

# *Policies-Bozeman Health Laboratory Services*

## **Animal Specimens**

Bozeman Health Laboratory Services accepts animal specimens 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 a payment, please include our invoice number on your check to ensure proper credit to your account.

*Patient* —Bozeman Health Laboratory Services will bill your patient's insurance, 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 a later date. Please advise your patients that they will receive a bill for laboratory services from Bozeman Health Laboratory Services for any personal responsibility after insurance payment. VISA® and MasterCard® are acceptable forms of payment.

## **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; and where multiple codes are listed, you should select codes for tests actually performed on your specimen. **BOZEMAN HEALTH LABORATORY SERVICES 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, handled, and performed the analysis) is necessary when results are to be used in a court of law.

Bozeman Health Laboratory Services has developed packaging and shipping materials that satisfy legal requirements for chain-of-custody. This service is available to Bozeman Health Laboratory Services legal clients.

## **Compliance Policies**

Bozeman Health Laboratory Services 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 Food and Drug Administration (FDA), and the Department of Transportation (DOT). Bozeman Health Laboratory Services develops, implements, and maintains policies, processes, and procedures throughout the organization which are designed to meet relevant requirements. In addition, Bozeman Health Laboratory Services has a robust internal and external audit and assessment program to monitor ongoing compliance. It is Bozeman Health Laboratory Services 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**

Bozeman Health Laboratory Services is committed to maintaining confidentiality of patient information according to HIPAA (Health Insurance Portability and Accountability Act of 1996-compliance for appropriate release of patient results).

**We appreciate your assistance in helping Bozeman Health Laboratory Services 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, Bozeman Health Laboratory Services 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 Bozeman Health Laboratory Services at 414-1010.

## **Framework for Quality**

Quality is the foundation for the development and implementation of the quality program for Bozeman Health Laboratory Services. 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 Bozeman Health Laboratory Services 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.

## **HIPAA Compliance**

Bozeman Health Laboratory Services 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 Bozeman Health Laboratory Services 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 Bozeman Health Laboratory Services 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 using the "Laboratory Supply Requisition" form, found on the Bozeman Health Laboratory Services home page under "Forms"

Shipping regulations require that infectious substances affecting humans must be shipped in a special manner.

## **Informed Consent Certification**

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

Bozeman Health Laboratory Services 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. Bozeman Health Laboratory Services 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 the ordering party.

## **Referral of Tests to another Laboratory**

Specimens shipped to Bozeman Health Laboratory Services for referral to an outside laboratory should not be sent in a glass vial due to restrictions set by many of the referral laboratories. Specimens should be poured off into a plastic, screw-capped vial prior to freezing. A specimen received frozen in a glass vial may be subject to cancellation at the performing laboratory's discretion.

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

## **Reflex Testing**

Bozeman Health Laboratory Services identifies tests that reflex when medically appropriate. In many cases, Bozeman Health Laboratory Services 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.

## **Reporting Communicable Diseases**

Bozeman Health Laboratory Services endeavors to comply with laboratory reporting requirements for the Montana state health department regarding communicable diseases. 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 Bozeman Health Laboratory Services at 414-1010.

## Request for Physician Name and Number

Bozeman Health Laboratory Services endeavors to provide high quality, timely results so that patients are able to receive appropriate care as quickly as possible. While providing esoteric reference testing, there are times when Bozeman Health Laboratory Services 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, signature, and phone number are requested as part of "Specimen Requirements." 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, Bozeman Health Laboratory Services 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, Bozeman Health Laboratory Services will request the physician's name and phone number so that our staff can consult with the physician.

Bozeman Health Laboratory Services appreciates 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

Bozeman Health Laboratory Services policy states that all specimens received for testing must be correctly and adequately labeled to assure positive identification.

1. Specimens must have **2** person-specific identifiers on the patient label. Person-specific identifiers shall always include:
  - a. Patient's first and last name.
  - b. Patient's date of birth.
2. The label shall contain the collectors' initials, date and time the specimen was collected.
3. Source Identification: Specimens other than blood and urine should have the specimen source written on the container.

Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and the information accompanying the specimen (e.g., computer system, request form, additional paperwork). When insufficient or inconsistent identification is submitted, Bozeman Health Laboratory Services 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 Requirements" 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 Bozeman Health Laboratory Services:

- 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 Requirements" section of each test includes the preferred volume for testing. The preferred volume has been established to optimize testing and allow the laboratory to quickly process specimen containers, present containers to instruments, perform tests, and repeat tests, 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 are often 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, (e.g., 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.

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

Bozeman Health Laboratory Services makes every possible effort to successfully test the patient's specimen. If you have concerns about submitting a specimen for testing, please call Bozeman Health Laboratory Services at 414-1010. Our staff will discuss the test and specimen you have available. In some cases specimens are inadequate for the 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 one of the following methods:

- Call Bozeman Health Laboratory Services at 414-1010
- Fax a "Supply Requisition" to 414-1841.

### **Test Development Process**

Bozeman Health Laboratory Services serves patients and health care providers in our region. 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 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
- Comparative evaluation with current and potential methods
- Limitations of the assay

### **Test Result Call-Backs**

Results will be phoned to a client when requested from the client. This can be requested on the Bozeman Health Laboratory Services request form, or from a phone call to Bozeman Health Laboratory Services.

### **Time-Sensitive Specimens (STATs)**

Please contact Bozeman Health Laboratory Services at 414-1010 prior to sending a specimen for testing of a time-sensitive nature.

### **Turnaround Time (TAT)**

Bozeman Health Laboratory Services 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. Bozeman Health Laboratory Services 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.

Bozeman Health Laboratory Services defines TAT as the analytical test time required. TAT is monitored continuously by each performing laboratory site. For the most up-to-date information on TAT for individual tests, please call Bozeman Health Laboratory Services at 414-1010.

### **Unlisted Tests**

New procedures are developed throughout the year. Therefore, some tests are not immediately listed in this catalog. For information about unlisted tests, call Bozeman Health Laboratory Services at 414-1010.

### **Unsatisfactory Analytic Results**

If Bozeman Health Laboratory Services is unable to obtain a satisfactory analytic result, there is no charge.