CPT® Proprietary Laboratory Analyses (PLA) Codes: Long Descriptors

It is important to note that further CPT Editorial Panel (Panel) or Executive Committee actions may affect these codes and/or descriptors. For this reason, code numbers and/or descriptor language in the CPT code set may differ at the time of publication. In addition, further Panel actions may result in gaps in code number sequencing.

Most recent changes to the CPT® Proprietary Laboratory Analyses (PLA) Long Descriptor document:

- Addition of 17 codes (0614U–0630U), revision of 2 codes (0256U, 0580U), and revision of the PLA guidelines accepted by the CPT Editorial Panel.
- Revision of the proprietary and laboratory name for code 0319U.
- Deleted codes in this document appear with a ~~strikethrough~~.

Proprietary laboratory analyses (PLA) codes describe proprietary clinical laboratory analyses and can be ~~either~~ provided either by a single ("sole-source," including the same or different locations, owned and operated by the same entity) laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]). PLA codes do not have a physician work component.

This subsection includes advanced diagnostic laboratory tests (ADLTs) and clinical diagnostic laboratory tests (CDLTs), as defined under the Protecting Access to Medicare Act (PAMA) of 2014. These analyses may include a range of medical laboratory tests including, but not limited to, multianalyte assays with algorithmic analyses (MAAA) and genomic sequencing procedures (GSP). The descriptor nomenclature follows, where possible, existing code conventions (eg, MAAA, GSP). An algorithm-only analysis of existing test results without biomarker analysis is not eligible for a PLA code.

~~Unless specifically noted, e~~Even though the Proprietary Laboratory Analyses section of the code set is located at the end of the Pathology and Laboratory section of the code set, a PLA code does not fulfill Category I code criteria. PLA codes are not required to fulfill the Category I criteria. The standards for inclusion in the PLA section are:

- The test must be commercially available in the United States for use on human specimens and
- The CLIA-certified or accredited clinical laboratory performing the PLA test or the manufacturer offering an FDA-approved, cleared, or classified in vitro diagnostic (IVD)~~that offers the~~ test must request the code.

For similar laboratory analyses that fulfill Category I criteria, see codes listed in the numeric 80000 series.

When a PLA code is available to report a given proprietary laboratory service, that PLA code takes precedence. The service should not be reported with any other CPT code(s) and other CPT code(s) should not be used to report services that may be reported with that specific PLA code. These codes encompass all analytical services required for the analysis (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection). For molecular analyses, additional procedures that are required prior to cell lysis (eg, microdissection [codes 88380 and 88381]) may be reported separately.

Codes in this subsection are released on a quarterly basis to expedite dissemination for reporting. PLA codes will be published electronically on the AMA CPT website (ama-assn.org/cpt-pla-codes), distributed via CPT data files on a quarterly basis, and, at a minimum, made available in print annually in the CPT codebook. Go to www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-pla-codes-long.pdf for the most current listing. See the Introduction section of the CPT code set for a complete list of the dates of release and implementation.

All codes that are included in this section are also included in Appendix O, with the procedure's proprietary name. In order to report a PLA code, the analysis performed must fulfill the code descriptor and must be the test represented by the proprietary name listed in Appendix O. In some instances, the descriptor language of PLA codes may be identical and the

code may only be differentiated by the listed proprietary name in Appendix O. When more than one PLA has an identical descriptor, the codes will be denoted by the symbol "~~⧺~~."

All PLA tests will have assigned codes in the PLA section of the code set. Any PLA coded test(s) that satisfies Category I criteria and has been accepted by the CPT Editorial Panel for Category I code status will ~~be designated by the addition of the symbol "↑↓" to the existing PLA code and will remain in the PLA~~receive a new CPT code number and be placed in the appropriate Pathology and Laboratory section of the code set.

The deletion of the existing PLA code will coincide with the effective date of the new Category I code. Once a PLA code changes to Category I in any other subsection, other than MAAA, of the Pathology and Laboratory section of the code set, it will no longer have proprietary status and will be deleted from Appendix O.

~~If a proprietary test has already been accepted for a Category I code and a code has not been published, subsequent application for a PLA code will take precedence. The code will only be placed in the PLA section.~~

The accuracy of a PLA code is to be maintained by the original applicant, or the current owner of the test kit or laboratory performing the proprietary test.

A new PLA code is required whenever the existing PLA has been updated in a manner that materially alters the original code descriptor, clinical indications, performance claims, or result reporting. Examples of changes that may trigger the need for a new PLA code include:

1. Additional nucleic acid (DNA or RNA) and/or protein analysis(es) are added to or removed from the current PLA test, ~~or~~
2. The algorithm (if used) has been materially changed so that it has expanded beyond its original intent, and
3. The name of the PLA test has changed in association with changes in test performance or test characteristics.

The addition or modification of the therapeutic applications of the test requires the submission of a code ~~–~~ change application, but it may not require a new code number.

Proprietary Name and Clinical Laboratory and/or Manufacturer	**Code**	**Long Code Descriptor**	**Released to AMA Website**	**Effective Date**	**Publication**
~~Serotonin Receptor Genotype (*HTR2A* and *HTR2C*), Mayo Clinic, Mayo Clinic~~	~~0033U~~	~~*HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C)* (eg, citalopram metabolism) gene analysis, common variants (ie, *HTR2A* rs7997012 [c.614-2211T>C], *HTR2C* rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027
~~+RNAinsight™ for BreastNext®, Ambry Genetics~~	~~+0131U~~	~~Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027

		~~sequence analysis panel (13 genes) (List separately in addition to code for primary procedure)~~ ~~(Use 0131U in conjunction with 81162, 81432, 0102U)~~			
~~+RNAinsight™ for OvaNext®, Ambry Genetics~~	~~+0132U~~	~~Hereditary ovarian cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure)~~ ~~(Use 0132U in conjunction with 81162, 81432, 0103U)~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027
~~+RNAinsight™ for GYNPlus®, Ambry Genetics~~	~~+0135U~~	~~Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure)~~ ~~(Use 0135U in conjunction with 81162)~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027
Trimethylamine (TMA) and TMA N-Oxide, Children's Hospital Colorado Laboratory	▲0256U	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, liquid chromatography tandem mass spectrometry (LC-MS/MS), urine, with algorithmic analysis and interpretive report	**Revision Released to AMA Website** December 30, 2025	**Revision Effective** April 1, 2026	**Revision Publication** CPT® 2027
PreTransplant Risk Assessment (PTRA)~~Clarava™~~, Verici Dx, Inc, Verici Dx, Inc	0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection	**Revision to Proprietary and Laboratory Name Released to AMA Website** December 30, 2025	**Revision to Proprietary and Laboratory Name Effective** April 1, 2026	**Revision to Proprietary and Laboratory Name Publication** CPT® 2027
~~Neurofilament Light Chain (NfL), Mayo Clinic, Mayo Clinic~~	~~0361U~~	~~Neurofilament light chain, digital immunoassay, plasma, quantitative~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027

~~VitaGraft™ Kidney Baseline + 1st Plasma Test, Oncocyte Corporation, Oncocyte Corporation~~	~~0508U~~	~~Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell-free DNA with risk for active rejection~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027
~~VitaGraft™ Kidney Subsequent, Oncocyte Corporation, Oncocyte Corporation~~	~~0509U~~	~~Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphisms (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection~~	**Deletion Released to AMA Website** October 1, 2025	**Deletion Effective** January 1, 2026	**Deletion Publication** CPT® 2027
PreClara™ Ratio (sFlt-1/PlGF), Thermo Fisher Scientific, Thermo Fisher Scientific	0524U	Obstetrics (preeclampsia), sFlt-1/PlGF ratio, immunoassay, utilizing serum or plasma, reported as a value	**Revision to Proprietary Name Released to AMA Website** October 1, 2025	**Revision to Proprietary Name Effective** January 1, 2026	**Revision Publication** CPT® 2027
~~VitaGraft™ Kidney 2.0, Oncocyte Corporation, Oncocyte Corporation~~	~~●0544U~~	~~Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA, percentage reported as risk for rejection~~	December 30, 2024 **Deletion Released to AMA Website** October 1, 2025	April 1, 2025 **Deletion Effective** January 1, 2026	CPT® 2026 **Deletion Publication** CPT® 2027
~~ClarityDx Prostate, Protean BioDiagnostics, Protean BioDiagnostics~~	~~●0550U~~	~~Oncology (prostate), enzyme-linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer~~	December 30, 2024 **Deletion Released to AMA Website** October 1, 2025	April 1, 2025 **Deletion Effective** January 1, 2026	CPT® 2026 **Deletion Publication** CPT® 2027
~~LucentAD p-Tau 217, Quanterix Corporation, Quanterix Corporation~~	~~●0551U~~	~~Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma~~	December 30, 2024 **Deletion Released to AMA Website**	April 1, 2025 **Deletion Effective** January 1, 2026	CPT® 2026 **Deletion Publication** CPT® 2027

			October 1, 2025		
iDart™ Lyme IgG ImmunoBlot Kit, ID-FISH Technology, Inc	▲0580U	Borrelia burgdorferi (Lyme disease), antibody detection of ~~24~~31 recombinant protein groups, by immunoassay, IgG	**Revision Released to AMA Website** December 30, 2025	**Revision Effective** April 1, 2026	**Revision Publication** CPT® 2027
Precivity-ApoE™, C2N Diagnostics, LLC	0596U	Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography with tandem mass spectrometry (LC-MS/MS), reported as an APOE ~~prototype~~proteotype	July 1, 2025 **Update to Long Code Descriptor Released to the AMA Website** October 1, 2025	October 1, 2025	CPT® 2026 **Update to Long Code Descriptor Publication** CPT® 2027
FidaLab Molecular Wound Infection Test, FidaLab LLC, FidaLab LLC	●0600U	Infectious disease (wound infection), identification of 65 organisms and 30 antibiotic resistance genes, wound swab, real-time PCR, reported as positive or negative for each organism	October 1, 2025	January 1, 2026	CPT® 2027
Synovasure® Comprehensive PJI Test Panel with SynTuition™, CD Laboratories, Inc, a division of Zimmer Biomet, CD Diagnostics, Inc, a division of Zimmer Biomet	●0601U	Infectious disease (periprosthetic joint infection), analysis of 11 biomarkers (alpha defensins 1–3, C-reactive protein, microbial antigens for Staphylococcus [SPA, SPB], Enterococcus, Candida, and C. acnes, total nucleated cell count, percent neutrophils, RBC count, and absorbance at 280 nm) using immunoassays, hematology, clinical chemistry, synovial fluid, and diagnostic algorithm reported as a probability score	October 1, 2025	January 1, 2026	CPT® 2027
Kihealth Inc® Diabetes Risk Test, Kihealth Inc® Laboratory	●0602U	Endocrinology (diabetes), insulin *(INS)* gene methylation using digital droplet PCR, insulin, and C-peptide immunoassay, serum, Hemoglobin A1c immunoassay, whole blood, algorithm reported as diabetes-risk score	October 1, 2025	January 1, 2026	CPT® 2027
SLL Comprehensive Drug Analysis, Soft Landing Labs, Soft Landing Labs	●0603U	Drug assay, presumptive, 77 drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry	October 1, 2025	January 1, 2026	CPT® 2027

		(LC-MS/MS), results reported as positive or negative			
Bradykinin, Quantitative, by LC-MS/MS, Virant Diagnostics, Inc	●0604U	Allergy and immunology (chronic recurrent angioedema), 4 bradykinin peptides, liquid chromatography and tandem mass spectrometry (LC-MS/MS), whole blood, quantitative	October 1, 2025	January 1, 2026	CPT® 2027
Tryptase Gene Copy Number Analysis by dPCR, Virant Diagnostics, Inc	●0605U	Allergy and immunology (hereditary alpha tryptasemia), DNA, analysis of *TPSAB1* gene copy number variation using digital PCR, whole blood, results reported with genotype-specific interpretation of alpha-tryptase copy number and algorithmic classification as normal or abnormal	October 1, 2025	January 1, 2026	CPT® 2027
Osmotic Gradient Ektacytometry, Cincinnati Children's Clinical Laboratories, RR Mechatronics	●0606U	Hematology (red cell membrane disorders), RBCs, osmotic gradient ektacytometry, whole blood, quantitative	October 1, 2025	January 1, 2026	CPT® 2027
EMMA (Endometrial Microbiome Metagenomic Analysis), Igenomix®, Igenomix® USA	●0607U	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 31 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations	October 1, 2025	January 1, 2026	CPT® 2027
ALICE (Analysis of Infectious Chronic Endometritis), Igenomix®, Igenomix® USA	●0608U	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 10 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations (Do not report 0608U in conjunction with 0607U)	October 1, 2025	January 1, 2026	CPT® 2027
ClarityDX Prostate, Protean BioDiagnostics, Nanostics Inc	●0609U	Oncology (prostate), immunoassay for total prostate-specific antigen (PSA) and free PSA, serum or plasma, combined with clinical features, algorithm reported as	October 1, 2025	January 1, 2026	CPT® 2027

		a probability score for clinically significant prostate cancer			
LifeScale Gram Negative Kit (LSGN) with the LifeScale AST system, Affinity Biosensors, LLC, Affinity Biosensors, LLC	●0610U	Infectious disease (antimicrobial susceptibility), phenotypic antimicrobial susceptibility testing of positive blood culture using microfluidic sensor technology to quantify bacterial growth response to multiple antibiotic types, reporting categorical susceptibility (susceptible, susceptible dose dependent, intermediate, resistant), minimum inhibitory concentration, and interpretive comments	October 1, 2025	January 1, 2026	CPT® 2027
HelioHCC™ Strat, Helio Genomics®, Helio Genomics®	♓●0611U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result (For additional PLA code with identical clinical descriptor, see 0612U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)	October 1, 2025	January 1, 2026	CPT® 2027
HelioHCC™ Trace, Helio Genomics®, Helio Genomics®	♓●0612U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result (For additional PLA code with identical clinical descriptor, see 0611U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)	October 1, 2025	January 1, 2026	CPT® 2027
AssureMDx™, Vesica Health® Inc	●0613U	Oncology (urothelial carcinoma), DNA methylation and mutation analysis of 6 biomarkers (TWIST1, OTX1, ONECUT2, FGFR3, HRAS, TERT promoter region), methylation-specific PCR and targeted next-generation sequencing, urine, algorithm	October 1, 2025	January 1, 2026	CPT® 2027

		reported as a probability index for bladder cancer and upper tract urothelial carcinoma			
Blue Native Polyacrylamide Gel Electrophoresis (PAGE), Children's Hospital Colorado Laboratory	●0614U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 4 enzyme complexes by stained blue native polyacrylamide gel electrophoresis (PAGE), frozen tissue (muscle, liver, heart, cultured skin fibroblasts), diagnostic qualitative result	December 30, 2025	April 1, 2026	CPT® 2027
iDart™ Lyme IgM ImmunoBlot Kit, ID-FISH Technology, Inc	●0615U	Borrelia burgdorferi (Lyme disease), antibody detection of 26 recombinant protein groups, by immunoassay, IgM	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Alzheimer's & MCI, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0616U	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS ASCVD, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0617U	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Bipolar, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0618U	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS COPD, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0619U	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Hepatocellular Carcinoma, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0620U	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027

TruD MDS Lyme Disease, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0621U	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Major Depressive Disorder, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0622U	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Multiple Sclerosis, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0623U	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS NASH, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0624U	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Osteoporosis, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0625U	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Parkinson's, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0626U	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
TruD MDS Schizophrenia, TruDiagnostic™, Inc, TruDiagnostic™, Inc	●0627U	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk	December 30, 2025	April 1, 2026	CPT® 2027
RenaDx™: Comprehensive Renal Disease Panel Test, Personalized Medicine Care Diagnostics, Personalized Medicine Care Diagnostics	●0628U	Nephrology (kidney disease-related genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles	December 30, 2025	April 1, 2026	CPT® 2027

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CRISPR-TB Blood Test™, Ruthenium Diagnostics, LLC	●0629U	Infectious disease (tuberculosis), DNA, analysis of 1 target by PCR with clustered regularly interspaced short palindromic repeat (CRISPR)-based probe detection, plasma or serum, qualitative report as detected or not detected	December 30, 2025	April 1, 2026	CPT® 2027
BluePrint® Molecular Subtyping Test, Agendia® Inc	●0630U	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2)	December 30, 2025	April 1, 2026	CPT® 2027

Updated December 30, 2025