

# 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:**

- Revision of 2 codes (0095U, 0365U), deletion of 5 codes (0346U, 0380U, 0428U, 0448U, 0456U) and addition of 10 codes (0521U–0530U) accepted by the CPT Editorial Panel.
- Update clinical laboratory name for codes 0301U, 0302U by adding “,” after “Diagnostics”.
- Update long descriptor for code 0440U by adding “J” after “CXCL1”.
- 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](https://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](https://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 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
<del>Oncotype DX Genomic Prostate Score, Genomic Health, Inc, Genomic Health, Inc Genomic Prostate Score® (GPS) Test, MDxHealth, Inc, MDxHealth, Inc</del>	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	<b>Revision to Proprietary, Laboratory, and/or Manufacturer Name Released to AMA Website</b> April 1, 2024	<b>Revision to Proprietary, Laboratory, and/or Manufacturer Name Effective</b> July 1, 2024	<b>Revision to Proprietary, Laboratory, and/or Manufacturer Name Publication</b> CPT® 2025
<del>INFINITI® Neural Response Panel, Personalized Dx Labs, AutoGenomics Inc</del>	0078U	<del>Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder</del>	<b>Deletion Released to AMA Website</b> July 1, 2024	<b>Deletion Effective</b> October 1, 2024	<b>Deletion Publication</b> CPT® 2025
Esophageal String Test™ (EST), Children's Hospital Colorado Department of	▲0095U	Eosinophilic esophagitis, 2 protein biomarkers (Eotaxin-3 [CCL26 {C-C motif chemokine ligand 26}] and <del>α</del> Major <del>α</del> Basic pProtein [PRG2 {proteoglycan 2,	<b>Revision Released to AMA Website</b> October 1, 2024	<b>Revision Effective</b> January 1, 2025	<b>Revision Publication</b> CPT® 2026

Pathology and Laboratory Medicine		<i>pro eosinophil major basic protein</i> }}, enzyme-linked immunosorbent assays (ELISA), specimen obtained by esophageal string test device, algorithm reported as probability of active or inactive eosinophilic esophagitis			
<del>Viracor Eurofins</del> TRAC™ dd-cfDNA, <del>Viracor Eurofins</del> , <del>Viracor Eurofins</del> Transplant Genomics Inc, Transplant Genomics Inc	0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA	<b>Revision to Proprietary, Laboratory, and/or Manufacturer Name Released to AMA Website</b> July 1, 2024	<b>Revision to Proprietary, Laboratory, and/or Manufacturer Name Effective</b> October 1, 2024	<b>Revision to Proprietary, Laboratory, and/or Manufacturer Name Publication</b> CPT® 2025
<del>ADEXUS Dx hCG Test</del> , <del>NOWDiagnostics</del> , <del>NOWDiagnostics</del>	0167U	<del>Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood</del>	<b>Deletion Released to AMA Website</b> July 1, 2024	<b>Deletion Effective</b> October 1, 2024	<b>Deletion Publication</b> CPT® 2025
<del>Afirma Xpression Atlas</del> , <del>Veracyte, Inc</del> , <del>Veracyte, Inc</del>	0204U	<del>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</del>	<b>Deletion Released to AMA Website</b> April 1, 2024	<b>Deletion Effective</b> July 1, 2024	<b>Deletion Publication</b> CPT® 2025
3D Predict Glioma, Kiyatec®, Inc	▲0248U	Oncology ( <del>brain</del> ), spheroid cell culture in a 3D microenvironment, 12-drug panel, <del>tumor brain- or brain metastasis-</del> response prediction for each drug	<b>Revision Released to AMA Website</b> July 1, 2024	<b>Revision Effective</b> October 1, 2024	<b>Revision Publication</b> 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  (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)	<b>Revised Parenthetical Note Released to AMA Website</b> April 1, 2024	<b>Revised Parenthetical Note Effective</b> July 1, 2024	<b>Revised Parenthetical Note Publication</b> CPT® 2025
Praxis Optical Genome Mapping, Praxis Genomics LLC	✕0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions,	<b>Revised Parenthetical Note Released</b>	<b>Revised Parenthetical Note Effective</b>	<b>Revised Parenthetical Note Publication</b>

		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)	<b>to AMA Website</b> April 1, 2024	July 1, 2024	CPT® 2025C
Bartonella ddPCR, Galaxy Diagnostics, Inc	0301U	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR);	October 1, 2021	January 1, 2022	CPT® 2025
Bartonella Digital ePCR™, Galaxy Diagnostics, Inc	0302U	following liquid enrichment	October 1, 2021	January 1, 2022	CPT® 2025
<del>QUEST AD-Detect™, Beta-Amyloid 42/40 Ratio, Plasma, Quest Diagnostics</del>	0346U	<del>Beta-amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma</del>	<b>Deletion Released to AMA Website</b> October 1, 2024	<b>Deletion Effective</b> January 1, 2025	<b>Deletion Publication</b> CPT® 2026
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, <u>or venous whole blood</u> , algorithm reported as likelihood of bacterial infection	<b>Revision Released to AMA Website</b> September 29, 2023	<b>Revision Effective</b> January 1, 2024	<b>Revision Publication</b> CPT® 2025
<del>Xpert® CT/NG, Cepheid®</del>	0353U	<del>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</del>	<b>Deletion Released to AMA Website</b> April 1, 2024	<b>Deletion Effective</b> July 1, 2024	<b>Deletion Publication</b> CPT® 2025
<del>PreTect HPV-Proofer® 7, GenePace Laboratories, LLC, PreTech</del>	0354U	<del>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)</del>	<b>Deletion Released to AMA Website</b> December 28, 2023	<b>Deletion Effective</b> April 1, 2024	<b>Deletion Publication</b> CPT® 2025
NavDx®, Naveris, Inc, Naveris, Inc	▲◆0356U	Oncology (oropharyngeal <u>or anal</u> ), evaluation of 17 DNA biomarkers using droplet digital	September 30, 2022	January 1, 2023	CPT® 2024

		PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence	<b>Revision Released to AMA Website</b> September 29, 2023	<b>Revision Effective</b> January 1, 2024	<b>Revision Publication</b> CPT® 2025
Oncuria® Detect, DiaCarta Clinical Lab, DiaCarta, Inc	▲0365U	Oncology (bladder), <del>analysis of</del> 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA), by immunoassays, urine, <del>diagnostic algorithm, including patient's age, race and gender, reported as a probability of harboring urothelial bladder cancer</del>	<b>Revision Released to AMA Website</b> October 1, 2024	<b>Revision Effective</b> January 1, 2025	<b>Revision Publication</b> CPT® 2026
PersonalisedRX, Lab Genomics LLC, Agena Bioscience, Inc	0380U	<del>Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype</del>	<b>Deletion Released to AMA Website</b> October 1, 2024	<b>Deletion Effective</b> January 1, 2025	<b>Deletion Publication</b> CPT® 2026
Spectrum PGT-M, Natera, Inc, Natera, Inc	0396U	<del>Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single gene germline conditions</del>	<b>Deletion Released to AMA Website</b> July 1, 2024	<b>Deletion Effective</b> October 1, 2024	<b>Deletion Publication</b> CPT® 2025
MyProstateScore 2.0, LynxDX, LynxDX	▲0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch <del>post-digital rectal examination urine (or processed first catch urine)</del> , algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer	<b>Revision Released to AMA Website</b> July 1, 2024	<b>Revision Effective</b> October 1, 2024	<b>Revision Publication</b> CPT® 2025
IntelXDKD™ kidneyintelX.dkdtm™, 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	<b>Revision to Proprietary Name Released to AMA Website</b> December 28, 2023	<b>Revision to Proprietary Name Effective</b> April 1, 2024	<b>Revision to Proprietary Name Publication</b> 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	<b>Deletion Released to AMA Website</b> December 28, 2023	<b>Deletion Effective</b> April 1, 2024	<b>Deletion Publication</b> 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 <i>MDK</i> , <i>HOXA13</i> , <i>CDC2</i> , <i>IGFBP5</i> , and <i>CXCR2</i> in combination with droplet digital PCR (ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) of genes <i>TERT</i> and <i>FGFR3</i> , 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 ( <i>GAPDH</i> , <i>SMAD4</i> , <i>ACY1</i> , <i>AREG</i> , <i>CDH1</i> , <i>KRAS</i> , <i>TNFRSF10B</i> , <i>EGLN2</i> ) 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-,	September 29, 2023	January 1, 2024	CPT® 2025

		moderate-, or elevated-risk of prostate cancer			
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
<del>Epic Sciences ctDNA Metastatic Breast Cancer Panel, Epic Sciences, Inc, Epic Sciences, Inc</del>	<del>●0428U</del>	<del>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</del>	September 29, 2023  <b>Deletion Released to AMA Website</b> October 1, 2024	January 1, 2024  <b>Deletion Effective</b> January 1, 2025	CPT® 2025  <b>Deletion Publication</b> CPT® 2026
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	●0430U	Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase	September 29, 2023	January 1, 2024	CPT® 2025

Clinic Laboratories, Mayo Clinic/Mayo Clinic Laboratories		and reducing substances, feces, quantitative			
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
Chemold®, Chemold® 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	●0438U	Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of	September 29, 2023	January 1, 2024	CPT® 2025



GENETWORx, GENETWORx		CYP2D6, including reported phenotypes and impacted gene-drug interactions			
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 as detected or not detected for CHD	December 28, 2023	April 1, 2024	CPT® 2025
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	●0442U	Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole	December 28, 2023	April 1, 2024	CPT® 2025

Diagnostics, LLC, Lumos Diagnostics, LLC		blood specimen, each biomarker reported as present or absent			
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, Progentec Diagnostics, Inc	●0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity	December 28, 2023	April 1, 2024	CPT® 2025
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
<del>oncoReveal™ DX Lung and Colon Cancer Assay,</del>	<del>●0448U</del>	<del>Oncology (lung and colon cancer), DNA, qualitative, next- generation sequencing detection</del>	December 28, 2023	April 1, 2024 <b>Deletion</b>	CPT® 2025

Pillar <sup>®</sup> Biosciences, Pillar <sup>®</sup> Biosciences		of single nucleotide variants and deletions in <i>EGFR</i> and <i>KRAS</i> genes, formalin-fixed paraffin-embedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options	<b>Deletion Released to AMA Website</b> October 1, 2024	<b>Effective</b> January 1, 2025	<b>Deletion Publication</b> CPT <sup>®</sup> 2026
UNITY Carrier Screen <sup>™</sup> , 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 ( <i>CFTR</i> , <i>SMN1</i> , <i>HBB</i> , <i>HBA1</i> , <i>HBA2</i> )	December 28, 2023	April 1, 2024	CPT <sup>®</sup> 2025
M-inSight <sup>®</sup> 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 <sup>®</sup> 2025
M-inSight <sup>®</sup> 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 <sup>®</sup> 2025
EarlyTect <sup>®</sup> Bladder Cancer Detection (EarlyTect <sup>®</sup> BCD), Promis Diagnostics, Inc, Promis Diagnostics, Inc	●0452U	Oncology (bladder), methylated <i>PENK</i> 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 <sup>®</sup> 2025
ColonAiQ <sup>®</sup> , Breakthrough Genomics, Singlera Genomics, Inc	●0453U	Oncology (colorectal cancer), cell-free DNA (cfDNA), methylation-based quantitative PCR assay ( <i>SEPTIN9</i> , <i>IKZF1</i> , <i>BCAT1</i> , <i>Septin9-2</i> , <i>VAV3</i> , <i>BCAN</i> ), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)	April 1, 2024	July 1, 2024	CPT <sup>®</sup> 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	April 1, 2024	July 1, 2024	CPT <sup>®</sup> 2025

		(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)			
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	<del>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</del>	April 1, 2024  <b>Deletion Released to AMA Website</b> October 1, 2024	July 1, 2024  <b>Deletion Effective</b> January 1, 2025	CPT® 2025  <b>Deletion Publication</b> CPT® 2026
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 (ELISA), tear fluid with age, algorithm reported as a risk score	April 1, 2024	July 1, 2024	CPT® 2025
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., <del>wholly owned</del> 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, algorithm reported as a positive or negative result	April 1, 2024	July 1, 2024	CPT® 2025
UriFind® Blood Cancer/Urothelial Carcinoma Assay, DiaCarta, Inc, AnchorDx	●0465U	Oncology (urothelial carcinoma), DNA, quantitative methylation-specific PCR of 2 genes ( <i>ONECUT2</i> , <i>VIM</i> ), algorithmic analysis reported as positive or negative	April 1, 2024  <b>Revision to Proprietary Name Released to AMA Website</b> July 1, 2024	July 1, 2024  <b>Revision to Proprietary Name Effective</b> October 1, 2024	<b>Revision Publication</b> 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,	April 1, 2024	July 1, 2024	CPT® 2025

		algorithm reported as polygenic risk to acquired heart disease			
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 performed, as comparators and/or maternal cell contamination	April 1, 2024	July 1, 2024	CPT® 2025
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 <i>KRAS</i> and <i>NRAS</i> 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), semiquantitative, blood, reported as predictive evidence of early Sjögren's 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
RightMed® Mental Health Gene Report, OneOme, LLC, OneOme, LLC	●0476U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder	July 1, 2024	October 1, 2024	CPT® 2025

		[ADHD], schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and <i>CYP2D6</i> copy number variant analysis and reported phenotypes			
RightMed® Mental Health Medication Report, OneOme, LLC, OneOme, LLC	●0477U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and <i>CYP2D6</i> copy number variant analysis, including impacted gene-drug interactions and reported phenotypes	July 1, 2024	October 1, 2024	CPT® 2025
Lung HDPCR™, Protean BioDiagnostics, Protean BioDiagnostics	●0478U	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes ( <i>EGFR</i> , <i>KRAS</i> , <i>BRAF</i> , <i>ALK</i> , <i>ROS1</i> , <i>RET</i> , <i>NTRK 1/2/3</i> , <i>ERBB2</i> , and <i>MET</i> ) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection	July 1, 2024	October 1, 2024	CPT® 2025
ALZpath pTau217, Neurocode USA, Inc, Quanterix/ALZpath	●0479U	Tau, phosphorylated, pTau217	July 1, 2024	October 1, 2024	CPT® 2025
Bacteria, Viruses, Fungus, and Parasite Metagenomic Sequencing, Spinal Fluid (MSCSF), Mayo Clinic, Laboratory Developed Test	●0480U	Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next-generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification	July 1, 2024	October 1, 2024	CPT® 2025
IDH1, IDH2, and TERT Mutation Analysis, Next-Generation Sequencing, Tumor (IDTRT), Mayo Clinic, Laboratory Developed Test	●0481U	<i>IDH1</i> (isocitrate dehydrogenase 1 [NADP+]), <i>IDH2</i> (isocitrate dehydrogenase 2 [NADP+]), and <i>TERT</i> (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions)	July 1, 2024	October 1, 2024	CPT® 2025



Preeclampsia sFlt-1/PIGF Ratio (PERA), Mayo Clinic, Laboratory Developed Test	●0482U	Obstetrics (preeclampsia), biochemical assay of soluble fms-like tyrosine kinase 1 (sFlt-1) and placental growth factor (PIGF), serum, ratio reported for sFlt-1/PIGF, with risk of progression for preeclampsia with severe features within 2 weeks	July 1, 2024	October 1, 2024	CPT® 2025
Ciprofloxacin Susceptibility of Neisseria gonorrhoeae, MedArbor Diagnostics, Speedx, Inc	●0483U	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance	July 1, 2024	October 1, 2024	CPT® 2025
Macrolide Resistance of Mycoplasma genitalium, MedArbor Diagnostics, Speedx, Inc	●0484U	Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance	July 1, 2024	October 1, 2024	CPT® 2025
Caris Assure™, Caris MPI, Inc d/b/a Caris Life Sciences®, Caris MPI, Inc d/b/a Caris Life Sciences®	●0485U	Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden	July 1, 2024	October 1, 2024	CPT® 2025
Northstar Response™, BillionToOne Laboratory, BillionToOne, Inc	●0486U	Oncology (pan-solid tumor), next-generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction	July 1, 2024	October 1, 2024	CPT® 2025
Northstar Select™, BillionToOne Laboratory, BillionToOne, Inc	●0487U	Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidy-corrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability	July 1, 2024	October 1, 2024	CPT® 2025
UNITY Fetal Antigen™ NIPT, BillionToOne	●0488U	Obstetrics (fetal antigen noninvasive prenatal test), cell-free DNA sequence analysis for	July 1, 2024	October 1, 2024	CPT® 2025

Laboratory, BillionToOne, Inc		detection of fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected			
UNITY Fetal Risk Screen™, BillionToOne Laboratory, BillionToOne, Inc	●0489U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA sequence analysis of 1 or more targets (eg, <i>CFTR</i> , <i>SMN1</i> , <i>HBB</i> , <i>HBA1</i> , <i>HBA2</i> ) to identify paternally inherited pathogenic variants, and relative mutation-dosage analysis based on molecular counts to determine fetal inheritance of maternal mutation, algorithm reported as a fetal risk score for the condition (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)	July 1, 2024	October 1, 2024	CPT® 2025
CELLSEARCH® Circulating Melanoma Cell (CMC) Test, Menarini Silicon Biosystems Inc, Menarini Silicon Biosystems Inc	●0490U	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, high molecular-weight melanoma-associated antigen, CD34 and CD45 protein biomarkers, peripheral blood	July 1, 2024	October 1, 2024	CPT® 2025
CELLSEARCH® ER Circulating Tumor Cell (CTC-ER) Test, Menarini Silicon Biosystems Inc, Menarini Silicon Biosystems Inc	●0491U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker-expressing cells, peripheral blood	July 1, 2024	October 1, 2024	CPT® 2025
CELLSEARCH® PD-L1 Circulating Tumor Cell (CTC-PD-L1) Test, Menarini Silicon Biosystems Inc, Menarini Silicon Biosystems Inc	●0492U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of	July 1, 2024	October 1, 2024	CPT® 2025

		PD-L1 protein biomarker—expressing cells, peripheral blood			
Prospera™, Natera™	●0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA	July 1, 2024	October 1, 2024	CPT® 2025
Rh Test, Natera™	●0494U	Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative	July 1, 2024	October 1, 2024	CPT® 2025
Stockholm3, BioAgilytix Diagnostics	●0495U	Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer	July 1, 2024	October 1, 2024	CPT® 2025
ColoScape™ PLUS, DiaCarta, Inc, DiaCarta, Inc	●0496U	Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk	July 1, 2024	October 1, 2024	CPT® 2025
OncoAssure™ Prostate, DiaCarta, Inc, DiaCarta, Inc	●0497U	Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes ( <i>FOXM1</i> , <i>MCM3</i> , <i>MTUS1</i> , <i>TTC21B</i> , <i>ALAS1</i> , and <i>PPP2CA</i> ), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer	July 1, 2024	October 1, 2024	CPT® 2025
OptiSeq™ Colorectal Cancer NGS Panel, DiaCarta, Inc, DiaCarta, Inc	●0498U	Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation	July 1, 2024	October 1, 2024	CPT® 2025

OptiSeq™ Dual Cancer Panel Kit, DiaCarta, Inc, DiaCarta, Inc	●0499U	Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes ( <i>NRAS</i> , <i>EGFR</i> , <i>CTNNB1</i> , <i>PIK3CA</i> , <i>APC</i> , <i>BRAF</i> , <i>KRAS</i> , and <i>TP53</i> ), mutation detection	July 1, 2024	October 1, 2024	CPT® 2025
QClamp® Plex VEXAS UBA1 Mutation Test, DiaCarta, Inc, DiaCarta, Inc	●0500U	Autoinflammatory disease (VEXAS syndrome), DNA, <i>UBA1</i> gene mutations, targeted variant analysis (M41T, M41V, M41L, c.118-2A>C, c.118-1G>C, c.118-9_118-2del, S56F, S621C)	July 1, 2024	October 1, 2024	CPT® 2025
QuantiDNA™ Colorectal Cancer Triage Test, DiaCarta, Inc, DiaCarta, Inc	●0501U	Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA)	July 1, 2024	October 1, 2024	CPT® 2025
QuantiVirus™ HPV E6/E7 mRNA Test for Cervical Cancer, DiaCarta, Inc, DiaCarta, Inc	●0502U	Human papillomavirus (HPV), E6/E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV	July 1, 2024	October 1, 2024	CPT® 2025
PrecivityAD2™, C2N Diagnostics, LLC, C2N Diagnostics, LLC	●0503U	Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (ptau217, np-tau217, ptau217/np-tau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as likelihood of positive or negative for amyloid plaques	July 1, 2024	October 1, 2024	CPT® 2025
Urinary Tract Infection Testing, NxGen MDx LLC, NxGen MDx LLC	●0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, real-time PCR, reported as positive or negative for each organism	July 1, 2024	October 1, 2024	CPT® 2025
Vaginal Infection Testing, NxGen MDx LLC, NxGen MDx LLC	●0505U	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism	July 1, 2024	October 1, 2024	CPT® 2025
EndoSign® Barrett's Esophagus Test, Cyted Health Inc, Cyted Health Inc	●0506U	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at	July 1, 2024	October 1, 2024	CPT® 2025

		least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus			
Avantect Ovarian Cancer Test, ClearNote® Health	●0507U	Oncology (ovarian), DNA, whole-genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected	July 1, 2024	October 1, 2024	CPT® 2025
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	July 1, 2024	October 1, 2024	CPT® 2025
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	July 1, 2024	October 1, 2024	CPT® 2025
PuriST <sup>SM</sup> , Tempus AI, Inc, Tempus AI, Inc	●0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole-transcriptome data, reported as probability of predicted molecular subtype	July 1, 2024	October 1, 2024	CPT® 2025
PARIS, Tempus AI, Inc, Tempus AI, Inc (by its wholly owned subsidiary SEngine Precision Medicine, LLC)	●0511U	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug	July 1, 2024	October 1, 2024	CPT® 2025
Tempus p-MSI, Tempus AI, Inc, Tempus AI, Inc	●0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of MSI-high (MSI-H)	July 1, 2024	October 1, 2024	CPT® 2025
Tempus p-Prostate, Tempus AI, Inc, Tempus AI, Inc	●0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of	July 1, 2024	October 1, 2024	CPT® 2025

		histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker			
Procise ADL™, ProciseDx Inc	●0514U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)	July 1, 2024	October 1, 2024	CPT® 2025
Procise IFX™, ProciseDx Inc	●0515U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of infliximab (IFX) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)	July 1, 2024	October 1, 2024	CPT® 2025
MyGenVar Pharmacogenomics Test, Geisinger Medical Laboratories, Geisinger Medical Laboratories	●0516U	Drug metabolism, whole blood, pharmacogenomic genotyping of 40 genes and CYP2D6 copy number variant analysis, reported as metabolizer status	July 1, 2024	October 1, 2024	CPT® 2025
PrecisView® CNS, Phenomics Health™ Inc, Phenomics Health™ Inc	●0517U	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications	July 1, 2024	October 1, 2024	CPT® 2025
SyncView® Pain, Phenomics Health™ Inc, Phenomics Health™ Inc	●0518U	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications	July 1, 2024	October 1, 2024	CPT® 2025
SyncView® PainPlus, Phenomics Health™ Inc, Phenomics Health™ Inc	●0519U	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LC-MS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic	July 1, 2024	October 1, 2024	CPT® 2025

		minimally effective range of prescribed, non-prescribed, and illicit medications in circulation			
SyncView® Rx, Phenomics Health™ Inc, Phenomics Health™ Inc	●0520U	Therapeutic drug monitoring, 200 or more drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications	July 1, 2024	October 1, 2024	CPT® 2025
Seronegative Rheumatoid Arthritis Panel, KSL Diagnostics-Beutner Laboratories, Inc, KSL Biomedical, Inc	●0521U	Rheumatoid factor IgA and IgM, cyclic citrullinated peptide (CCP) antibodies, and scavenger receptor A (SR-A) by immunoassay, blood	October 1, 2024	January 1, 2025	CPT® 2026
Tissue Specific Markers for Early Diagnosis of Sjogren's Disease, KSL Diagnostics, Inc, KSL Diagnostics, Inc	●0522U	Carbonic anhydrase VI, parotid specific/secretory protein and salivary protein 1 (SP1), IgG, IgM, and IgA antibodies, chemiluminescence, semiquantitative, blood	October 1, 2024	January 1, 2025	CPT® 2026
oncoReveal™ CDx, Pillar Biosciences, Inc, Pillar Biosciences, Inc	●0523U	Oncology (solid tumor), DNA, qualitative, next-generation sequencing (NGS) of single-nucleotide variants (SNV) and insertion/deletions in 22 genes utilizing formalin-fixed paraffin-embedded tissue, reported as presence or absence of mutation(s), location of mutation(s), nucleotide change, and amino acid change	October 1, 2024	January 1, 2025	CPT® 2026
sFlt-1/PIGF, Thermo Fisher Scientific, Thermo Fisher Scientific	●0524U	Obstetrics (preeclampsia), sFlt-1/PIGF ratio, immunoassay, utilizing serum or plasma, reported as a value	October 1, 2024	January 1, 2025	CPT® 2026
3D Predict™ Ovarian, KIYATEC®, Inc, KIYATEC®, Inc	●0525U	Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug	October 1, 2024	January 1, 2025	CPT® 2026
CXCL10 Urine Test, One Lambda™, Inc, One Lambda™, Inc	●0526U	Nephrology (renal transplant), quantification of CXCL10 chemokines, flow cytometry, urine, reported as pg/mL creatinine baseline and monitoring over time	October 1, 2024	January 1, 2025	CPT® 2026

Abbott Alinity™ m HSV 1 & 2 / VZV Assay, Abbott Molecular, Inc	●0527U	Herpes simplex virus (HSV) types 1 and 2 and Varicella zoster virus (VZV), amplified probe technique, each pathogen reported as detected or not detected	October 1, 2024	January 1, 2025	CPT® 2026
BIOFIRE® FILMARRAY® Pneumonia (PN) Panel, bioMérieux, bioMérieux	●0528U	Lower respiratory tract infectious agent detection, 18 bacteria, 8 viruses, and 7 antimicrobial-resistance genes, amplified probe technique, including reverse transcription for RNA targets, each analyte reported as detected or not detected with semiquantitative results for 15 bacteria	October 1, 2024	January 1, 2025	CPT® 2026
Lifetime Genomics Risk Assessment, VTE, GenomicMD, Inc, GenomicMD, Inc	●0529U	Hematology (venous thromboembolism [VTE]), genome-wide single-nucleotide polymorphism variants, including <i>F2</i> and <i>F5</i> gene analysis, and Leiden variant, by microarray analysis, saliva, report as risk score for VTE	October 1, 2024	January 1, 2025	CPT® 2026
LiquidHALLMARK®, Lucence Health, Inc, Lucence Health, Inc	●0530U	Oncology (pan-solid tumor), ctDNA, utilizing plasma, next-generation sequencing (NGS) of 77 genes, 8 fusions, microsatellite instability, and tumor mutation burden, interpretative report for single-nucleotide variants, copy-number alterations, with therapy association	October 1, 2024	January 1, 2025	CPT® 2026