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 10 PLA codes, 0035U-0044U, approved at the February 2018 CPT Editorial Panel meeting.
- Revision of Laboratory manufacturer name from "Agena Bioscience, Inc." to "InSource Diagnostics" for 0020U.
- 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).

These codes are not required to fulfill the Category I criteria. The standards for inclusion in this 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 (www.ama-assn.org/practice-management/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.

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, it is denoted by the symbol "♓".◄

Proprietary Name and Clinical Laboratory and/or Manufacturer	Code	Long Code Descriptor	Released to AMA Website	Effective Date	Publication
PreciseType® HEA Test Immucor, Inc.	●0001U	Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported	December 2, 2016	February 1, 2017	CPT® 2018
PolypDX™ Atlantic Diagnostic Laboratories, LLC Metabolomic Technologies Inc.	●0002U	Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps	December 2, 2016	February 1, 2017	CPT® 2018
Overa (OVA1 Next Generation) Aspira Labs, Inc. Vermillion, Inc.	●0003U	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score	December 2, 2016	February 1, 2017	CPT® 2018
~~Gram-Negative Bacterial Resistance Gene PCR Panel~~ ~~Mayo Clinic~~ ~~Check-Points Health BV, Wageningen, Netherlands~~	~~●0004U~~	~~Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate~~ ►(0004U has been deleted)◄	~~March 1, 2017~~ **Deletion Released to AMA Website** December 1, 2017	~~May 1, 2017~~ **Deletion Effective** January 1, 2018	~~CPT® 2018~~ **Deletion Publication** CPT® 2019

ExosomeDx® Prostate (IntelliScore) Exosome Diagnostics, Inc.	●0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes *(ERG*, *PCA3*, and *SPDEF*), urine, algorithm reported as risk score	March 1, 2017	May 1, 2017	CPT® 2018
Aegis Drug-Drug Interaction Test Aegis Sciences Corporation	●0006U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service	June 1, 2017	August 1, 2017	CPT® 2018
ToxProtect Genotox Laboratories LTD	♓●0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service ►(For additional PLA code with identical clinical descriptor, see 0020U. See Appendix O to determine appropriate code assignment)◄	June 1, 2017	August 1, 2017	CPT® 2018
AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel American Molecular Laboratories, Inc.	●0008U	Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin-embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin	June 1, 2017	August 1, 2017	CPT® 2018
DEPArray™ HER2 PacificDx	●0009U	Oncology (breast cancer), *ERBB2* (HER2) copy number by FISH, tumor cells from formalin-fixed paraffin-embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as *ERBB2* gene amplified or non-amplified	June 1, 2017	August 1, 2017	CPT® 2018

Bacterial Typing by Whole Genome Sequencing Mayo Clinic	●0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate	June 1, 2017	August 1, 2017	CPT® 2018
Cordant CORE™ Cordant Health Solutions	●0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites	June 1, 2017	August 1, 2017	CPT® 2018
MatePair Targeted Rearrangements, Congenital Mayo Clinic	●0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)	June 1, 2017	August 1, 2017	CPT® 2018
MatePair Targeted Rearrangements, Oncology Mayo Clinic	●0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)	June 1, 2017	August 1, 2017	CPT® 2018
MatePair Targeted Rearrangements, Hematologic Mayo Clinic	●0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)	June 1, 2017	August 1, 2017	CPT® 2018
~~OneOme RightMed Pharmacogenomic Test~~ ~~OneOme, LLC~~	~~●0015U~~	~~Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support~~ ►(0015U has been deleted)◄	~~June 1, 2017~~ **Deletion Released to AMA Website** December 1, 2017	~~August 1, 2017~~ **Deletion Effective** January 1, 2018	~~CPT® 2018~~ **Deletion Publication** CPT® 2019

Updated March 1, 2018

BCR-ABL1 major and minor breakpoint fusion transcripts University of Iowa, Department of Pathology, Asuragen	●0016U	Oncology (hematolymphoid neoplasia), RNA, *BCR/ABL1* major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation	June 1, 2017	August 1, 2017	CPT® 2018
JAK2 Mutation University of Iowa, Department of Pathology	●0017U	Oncology (hematolymphoid neoplasia), *JAK2* mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of *JAK2* mutation not detected or detected	June 1, 2017	August 1, 2017	CPT® 2018
ThyraMIR Interpace Diagnostics Interpace Diagnostics	●0018U	Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy	August 31, 2017	October 1, 2017	CPT® 2019
OncoTarget/ OncoTreat Columbia University Department of Pathology and Cell Biology Darwin Health	●0019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents	August 31, 2017	October 1, 2017	CPT® 2019
ToxLok InSource Diagnostics ~~Agena Bioscience, Inc~~. InSource Diagnostics	♓●0020U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, with specimen verification including DNA authentication in comparison to buccal DNA, per date of service ►(For additional PLA code with identical clinical descriptor, see 0007U. See Appendix O to determine appropriate code assignment)◄	August 31, 2017	October 1, 2017	CPT® 2019

Apifiny® Armune BioScience, Inc.	●0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score	August 31, 2017	October 1, 2017	CPT® 2019
Oncomine™ Dx Target Test Thermo Fisher Scientific	●0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider	August 31, 2017	October 1, 2017	CPT® 2019
LeukoStrat® CDx FLT3 Mutation Assay LabPMM LLC, an Invivoscribe Technologies, Inc. company Invivoscribe Technologies, Inc.	●0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of *FLT3* mutation and indication for or against the use of midostaurin	August 31, 2017	October 1, 2017	CPT® 2019
GlycA Laboratory Corporation of America Laboratory Corporation of America	●0024U	Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative	December 1, 2017	January 1, 2018	CPT® 2019
UrSure Tenofovir Quantification Test Synergy Medical Laboratories UrSure Inc.	●0025U	Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative	December 1, 2017	January 1, 2018	CPT® 2019
Thyroseq Genomic Classifier CBLPath, Inc. University of Pittsburgh Medical Center	●0026U	Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy")	December 1, 2017	January 1, 2018	CPT® 2019

JAK2 Exons 12 to 15 Sequencing Mayo Clinic Mayo Clinic	●0027U	*JAK2* (*Janus kinase 2*) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15	December 1, 2017	January 1, 2018	CPT® 2019
CYP2D6 Genotype Cascade Mayo Clinic Mayo Clinic	●0028U	*CYP2D6* (*cytochrome P450, family 2, subfamily D, polypeptide 6*) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis	December 1, 2017	January 1, 2018	CPT® 2019
Focused Pharmacogenomics Panel Mayo Clinic Mayo Clinic	●0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, *CYP1A2*, *CYP2C19*, *CYP2C9*, *CYP2D6*, *CYP3A4*, *CYP3A5*, *CYP4F2*, *SLCO1B1*, *VKORC1* and rs12777823)	December 1, 2017	January 1, 2018	CPT® 2019
Warfarin Response Genotype Mayo Clinic Mayo Clinic	●0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, *CYP2C9*, *CYP4F2*, *VKORC1*, rs12777823)	December 1, 2017	January 1, 2018	CPT® 2019
Cytochrome P450 1A2 Genotype Mayo Clinic Mayo Clinic	●0031U	*CYP1A2* (*cytochrome P450 family 1, subfamily A, member 2*)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)	December 1, 2017	January 1, 2018	CPT® 2019
Catechol-O-Methyltransferase (*COMT*) Genotype Mayo Clinic Mayo Clinic	●0032U	*COMT* (*catechol-O-methyltransferase)* (drug metabolism) gene analysis, c.472G>A (rs4680) variant	December 1, 2017	January 1, 2018	CPT® 2019

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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])	December 1, 2017	January 1, 2018	CPT® 2019
Thiopurine Methyltransferase (*TPMT*) and Nudix Hydrolase (*NUDT15*) Genotyping Mayo Clinic Mayo Clinic	●0034U	*TPMT* (*thiopurine S-methyltransferase*), *NUDT15* (*nudix hydroxylase 15)* (eg, thiopurine metabolism), gene analysis, common variants (ie, *TPMT* *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; *NUDT15* *3, *4, *5)	December 1, 2017	January 1, 2018	CPT® 2019
Real-time quaking-induced conversion for prion detection (RT-QuIC) National Prion Disease Pathology Surveillance Center	●0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative	March1, 2018	April 1, 2018	CPT® 2019
EXaCT-1 Whole Exome Testing Lab of Oncology-Molecular Detection Weill Cornell Medicine-Clinical Genomics Laboratory	●0036U	Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses	March1, 2018	April 1, 2018	CPT® 2019
FoundationOne CDx™ (F1CDx) Foundation Medicine, Inc. Foundation Medicine, Inc.	●0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	March1, 2018	April 1, 2018	CPT® 2019

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Sensieva™ Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay InSource Diagnostics InSource Diagnostics	●0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative	March1, 2018	April 1, 2018	CPT® 2019
Anti-dsDNA, High Salt/Avidity University of Washington, Department of Laboratory Medicine Bio-Rad	●0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	March1, 2018	April 1, 2018	CPT® 2019
MRDx BCR-ABL Test MolecularMD MolecularMD	●0040U	*BCR/ABL1 (t(9;22))* (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative	March1, 2018	April 1, 2018	CPT® 2019
Lyme ImmunoBlot IgM IGeneX Inc ID-FISH Technology Inc. (ASR) (Lyme ImmunoBlot IgM Strips Only)	●0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	March1, 2018	April 1, 2018	CPT® 2019
Lyme ImmunoBlot IgG IGeneX Inc ID-FISH Technology Inc. (ASR) (Lyme ImmunoBlot IgG Strips Only)	●0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	March1, 2018	April 1, 2018	CPT® 2019
Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgM Test IGeneX Inc ID-FISH Technology	●0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM	March1, 2018	April 1, 2018	CPT® 2019

Inc. (Provides TBRF ImmunoBlot IgM Strips)					
Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgG Test IGeneX Inc ID-FISH Technology Inc. (Provides TBRF ImmunoBlot IgG Strips)	●0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG	March1, 2018	April 1, 2018	CPT® 2019

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