

Policies—Sky Lakes Medical Center

Animal Specimens

We accept some animal specimens for laboratory testing. Call 541-274-6240 for details.

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. Sky Lakes Laboratory has developed packaging and shipping materials that satisfy legal requirements for chain-of-custody. This service is only offered for drug testing.

Compliance Policies

Sky Lakes Laboratory is committed to compliance with applicable laws and regulations such as The Joint Commission (JC) and 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 Food and Drug Administration (FDA), and the Department of Transportation (DOT). Sky Lakes Laboratory develops, implements, and maintains policies, processes, and procedures throughout our organization which are designed to meet relevant requirements. In addition, Sky Lakes Laboratory has a robust internal and external audit and assessment program to monitor ongoing compliance. It is Sky Lakes Laboratory's expectation that clients utilizing our 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

Sky Lakes Laboratory is committed to maintaining confidentiality of patient information. To ensure Health Insurance Portability and Accountability Act (HIPAA) of 1996 compliance for appropriate release of patient results, Sky Lakes Laboratory has adopted the following policies:

Phone Inquiry Policy-One of the following unique identifiers will be required:

- Sky Lakes Laboratory accession identification number for specimen; **or**
- Client (C#) or patient (Z#) account number from Sky Lakes Laboratory; **or**
- Medical Record identification number (M #); **or**
- Identification by individual that he or she is, in fact, the “referring physician” identified on the requisition form by Sky Lakes Laboratory client

We appreciate your assistance in helping Sky Lakes 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, we are 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 Sky Lakes Laboratory at 541-274-6240.

Framework for Quality

“Framework for Quality” is the foundation for the development and implementation of the quality program for Sky Lakes 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 Sky Lakes 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 (e.g., 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. Sky Lakes Laboratory utilizes Quality Communication, Project Request, Incident Report, and “Root Cause Analysis” 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

Sky Lakes Laboratory is fully committed to compliance with all privacy, security, and electronic transaction code requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Although Sky Lakes 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 Sky Lakes 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 us by contacting our courier or main laboratory.

Informed Consent Certification

Submission of an order for any tests constitutes certification to Sky Lakes 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 Sky Lakes Laboratory to report results of each test ordered directly to the ordering physician.

Sky Lakes 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. Sky Lakes Laboratory will request that 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 Sky Lakes Laboratory.

Proficiency Testing

We are a JC-accredited, CLIA-licensed facility that voluntarily participates in an inter-laboratory proficiency testing program.

Inter-laboratory proficiency testing includes participation in programs conducted by College of American Pathologists (CAP) such as:

- American Association of Bioanalysts (AAB)
- AABB (formerly American Association of Blood Banks) Immunohematology Reference Laboratory
- CAP Surveys

We conduct internal assessments to ensure the accuracy and reliability of patient testing when inter-laboratory comparison is not available or additional quality monitoring is desired.

Referral of Tests to Another Laboratory

Specimens shipped to Sky Lakes Laboratory for referral or to an outside laboratory should not be sent in glass vials due to

restrictions set by many of the referral laboratories. Specimens should be poured off into plastic, screw-capped vials prior to freezing. A specimen received frozen in a glass vial may be subject to cancellation at the performing laboratory's discretion. Call Sky Lakes Laboratory at 541-274-6240 for information regarding specimen requirement and fee.

Reflex Testing

Sky Lakes Laboratory identifies tests that reflex when medically appropriate. In many cases, Sky Lakes 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.

Reportable Disease

The Sky Lakes Laboratory and Mayo Medical Laboratories endeavor to comply with laboratory reporting requirements for each state health department regarding reportable diseases. We report by fax, form, or phone depending upon your individual state health department regulations. In addition, we report electronically where available. Sky Lakes Laboratory and Mayo Medical Laboratories reports to the appropriate state health department based upon the state listed in the client 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 Sky Lakes Laboratory at 541-274-6240.

Request for Physician Name and Number

Sky Lakes Laboratory and Mayo Medical Laboratories endeavor to provide high quality, timely results so patients are able to receive appropriate care as quickly as possible. There are times when Sky Lakes Laboratory or Mayo Medical Laboratories will need to contact the ordering physician directly. The following are two 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, we will call you 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, Sky Lakes Laboratory will request physician's name and phone number so that one of our staff can consult with the physician.

We appreciate your rapid assistance in supplying us with 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

Sky Lakes Laboratory's policy states that all specimens received for testing must be correctly and adequately labeled to ensure positive identification. Specimens must have two person-specific identifiers on the patient label. Person-specific identifiers must include the patient's first name, last name, and date of birth. Other identifiers that may also be included are accession number or Social Security number. Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and information accompanying the specimen (e.g., computer system, requisition form, additional paperwork). When insufficient or inconsistent identification is submitted, Sky Lakes Laboratory 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 to Sky Lakes Laboratory:

- Full 24 hours for timed urine collection
- Lack of hemolysis/lipemia
- Specimen type (plasma, serum, whole blood, etc.)
- Patient information requested
- Patient/specimen properly identified
- Specimen container (metal-free, separation gel, appropriate preservative, etc.)
- Transport medium
- Temperature (ambient, frozen, refrigerate)

Specimen Volume

The "Specimen Required" section of each test includes the preferred collection volumes. 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 testing, if necessary. Many of our testing processes are fully automated; this allows hands-free testing and a quicker 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 the venipuncture is technically difficult or the patient is at risk of complications from blood loss (e.g., pediatric or intensive care patients); smaller volumes may be necessary. Call Sky Lakes Laboratory at 541-274-6240 for minimum amount required to perform testing.

When patient conditions do not mandate reduced collection volumes, we ask that our clients submit the 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 the test.

Sky Lakes Laboratory makes every possible effort to successfully test your patient's specimen. If you have concerns about submitting a specimen for testing, please call Sky Lakes Laboratory at 541-274-6240. 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

Specimen vials, special specimen collection containers and kits, sterile vials, stool containers, and request forms are supplied without charge for testing performed at Sky Lakes Laboratory. Supplies can be requested by calling Sky Lakes Distribution at 541-274-6134.

Test Development Process

Sky Lakes Laboratory serves patients and health care providers. 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 at Sky Lakes Laboratory including all point-of-care tests, whether developed on site 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: stability at ambient, refrigerated, and frozen temperatures and with 7 preservatives; at 1, 3, and 7 days
- Comparative evaluation: with current and potential methods
- Reference values: using medically evaluated healthy volunteers, male and female, across age groups. The number of observations required for each test is determined by biostatistic analysis. Unless otherwise stated, reference values provided by Sky Lakes Laboratory are derived from studies performed in our laboratories. When reference values are obtained from other sources, the source is indicated in the "Reference Values" field.
- Workload recording
- Limitations of the assay

Test Result Call Back

Results will be phoned to a client when requested from the client (either on Sky Lakes Laboratory's request form or from a phone call to Sky Lakes Laboratory from the client).

Time-Sensitive Specimens

Please contact Sky Lakes Laboratory at 541-274-6240 prior to sending a specimen for testing of a time-sensitive nature. Relay the following information: facility name, account number, patient name and/or Sky Lakes Laboratory accession number, shipping information (i.e., courier service, FedEx, etc.), date to be sent, and test to be performed. Place specimen in a separate Sky Lakes Laboratory temperature appropriate bag. Please write "Expedite" in large print on outside of bag.

Turnaround Time (TAT)

Sky Lakes Laboratory's extensive 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. We consider 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.

Sky Lakes Laboratory defines TAT as the analytical test time required. TAT is monitored continuously by each performing laboratory site.

Unsatisfactory Analytic Results

If Sky Lakes Laboratory is unable to obtain a satisfactory analytic result, there is no charge. The health care provider will be notified.