisfactory analytic result, there is no charge.