ARUP LABORATORIES

A nonprofit enterprise of the University of Utah and its Department of Pathology

500 Chipeta Way | Salt Lake City, UT 84108-1221
phone: 801-583-2787 | toll free: 800-242-2787 | aruplab.com

TECHNICAL GUIDELINES AND GENERAL INFORMATION

Acceptable Specimen Volumes

Test entries list minimum acceptable specimen volumes. The minimum volume is defined as the absolute minimum needed to run a validated test algorithm. If there is insufficient specimen volume for testing, attempts will be made to locate any additional specimen collected on the same date and time. This may cause delays, and the request may be referred to ARUP's Exception Handling department.

Accreditation/Licensure

ARUP participates in the College of American Pathologists (CAP) Laboratory Accreditation Program, is CAP ISO 15189 accredited, and has Clinical Laboratory Improvement Amendments (CLIA) certification through the Centers for Medicare and Medicaid Services (CMS). ARUP also maintains current licenses, permits, and registrations required by state and/or local regulations. For additional information or copies of certificates, please refer to ARUP's website at **aruplab.com/compliance/licensure-accreditations** or contact ARUP Client Services.

Clinical Research and Study Testing

Prior to the submission of study specimens and, preferably, prior to collection, contact ARUP Clinical Trials at **clinicaltrials@aruplab.com** or submit information through ARUP's website at **aruplab.com/research/pharma/clinical-trials**. Unless otherwise approved, study specimens submitted must meet all requirements for the submission of clinical specimens.

CPT Codes

The American Medical Association's (AMA) Current Procedural Terminology (CPT) codes in ARUP's Laboratory Test Directory are provided for informational purposes only. The codes reflect our interpretation of CPT coding requirements based on annually published AMA guidelines. CPT codes are provided only as a guide to assist clients with billing. ARUP strongly recommends that clients confirm CPT codes with their Medicare administrative contractor, as requirements may differ. CPT coding is the sole responsibility of the billing party. ARUP Laboratories assumes no responsibility for billing errors due to reliance on the published CPT codes.

Crisis Contingency Plan

ARUP maintains a corporate contingency plan for crisis recovery and business continuation. The purpose of this plan is to ensure prompt recovery of ARUP Laboratories' critical business functions in the event of a crisis affecting any aspect of our continued patient care service. In the event of a local, regional, or national crisis that adversely affects timely delivery of specimens to ARUP facilities, ARUP will expeditiously initiate specific client notification procedures to provide clients with necessary information and instruction on prearranged transportation and testing alternatives.

Patient Privacy Policy

ARUP Laboratories is committed to compliance with privacy and security standards promulgated in the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), as well as the European Union's General Data Protection Regulation (GDPR).

ARUP has implemented policies, processes, and procedures designed to ensure compliance with these standards. Compliance is continuously monitored and audited for effectiveness. Workforce training is completed annually.

ARUP's Notice of Privacy Practices for U.S. Patients and EU Data Protection Notice may be found at **aruplab.com/privacy**.

ARUP complies with security standards by ensuring that systems, policies, and procedures meet or exceed all required and addressable implementation specifications. Internet and interface connectivity is encrypted and/or password protected, and electronic access is limited to authorized entities. Breaches of protected health information (PHI) are reviewed and reported to the appropriate authority as necessary. For questions regarding ARUP's HIPAA or GDPR compliance, contact:

ARUP Privacy Officer
ARUP Laboratories
500 Chipeta Way, MS241,
Salt Lake City, Utah 84108-1221
800-242-2787 ext. 2063
privacy@aruplab.com

Inappropriate Submissions

All specimens must be collected, labeled, transported, and processed according to procedure. Review the appropriate container type, volume, and special handling requirements needed for analysis before the specimen is collected. If any of the guidelines for these processes are not met, the specimen may be rejected, or the test may be canceled. ARUP's Exception Handling department will contact the client for resolution. The following list represents some possible causes for specimen rejection or test cancellation:

- Compromised specimen (e.g., hemolyzed, lipemic, or clotted specimens) *
- Improper specimen transport
- Improperly labeled specimen
- Inappropriate specimen container
- Inappropriate specimen type
- Insufficient volume for analysis
- No source provided*
- No specimen type provided
- Prioritize testing (insufficient number of specimens submitted)
- Specimen has been submitted in incorrect or expired transport media
- Specimen has leaked in transit
- Specimen without a test order
- Test order without a specimen

* The source of a specimen, when appropriate, must be included electronically with Interfaced or Connect orders. The source of a specimen is required for all infectious disease testing, including PCR tests.

Laboratory Result Reporting

ARUP communicates laboratory results to clients by several means, including printed reports, web-enabled electronic results, direct interfaces, and access to Client Services for verbal results. Clients may request a phone notification or fax report by writing the request on the test request form and providing the appropriate contact information. Enhanced reports, which are available for some tests, can be downloaded by clients and physicians from ARUP Connect™ with login information that accompanies the original, text-based patient test result.

Preliminary results may be offered for infectious diseases and other tests in which a final report follows. Final results are generated at the completion of the test and may contain updated information from the preliminary result. When critical values are obtained, results are called to the requesting lab.

ARUP Laboratories complies with state laws by reporting certain state-defined reportable diseases and conditions to state departments of health. These reports include patient demographics and test information as required by each state's regulations. The referring laboratory must follow applicable local and state reporting requirements, which includes providing all required patient demographic information to ARUP for such purposes.

Critical Results

ARUP's testing laboratories operate 24/7. Critical results are reported as soon as testing has been completed and a critical result has been identified. ARUP reports critical results immediately to the contact(s) provided by our client(s) in accordance with the Laboratory Accreditation Program Inspection Checklists from CAP.

LOINC Codes

The Logical Observation Identifier Names and Codes (LOINC) database provides a universal code system for reporting laboratory and other clinical observations. LOINC codes are being used by large reference laboratories and federal agencies (e.g., the CDC and the Department of Veterans Affairs) and are part of the HIPAA attachment proposal. To request LOINC codes, call Client Services at 800-522-2787.

Medicare Coverage of Laboratory Testing

When ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements may apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests, except for certain specifically approved procedures, and may not pay for non-FDA-approved tests or tests considered experimental.

2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.

3. The ordering physician must provide an ICD-9 diagnosis code, not a narrative description, if required by the Medicare administrative contractor.

4. Organ- or disease-oriented panels should be billed to Medicare only when every component of the panel is medically necessary.

5. ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.

6. Medicare National Limitation Amounts for CPT codes are available through CMS or its contractors. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

Panels and Reflex Testing

ARUP offers groups of tests based on accepted clinical practice, as well as those defined by the AMA's CPT codes. Components of these panels may be ordered individually, unless otherwise indicated.

ARUP offers reflex testing, in which additional testing will be performed on specimens depending on the results of the initial test. There are two types of reflex panels: standard reflex test panels and compulsory reflex test panels. A standard reflex test panel allows the physician the option of ordering either the reflex test group or a single test. A compulsory reflex test panel automatically generates a request for additional testing if the result of the initial test meets or falls outside certain ranges. In many cases, and especially in infectious diseases and blood bank procedures, compulsory reflex test panels have been predetermined based on specific medical criteria accepted as standard-of-care by the medical community. These panels may not be available for ordering at the individual component level.

Patient History Forms

Patient history forms provide ARUP with information necessary to interpret patient results. Tests that require this information have a link to the patient history form in the laboratory test directory.

These forms are also available on **aruplab.com** and should be submitted with the test request form or electronic packing list.

Patient Informed Consent Forms

Patient informed consent forms are required by state or federal laws for a number of genetic tests. ARUP has provided forms on **aruplab.com** for clients and their physicians who do not have their own forms. These forms should be filled out by the physician and patient and retained in the patient's file. Tests that require this information have a link to the informed consent form in the laboratory test directory.

The request to order tests published in this Laboratory Test Directory certifies to ARUP that the ordering physician has obtained the informed consent of the patient as required by applicable state or federal laws for each test ordered, and that the ordering physician has authorization from the patient permitting ARUP to report the results of each test ordered to the ordering physician.

Counseling and informed consent are recommended for genetic testing. Consent forms are available on **aruplab.com**.

ARUP Laboratories | 500 Chipeta Way, Salt Lake City, UT 84108-1221 | phone: 801-583-2787 | toll free: 800-242-2787 | fax: 801-584-5249 | aruplab.com

Reference Intervals

ARUP strives to provide clear, unambiguous reference intervals and has adopted a nonoverlapping style for age groups. For example, an age group listed as 0 to 2 years should be used for all subjects from birth up to their third birthday. When reference values have been obtained from literature, ARUP conducts validation testing to confirm the values. The literature-provided age groups may be revised by ARUP in order to conform to our standard style.

ARUP Laboratories | 500 Chipeta Way, Salt Lake City, UT 84108-1221 | phone: 801-583-2787 | toll free: 800-242-2787 | fax: 801-584-5249 | aruplab.com