

20 Independent Laboratory

Laboratory services are professional and technical laboratory services in one of the following four categories. Independent lab services are:

- Ordered, provided by, or under the direction of a provider within the scope of their practice as defined by state law
- Ordered by a physician but provided by a referral laboratory
- Provided in an office or similar facility other than a hospital outpatient department or clinic
- Provided by a laboratory that meets the requirements for participation in Medicare

The policy provisions for Independent Laboratory providers can be found in the *Alabama Medicaid Agency Administrative Code*, Chapter 9.

20.1 Enrollment

HPE enrolls Independent Laboratory providers and issues provider contracts to applicants who meet the licensure and certification requirements of the state of Alabama, the Code of Federal Regulations, the *Alabama Medicaid Agency Administrative Code*, and the *Alabama Medicaid Provider Manual*.

Refer to Chapter 2, *Becoming a Medicaid Provider*, for general enrollment instructions and information. Failure to provide accurate and truthful information or intentional misrepresentation might result in action ranging from denial of application to permanent exclusion.

Federal requirements mandate providers re-enroll periodically with the Alabama Medicaid program. Providers will be notified when they are scheduled to re-enroll. When the provider fails to re-enroll with the appropriate documentation, the provider file will be end-dated. If the provider file is end dated, the provider be required to submit a new enrollment application.

National Provider Identifier, Type, and Specialty

A provider who contracts with Alabama Medicaid as an independent laboratory provider is added to the Medicaid system with the National Provider Identifier provided at the time the application is made. An appropriately assigned specialty code enables the provider to submit requests and receive reimbursements for laboratory-related claims.

NOTE:

The 10-digit NPI is required when filing a claim.

Alabama Medicaid uses provider type 28 to identify Independent Laboratory. The valid specialties for Independent Lab providers include the following:

- Independent Lab (280)
- Department of Public Health Lab (550)

Enrollment Policy for Independent Laboratories

To participate in the Alabama Medicaid Program, Independent Laboratories must meet the following requirements:

- Possess certification as a Medicare provider
- Possess certification as a valid CLIA provider if a clinical lab
- Exist independently of any hospital, clinic, or physician's office
- Possess licensure in the state where located, when it is required by that state

Change of Ownership (CHOW) and Closures

Medicaid will mirror Medicare's Change of Ownership (CHOW) policy. Refer to Chapter 19, Hospital for additional information on Change of Ownership.

20.2 Benefits and Limitations

This section describes program-specific benefits and limitations. Refer to Chapter 3, Verifying Recipient Eligibility, for general benefit information and limitations. Refer to Chapter 7, Understanding Your Rights and Responsibilities as a Provider, for general criteria on Medical Necessity/ Medically Necessary Care.

20.2.1 Covered Services

Added: In some cases... Public Health Lab (550).

Medicaid reimburses Independent Labs for services described by procedures that fall between ranges 80049-89399 in the CPT manual. In some cases, procedures within this range may only be payable to Department of Public Health Lab (550).

Medicaid also pays for procedures defined in the locally assigned Healthcare Common Procedural Coding System (HCPCS) to supplement the listing in the CPT manual.

Medicaid Independent Lab providers receive reimbursement for covered services within their CLIA certification.

Independent Lab providers may only bill for routine venipuncture for collection of laboratory specimens when sending blood specimens to another site for analysis. Labs may not bill the collection fee if the lab work and specimen collection is performed at the same site. Labs may not bill the collection fee if they perform analysis in a lab owned, operated, or financially associated with the site in which the specimen was drawn.

New Presumptive Drug Class Screening Codes (This policy was effective for dates of service on or after January 1, 2015)

Presumptive Drug testing reported value may be qualitative, semi-quantitative or quantitative depending on the purpose of the testing. A qualitative drug screen is used to detect the presence of a drug in the body. A quantitative test tells you the amount (the quantity) that is present. Methods that cannot distinguish between structural isomers (such as morphine and hydromorphone) are considered presumptive. ALL drug class immunoassays are considered presumptive, whether qualitative, semi-quantitative, or quantitative values are provided.

The following screening codes clearly define the drug class and test methodology. These screenings represent routine drug screening based on the drug class and method used for test. These screening code are limited to one specimen every seven days per recipient, per provider (providers within the group are considered a single provider), and may not be billed in any combination:

Drug Assays- Presumptive Drug Class Screening CPT Code	Code Description
80301	Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service
80302	Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (e.g., ELISA) or non-TLC chromatography without mass spectrometry (e.g., GC, HPLC), each procedure
80303	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; thin layer chromatography procedures(s) (TLC) (e.g., acid, neutral, alkaloid plate), per date of service
80304	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (e.g., TOF, MALDI, LDTD, DESI, DART), each procedure

NOTE:

Medicaid will only reimburse one screen based on a seven day period. (Per recipient, per provider.)

Drugs or classes of drugs that are commonly assayed by qualitative screen, followed by confirmation with a second method, include the following:

- Alcohols
- Alkaloids
- Amphetamines
- Anabolic steroids
- Analgesics
- Antidepressants
- Antiepileptic
- Barbiturates
- Benzodiazepines
- Buprenorphine
- Cocaine and Metabolites
- Cannabinoids
- Fentanyl
- Gabapentin
- Heroin
- Ketamine and Norketamine
- Methadones
- Methaqualones
- Methylenedioxyamphetamines
- Methyphenidate
- Opiates
- Pregabalin
- Phencyclidines
- Phenothiazines
- Propoxyphenes
- Tetrahydrocannabinoids
- Tricyclic Antidepressants

NOTE:

Use the appropriate chemistry code (82009-84999) for quantitation of drugs screened, and the appropriate therapeutic drug assay code (80150-80299) for therapeutic drug levels.

Drug Screening Test Frequency

Medicaid allows payment of a screening test frequency of once per every seven-day period.

Coverage Criteria

Medicaid will cover medically necessary qualitative drug screens as follows:

1. Suspected drug overdose, indicated by one or more of the following conditions:
 - Unexplained delirium or coma;
 - Unexplained altered mental status;
 - Severe or unexplained cardiovascular instability (cardiotoxicity);
 - Unexplained metabolic or respiratory acidosis;
 - Unexplained head trauma with neurological signs and symptoms; and/or,
 - Seizures with an undetermined history.
2. Beneficiary presents with clinical signs/symptoms of substance abuse.
3. High risk pregnancy only when the documented patient history demonstrates that the procedure is medically necessary. Medicaid does not consider a qualitative drug screen as a routine component of assessment.
4. EPSDT services only when the documented patient history demonstrates that the procedure is medically necessary. Medicaid does **not** consider a qualitative drug screen as a routine component of assessment.

Exclusions

Medicaid will **not** cover qualitative drug screens for the following:

- To screen for the same drug with both a blood and a urine specimen simultaneously.
- For medicolegal purposes, including those listed under ICD-9 code V70.4 or ICD-10 codes Z02.81 and Z02.83 (Blood-alcohol tests, paternity testing and blood-drug tests). Deleted: Z02.82
Added: Z02.83
- For employment purposes (i.e., as a pre-requisite for employment or as a means for continuation of employment). Deleted: Z02.1, Z02.3, and Z02.89
- For active treatment of substance abuse, including monitoring for compliance. Added: Z00.12, Z02.0, Z02.1, Z02.2, Z02.3, Z02.89 and Z11.3
- As a component of routine physical/medical examination ICD-9 code V70.5 or ICD-10 codes Z00.12, Z02.0, Z02.1, Z02.2, Z02.3, Z02.89 and Z11.3- health exam of defined subpopulations; (Armed forces personnel, Inhabitants of institutions, Occupational health examinations, Pre-employment screening, preschool children, Prisoners, Prostitutes, Refugees, School children and Students). Added: Z02.0, Z02.2, Z02.4, Z02.82 and
- As a component of medical examination for administrative purposes, including those listed under ICD-9 code V70.3 or ICD-10 code Z02.0, Z02.2, Z02.4, Z02.82 and Z02.89. (General medical examination for: admission to old age home, adoption, camp, driving license, immigration and naturalization, insurance

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certification, marriage, prison, school admission and sports competition).

Prior Approval

Prior approval will not be required for qualitative drug screens.

Documentation Requirements

The ordering/ referring provider must retain the following in the medical record:

- Documentation validating Medical Necessity
- Copy of the lab results

All tests must be ordered in writing, and all drugs/drug classes to be screened must be indicated in the order. If the provider rendering the service is other than the ordering/referring provider, the provider must maintain (hard copy) documentation of the ordering/referring provider's order along with all drugs/drug classes to be screened.

Documentation must be legible and available for review upon request.

Chlamydia and Gonorrhea

Effective for dates of service on or after September 1, 2012, Chlamydia (87491) or gonorrhea (87591), when billed on the same date of service for any one patient will deny. If both procedures are performed on the same date of service, procedure code 87801 (infectious agent antigen detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique) should be billed instead.

End Stage Renal Disease (ESRD) Laboratory Services

Laboratory tests listed in Chapter 35 (Renal Dialysis Facility) are considered routine and are included in the composite rate of reimbursement. When any of these tests are performed at a frequency greater than specified, the additional tests are separately billable and are covered only if they are medically necessary and billed directly by the actual provider of the service. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim.

20.2.2 Non-Covered Services

Medicaid does not pay packing and handling charges for referred laboratory services. The referred laboratory receives payment for referred tests only at the normal rate. Medicaid shall monitor this policy through post-payment review.

20.2.3 Clinical Laboratory Improvement Amendments (CLIA)

All laboratory testing sites providing services to Medicaid recipients, either directly by provider, or through contract, must be CLIA certified to provide the level of complexity testing required. The Independent Lab must adhere to all CLIA regulations. As regulations change, Independent Labs must modify practices to comply with the changes. Providers are responsible for providing Medicaid waiver or certification numbers as applicable.

Laboratories which do not meet CLIA certification standards are not eligible to provide services to Medicaid recipients or to participate in Medicaid.

NOTE:

The Health Care Financing Administration (HCFA), now known as CMS, implemented the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), effective for dates of service on or after September 1, 1992. The CLIA regulations were published in the February 28, 1992 Federal Register. More detailed information regarding CLIA can be found at <http://www.cms.hhs.gov/clia/>

CLIA certificates may limit the holder to performing only certain tests. Medicaid bills must accurately reflect those services authorized by the CLIA program and no other procedures. There are two types of certificates that limit holders to only certain test procedures:

- Waiver certificates – Level 2 certification
- Provider Performed Microscopy Procedure (PPMP) certificates – Level 4 certification

A complete listing of laboratory procedures limited to waived certificates (level 2 certification) and PPMP certificates (level 4 certification) may be accessed via the web at www.cms.hhs.gov/clia/.

The Trofile Assay will be a covered service by Medicaid with prior authorization (PA) effective December 1, 2008. The procedure code to be billed is 87999 (unlisted microbiology procedure). In order to be reimbursed by Medicaid for the Trofile Assay, the ordering provider must submit a Prior Authorization electronically or by paper on form 342. The PA must be received by the fiscal agent within 30 days of the date of service.

Providers requesting a PA should include:

- Any past history of antiretroviral medications prescribed to include date prescribed and the date the drug was discontinued;
- The name and contact information of the HIV clinic that the provider is affiliated with if the requesting provider is not enrolled in Medicaid with specialty of infectious disease, and;
- The result of the most current HIV-1 RNA.

If you need further information, refer to chapter 4, Obtaining Prior Authorization, for general guidelines.

20.3 Cost Sharing (Copayment)

Copayment amount does not apply to services provided for laboratory services.

20.4 Completing the Claim Form

To enhance the effectiveness and efficiency of Medicaid processing, providers should bill Medicaid claims electronically.

Independent Laboratory providers who bill Medicaid claims electronically receive the following benefits:

- Quicker claim processing turnaround
- Immediate claim correction
- Enhanced online adjustment functions
- Improved access to eligibility information

Refer to Appendix B, Electronic Media Claims Guidelines, for more information about electronic filing.

NOTE:

When filing a paper claim, a CMS-1500 claim form is required. Medicare-related claims must be filed using the Medical Medicaid/Medicare-related Claim Form 340. All paper claims must be a one page red drop ink form.

This section describes program-specific claims information. Refer to Chapter 5, Filing Claims, for general claims filing information and instructions.

20.4.1 Time Limit for Filing Claims

Medicaid requires all claims for Independent Laboratory providers to be filed within one year of the date of service. Refer to Chapter 5, Filing Limits, for more information regarding timely filing limits and exceptions.

20.4.2 Diagnosis Codes

Claims for lab services must contain a valid diagnosis code. The *International Classification of Diseases - 10th Revision - Clinical Modification* (ICD-10-CM) manual lists required diagnosis codes. These manuals may be obtained by contacting the American Medical Association, AMA Plaza 330 North Wabash Ave, Suite 39300 Chicago, IL 60611-5885, or 1-800-621-8335.

NOTE:

ICD-9 codes should be used for claims submitted with dates of service prior to or equal to 09/30/2015.

ICD-10 codes should be used for claims submitted with dates of service on/after 10/01/2015.

NOTE:

ICD-9 or ICD-10 diagnosis codes must be listed to the highest number of digits possible (3, 4, or 5 digits). Do not use decimal points in the diagnosis code field.

20.4.3 Procedure Codes and Modifiers

Medicaid uses the Healthcare Common Procedure Coding System (HCPCS). HCPCS is composed of the following:

- American Medical Association's Current Procedural Terminology (CPT)
- Nationally assigned codes developed for Medicare
- Locally assigned codes issued by Medicaid. Effective for dates of service on or after 01/01/2004, use national codes.

The CPT manual lists most procedure codes required by Medicaid. This manual may be obtained by contacting the Order Department, American Medical Association, 515 North State Street, Chicago, IL 60610-9986.

Medicaid denies claims without procedure codes or with codes that are invalid.

Medicaid also recognizes modifiers when applicable. The (837) Institutional electronic claim and the paper claim have been modified to accept up to four Procedure Code Modifiers.

The following sections describe modifiers that may apply to a procedure code when filing claims for independent lab services.

Modifier 91 - Repeat Laboratory Procedures

Modifier 91 should be appended to laboratory procedure(s) or service(s) to indicate a repeat of clinical diagnostic laboratory test or procedure on the same day. This modifier indicates to the carriers or fiscal intermediaries that the physician had to perform a repeat clinical diagnostic laboratory test that was distinct or separate from a lab panel or other lab services. This should not be appended to the initial lab procedure code. Modifier '91' may not be used when laboratory tests are rerun:

- To confirm initial results
- Due to testing problems encountered with specimens or equipment
- For any other reason when a normal, one-time, reportable result is all that is required.
- When the code being used or other codes describe a series of test results (e.g., glucose tolerance tests, evocative/suppression testing).

Modifier 76 – Repeat Laboratory Modifier

Modifier 76 is reported to communicate that a service or procedure was repeated by the same practitioner subsequent to the original procedure or service. This modifier may be used whenever the circumstances warrant the repeat procedure. Based on the definition of modifier 76, it would be inappropriate to append modifier 76 to clinical laboratory tests on the same day.

Modifier 77 – Repeat Laboratory Procedure

Repeat procedure/ service performed by another physician or other qualified health care professional. This modifier may be used for billing multiple services on the same day and the service cannot be quantity billed. It is inappropriate to use with services considered bundled.

Modifier 59 - Distinct Procedural Service

This modifier indicates that one procedure/ service is distinct and independent of another procedure/ service performed on the same day. These services are not normally reported together, but are appropriate under the circumstances.

Modifier 59 is an important NCCI- associated modifier. Its primary purpose is to indicate that two or more procedures are performed at different anatomic sites or different patient encounters. Claims billed with the same procedure two or more times for the same date of service, should be submitted with the appropriate repeat procedure modifier rather than using Modifier 59.

Modifier 26 – Professional Component

Modifier 26 is used to indicate that the physician component for the diagnostic (interpretation of a test) is reported separately from the technical component.

Modifier TC (Technical Component)

Modifier TC is used to indicate the technical component of the diagnostic procedure is reported separately from the professional component. Do not submit the technical component separately when one physician performs both the professional and technical component on the same day.

Blood Specimens

Collection of laboratory specimens may be billed only when sending specimens to another site for analysis if the other site is not owned, operated, or financially associated with the site in which the specimen was collected.

The collection fee may not be billed if the lab work is done at the same site where the specimen was collected or in a lab owned, operated, or financially associated with the site in which the specimen was collected.

Independent laboratory providers will not be paid for and should not submit claims for laboratory work done for them by other independent laboratories or by hospital laboratories.

Providers may submit claims for laboratory work done by them in their own laboratory facilities.

A hospital lab may bill Medicaid on behalf of the reference lab that a specimen is sent to for analysis. It is the responsibility of the referring lab (hospital) to make sure that the reference lab does not bill these services to Medicaid.

Providers who send specimens to another independent laboratory for analysis may bill a collection fee. This fee shall not be paid to any provider who has not actually extracted the specimen from the patient.

NOTE:

Providers should use procedure code 36415-90 for routine venipuncture collection, 36416-90 for collection of capillary blood specimen (eg, finger, heel, ear stick) and Q0091-90 for collection of Pap smear specimen.

Laboratory Paneling and Unbundling

A *panel* is a group of tests performed together or in combination. Medicaid follows the CPT guidelines for panel tests.

Unbundling occurs when the procedures, services and supplies are listed with their own separate, distinct codes. This refers to the practice of using more than one procedure code to bill for a procedure that can more appropriately be described using fewer codes. The use of unbundled codes results in denial of payment, with the exception of organ and disease panels.

All organ and disease oriented panels must include the tests listed with no substitutions. If only part of the tests included in a defined panel is performed, the panel code should not be reported. If additional tests to those indicated in a panel are performed, those tests should be reported separately in addition to the panel code. If two panels overlap, the physician or laboratory will be required to unbundle one of the panels and bill only for the tests that are not duplicative.

Urinalysis – Claims for the same recipient billed by the same provider that contain two or more of the following services (81000, 81001, 81002, 81003, 81005, 81007, 81015, and 81020) for the same date of service will be considered an unbundled service and will be denied.

During post-payment review, Medicaid may recoup payment from providers for claims submitted containing unbundling of laboratory services.

Modifiers

<i>Modifier</i>	<i>HCPCS-Modifier(s)</i>	<i>Description</i>	<i>Note</i>
26	26	Professional Component	Labs providing professional component services-such as reporting the physician's interpretation of the test.
59	59	Distinct Procedural Service	Services not normally reported together, but are appropriate under the circumstances
76	76	Repeat Procedure/service by the same physician	Used whenever the circumstances warrant the repeat procedure/service

<i>Modifier</i>	<i>HCPCS-Modifier(s)</i>	<i>Description</i>	<i>Note</i>
77	77	Repeat procedure/service by different physician	Used for billing multiple services not considered bundled
91	91	Repeat Clinical Diagnostic laboratory Test	Perform a repeat clinical diagnostic laboratory test that was distinct or separate from a lab panel or other lab services
TC	TC	Technical Component	Technical Component refers to certain procedures that are a combination of a physician component and a technical component.

NOTE:

Claims submitted for a repeat of the same procedure on the same date of service without modifiers will be denied as duplicate services.

Oncotype DX™

Effective for dates of service, July 1, 2013 and thereafter, Medicaid will cover the Oncotype DX™ genetic profiling lab test if the patient meets Medicaid's prior authorization criteria. (PA). The PA must be received by the fiscal agent within 30 days of the date of service.

Oncotype DX™ is a genetic profiling test developed to classify the risk of recurrence among women treated for early stage breast cancer.

The use of the 21-gene RT-PCR Assay (i.e., Oncotype DX™) to determine recurrence risk for deciding whether or not to undergo adjuvant chemotherapy meets Alabama Medicaid's medical criteria for coverage in women with early stage breast cancer with **ALL** of the following characteristics:

- Newly diagnosed, primary, early stage breast cancer (stage I or stage II) in a female without significant co-morbidities;
- Unilateral, non-fixed tumor;
- Hormone receptor positive (ER-positive or PR-positive);
- HER2-negative;
- Tumor size 0.6-1cm with moderate/poor differentiation or unfavorable features OR tumor size > 1cm;
- Node negative;
- Will be treated with adjuvant endocrine therapy, e.g., tamoxifen or aromatase inhibitors; AND
- When the test result will aid the patient in making the decision regarding chemotherapy (i.e., when chemotherapy is considered a therapeutic option); AND
- When ordered within 6 months following breast cancer diagnosis.

Limitations:

- The 21-gene RT-PCR Assay Oncotype DX™ should only be ordered on a tissue specimen obtained during surgical removal of the tumor and after subsequent pathology examination of the tumor has been completed and determined to meet the above criteria (i.e., the test should not be ordered on a preliminary core biopsy).
- The test should be ordered in the context of a physician-patient discussion regarding risk preferences when the test result will aid in making decisions regarding chemotherapy. This discussion must be documented in the patient's clinical record and a copy of the progress note (signed by the ordering physician) must accompany the PA request (Form 342).
- The Oncotype DX™ test will be limited to one per lifetime, per recipient.
- Repeat tests will not be covered.
- The test will be limited to the following diagnoses: malignant neoplasm of the female breast, carcinoma in situ of breast, and personal history of malignant neoplasm, breast.

Billing providers must bill procedure code 81519 (Test for detecting genes associated with breast cancer).

The Oncotype DX™ will be exempt from Patient 1st and EPSDT requirements. The Form 342 must be completely filled out, signed by the ordering physician and indicate the name and phone number of the ordering physician. The Form 342 will suffice as the prescription for the test. The test must be performed by an enrolled independent laboratory and ordered by a physician.

Professional and Technical Components

Some procedure codes in the 70000, 80000, 90000, and G series are a combination of a professional component and a technical component. Therefore, these codes may be billed three different ways; (1) as a global, (2) as a professional component, or (3) as a technical component.

- **Global**, the provider must own the equipment, pay the technician, review the results, and provide a written report of the findings. The procedure code is billed with no modifiers.
- **Professional component**, the provider does **not** own the equipment. The provider operates the equipment and/or reviews the results, and provides a written report of the findings. The professional component is billed by adding modifier 26 to the procedure code.
- **Technical component**, the provider must own the equipment, but does not review and document the results. The technical component charges are the facility's charges and are not billed separately by physicians. The technical component is billed by adding modifier TC to the procedure code.

20.4.4 Place of Service Codes

The only valid Place of Service Codes for Independent Laboratory providers is 81.

<i>POS Code</i>	<i>Description</i>
81	Independent Laboratory

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20.4.5 Required Attachments

To enhance the effectiveness and efficiency of Medicaid processing, your attachments should be limited to Claims with Third Party Denials.

NOTE:

When an attachment is required, a on page paper copy CMS-1500 red drop ink claim form must be submitted.

Refer to Chapter 5, for more information on attachments.

20.5 For More Information

This section contains a cross-reference to other relevant sections in the manual.

Resource	Where to Find It
CMS-1500 Claim Filing Instructions	Chapter 5
Medical Medicaid/Medicare-related Claim Filing Instructions	Chapter 5
Medical Necessity/Medically Necessary Care	Chapter 7
Electronic Media Claims (EMC) Submission Guidelines	Appendix B
AVRS Quick Reference Guide	Appendix L
Alabama Medicaid Contact Information	Appendix N