POLICIES

Animal Specimens

The AVH Laboratory does accept limited animal specimens for laboratory testing from local Veterinarians who have set up a Client Account with Aspen Valley Hospital's Billing department. The Laboratory does not supply animal-related Reference Ranges on the testing reports.

Billing

Client —Each month you will receive an itemized invoice/statement which will indicate the date of service, patient name, AVH billing procedure code, test name, quantity, and test charge. Payment terms are net 30 days.

Patient —AVH Laboratory will bill patient's insurance. Please include the following required billing information: responsible party, patient's name, current address, zip code, phone number, Social Security number, diagnosis code, and insurance information. 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 AVH 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. **ASPEN VALLEY 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; and 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. This service is only offered for drug testing. This service is not routinely offered by AVH Laboratory. Please contact the Laboratory Director at 970-544-1445 if this service is required in a special circumstance.

Compliance Policies

AVH 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). AVH develops, implements, and maintains policies,
processes, and procedures throughout our organization which are designed to meet relevant requirements. In addition, AVH has a robust internal and external audit and assessment program to monitor ongoing compliance. It is AVH's expectation that clients utilizing our services will ensure their compliance with
patient confidentiality, diagnosis coding, anti-kickback statutes, professional courtesy, CPT-4 coding, and other similar regulatory requirements. Also see "Accreditation and Licensure," "HIPAA Compliance," and "Reportable Disease."

Confidentiality of Results

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

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

- AVH specimen ID number for specimen; **or**
- Patient name and date of birth; **or**
- Identification by individual that he or she is, in fact, "referring physician" identified on request form by AVH client.

We appreciate your assistance in helping AVH preserve patient confidentiality. Provision of appropriate identifiers will greatly assist prompt and accurate response to inquiries and reporting.

Critical Value Notification Protocol

Purpose: To ensure the most efficient, effective, and safest method for reporting critical test results and seeking proper treatment for the patient, within a stated time frame from when critical test result is available until notification and confirmation has been obtained by ordering physician and/or responsible licensed independent practitioner (LIP). Documentation of notification of appropriate clinical individuals of all critical values will be done in Meditech system.

- The Laboratory technologist performing testing will call a critical value within 5 minutes.
- If result is on an outpatient (SDS/PRE-OP/IVTHER/CHEMO/CLIENT/OP), the technologist will call results directly to the physician office during office hours. Preferably, results will be given directly to the ordering physician. If he/she is unavailable, then technologist will leave a message with office personnel, asking the physician to call the laboratory back as soon as possible.
  —*After office hours*: first, the technologist will page ordering physician. If there is no response after 15 minutes, a 2nd attempt will be made. If there is no response after a total of 30 minutes, a 3rd attempt will be made. If there is still no response, the physician on call for the respective department or the department chairperson or physician on call for office practice will be notified. (List is located on hospital intranet site.)
- A critical result will not be left on an answering machine or pager. Instead, a message will be left for doctor or office to call the laboratory for results.

Disclosure 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 the AVH Laboratory Director at 544-1445.

Framework for Quality

"Framework for Quality" is the foundation for the development and implementation of the quality program for Aspen Valley Hospital. 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 Aspen Valley Hospital 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. AVH utilizes “Failure Mode Effect Analysis (FMEA),” “Plan Do Study Act (PDSA),” “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
  - Call response time
  - Call abandoned rate
  - Call completion rate
  - Customer complaints
  - Customer satisfaction surveys

HIPAA Compliance

AVH 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 AVH Lab 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 AVH that involve joint efforts will be done in a manner which enables our clients to be HIPAA compliant.

Informed Consent Certification

Submission of an order for any tests contained in this catalog constitutes certification to AVH Lab 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 AVH Lab to report results of each test ordered directly to ordering physician.

AVH Lab 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. AVH 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 the AVH Laboratory. Contact the Laboratory Director at 544-1445 for further information.

Proficiency Testing

We are a College of American Pathologists (CAP)-accredited, CLIA-licensed facility that voluntarily participates in many diverse Interlaboratory (national and international) proficiency testing programs.

Interlaboratory proficiency testing includes participation in programs conducted by CAP and the Centers for Disease Control (CDC) along with independent state, national, and international programs. Our participation includes College of American Pathologists (CAP) Surveys.

AVH conducts internal assessments to ensure the accuracy and reliability of patient testing when interlaboratory comparison is not available or additional quality monitoring is desired.

Referral of Tests to Another Laboratory

Specimens shipped to AVH 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 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. AVH Laboratory invoices for all testing referred to another laboratory at the price charged to AVH. These prices are subject to change, at the discretion of the referred to laboratory, without notification. In addition, AVH charges a per test specimen handling and/or shipping fee.

Reflex Testing

AVH Lab identifies tests that reflex when medically appropriate. In many cases, AVH Lab 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

AVH Laboratory endeavors to comply with laboratory reporting requirements for the Colorado Department of Health regarding reportable diseases. AVH Laboratory reports by fax, form, or phone depending upon the Colorado State Health Department regulations. If you need further information, please do not hesitate to contact the Laboratory Director at 544-1445 for further information.

Specimen Identification Policy

AVH Laboratory's 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, patient's initials, 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, AVH Laboratory will recommend that a new specimen be obtained, if feasible, and will contact the office about any problems.

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 AVH Lab:

- 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 2 volumes - preferred volume and minimum volume. 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; and 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 the test.

AVH Laboratory makes every possible effort to successfully test your patient’s specimen. If you have concerns about submitting a specimen for testing, please call the AVH Laboratory at 544-1570, option #4. 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.

Test Development Process

AVH Laboratory serves patients and health-care providers from the Roaring Fork Valley. 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 AVH Laboratory, 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**
- **Comparative evaluation: with current and potential methods**
- **Reference values: Unless otherwise stated, reference values provided by AVH Laboratory are based on manufacturer’s recommendations.**
- **Workload recording**
- **Limitations of the assay**

Test Result Call-Backs

Results will be phoned to a client when requested from the client (either on AVH Lab’s request form or from a phone call to AVH Lab from the client).

Time-Sensitive Specimens

Please contact AVH Laboratory prior to sending a specimen for testing of a time-sensitive nature. Relay the following information: patient name, date to be sent, and test to be performed.

Turnaround Time (TAT)

AVH 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. Our history of service and our quality metrics will document our ability to deliver on all areas of service including TAT.

AVH Lab defines TAT as the analytical test time required. TAT is monitored continuously by the Laboratory Director. For the most up-to-date information on TAT for individual tests, please contact the Laboratory Director at 544-1445.

Unsatisfactory Analytic Results

If AVH Lab is unable to obtain a satisfactory analytic result, there is no charge.