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:

- Deletion of 2 codes (0204U, 0353U) and addition of 26 codes (0450U–0475U) accepted by the CPT Editorial Panel.
- Revision of parenthetical notes following codes 0260U and 0264U.
- Revision to proprietary, laboratory, and/or manufacturer name for code 0047U 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

Updated April 1, 2024

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 will be designated by the addition of the symbol "↑↓" 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**
~~Oncotype DX Genomic Prostate Score, Genomic Health, Inc,~~ ~~Genomic Health, Inc~~ Genomic Prostate Score® (GPS) Test, MDxHealth, Inc, MDxHealth, Inc	0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score	**Revision to Proprietary, Laboratory, and/or Manufacturer Name Released to AMA Website** April 1, 2024	**Revision to Proprietary, Laboratory, and/or Manufacturer Name Effective** July 1, 2024	**Revision to Proprietary, Laboratory, and/or Manufacturer Name Publication** CPT® 2025
~~Afirma Xpression Atlas, Veracyte, Inc, Veracyte, Inc~~	~~0204U~~	~~Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including *BRAF, RAS, RET, PAX8,* and *NTRK)* for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected~~	**Deletion Released to AMA Website** April 1, 2024	**Deletion Effective** July 1, 2024	**Deletion Publication** CPT® 2025
Augusta Optical Genome Mapping, Georgia Esoteric and Molecular (GEM) Laboratory, LLC, Bionano Genomics Inc	♓0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	**Revised Parenthetical Note Released to AMA Website** April 1, 2024	**Revised Parenthetical Note Effective** July 1, 2024	**Revised Parenthetical Note Publication** CPT® 2025

		(For additional PLA codes with identical clinical descriptor, see 0264U, 0454U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)			
Praxis Optical Genome Mapping, Praxis Genomics LLC	⌘0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping (For additional PLA codes with identical clinical descriptor, see 0260U, 0454U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)	**Revised Parenthetical Note Released to AMA Website** April 1, 2024	**Revised Parenthetical Note Effective** July 1, 2024	**Revised Parenthetical Note Publication** CPT® 2025
MeMed BV®, MeMed Diagnostics, Ltd, MeMed Diagnostics, Ltd	▲0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, or venous whole blood, algorithm reported as likelihood of bacterial infection	**Revision Released to AMA Website** September 29, 2023	**Revision Effective** January 1, 2024	**Revision Publication** CPT® 2025
~~Xpert® CT/NG, Cepheid®~~	~~0353U~~	~~Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected~~	**Deletion Released to AMA Website** April 1, 2024	**Deletion Effective** July 1, 2024	**Deletion Publication** CPT® 2025
~~PreTect HPV-Proofer' 7, GenePace Laboratories, LLC, PreTech~~	~~0354U~~	~~Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)~~	**Deletion Released to AMA Website** December 28, 2023	**Deletion Effective** April 1, 2024	**Deletion Publication** CPT® 2025
NavDx®, Naveris, Inc, Naveris, Inc	▲●0356U	Oncology (oropharyngeal or anal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence	September 30, 2022 **Revision Released to AMA Website** September 29, 2023	January 1, 2023 **Revision Effective** January 1, 2024	CPT® 2024 **Revision Publication** CPT® 2025

~~IntelxDKD™~~ kidneyintelX.dkd™, Renalytix Inc, Renalytix Inc, NYC, NY	0407U	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function	**Revision to Proprietary Name Released to AMA Website** December 28, 2023	**Revision to Proprietary Name Effective** April 1, 2024	**Revision to Proprietary Name Publication** CPT® 2025
~~GENETWORx UTI with ABR, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx~~	~~0416U~~	~~Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine~~	**Deletion Released to AMA Website** December 28, 2023	**Deletion Effective** April 1, 2024	**Deletion Publication** CPT® 2025
Cxbladder Detect+, Pacific Edge Diagnostics USA LTD, Pacific Edge Diagnostics USA LTD	●0420U	Oncology (urothelial), mRNA expression profiling by real-time quantitative PCR of *MDK, HOXA13, CDC2, IGFBP5,* and *CXCR2* in combination with droplet digital PCR (ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) genes *TERT* and *FGFR3,* urine, algorithm reported as a risk score for urothelial carcinoma	September 29, 2023	January 1, 2024	CPT® 2025
Colosense™, Geneoscopy, Inc, Geneoscopy, Inc	●0421U	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers *(GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2)* and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk	September 29, 2023	January 1, 2024	CPT® 2025
Guardant360 Response™, Guardant Health, Inc, Guardant Health, Inc	●0422U	Oncology (pan-solid tumor), analysis of DNA biomarker response to anti-cancer therapy using cell-free circulating DNA, biomarker comparison to a previous baseline pre-treatment cell-free circulating DNA analysis using next-generation sequencing, algorithm reported as a quantitative change from baseline, including specific alterations, if appropriate	September 29, 2023	January 1, 2024	CPT® 2025

Genomind® Pharmacogenetics Report – Full, Genomind®, Inc, Genomind®, Inc	●0423U	Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition	September 29, 2023	January 1, 2024	CPT® 2025
miR Sentinel™ Prostate Cancer Test, miR Scientific®, LLC, miR Scientific®, LLC	●0424U	Oncology (prostate), exosome-based analysis of 53 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as no molecular evidence, low-, moderate- or elevated-risk of prostate cancer	September 29, 2023	January 1, 2024	CPT® 2025
RCIGM Rapid Whole Genome Sequencing, Comparator Genome, Rady Children's Institute for Genomic Medicine, Rady Children's Institute for Genomic Medicine	●0425U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings)	September 29, 2023	January 1, 2024	CPT® 2025
RCIGM Ultra-Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine, Rady Children's Institute for Genomic Medicine	●0426U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis	September 29, 2023	January 1, 2024	CPT® 2025
Early Sepsis Indicator, Beckman Coulter, Inc	+●0427U	Monocyte distribution width, whole blood (List separately in addition to code for primary procedure) (Use 0427U in conjunction with 85004, 85025)	September 29, 2023	January 1, 2024	CPT® 2025
Epic Sciences ctDNA Metastatic Breast Cancer Panel, Epic Sciences, Inc, Epic Sciences, Inc	●0428U	Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden	September 29, 2023	January 1, 2024	CPT® 2025

Omnipathology Oropharyngeal HPV PCR Test, OmniPathology Solutions, Medical Corporation, OmniPathology Solutions, Medical Corporation	●0429U	Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)	September 29, 2023	January 1, 2024	CPT® 2025
Malabsorption Evaluation Panel, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	●0430U	Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase and reducing substances, feces, quantitative	September 29, 2023	January 1, 2024	CPT® 2025
Glycine Receptor Alpha1 IgG, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	●0431U	Glycine receptor alpha1 IgG, serum or cerebrospinal fluid (CSF), live cell-binding assay (LCBA), qualitative	September 29, 2023	January 1, 2024	CPT® 2025
Kelch-Like Protein 11 Antibody, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories	●0432U	Kelch-like protein 11 (KLHL11) antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative	September 29, 2023	January 1, 2024	CPT® 2025
EpiSwitch® Prostate Screening Test (PSE), Oxford BioDynamics Inc, Oxford BioDynamics PLC	●0433U	Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer	September 29, 2023	January 1, 2024	CPT® 2025
RightMed® Gene Test Exclude F2 and F5, OneOme® LLC, OneOme® LLC	●0434U	Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes	September 29, 2023	January 1, 2024	CPT® 2025
ChemoID®, ChemoID® Lab, Cordgenics, LLC	●0435U	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on cytotoxicity percentage observed, minimum of 14 drugs or drug combinations	September 29, 2023	January 1, 2024	CPT® 2025
PROphet® NSCLC Test, OncoHost, Inc, OncoHost, Inc	●0436U	Oncology (lung), plasma analysis of 388 proteins, using aptamer-based proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy	September 29, 2023	January 1, 2024	CPT® 2025

MindX One™ Blood Test – Anxiety, MindX Sciences, MindX Sciences	●0437U	Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score	September 29, 2023	January 1, 2024	CPT® 2025
EffectiveRX™ Comprehensive Panel, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	●0438U	Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of *CYP2D6,* including reported phenotypes and impacted gene-drug interactions	September 29, 2023	January 1, 2024	CPT® 2025
Epi+Gen CHD™, Cardio Diagnostics, Inc, Cardio Diagnostics, Inc	●0439U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/LOC107986769], rs6820447 [intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD	December 28, 2023	April 1, 2024	CPT® 2025
PrecisionCHD™, Cardio Diagnostics, Inc, Cardio Diagnostics, Inc	●0440U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) (rs710987 [LINC010019], rs1333048 [CDKN2B-AS1], rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1, cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRR], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported	December 28, 2023	April 1, 2024	CPT® 2025

		as detected or not detected for CHD			
IntelliSep® test, Cytovale®	●0441U	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index	December 28, 2023	April 1, 2024	CPT® 2025
FebriDx® Bacterial/Non-Bacterial Point-of-Care Assay, Lumos Diagnostics, LLC, Lumos Diagnostics, LLC	●0442U	Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent	December 28, 2023	April 1, 2024	CPT® 2025
Neurofilament Light Chain (NfL), Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine, Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine	●0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid	December 28, 2023	April 1, 2024	CPT® 2025
Aventa FusionPlus™, Aventa Genomics, LLC	●0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-fixed paraffin-embedded (FFPE) tumor tissue, report of clinically significant variant(s)	December 28, 2023	April 1, 2024	CPT® 2025
Elecsys® Phospho-Tau (181P) CSF (pTau181) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio, Roche Diagnostics Operations, Inc (US owner/operator)	●0445U	β-amyloid (Abeta42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology	December 28, 2023	April 1, 2024	CPT® 2025
aisle® DX Disease Activity Index, Progentec Diagnostics, Inc,	●0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual	December 28, 2023	April 1, 2024	CPT® 2025

Progentec Diagnostics, Inc		components reported with an algorithmic risk score for current disease activity			
aisle® DX Flare Risk Index, Progentec Diagnostics, Inc, Progentec Diagnostics, Inc	●0447U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare	December 28, 2023	April 1, 2024	CPT® 2025
oncoReveal™ DX Lung and Colon Cancer Assay, Pillar® Biosciences, Pillar® Biosciences	●0448U	Oncology (lung and colon cancer), DNA, qualitative, next-generation sequencing detection of single-nucleotide variants and deletions in *EGFR* and *KRAS* genes, formalin-fixed paraffin-embedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options	December 28, 2023	April 1, 2024	CPT® 2025
UNITY Carrier Screen™, BillionToOne Laboratory, BillionToOne, Inc	●0449U	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes *(CFTR, SMN1, HBB, HBA1, HBA2)*	December 28, 2023	April 1, 2024	CPT® 2025
M-inSight® Patient Definition Assay, Corgenix Clinical Laboratory, Sebia	●0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LC-MS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides	April 1, 2024	July 1, 2024	CPT® 2025
M-inSight® Patient Follow-Up Assessment, Corgenix Clinical Laboratory, Sebia	●0451U	Oncology (multiple myeloma), LC-MS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance	April 1, 2024	July 1, 2024	CPT® 2025
EarlyTect® Bladder Cancer Detection (EarlyTect® BCD), Promis Diagnostics, Inc, Promis Diagnostics, Inc	●0452U	Oncology (bladder), methylated *PENK* DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer	April 1, 2024	July 1, 2024	CPT® 2025

ColonAiQ®, Breakthrough Genomics, Singlera Genomics, Inc	●0453U	Oncology (colorectal cancer), cell-free DNA (cfDNA), methylation-based quantitative PCR assay *(SEPTIN9, IKZF1, BCAT1,* Septin9-2, *VAV3, BCAN),* plasma, reported as presence or absence of circulating tumor DNA (ctDNA)	April 1, 2024	July 1, 2024	CPT® 2025
Chromosome Genome Mapping, UR Medicine Labs, Bionano Genomics, Inc	♓●0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping (For additional PLA codes with identical clinical descriptor, see 0260U, 0264U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)	April 1, 2024	July 1, 2024	CPT® 2025
Abbott Alinity™ m STI Assay, Abbott Molecular, Inc	●0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected	April 1, 2024	July 1, 2024	CPT® 2025
PrismRA®, Scipher Medicine®, Scipher Medicine®	●0456U	Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anti-cyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy	April 1, 2024	July 1, 2024	CPT® 2025
PFAS (Forever Chemicals) 9 Panel, Quest Diagnostics®, Quest Diagnostics®	●0457U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative	April 1, 2024	July 1, 2024	CPT® 2025
Auria®, Namida Lab, Inc, Namida Lab, Inc	●0458U	Oncology (breast cancer), S100A8 and S100A9, by enzyme-linked immunosorbent assay	April 1, 2024	July 1, 2024	CPT® 2025

		(ELISA), tear fluid with age, algorithm reported as a risk score			
Elecsys® Total Tau CSF (tTau) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio, Roche Diagnostics Operations, Inc (US owner/operator)	●0459U	β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology	April 1, 2024	July 1, 2024	CPT® 2025
RightMed® Oncology Gene Report, OneOme® LLC, OneOme® LLC	●0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes	April 1, 2024	July 1, 2024	CPT® 2025
RightMed® Oncology Medication Report, OneOme® LLC, OneOme® LLC	●0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes	April 1, 2024	July 1, 2024	CPT® 2025
Salimetrics® Salivary Melatonin Profile (Circadian Phase Assessment), Salimetrics® Clinical Laboratory, Salimetrics®, LLC	●0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary	April 1, 2024	July 1, 2024	CPT® 2025
Proofer '7 HPV mRNA E6 and E7 Biomarker Test, Global Diagnostics Labs, LLC, PreTect AS, a Mel-Mont Medical, Inc, wholly-owned subsidiary	●0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker	April 1, 2024	July 1, 2024	CPT® 2025
Cologuard Plus™, Exact Sciences Laboratories, LLC, Exact Sciences Corporation	●0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool,	April 1, 2024	July 1, 2024	CPT® 2025

		algorithm reported as a positive or negative result			
UriFind® Blood Cancer Assay, DiaCarta, Inc, AnchorDx	●0465U	Oncology (urothelial carcinoma), DNA, quantitative methylation-specific PCR of 2 genes *(ONECUT2, VIM),* algorithmic analysis reported as positive or negative	April 1, 2024	July 1, 2024	CPT® 2025
CardioRisk+, Gene by Gene, Ltd, OpenDNA, Ltd	●0466U	Cardiology (coronary artery disease [CAD]), DNA, genome-wide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease	April 1, 2024	July 1, 2024	CPT® 2025
UroAmp MRD, Convergent Genomics, Inc, Convergent Genomics, Inc	●0467U	Oncology (bladder), DNA, next-generation sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden	April 1, 2024	July 1, 2024	CPT® 2025
NASHnext™ (NIS4™), Labcorp, Labcorp	●0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a-5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis	April 1, 2024	July 1, 2024	CPT® 2025
IriSight™ CNV Analysis, Variantyx Inc, Variantyx Inc	●0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if	April 1, 2024	July 1, 2024	CPT® 2025

		performed, as comparators and/or maternal cell contamination			
HPV-SEQ Test, Sysmex Inostics, Inc, Sysmex Inostics, Inc	●0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma	April 1, 2024	July 1, 2024	CPT® 2025
CRCdx® RAS Mutation Detection Kit, EntroGen, Inc, EntroGen, Inc	●0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of *KRAS* and *NRAS* genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations	April 1, 2024	July 1, 2024	CPT® 2025
Early Sjögren's Syndrome Profile, Immco Diagnostics, Inc, Immco Diagnostics, Inc	●0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiqualitative, blood, reported as predictive evidence of early Sjögren syndrome	April 1, 2024	July 1, 2024	CPT® 2025
xT CDx, Tempus AI, Inc, Tempus AI, Inc	●0473U	Oncology (solid tumor), next-generation sequencing (NGS) of DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden	April 1, 2024	July 1, 2024	CPT® 2025
GeneticsNow® Comprehensive Germline Panel, GoPath Diagnostics, Inc, GoPath Diagnostics, Inc	●0474U	Hereditary pan-cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using next-generation sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene	April 1, 2024	July 1, 2024	CPT® 2025

ProstateNow™ Prostate Germline Panel, GoPath Diagnostics, Inc, GoPath Diagnostics, Inc	●0475U	Hereditary prostate cancer-related disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer	April 1, 2024	July 1, 2024	CPT® 2025