

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 6 new PLA codes (0242U-0247U), three deleted codes (0098U-0100U), and one parenthetical note accepted by the CPT Editorial Panel.
- Deleted codes in this document appear with a strikethrough.

Proprietary laboratory analyses (PLA) codes describe proprietary clinical laboratory analyses and can be either provided by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]).

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).

Unless specifically noted, 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 clinical laboratory or manufacturer 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 " \mathcal{H} ."

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 will be designated by the addition of the symbol "14" to the existing PLA code and will remain in the PLA section of the code set.

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 when:

- 1. Additional nucleic acid (DNA or RNA) and/or protein analysis(es) are added to the current PLA test, or
- 2. 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 require 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
BioFire [®] -FilmArray [®] Respiratory Panel (RP) EZ, BioFire [®] -Diagnostics	0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/ enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae)	Deletion Released to AMA Website December 30, 2020	Deletion Effective April 1, 2021	Deletion Publication CPT [®] 2022
BioFire [®] -FilmArray [®] Respiratory Panel (RP), BioFire [®] -Diagnostics	0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory	Deletion Released to AMA Website December 30, 2020	Deletion Effective April 1, 2021	Deletion Publication CPT [®] 2022



		syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)			
BioFire [®] -FilmArray [®] Respiratory Panel 2 (RP2), BioFire [®] Diagnostics	0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella portussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)	Deletion Released to AMA Website December 30, 2020	Deletion Effective April 1, 2021	Deletion Publication CPT [®] 2022
Lymph3Cx Lymphoma Molecular Subtyping Assay, Mayo Clinic, Laboratory Developed Test	0120U	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter ► (Do not report 0120U in conjunction with 0017M) ◄	Parenthetical Note Posted to AMA Website December 30, 2020	Parenthetical Note Effective January 1, 2021	Parenthetical Note Publication CPT [®] 2022
Karius [®] Test, Karius Inc, Karius Inc	● <u>▲</u> 0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), <u>microbial cell-free</u> DNA, <u>PCR and plasma, untargeted</u> next-generation sequencing, plasma, detection of >1,000 potential microbial organisms-report for significant positive pathogens	Revision Posted to AMA Website October 1, 2020	Revision Effective January 1, 2021	Revision Publication CPT [®] 2022
BioFire [®] Respiratory Panel 2.1 (RP2.1), BioFire [®] Diagnostics, BioFire [®] Diagnostics, LLC	₩ ●0202U	 Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected ▶(For additional PLA code with identical clinical descriptor, see 0223U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment) ◄ 			Duplicate PLA Symbol and Parentheti cal Note Added to Publication CPT [®] 2022



QIAstat-Dx Respiratory SARS CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH	₩ ●0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected ► (For additional PLA code with identical clinical descriptor, see 0202U. See Appendix O or the most current listing on the AMA CPT website to determine one provide a sedimentation of the acute acute of the provide acute of the acute acute acute of the acute	June 25, 2020	June 25, 2020	CPT [®] 2022
COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory	●0224U	determine appropriate code assignment) ◀ Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), includes titer(s), when performed ► (Do not report 0224U in conjunction with 86769) ◀	June 25, 2020	June 25, 2020	CPT [®] 2022
ePlex [®] Respiratory Pathogen Panel 2, GenMark Dx, GenMark Diagnostics, Inc	●0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	August 10, 2020	August 10, 2020	CPT [®] 2022
Tru-Immune TM , Ethos Laboratories, GenScript [®] USA Inc	●0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID- 19]), ELISA, plasma, serum	August 10, 2020	August 10, 2020	CPT [®] 2022
Comprehensive Screen, Aspenti Health	●0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation	October 1, 2020	January 1, 2021	CPT [®] 2022
PanGIA Prostate, Genetics Institute of America, Entopsis, LLC	●0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer	October 1, 2020	January 1, 2021	CPT [®] 2022
Colvera [®] , <u>ColveraClinical</u> <u>Genomics Pathology Inc</u>	●0229U	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis	October 1, 2020	January 1, 2021	CPT [®] 2022



Genomic Unity [®] AR Analysis, Variantyx Inc, Variantyx Inc	●0230U	<i>AR</i> (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] CACNA1A Analysis, Variantyx Inc, Variantyx Inc	●0231U	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] CSTB Analysis, Variantyx Inc, Variantyx Inc	●0232U	<i>CSTB (cystatin B)</i> (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] FXN Analysis, Variantyx Inc, Variantyx Inc	●0233U	<i>FXN (frataxin)</i> (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] MECP2 Analysis, Variantyx Inc, Variantyx Inc	●0234U	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] PTEN Analysis, Variantyx Inc, Variantyx Inc	●0235U	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] SMN1/2 Analysis, Variantyx Inc, Variantyx Inc	●0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions	October 1, 2020	January 1, 2021	CPT [®] 2022
Genomic Unity [®] Cardiac Ion Channelopathies Analysis, Variantyx Inc, Variantyx Inc	●0237U	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including <i>ANK2</i> , <i>CASQ2</i> , <i>CAV3</i> , <i>KCNE1</i> , <i>KCNE2</i> , <i>KCNH2</i> , <i>KCNJ2</i> , <i>KCNQ1</i> , <i>RYR2</i> , and <i>SCN5A</i> , including small sequence	October 1, 2020	January 1, 2021	CPT [®] 2022

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		changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions			
Genomic Unity [®] Lynch Syndrome Analysis, Variantyx Inc, Variantyx Inc	●0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of <i>MLH1, MSH2, MSH6,</i> <i>PMS2,</i> and <i>EPCAM,</i> including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	October 1, 2020	January 1, 2021	CPT [®] 2022
FoundationOne [®] Liquid CDx, FOUNDATION MEDICINE, INC, FOUNDATION MEDICINE, INC	●0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations	October 1, 2020	January 1, 2021	CPT [®] 2022
Xpert [®] Xpress SARS- CoV-2/Flu/RSV (SARS- CoV-2 & Flu targets only), Cepheid	●0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected	October 6, 2020	October 6, 2020	CPT [®] 2022
Xpert [®] Xpress SARS- CoV-2/Flu/RSV (all targets), Cepheid	●0241U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected	October 6, 2020	October 6, 2020	CPT [®] 2022
Guardant360 [®] CDx, Guardant Health Inc, Guardant Health Inc	●0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	December 30, 2020	April 1, 2021	CPT [®] 2022
PIGF Preeclampsia Screen, PerkinElmer Genetics, PerkinElmer Genetics, Inc	●0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	December 30, 2020	April 1, 2021	CPT [®] 2022
Oncotype MAP™ Pan- Cancer Tissue Test, Paradigm Diagnostics, Inc, Paradigm Diagnostics, Inc	●0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin- embedded tumor tissue	December 30, 2020	April 1, 2021	CPT [®] 2022



ThyGeNEXT [®] Thyroid Oncogene Panel, Interpace Diagnostics, Interpace Diagnostics	●0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	December 30, 2020	April 1, 2021	CPT [®] 2022
PrecisionBlood™, San Diego Blood Bank, San Diego Blood Bank	●0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens	December 30, 2020	April 1, 2021	CPT [®] 2022
PreTRM [®] , Sera Prognostics, Sera Prognostics, Inc [®]	●0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone- binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth	December 30, 2020	April 1, 2021	CPT [®] 2022