Pathology: Billing and Modifiers

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This section includes information about the billing and reimbursement of pathology services.

Note: Only a provider with a *Clinical Laboratory Improvement Amendments* (CLIA) certificate and state license or registration appropriate to the level of tests performed may be reimbursed for clinical laboratory tests or examinations. Additional information and links to websites regarding licensing requirements are provided below.

For complete allergy testing information, see the *Allergy Testing and Desensitization* section in the appropriate Part 2 manual.

Diagnosis Code Requirement

All claims for clinical laboratory tests or examinations (CPT® 80000 series codes) require an ICD-10-CM diagnosis code.

Providers may not submit the following non-specific diagnosis codes when ordering billing for laboratory procedures:

Z00.00	Z00.8	Z01.89
Z00.5	Z01.00	Z02.1
Z00.6	Z01.10	Z02.3

The exceptions are:

- CPT codes 86701 thru 86703. CPT codes 87389; 87390 and 87806 for HIV testing. CPT code 81528 for colorectal cancer screening and HCPCS code G0499 for hepatitis B screening may be billed with any ICD-10-CM diagnosis code.
- CPT codes 80061, 82270, 82272, 82274, 82465, 83718, 83719, 83721 and 84478 may be billed with non-specific ICD-10-CM diagnosis codes Z00.00 and Z00.8.
- CPT codes 86803 and 86804 may be billed with any ICD-10-CM code.

Billing Method Guidelines

Clinical laboratory tests or examinations (CPT 80000 series codes) are billed using different methods. Although the method used depends on the contractual or other type of mutual agreement between the facility and the physician and will apply to both inpatient and outpatient services, the principal determinant will be the provisions of the contract the facility has with the Medi-Cal program. Those facilities that are not under contract to Medi-Cal may make an arrangement with the physician that is mutually agreeable within these policy guidelines.

The Department of Health Care Services (DHCS) has defined the billing options as follows:

Split-Billable

Split-billable services: When billing for both the professional and technical service components, a modifier is neither required nor allowed. When billing for only the professional component, use modifier 26. When billing for only the technical component, use modifier TC.

- Physician Billing – Facility bills for both the technical and professional components using one line without a modifier. The facility reimburses the pathologist/pathology group for the professional component per their mutual agreements.
  - Facility Billing – Physician bills for both the professional and technical components using one line without a modifier. The physician subsequently reimburses the facility for the technical component according to their mutual agreements.

Not Split-Billable

Services that are not split-billable: These codes are not separately reimbursable to different providers for a professional or technical component. Only one provider may bill for these codes. These codes must not be submitted with modifier 26, TC or 99, and do not require a modifier.

Modifiers

The use of modifiers with the procedure codes directs the claims adjudication system to reimburse the correct percentage for the component billed.

Claims for clinical laboratory tests and examinations (CPT 80000 series codes) that are split-billable allow one of the following modifiers:

Note: Modifier 99 must not be billed in conjunction with modifier 26 and/or modifier TC. The claim will be denied.

‹‹**Table of Spilt Billable Modifiers**››

Modifier	Description
26	Professional component (Split Billing)
TC	Technical component
QW	CLIA waived tests; indicates that the provider is performing testing for the procedure with the use of a specific test kit from manufacturers identified by the Centers for Medicare & Medicaid Services (CMS). Providers must have a current CLIA Certificate of Waiver number registered with the California Department of Public Health (CDPH) Laboratory Field Services (LFS) and Medi-Cal Provider Enrollment Division (PED) to be reimbursed.
90	Used when service is performed by an outside laboratory but billed by another provider. Only specified providers may use this modifier.
99	Used when two or more modifiers are necessary to define the procedure. The multiple modifiers used must be explained in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim.

Note: When billing for both the professional and technical service components, a modifier is neither required nor allowed.

Modifier 33

Claims billed using modifier 33 are not subject to specific ICD-10-CM inclusion and/or exclusion criteria. Use of modifier 33 indicates the service was provided in accordance with a U.S. Preventive Services Task Force (USPSTF) A or B recommendation.

Billing for Reference Clinical Laboratories With Modifier 90

The following providers may also be reimbursed for clinical laboratory tests or examinations with modifier 90:

- A licensed clinical laboratory billing for clinical laboratory tests or examinations referred to and performed by another licensed clinical laboratory.
- Physicians billing for a newborn metabolic screening panel (HCPCS code S3620).

Professional (Split Billing) Component Restrictions

Emergency room physicians, orthopedic surgeons, trauma specialists, surgeons, internists, family physicians, podiatrists and other treating physicians who routinely review pathology results as an integral part of their reimbursed patient care services are not entitled to an additional reimbursement of a professional component for that review. This service, like other diagnostic data evaluation, is covered by the reimbursement for office visit and treatment.

Modifier 26

Providers are not reimbursed for the professional component (modifier 26) of pathology claims billed with an Evaluation and Management (E&M) procedure performed by the same provider on the same date of service.

Providers are not reimbursed for the professional component when billing for both the professional and technical service components when pathology services are billed with an E&M procedure performed by the same provider on the same date of service.

Laboratory Codes: Split-Billable

When billing for both the professional and technical service components, a modifier is neither required nor allowed. When billing for only the professional component, use modifier 26. When billing for only the technical component, use modifier TC.

Note: Modifier 99 must not be billed in conjunction with modifier 26 and modifier TC. The claim will be denied.

Laboratory Codes: Not Split-Billable

Although most laboratory codes are split-billable, the following laboratory codes are not split-billable and must not be billed with modifier 26, TC or 99:

‹‹**Table of HCPCS Codes Not Split Billable**››

HCPCS Code	Description
G0472	Hepatitis C antibody screening, for individual at high risk and other covered indication(s)
G0499	Hepatitis B screening in non-pregnant, high risk individual includes hepatitis B surface antigen (HBsAg) followed by a neutralizing confirmatory test for initially reactive results, and antibodies to HBsAg (anti-HBs) and hepatitis B core antigen (anti-HBc)
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays and enzymatic methods, performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

‹‹**Table of CPT Codes Not Split Billable**››

CPT Code	Description
80145	Adalimumab
80163	Digoxin; free
80165	Valproic acid (dipropylacetic acid); free
80187	Prosaconazole
80230	Infliximab
80235	Lacosamide
80280	Vedolizumab
80285	Voriconazole
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation, includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers, chromatography, and mass spectrometry either with or without chromatography, includes sample validation when performed, per date of service
80500 thru 80502	Consultations (Clinical Pathology)
81007	Urinalysis; bacteriuria screen, except by culture or dipstick
81025	Urine pregnancy test, by visual color comparison methods
81050	Volume measurement for timed collection, each
81277	Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities
81288	MLH1 (*mutL homolog 1, colon cancer, nonpolyposis type 2*) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis
81413	Cardiac ion channelopathies; genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A
81414	Cardiac ion channelopathies; duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21

‹‹**Table of CPT Codes Not Split Billable (continued)**››

CPT Code	Description
81435	Hereditary colon cancer syndromes (e.g., Lynch syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2
81436	Hereditary colon cancer syndromes (e.g., Lynch syndrome, familial adenomatosis polyposis); duplication/deletion gene analysis panel, must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH
81439	Inherited cardiomyopathy genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score
81522	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence risk score
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result **Note**: CPT code 81528 may be billed with modifier 90
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
82044	Albumin; urine, microalbumin, semiquantitative (e.g., reagent strip assay)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

‹‹**Table of CPT Codes Not Split Billable (continued)**››

CPT Code	Description
83013	Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope
83014	Helicobacter pylori; drug administration
83876	Myeloperoxidase (MPO)
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP)
84410	Testosterone; bioavailable, direct measurement
85060	Blood smear, peripheral, interpretation by physician with written report
85097	Bone marrow, smear interpretation
85397	Coagulation and fibrinolysis, functional activity, not otherwise specified, (e.g., ADMTS-13) each analyte
86077	Blood bank physician services; difficult cross match and/or evaluation of irregular antibody(s), interpretation and written report
86078	Blood bank physician services; investigation of transfusion reaction including suspicion of transmissible disease, interpretation and written report
86079	Blood bank physician services; authorization for deviation from standard blood banking procedures (e.g., use of outdated blood, transfusion of Rh incompatible units), with written report
86485 thru 86580	Immunology
86930	Frozen blood, each unit; freezing (includes preparation)
86931	Frozen blood, each unit; thawing
86932	Frozen blood, each unit; freezing (includes preparation) and thawing
87483	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12 thru 25 targets
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3 thru 5 targets

‹‹**Table of CPT Codes Not Split Billable (continued)**››

CPT Code	Description
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6 thru 11 targets
87507	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12 thru 25 targets
87563	Infectious agent detection by nucleic acid (DNA or RNA); mycoplasma genitalium, amplified probe technique
87624	Human Papillomavirus (HPV), high-risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 56, 58, 59, 68)
87625	Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed
87662	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique
87806	Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
87905	Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)
88141	Cytopathology, cervical or vaginal (any reporting system); requiring interpretation by physician
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
88185	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker
88187	Flow cytometry, interpretation; 2 to 8 markers
88188	Flow cytometry, interpretation; 9 to 15 markers
88189	Flow cytometry, interpretation; 16 or more markers
88291	Cytogenetics and molecular cytogenetics, interpretation and report
88321	Consultation and report on referred slides prepared elsewhere
88720	Bilirubin, total, transcutaneous
89055	Leukocyte assessment, fecal, qualitative or semiquantitative

Waived Laboratory Codes

The following tests are considered to be CLIA-waived when performed with a CLIA-waived test kit. These HCPCS and CPT codes must be billed with modifier QW to be recognized as a waived test with the exception of codes 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, 85651 ‹‹and 87426››. Modifier QW also indicates that the test was performed by a laboratory with a current and appropriate CLIA certificate and a California clinical laboratory Certificate of Registration.

Note: These procedure codes are not waived tests when billed without modifier QW

Table of Waived Laboratory HCPCS Codes

HCPCS Code	Description
G0433	Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening
G0475	HIV antigen/antibody, combination assay, screening
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC

Table of Waived Laboratory CPT Codes

CPT Code	Description
80047	Basic metabolic panel (calcium, ionized)
80048	Basic metabolic panel (calcium, total)
80051	Electrolyte panel
80053	Comprehensive metabolic panel
80061	Lipid panel
80069	Renal function panel
80178	Lithium
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only includes sample validation when performed, per date of service
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated without microscopy
81007	Urinalysis; bacteriuria screen, except by culture or dipstick
82010	Ketone body(s) (e.g., acetone, acetonacetic acid, beta-hydroxybutyrate); quantitative
82040	Albumin; serum, plasma or whole blood
82043	Albumin; urine, microalbumin, quantitative
82044	Albumin; urine, microalbumin, semiquantitative (e.g., reagent strip assay)

‹‹**Table of Waived Laboratory CPT Codes (continued)**››

CPT Code	Description
82120	Amines, vaginal fluid, qualitative
82150	Amylase
82247	Bilirubin; total
82271	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; other sources
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1 thru 3 simultaneous determinations
82310	Calcium; total
82330	Calcium; ionized
82374	Carbon dioxide (bicarbonate)
82435	Chloride; blood
82465	Cholesterol, serum or whole blood, total
82523	Collagen cross links, any method
82550	Creatine kinase (CK), (CPK); total
82565	Creatinine; blood
82570	Creatinine; other source
82679	Estrone
82947	Glucose; quantitative, blood (except reagent strip)
82950	Glucose; post glucose dose (includes glucose)
82951	Glucose; tolerance test (GTT), three specimens (includes glucose)
82952	Glucose; tolerance test, each additional beyond three specimens
82977	Glutamyltransferase, gamma (GGT)
82985	Glycated protein
83001	Gonadotropin; follicle stimulating hormone (FSH)
83002	Gonadotropin; luteinizing hormone (LH)
83036	Hemoglobin; glycosylated (A1C)
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
83605	Lactate (lactic acid)
83655	Lead
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721	Lipoprotein, direct measurement; LDL cholesterol
83861	Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity
83880	Natriuretic peptide
83986	pH, body fluid, not otherwise specified
84075	Phosphatase, alkaline
84132	Potassium; serum, plasma or whole blood
84155	Protein, total, except by refractometry; serum, plasma or whole blood

Table of Waived Laboratory CPT Codes (continued)

CPT Code	Description
84295	Sodium; serum, plasma or whole blood
84443	Thyroid stimulating hormone (TSH)
84450	Transferase; aspartate amino (AST) (SGOT
84460	Transferase; alanine amino (ALT) (SGPT)
84478	Triglycerides
84520	Urea nitrogen; quantitative
84550	Uric acid; blood
84703	Gonadotropin, chorionic (hCG); qualitative
85014	Blood count; hematocrit (Hct)
85018	Blood count; hemoglobin (Hgb)
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85576	Platelet; aggregation (in vitro), each agent
85610	Prothrombin time
86294	Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen)
86308	Heterophile antibodies; screening
86318	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent strip)
86618	Antibody; Borrelia burgdorferi (Lyme disease)
86701	Antibody; HIV-1
86703	Antibody; HIV-1 and HIV-2, single result
86780	Antibody; Treponema pallidum
86803	Hepatitis C antibody
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87338	Infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative, multiple-step method; Helicobacter pylori, stool
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])
‹‹87428››	‹‹Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B››

Table of Waived Laboratory CPT Codes (continued)

CPT Code	Description
87449	Infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative; multiple-step method, not otherwise specified, each organism
87502	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types
87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12 thru 25 targets
87634	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19], amplified probe technique)
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
87804	Infectious agent antigen detection by immunoassay with direct optical observation; Influenza
87806	Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
87807	Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus
87808	Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis
87809	Infectious agent antigen detection by immunoassay with direct optical observation; adenovirus
‹‹87811››	‹‹Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])››
87880	Infectious agent antigen detection by immunoassay with direct optical observation; Streptococcus, group A
87899	Infectious agent antigen detection by immunoassay with direct optical observation; not otherwise specified
87905	Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)

Laboratory procedure codes listed below are considered to be CLIA-waived tests and do not require modifier QW:

‹‹**Table of CLIA Waived CPT Codes** ››

CPT Code	Description
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81025	Urine pregnancy test, by visual color comparison methods
82270	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening
82272	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces, 1 thru 3 simultaneous determinations, performed for other than colorectal neoplasm screening
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
83026	Hemoglobin; by copper sulfate method, non-automated
84830	Ovulation tests, by visual color comparison methods for human luteinizing hormone
85013	Blood count; spun microhematocrit
85651	Sedimentation rate, erythrocyte; non-automated

Clinical Laboratory Improvement Amendments (CLIA) Certification & Billing for Pathology

All Medi-Cal providers billing for laboratory services must have a current CLIA certificate and must be enrolled and participate in required proficiency testing to be reimbursed. With the exception of those tests that are excluded from CLIA edits as defined by the Centers for Medicare & Medicaid Services (CMS).

CLIA requires all facilities that perform even one test, including waived tests, on “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings,” to meet certain federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

Medi-Cal providers with a CLIA Certificate of Waiver or Provider Performed Microscopy Certificate must obtain a Certificate of California Clinical Laboratory Registration from the California Department of Public Health (CDPH), Laboratory Field Services (LFS). Additional information and instructions may be found at the following website: *www.cdph.ca.gov/programs/lfs/Documents/F-Registration-Instructions.pdf*

Medi-Cal providers with a CLIA Certificate of Compliance or Accreditation must obtain a California Clinical Laboratory License from the CDPH, Laboratory Field Services. Additional information and instructions may be found at the following website: *www.cdph.ca.gov/programs/lfs/Documents/F-Lic-Application-Instructions.pdf*

All types of Certificates are effective for two years, and include:

Certificate of Waiver

- Issued to a laboratory that performs only waived tests as listed in *Code of Federal Regulations*, Title 42, Part 493.15.
- Waived tests are those tests that have been determined to be so simple that if performed incorrectly will pose no risk of harm.
- The laboratory must comply with CLIA registration and certificate requirements and follow the manufacturer's instructions for test performance.

Certificate of Provider Performed Microscopy (PPM) Procedures

- Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit.
- A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.

Certificate of Registration

- Issued to laboratory to allow the laboratory to conduct non-waived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations.
- Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- Laboratories must provide CMS with proof of accreditation by an approved accreditation program within 11 months of issuance of the Certificate of Registration.

Certificate of Compliance

- Issued to a laboratory once the State Department of Public Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements.
- This type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.

Note: The above information can also be found in the *Pathology: An Overview of Enrollment and Proficiency Testing Requirements* section of this manual.

Procedures Subject to Proficiency Testing

Laboratory certification (LC) codes CLIA Specialty and Subspecialty list is as follows:

Specialty	Subspecialty	LC Code
Histocompatibility	None	010
Microbiology	Bacteriology	110
Microbiology	Mycobacteriology	115
Microbiology	Mycology	120
Microbiology	Parasitology	130
Microbiology	Virology	140
Diagnostic Immunology	Syphilis Serology	210

Specialty	Subspecialty	LC Code
Diagnostic Immunology	General Immunology	220
Chemistry	Routine Chemistry	310
Chemistry	Urinalysis	320
Chemistry	Endocrinology	330
Chemistry	Toxicology	340
Hematology	None	400
Immunohematology	ABO Group & Rh type	510
Immunohematology	Antibody Detection (transfusion)	520
Immunohematology	Antibody Detection (non-transfusion)	530
Immunohematology	Antibody Identification	540
Immunohematology	Compatibility Testing	550
Pathology	Histopathology	610
Pathology	Oral Pathology	620
Pathology	Cytology	630
Radiobioassay	None	900

Criteria for One Certificate for Multiple Sites

Criteria for one certificate for multiple sites is as follows:

Location

Each location where laboratory tests are performed must file a separate application, unless it meets one of the following exceptions as outlined in CFR, Title 42, Sections 493.35(b), 493.43(b) or 493.55(b):

- Laboratories that are not at a fixed location, for example, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the CLIA certificate and address of the designated primary site or home base.
- Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 types of moderately complex or waived tests per certificate) public health testing may file a single application.
- Laboratories within a hospital that are located at a contiguous building on the same campus and under common direction may file a single application or multiple applications for CLIA certificate(s) for the laboratory sites within the same physical location or street address.

Home Health Agencies

A parent Home Health Agency (HHA) with multiple branches may apply for one CLIA certificate as long as these sites are under one National Provider Identifier (NPI), for example, parent branch. Subunits by definition operate independently and have a unique provider number; therefore, each subunit must apply for a separate CLIA certificate.

Note: The parent or provider location must perform laboratory testing. Because branches cannot operate independently, the parent defines the services provided in the branches and is responsible for the day-to-day operation, supervision, and administration of laboratory testing, including the employment of qualified personnel. (For consistency, the Medicare designated terms parent and branches are used for this policy.)

Hospices

The guidance for HHAs applies to hospices. The Medicare designated term for hospice multiple sites is "multiple locations" rather than branches.

See CMS Update: *www.cms.hhs.gov*

Note: The above information can also be found in the *Pathology: An Overview of Enrollment and Proficiency Testing Requirements* section of this manual.

Electronic Billing of Laboratory Services

Providers billing electronically for laboratory services that require medical justification may enter the medical justification in the electronic filing *Remarks* field. Medical justification statements entered in the electronic filing *Remarks* field must not exceed 1,500 characters. If the statement exceeds the character limit, providers must submit a hard copy with the appropriate medical justification documents accompanying the claim.

Exceptions

Claims and "By Report" attachments for the following CPT codes may not be submitted electronically.

Note: Refer to the *Pathology: Microbiology* section in this manual for billing information regarding CPT codes 87900, 87903, 87904 and 87906

CPT Code	Description
83013	Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope
87900	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics
87901	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV 1, reverse transcriptase and protease regions
87906	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)
87903	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; first through 10 drugs tested
87904	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; each additional drug tested

Gender Override

Instructions for overriding gender limitations for procedures are in the *Transgender* Services section in the appropriate Part 2 provider manual

‹‹Legend››

‹‹Symbols used in the document above are explained in the following table.››

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.