AAPC Appendix O
Multianalyte Assays With Algorithmic Analyses and Proprietary Laboratory Analyses

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Category I Codes for Multianalyte Assays with Algorithmic Analyses (MAAA)		
Vectra®, Labcorp	**81490**	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score
Corus® CAD, CardioDx, Inc	**81493**	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score
Risk of Ovarian Malignancy Algorithm (ROMA)™, Fujirebio Diagnostics	**81500**	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score
OVA1™, Vermillion, Inc	**81503**	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score
Tissue of Origin Test Kit-FFPE, Cancer Genetics, Inc	**81504**	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
PreDx Diabetes Risk Score™, Tethys Clinical Laboratory	**81506**	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score
Harmony™ Prenatal Test, Ariosa Diagnostics	**81507**	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy
No proprietary name and clinical laboratory or manufacturer. Maternal serum screening procedures are well-established procedures and are performed by many laboratories throughout the country. The concept of prenatal screens has existed and evolved for over 10 years and is not exclusive to any one facility.	**81508**	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
	81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
	81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
	81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
	81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score
Aptima® BV Assay, Hologic, Inc	**81513**	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
BD MAX™ Vaginal Panel, Becton Dickinson and Company	**81514**	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported
Enhanced Liver Fibrosis™ (ELF™) Test, Siemens Healthcare Diagnostics Inc/ Siemens Healthcare Laboratory LLC	**81517**	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
Breast Cancer Index, Biotheranostics, Inc	**81518**	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy
Oncotype DX®, Genomic Health	**81519**	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
Prosigna® Breast Cancer Assay, NanoString Technologies, Inc	**81520**	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
MammaPrint®, Agendia, Inc	**81521**	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
EndoPredict®, Myriad Genetic Laboratories, Inc	**81522**	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
MammaPrint®, Agendia, Inc	**81523**	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis
Oncotype DX® Colon Cancer Assay, Genomic Health	**81525**	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score
Cologuard™, Exact Sciences, Inc	**81528**	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
DecisionDx® Melanoma, Castle Biosciences, Inc	**81529**	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
ChemoFX®, Helomics, Corp	**81535**	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination
	81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)
VeriStrat, Biodesix, Inc	**81538**	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival
4Kscore test, OPKO Health, Inc	**81539**	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score
CancerTYPE ID, bioTheranostics, Inc	**81540**	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype
Prolaris®, Myriad Genetic Laboratories, Inc	**81541**	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score
Decipher® Prostate, Decipher® Biosciences	**81542**	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
Afirma® Genomic Sequencing Classifier, Veracyte, Inc	**81546**	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)
ConfirmMDx® for Prostate Cancer, MDxHealth, Inc	**81551**	Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy
DecisionDx®-UM test, Castle Biosciences, Inc	**81552**	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
Envisia® Genomic Classifier, Veracyte, Inc	**81554**	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])
Pleximmune™, Plexision, Inc	**81560**	Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
AlloMap®, CareDx, Inc	**81595**	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score
HCV FibroSURE™, FibroTest™, BioPredictive S.A.S.	**81596**	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
—	**81599**	Unlisted multianalyte assay with algorithmic analysis
Administrative Codes for Multianalyte Assays with Algorithmic Analyses (MAAA)		
ASH FibroSURE™, BioPredictive S.A.S	**0002M**	Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and alcoholic steatohepatitis (ASH)
NASH FibroSURE™, BioPredictive S.A.S	**0003M**	Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH)
ScoliScore™ Transgenomic	**0004M**	Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score
HeproDX™, GoPath Laboratories, LLC	**0006M**	Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier
NETest, Wren Laboratories, LLC	**0007M**	Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index
NeoLAB™ Prostate Liquid Biopsy, NeoGenomics Laboratories	**0011M**	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and urine, algorithms to predict high-grade prostate cancer risk
Cxbladder™ Detect, Pacific Edge Diagnostics USA, Ltd	**0012M**	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma
Cxbladder™ Monitor, Pacific Edge Diagnostics USA, Ltd	**0013M**	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma
Adrenal Mass Panel, 24 Hour, Urine, Mayo Clinic Laboratories (MCL), Mayo Clinic	**0015M**	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy
Decipher Bladder, Veracyte Labs SD	**0016M**	Oncology (bladder), mRNA, microarray gene expression profiling of 219 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)
Lymph2Cx, Mayo Clinic Arizona Molecular Diagnostics Laboratory	**0017M**	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue, algorithm reported as cell of origin
Pleximark™, Plexision, Inc	**0018M**	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
SOMAmer®, SomaLogic	**0019M**	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations
Proprietary Laboratory Analyses (PLA)		
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

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
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
Overa (OVA1 Next Generation), Asprira 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
ExosomeDx® Prostate (IntelliScore), Exosome Diagnostics, Inc, 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
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
AmHPR® H. pylori Antibiotic Resistance 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 or fecal sample, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline, and rifabutin
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
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
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
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
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
ThyraMIR™, 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
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
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
Oncomine™ Dx Target Test, Thermo Fisher Scientific, 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 or absence of variants and associated therapy(ies) to consider

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
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
GlycA, Laboratory Corporation of America, Laboratory Corporation of America	**0024U**	Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative
UrSure Tenofovir Quantification Test, Synergy Medical Laboratories, UrSure Inc	**0025U**	Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative
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")
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
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)
Warfarin Response Genotype, Mayo Clinic, Mayo Clinic	**0030U**	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823)
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)
Catechol-O-Methyltransferase (COMT) Genotype, Mayo Clinic, Mayo Clinic	**0032U**	COMT (catechol-O-methyltransferase) (eg, drug metabolism) gene analysis, c.472G>A (rs4680) variant
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])
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)
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
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
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
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
Anti-dsDNA, High Salt/Avidity, University of Washington, Department of Laboratory Medicine, Bio-Rad	**0039U**	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity
MRDx BCR-ABL Test, MolecularMD, MolecularMD	**0040U**	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
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
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
Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgM Test, IGeneX Inc, ID-FISH Technology (Provides TBRF ImmunoBlot IgM Strips)	**0043U**	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM
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
The Oncotype DX® Breast DCIS Score™ Test, Genomic Health, Inc, Genomic Health, Inc	**0045U**	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
FLT3 ITD MRD by NGS, LabPMM LLC, an Invivoscribe Technologies, Inc Company	**0046U**	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
Oncotype DX Genomic Prostate Score, Genomic Health, Inc, Genomic Health, 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
MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets), Memorial Sloan Kettering Cancer Center	**0048U**	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
NPM1 MRD by NGS, LabPMM LLC, an Invivoscribe Technologies, Inc Company	**0049U**	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative
MyAML NGS Panel, LabPMM LLC, an Invivoscribe Technologies, Inc Company	**0050U**	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
UCompliDx, Elite Medical Laboratory Solutions, LLC, Elite Medical Laboratory Solutions, LLC (LDT)	**0051U**	Prescription drug monitoring, evaluation of drugs present by liquid chromatography tandem mass spectrometry (LC-MS/MS), urine or blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service
VAP Cholesterol Test, VAP Diagnostics Laboratory, Inc, VAP Diagnostics Laboratory, Inc	**0052U**	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation
AssuranceRx Micro Serum, Firstox Laboratories, LLC, Firstox Laboratories, LLC	**0054U**	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service
myTAIHEART, TAI Diagnostics, Inc, TAI Diagnostics, Inc	**0055U**	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma
Merkel SmT Oncoprotein Antibody Titer, University of Washington, Department of Laboratory Medicine	**0058U**	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Merkel Virus VP1 Capsid Antibody, University of Washington, Department of Laboratory Medicine	**0059U**	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative
Twins Zygosity PLA, Natera, Inc, Natera, Inc	**0060U**	Twin zygosity, genomic-targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
Transcutaneous multispectral measurement of tissue oxygenation and hemoglobin using spatial frequency domain imaging (SFDI), Modulated Imaging, Inc, Modulated Imaging, Inc	**0061U**	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis
SLE-key® Rule Out, Veracis Inc, Veracis Inc	**0062U**	Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score
NPDX ASD ADM Panel I, Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX	**0063U**	Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder
BioPlex 2200 Syphilis Total & RPR Assay, Bio-Rad Laboratories, Bio-Rad Laboratories	**0064U**	Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative
BioPlex 2200 RPR Assay, Bio-Rad Laboratories, Bio-Rad Laboratories	**0065U**	Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)
BBDRisk Dx™, Silbiotech, Inc, Silbiotech, Inc	**0067U**	Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score
MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 6 Candida species, RealTime Laboratories, Inc/ MycoDART, Inc, RealTime Laboratories, Inc	**0068U**	Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species
miR-31now™, GoPath Laboratories, GoPath Laboratories	**0069U**	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score
CYP2D6 Common Variants and Copy Number, Mayo Clinic, Laboratory Developed Test	**0070U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, common and select rare variants (ie, *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xN)
CYP2D6 Full Gene Sequencing, Mayo Clinic, Laboratory Developed Test	**0071U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence (List separately in addition to code for primary procedure)
CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis, Mayo Clinic, Laboratory Developed Test	**0072U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure)
CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis, Mayo Clinic, Laboratory Developed Test	**0073U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure)

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
CYP2D6 trans-duplication/multiplication non-duplicated gene targeted sequence analysis, Mayo Clinic, Laboratory Developed Test	**0074U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, non-duplicated gene when duplication/multiplication is trans) (List separately in addition to code for primary procedure)
CYP2D6 5' gene duplication/multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test	**0075U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (List separately in addition to code for primary procedure)
CYP2D6 3' gene duplication/multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test	**0076U**	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3' gene duplication/multiplication) (List separately in addition to code for primary procedure)
M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry, Mayo Clinic, Laboratory Developed Test	**0077U**	Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype
INFINITI® Neural Response Panel, PersonalizeDx Labs, AutoGenomics Inc	**0078U**	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
ToxLok™, InSource Diagnostics, InSource Diagnostics	**0079U**	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification
BDX-XL2, Biodesix®, Inc, Biodesix®, Inc	**0080U**	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
NextGen Precision™ Testing, Precision Diagnostics, Precision Diagnostics LBN Precision Toxicology, LLC	**0082U**	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
Onco4D™, Animated Dynamics, Inc, Animated Dynamics, Inc	**0083U**	Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations
BLOODchip® ID CORE XT™, Grifols Diagnostic Solutions Inc	**0084U**	Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens
Accelerate PhenoTest™ BC kit, Accelerate Diagnostics, Inc	**0086U**	Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility
Molecular Microscope® MMDx—Heart, Kashi Clinical Laboratories	**0087U**	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score
Molecular Microscope® MMDx—Kidney, Kashi Clinical Laboratories	**0088U**	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection
Pigmented Lesion Assay (PLA), DermTech	**0089U**	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
myPath® Melanoma, Castle Biosciences, Inc	**0090U**	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)
FirstSight^{CRC}, CellMax Life	**0091U**	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result
REVEAL Lung Nodule Characterization, MagArray, Inc	**0092U**	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy
ComplyRX, Claro Labs	**0093U**	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected
RCIGM Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine (RCIGM)	**0094U**	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis
Esophageal String Test™ (EST), Children's Hospital Colorado Department of Pathology and Laboratory Medicine	**0095U**	Eosinophilic esophagitis (Eotaxin-3 [CCL26 {C-C motif chemokine ligand 26}] and major basic protein [PRG2 {proteoglycan 2, pro eosinophil major basic protein}]), enzyme-linked immunosorbent assays (ELISA), specimen obtained by esophageal string test device, algorithm reported as probability of active or inactive eosinophilic esophagitis
HPV, High-Risk, Male Urine, Molecular Testing Labs	**0096U**	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine
ColoNext®, Ambry Genetics®, Ambry Genetics®	**0101U**	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])
BreastNext®, Ambry Genetics®, Ambry Genetics®	**0102U**	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])
OvaNext®, Ambry Genetics®, Ambry Genetics®	**0103U**	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])
KidneyIntelX™, RenalytixAI, RenalytixAI	**0105U**	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)
13C-Spirulina Gastric Emptying Breath Test (GEBT), Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC, Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC	**0106U**	Gastric emptying, serial collection of 7 timed breath specimens, non-radioisotope carbon-13 (13C) spirulina substrate, analysis of each specimen by gas isotope ratio mass spectrometry, reported as rate of 13CO2 excretion

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Singulex Clarity C. diff toxins A/B Assay, Singulex	**0107U**	Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method
TissueCypher® Barrett's Esophagus Assay, Cernostics, Cernostics	**0108U**	Gastroenterology (Barrett's esophagus), whole slide-digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer
MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species, RealTime Laboratories, Inc/MycoDART, Inc	**0109U**	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species
Oral OncolyticAssuranceRX, Firstox Laboratories, LLC, Firstox Laboratories, LLC	**0110U**	Prescription drug monitoring, one or more oral oncology drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood, quantitative report with steady-state range for the prescribed drug(s) when detected
Praxis™ Extended RAS Panel, Illumina, Illumina	**0111U**	Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and 61) gene analysis, utilizing formalin-fixed paraffin-embedded tissue
MicroGenDX qPCR & NGS For Infection, MicroGenDX, MicroGenDX	**0112U**	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene
MyProstateScore, Lynx DX, Lynx DX	**0113U**	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score
EsoGuard™, Lucid Diagnostics, Lucid Diagnostics	**0114U**	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus
ePlex Respiratory Pathogen (RP) Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	**0115U**	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
Snapshot Oral Fluid Compliance, Ethos Laboratories	**0116U**	Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications
Foundation PI℠, Ethos Laboratories	**0117U**	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain
Viracor TRAC™ dd-cfDNA, Viracor Eurofins, Viracor Eurofins	**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
MI-HEART Ceramides, Plasma, Mayo Clinic, Laboratory Developed Test	**0119U**	Cardiology, ceramides by liquid chromatography-tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Lymph3Cx Lymphoma Molecular Subtyping Assay, Mayo Clinic, Laboratory Developed Test	**0120U**	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter
Flow Adhesion of Whole Blood on VCAM-1 (FAB-V), Functional Fluidics, Functional Fluidics	**0121U**	Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood
Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL), Functional Fluidics, Functional Fluidics	**0122U**	Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood
Mechanical Fragility, RBC by shear stress profiling and spectral analysis, Functional Fluidics, Functional Fluidics	**0123U**	Mechanical fragility, RBC, shear stress and spectral analysis profiling
BRCAplus, Ambry Genetics	**0129U**	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)
+RNAinsight™ for ColoNext®, Ambry Genetics	**0130U**	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure)
+RNAinsight™ for BreastNext®, Ambry Genetics	**0131U**	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure)
+RNAinsight™ for OvaNext®, Ambry Genetics	**0132U**	Hereditary ovarian cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure)
+RNAinsight™ for ProstateNext®, Ambry Genetics	**0133U**	Hereditary prostate cancer-related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure)
+RNAinsight™ for CancerNext®, Ambry Genetics	**0134U**	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure)
+RNAinsight™ for GYNPlus®, Ambry Genetics	**0135U**	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure)
+RNAinsight™ for ATM, Ambry Genetics	**0136U**	ATM (ataxia telangiectasia mutated) (eg, ataxia telangiectasia) mRNA sequence analysis (List separately in addition to code for primary procedure)
+RNAinsight™ for PALB2, Ambry Genetics	**0137U**	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)
+RNAinsight™ for BRCA1/2, Ambry Genetics	**0138U**	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
ePlex® BCID Fungal Pathogens Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	**0140U**	Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected
ePlex® BCID Gram-Positive Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	**0141U**	Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected
ePlex® BCID Gram-Negative Panel, GenMark Diagnostics, Inc, GenMark Diagnostics, Inc	**0142U**	Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected
Karius® Test, Karius Inc, Karius Inc	**0152U**	Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, plasma, untargeted next-generation sequencing, report for significant positive pathogens
Insight TNBCtype™, Insight Molecular Labs	**0153U**	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
therascreen® FGFR RGQ RT-PCR Kit, QIAGEN, QIAGEN GmbH	**0154U**	Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3), utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status
therascreen PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH	**0155U**	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin-embedded breast tumor tissue, reported as PIK3CA gene mutation status
SMASH™, New York Genome Center, Marvel Genomics™	**0156U**	Copy number (eg, intellectual disability, dysmorphology), sequence analysis
CustomNext + RNA: APC, Ambry Genetics®, Ambry Genetics®	**0157U**	APC (APC regulator of WNT signaling pathway) (eg, familial adenomatosis polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure)
CustomNext + RNA: MLH1, Ambry Genetics®, Ambry Genetics®	**0158U**	MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
CustomNext + RNA: MSH2, Ambry Genetics®, Ambry Genetics®	**0159U**	MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
CustomNext + RNA: MSH6, Ambry Genetics®, Ambry Genetics®	**0160U**	MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
CustomNext + RNA: PMS2, Ambry Genetics®, Ambry Genetics®	**0161U**	PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2), Ambry Genetics®, Ambry Genetics®	**0162U**	Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
BeScreened™-CRC, Beacon Biomedical Inc, Beacon Biomedical Inc	**0163U**	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas
ibs-smart™, Gemelli Biotech, Gemelli Biotech	**0164U**	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
VeriMAP™ Peanut Dx – Bead-based Epitope Assay, AllerGenis™ Clinical Laboratory, AllerGenis™ LLC	**0165U**	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
LiverFASt™, Fibronostics	**0166U**	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation
ADEXUSDx hCG Test, NOWDiagnostics, NOWDiagnostics	**0167U**	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood
NT (NUDT15 and TPMT) genotyping panel, RPRD Diagnostics	**0169U**	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
Clarifi™, Quadrant Biosciences, Inc, Quadrant Biosciences, Inc	**0170U**	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis
MyMRD® NGS Panel, Laboratory for Personalized Molecular Medicine, Laboratory for Personalized Molecular Medicine	**0171U**	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence
myChoice® CDx, Myriad Genetics Laboratories, Inc, Myriad Genetics Laboratories, Inc	**0172U**	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score
Psych HealthPGx Panel, RPRD Diagnostics, RPRD Diagnostics	**0173U**	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
LC-MS/MS Targeted Proteomic Assay, OncoOmicDx Laboratory, LDT	**0174U**	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents
Genomind® Professional PGx Express™ CORE, Genomind, Inc, Genomind, Inc	**0175U**	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes
IB*Schek*®, Commonwealth Diagnostics International, Inc, Commonwealth Diagnostics International, Inc	**0176U**	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
therascreen® PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH	**0177U**	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
VeriMAP™ Peanut Reactivity Threshold–Bead Based Epitope Assay, AllerGenis™ Clinical Laboratory, AllerGenis™ LLC	**0178U**	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction
Resolution ctDx Lung™, Resolution Bioscience, Resolution Bioscience, Inc	**0179U**	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)
Navigator ABO Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0180U**	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons
Navigator CO Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0181U**	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1
Navigator CROM Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0182U**	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10
Navigator DI Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0183U**	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19
Navigator DO Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0184U**	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2
Navigator FUT1 Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0185U**	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4
Navigator FUT2 Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0186U**	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2
Navigator FY Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0187U**	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2
Navigator GE Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0188U**	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4
Navigator GYPA Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0189U**	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2
Navigator GYPB Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0190U**	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3
Navigator IN Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0191U**	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6
Navigator JK Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0192U**	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9
Navigator JR Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0193U**	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26
Navigator KEL Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0194U**	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Navigator KLF1 Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0195U**	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)
Navigator LU Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0196U**	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3
Navigator LW Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0197U**	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1
Navigator RHD/CE Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0198U**	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5
Navigator SC Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0199U**	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12
Navigator XK Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0200U**	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3
Navigator YT Sequencing, Grifols Immunohematology Center, Grifols Immunohematology Center	**0201U**	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2
BioFire® Respiratory Panel 2.1 (RP2.1), BioFire® Diagnostics, BioFire® Diagnostics, LLC	**0202U**	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
PredictSURE IBD™ Test, KSL Diagnostics, PredictImmune Ltd	**0203U**	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness
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
Vita Risk®, Arctic Medical Laboratories, Arctic Medical Laboratories	**0205U**	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements
DISCERN™, NeuroDiagnostics, NeuroDiagnostics	**0206U**	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease
	0207U	Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)
CNGnome™, PerkinElmer Genomics, PerkinElmer Genomics	**0209U**	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
BioPlex 2200 RPR Assay – Quantitative, Bio-Rad Laboratories, Bio-Rad Laboratories	**0210U**	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)
MI Cancer Seek™ - NGS Analysis, Caris MPI d/b/a Caris Life Sciences, Caris MPI d/b/a Caris Life Sciences	**0211U**	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association
Genomic Unity® Whole Genome Analysis – Proband, Variantyx Inc, Variantyx Inc	**0212U**	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
Genomic Unity® Whole Genome Analysis – Comparator, Variantyx Inc, Variantyx Inc	**0213U**	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling)
Genomic Unity® Exome Plus Analysis – Proband, Variantyx Inc, Variantyx Inc	**0214U**	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
Genomic Unity® Exome Plus Analysis – Comparator, Variantyx Inc, Variantyx Inc	**0215U**	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (eg, parent, sibling)
Genomic Unity® Ataxia Repeat Expansion and Sequence Analysis, Variantyx Inc, Variantyx Inc	**0216U**	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis, Variantyx Inc, Variantyx Inc	**0217U**	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
Genomic Unity® DMD Analysis, Variantyx Inc, Variantyx Inc	**0218U**	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
Sentosa® SQ HIV-1 Genotyping Assay, Vela Diagnostics USA, Inc, Vela Operations Singapore Pte Ltd	**0219U**	Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility
PreciseDx™ Breast Cancer Test, PreciseDx, PreciseDx	**0220U**	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
Navigator ABO Blood Group NGS, Grifols Immunohematology Center, Grifols Immunohematology Center	**0221U**	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Navigator Rh Blood Group NGS, Grifols Immunohematology Center, Grifols Immunohematology Center	**0222U**	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3
QIAstat-Dx Respiratory SARS CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH	**0223U**	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory	**0224U**	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), includes titer(s), when performed
ePlex® Respiratory Pathogen Panel 2, GenMark Dx, GenMark Diagnostics, Inc	**0225U**	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
Tru-Immune™, Ethos Laboratories, GenScript® USA Inc	**0226U**	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), ELISA, plasma, serum
Comprehensive Screen, Aspenti Health	**0227U**	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation
PanGIA Prostate, Genetics Institute of America, Entopsis, LLC	**0228U**	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
Colvera®, Clinical Genomics Pathology Inc	**0229U**	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
Genomic Unity® AR Analysis, Variantyx Inc, Variantyx Inc	**0230U**	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
Genomic Unity® CACNA1A Analysis, Variantyx Inc, Variantyx Inc	**0231U**	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions
Genomic Unity® CSTB Analysis, Variantyx Inc, Variantyx Inc	**0232U**	CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
Genomic Unity® FXN Analysis, Variantyx Inc, Variantyx Inc	**0233U**	FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
Genomic Unity® MECP2 Analysis, Variantyx Inc, Variantyx Inc	**0234U**	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Genomic Unity® PTEN Analysis, Variantyx Inc, Variantyx Inc	**0235U**	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
Genomic Unity® SMN1/2 Analysis, Variantyx Inc, Variantyx Inc	**0236U**	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications, deletions, and mobile element insertions
Genomic Unity® Cardiac Ion Channelopathies Analysis, Variantyx Inc, Variantyx Inc	**0237U**	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
Genomic Unity® Lynch Syndrome Analysis, Variantyx Inc, Variantyx Inc	**0238U**	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
FoundationOne® Liquid CDx, Foundation Medicine, Inc, Foundation Medicine, Inc	**0239U**	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations
Xpert® Xpress CoV-2/Flu/RSV plus (SARS-CoV-2 and Flu targets), Cepheid®	**0240U**	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
Xpert® Xpress CoV-2/Flu/RSV plus (all targets), Cepheid®	**0241U**	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
Guardant360® CDx, Guardant Health Inc, Guardant Health Inc	**0242U**	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements
PlGF Preeclampsia Screen, PerkinElmer Genetics, PerkinElmer Genetics, Inc	**0243U**	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia
Oncotype MAP™ Pan-Cancer Tissue Test, Paradigm Diagnostics, Inc, Paradigm Diagnostics, Inc	**0244U**	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue
ThyGeNEXT® Thyroid Oncogene Panel, Interpace Diagnostics, Interpace Diagnostics	**0245U**	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage
PrecisionBlood™, San Diego Blood Bank, San Diego Blood Bank	**0246U**	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
PreTRM®, Sera Prognostics, Sera Prognostics, Inc®	**0247U**	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth
3D Predict Glioma, KIYATEC®, Inc	**0248U**	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug
Theralink® Reverse Phase Protein Array (RPPA), Theralink® Technologies, Inc, Theralink® Technologies, Inc	**0249U**	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report
PGDx elio™ tissue complete, Personal Genome Diagnostics, Inc, Personal Genome Diagnostics, Inc	**0250U**	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden
Intrinsic Hepcidin IDx™ Test, IntrinsicDx, Intrinsic LifeSciences™ LLC	**0251U**	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma
POC (Products of Conception), Igenomix®, Igenomix® USA	**0252U**	Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy
ERA® (Endometrial Receptivity Analysis), Igenomix®, Igenomix® USA	**0253U**	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)
SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy), Igenomix®, Igenomix® USA	**0254U**	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested
Cap-Score™ Test, Androvia LifeSciences, Avantor Clinical Services (previously known as Therapak)	**0255U**	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score
Trimethylamine (TMA) and TMA N-Oxide, Children's Hospital Colorado Laboratory	**0256U**	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report
Very-Long Chain Acyl-CoA Dehydrogenase (VLCAD) Enzyme Activity, Children's Hospital Colorado Laboratory	**0257U**	Very long chain acyl-coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood
Mind.Px, Mindera, Mindera Corporation	**0258U**	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics
GFR by NMR, Labtech™ Diagnostics	**0259U**	Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative
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

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Immunoscore®, HalioDx, HalioDx	**0261U**	Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score
OncoSignal 7 Pathway Signal, Protean BioDiagnostics, Philips Electronics Nederland BV	**0262U**	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score
NPDX ASD and Central Carbon Energy Metabolism, Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc	**0263U**	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)
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
Praxis Whole Genome Sequencing, Praxis Genomics LLC	**0265U**	Rare constitutional and other heritable disorders, whole genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants
Praxis Transcriptome, Praxis Genomics LLC	**0266U**	Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and next-generation sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes
Praxis Combined Whole Genome Sequencing and Optical Genome Mapping, Praxis Genomics LLC	**0267U**	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole genome sequencing
Versiti™ aHUS Genetic Evaluation, Versiti™ Diagnostic Laboratories, Versiti™	**0268U**	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid
Versiti™ Autosomal Dominant Thrombocytopenia Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0269U**	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 22 genes, blood, buccal swab, or amniotic fluid
Versiti™ Coagulation Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0270U**	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid
Versiti™ Congenital Neutropenia Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0271U**	Hematology (congenital neutropenia), genomic sequence analysis of 24 genes, blood, buccal swab, or amniotic fluid
Versiti™ Comprehensive Bleeding Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0272U**	Hematology (genetic bleeding disorders), genomic sequence analysis of 60 genes and duplication/deletion of PLAU, blood, buccal swab, or amniotic fluid, comprehensive
Versiti™ Fibrinolytic Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0273U**	Hematology (genetic hyperfibrinolysis, delayed bleeding), analysis of 9 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2 by next-generation sequencing, and PLAU by array comparative genomic hybridization), blood, buccal swab, or amniotic fluid
Versiti™ Comprehensive Platelet Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0274U**	Hematology (genetic platelet disorders), genomic sequence analysis of 62 genes and duplication/deletion of PLAU, blood, buccal swab, or amniotic fluid
Versiti™ Heparin-Induced Thrombocytopenia Evaluation – PEA, Versiti™ Diagnostic Laboratories, Versiti™	**0275U**	Hematology (heparin-induced thrombocytopenia), platelet antibody reactivity by flow cytometry, serum

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Versiti™ Inherited Thrombocytopenia Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0276U**	Hematology (inherited thrombocytopenia), genomic sequence analysis of 42 genes, blood, buccal swab, or amniotic fluid
Versiti™ Platelet Function Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0277U**	Hematology (genetic platelet function disorder), genomic sequence analysis of 40 genes and duplication/deletion of PLAU, blood, buccal swab, or amniotic fluid
Versiti™ Thrombosis Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0278U**	Hematology (genetic thrombosis), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid
Versiti™ VWF Collagen III Binding, Versiti™ Diagnostic Laboratories, Versiti™	**0279U**	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen III binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen III binding
Versiti™ VWF Collagen IV Binding, Versiti™ Diagnostic Laboratories, Versiti™	**0280U**	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen IV binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen IV binding
Versiti™ VWF Propeptide Antigen, Versiti™ Diagnostic Laboratories, Versiti™	**0281U**	Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level
Versiti™ Red Cell Genotyping Panel, Versiti™ Diagnostic Laboratories, Versiti™	**0282U**	Red blood cell antigen typing, DNA, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes
Versiti™ VWD Type 2B Evaluation, Versiti™ Diagnostic Laboratories, Versiti™	**0283U**	von Willebrand factor (VWF), type 2B, platelet-binding evaluation, radioimmunoassay, plasma
Versiti™ VWD Type 2N Binding, Versiti™ Diagnostic Laboratories, Versiti™	**0284U**	von Willebrand factor (VWF), type 2N, factor VIII and VWF binding evaluation, enzyme-linked immunosorbent assays (ELISA), plasma
RadTox™ cfDNA test, DiaCarta Clinical Lab, DiaCarta Inc	**0285U**	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score
CNT (CEP72, TPMT and NUDT15) genotyping panel, RPRD Diagnostics	**0286U**	CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
ThyroSeq® CRC, CBLPath, Inc, University of Pittsburgh Medical Center	**0287U**	Oncology (thyroid), DNA and mRNA, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)
DetermaRx™, Oncocyte Corporation	**0288U**	Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score
MindX Blood Test™ - Memory/Alzheimer's, MindX Sciences™ Laboratory, MindX Sciences™ Inc	**0289U**	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score
MindX Blood Test™ - Pain, MindX Sciences™ Laboratory, MindX Sciences™ Inc	**0290U**	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score
MindX Blood Test™ - Mood, MindX Sciences™ Laboratory, MindX Sciences™ Inc	**0291U**	Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score
MindX Blood Test™ - Stress, MindX Sciences™ Laboratory, MindX Sciences™ Inc	**0292U**	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
MindX Blood Test™ - Suicidality, MindX Sciences™ Laboratory, MindX Sciences™ Inc	**0293U**	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score
MindX Blood Test™ - Longevity, MindX Sciences™ Laboratory, MindX Sciences™ Inc	**0294U**	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score
DCISionRT®, PreludeDx™, Prelude Corporation	**0295U**	Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score
mRNA CancerDetect™, Viome Life Sciences, Inc, Viome Life Sciences, Inc	**0296U**	Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing of at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy
Praxis Somatic Whole Genome Sequencing, Praxis Genomics LLC	**0297U**	Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification
Praxis Somatic Transcriptome, Praxis Genomics LLC	**0298U**	Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification
Praxis Somatic Optical Genome Mapping, Praxis Genomics LLC	**0299U**	Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification
Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping, Praxis Genomics LLC	**0300U**	Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification
Bartonella ddPCR, Galaxy Diagnostics Inc	**0301U**	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR);
Bartonella Digital ePCR™, Galaxy Diagnostics Inc	**0302U**	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR); following liquid enrichment
Hypoxic BioChip Adhesion, BioChip Labs™, BioChip Labs™	**0303U**	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; hypoxic
Normoxic BioChip Adhesion, BioChip Labs™, BioChip Labs™	**0304U**	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; normoxic
Ektacytometry, BioChip Labs™, BioChip Labs™	**0305U**	Hematology, red blood cell (RBC) functionality and deformity as a function of shear stress, whole blood, reported as a maximum elongation index
Invitae PCM Tissue Profiling and MRD Baseline Assay, Invitae Corporation, Invitae Corporation	**0306U**	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Invitae PCM MRD Monitoring, Invitae Corporation, Invitae Corporation	**0307U**	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD
HART CADhs®, Atlas Genomics, Prevencio, Inc	**0308U**	Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) with 3 clinical parameters (age, sex, history of cardiac intervention), plasma, algorithm reported as a risk score for obstructive CAD
HART CVE®, Atlas Genomics, Prevencio, Inc	**0309U**	Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
HART KD®, Atlas Genomics, Prevencio, Inc	**0310U**	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD
Accelerate PhenoTest® BC kit, AST configuration, Accelerate Diagnostics, Inc, Accelerate Diagnostics, Inc	**0311U**	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility for each organism identified
Avise® Lupus, Exagen Inc, Exagen Inc	**0312U**	Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment
PancreaSeq® Genomic Classifier, Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center	**0313U**	Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)
DecisionDx® DiffDx™- Melanoma, Castle Biosciences, Inc, Castle Biosciences, Inc	**0314U**	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)
DecisionDx®-SCC, Castle Biosciences, Inc, Castle Biosciences, Inc	**0315U**	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B)
Lyme Borrelia Nanotrap® Urine Antigen Test, Galaxy Diagnostics Inc	**0316U**	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine
LungLB®, LungLife AI®, LungLife AI®	**0317U**	Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer
EpiSign Complete, Greenwood Genetic Center	**0318U**	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
Clarava™, Verici Dx, Verici Dx, Inc	**0319U**	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
Tuteva™, Verici Dx, Verici Dx, Inc	**0320U**	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Bridge Urinary Tract Infection Detection and Resistance Test, Bridge Diagnostics	**0321U**	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
NPDX ASD Test Panel III, Stemina Biomarker Discovery d/b/a NeuroPointDX, Stemina Biomarker Discovery d/b/a NeuroPointDX	**0322U**	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma, results reported as negative or positive for risk of metabolic subtypes associated with ASD
Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics, Johns Hopkins Medical Microbiology Laboratory	**0323U**	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi
Guardant360®, Guardant Health, Inc, Guardant Health, Inc	**0326U**	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
Vasistera™, Natera, Inc, Natera, Inc	**0327U**	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed
CareView360, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC	**0328U**	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service
Oncomap™ ExTra, Exact Sciences, Inc, Genomic Health Inc	**0329U**	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
Bridge Women's Health Infectious Disease Detection Test, Bridge Diagnostics, Thermo Fisher and Hologic Test Kit on Panther Instrument	**0330U**	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
Augusta Hematology Optical Genome Mapping, Georgia Esoteric and Molecular Labs, Augusta University, Bionano	**0331U**	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alterations
EpiSwitch® CiRT (Checkpoint-inhibitor Response Test), Next Bio-Research Services, LLC, Oxford BioDynamics, PLC	**0332U**	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint-inhibitor therapy
HelioLiver™ Test, Fulgent Genetics, LLC, Helio Health, Inc	**0333U**	Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in high-risk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gamma-carboxy-prothrombin (DCP), algorithm reported as normal or abnormal result
Guardant360 TissueNext™, Guardant Health, Inc, Guardant Health, Inc	**0334U**	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
IriSight™ Prenatal Analysis – Proband, Variantyx, Inc, Variantyx, Inc	**0335U**	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants
IriSight™ Prenatal Analysis – Comparator, Variantyx, Inc, Variantyx, Inc	**0336U**	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent)
CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC) Test, Menarini Silicon Biosystems, Inc, Menarini Silicon Biosystems, Inc	**0337U**	Oncology (plasma cell disorders and myeloma), circulating plasma cell immunologic selection, identification, morphological characterization, and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood
CELLSEARCH® HER2 Circulating Tumor Cell (CTC-HER2) Test, Menarini Silicon Biosystems, Inc, Menarini Silicon Biosystems, Inc	**0338U**	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker-expressing cells, peripheral blood
SelectMDx® for Prostate Cancer, MDxHealth®, Inc, MDxHealth®, Inc	**0339U**	Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer
Signatera™, Natera, Inc, Natera, Inc	**0340U**	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate
Single Cell Prenatal Diagnosis (SCPD) Test, Luna Genetics, Inc, Luna Genetics, Inc	**0341U**	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid
IMMray® PanCan-d, Immunovia, Inc, Immunovia, Inc	**0342U**	Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline
miR Sentinel™ Prostate Cancer Test, miR Scientific, LLC, miR Scientific, LLC	**0343U**	Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high-risk of prostate cancer
OWLiver®, CIMA Sciences, LLC	**0344U**	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH
GeneSight® Psychotropic, Assurex Health, Inc, Myriad Genetics, Inc	**0345U**	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
QUEST AD-Detect™, Beta-Amyloid 42/40 Ratio, Plasma, Quest Diagnostics	**0346U**	Beta amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma
RightMed® PGx16 Test, OneOme®, OneOme®, LLC	**0347U**	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes
RightMed® Comprehensive Test Exclude F2 and F5, OneOme®, OneOme®, LLC	**0348U**	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes
RightMed® Comprehensive Test, OneOme®, OneOme®, LLC	**0349U**	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis, including reported phenotypes and impacted gene-drug interactions
RightMed® Gene Report, OneOme®, OneOme®, LLC	**0350U**	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes
MeMed BV®, MeMed Diagnostics, Ltd, MeMed Diagnostics, Ltd	**0351U**	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosisinducing 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
Xpert® Xpress MVP, Cepheid®	**0352U**	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected
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
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)
Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping, Quest Diagnostics®, Quest Diagnostics®	**0355U**	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)
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
Lumipulse® G ß-Amyloid Ratio (1-42/1-40) Test, Fujirebio Diagnostics, Inc, Fujirebio Diagnostics, Inc	**0358U**	Neurology (mild cognitive impairment), analysis of β-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative
IsoPSA®, Cleveland Diagnostics, Inc, Cleveland Diagnostics, Inc	**0359U**	Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer
Nodify CDT®, Biodesix, Inc, Biodesix, Inc	**0360U**	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy
Neurofilament Light Chain (NfL), Mayo Clinic, Mayo Clinic	**0361U**	Neurofilament light chain, digital immunoassay, plasma, quantitative

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Thyroid GuidePx®, Protean BioDiagnostics, Qualisure Diagnostics	**0362U**	Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture-enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes
Cxbladder™ Triage, Pacific Edge Diagnostics USA, Ltd, Pacific Edge Diagnostics USA, Ltd	**0363U**	Oncology (urothelial), mRNA, gene-expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma
clonoSEQ® Assay, Adaptive Biotechnologies	**0364U**	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
Oncuria® Detect, DiaCarta Clinical Lab, DiaCarta, Inc	**0365U**	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1, and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer
Oncuria® Monitor, DiaCarta Clinical Lab, DiaCarta, Inc	**0366U**	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1, and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer
Oncuria® Predict, DiaCarta Clinical Lab, DiaCarta, Inc	**0367U**	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1, and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection
ColoScape™ Colorectal Cancer Detection, DiaCarta Clinical Lab, DiaCarta, Inc	**0368U**	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132, and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
GI assay (Gastrointestinal Pathogen with ABR), Lab Genomics LLC, Thermo Fisher Scientific	**0369U**	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique
Lesion Infection (Wound), Lab Genomics LLC, Thermo Fisher Scientific	**0370U**	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, wound swab
Qlear UTI, Lifescan Labs of Illinois, Thermo Fisher Scientific	**0371U**	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine
Qlear UTI - Reflex ABR, Lifescan Labs of Illinois, Thermo Fisher Scientific	**0372U**	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score
Respiratory Pathogen with ABR (RPX), Lab Genomics LLC, Thermo Fisher Scientific	**0373U**	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Urogenital Pathogen with Rx Panel (UPX), Lab Genomics LLC, Thermo Fisher Scientific	**0374U**	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
OvaWatch℠, Aspira Women's Health℠, Aspira Labs, Inc	**0375U**	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score
ArteraAI Prostate Test, Artera Inc®, Artera Inc®	**0376U**	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate
Liposcale®, CIMA Sciences, LLC	**0377U**	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)
UCGSL RFC1 Repeat Expansion Test, University of Chicago Genetic Services Laboratories	**0378U**	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab
Solid Tumor Expanded Panel, Quest Diagnostics®, Quest Diagnostics®	**0379U**	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
PersonalisedRX, Lab Genomics LLC, Agena Bioscience, Inc	**0380U**	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
Branched-Chain Amino Acids, Self-Collect, Blood Spot, Mayo Clinic, Laboratory Developed Test	**0381U**	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of allo-isoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
Phenylalanine and Tyrosine, Self-Collect, Blood Spot, Mayo Clinic, Laboratory Developed Test	**0382U**	Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
Tyrosinemia Follow-Up Panel, Self-Collect, Blood Spot, Mayo Clinic, Laboratory Developed Test	**0383U**	Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
NaviDKD™ Predictive Diagnostic Screening for Kidney Health, Journey Biosciences, Inc, Journey Biosciences, Inc	**0384U**	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease
PromarkerD, Sonic Reference Laboratory, Proteomics International Pty Ltd	**0385U**	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease
AMBLor® melanoma prognostic test, Avero® Diagnostics	**0387U**	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalin-fixed paraffin-embedded (FFPE) tissue, report for risk of progression

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
InVisionFirst®-Lung Liquid Biopsy, Inivata, Inc, Inivata, Inc	**0388U**	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
KawasakiDx, OncoOmicsDx Laboratory, mProbe	**0389U**	Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha-inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using quantitative reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD
PEPredictDx, OncoOmicsDx Laboratory, mProbe	**0390U**	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
Strata Select™, Strata Oncology, Inc, Strata Oncology, Inc	**0391U**	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score
Medication Management Neuropsychiatric Panel, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx	**0392U**	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug
SYNTap® Biomarker Test, Amprion Clinical Laboratory, Amprion Clinical Laboratory	**0393U**	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative
PFAS Testing & PFASure™, National Medical Services, NMS Labs, Inc	**0394U**	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
OncobiotaLUNG, Micronoma™, Micronoma™	**0395U**	Oncology (lung), multi-omics (microbial DNA by shotgun next-generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease
Spectrum PGT-M, Natera, Inc, Natera, Inc	**0396U**	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
ESOPREDICT® Barrett's Esophagus Risk Classifier Assay, Capsulomics, Inc d/b/a Previse	**0398U**	Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer
FRAT® (Folate Receptor Antibody Test), Religen Inc, Religen Inc	**0399U**	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgG-binding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected
Genesys Carrier Panel, Genesys Diagnostics, Inc	**0400U**	Obstetrics (expanded carrier screening), 145 genes by next-generation sequencing, fragment analysis and multiplex ligation-dependent probe amplification, DNA, reported as carrier positive or negative
CARDIO inCode-Score (CIC-SCORE), GENinCode U.S. Inc, GENinCode U.S. Inc	**0401U**	Cardiology (coronary heart disease [CHD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
Abbott Alinity™ m STI Assay, Abbott Molecular, Inc	**0402U**	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected
MyProstateScore 2.0, LynxDX, LynxDX	**0403U**	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed first-catch urine), algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer
DiviTum®TKa, Biovica Inc, Biovica International AB	**0404U**	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression
BTG Early Detection of Pancreatic Cancer, Breakthrough Genomics, Breakthrough Genomics	**0405U**	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected
CyPath® Lung, Precision Pathology Services, bioAffinity Technologies, Inc	**0406U**	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer
IntelxDKD™, 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
Omnia™ SARS-CoV-2 Antigen Test, Qorvo Biotechnologies, Qorvo Biotechnologies	**0408U**	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
LiquidHALLMARK®, Lucence Health, Inc	**0409U**	Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability
Avantect™ Pancreatic Cancer Test, ClearNote™ Health, ClearNote™ Health	**0410U**	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected
IDgenetix®, Castle Biosciences, Inc, Castle Biosciences, Inc	**0411U**	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
PrecivityAD® blood test, C2N Diagnostics LLC, C2N Diagnostics LLC	**0412U**	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology
DH Optical Genome Mapping/Digital Karyotyping Assay, The Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health, Bionano Genomics	**0413U**	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations
LungOI, Imagene	**0414U**	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
SmartHealth Vascular Dx™, Morningstar Laboratories, LLC, SmartHealth DX	**0415U**	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS
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
Genomic Unity® Comprehensive Mitochondrial Disorders Analysis, Variantyx Inc, Variantyx Inc	**0417U**	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder-associated genetic variants
PreciseDx Breast Biopsy Test, PreciseDx, PreciseDx, Inc NYC, NY	**0418U**	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score
Tempus nP, Tempus Labs, Inc, Tempus Labs, Inc	**0419U**	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype
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
ColosenseTM, 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
Guardant360 ResponseTM, 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
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
miR SentinelTM 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
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)
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
Early Sepsis Indicator, Beckman Coulter, Inc	**0427U**	Monocyte distribution width, whole blood (List separately in addition to code for primary procedure)

Proprietary Name and Clinical Laboratory or Manufacturer	CPT® Code	Descriptor
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
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)
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
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
Kelch-Like Protein 11 Antibody, Mayo Clinic/Mayo Clinic Lab®oratories, Mayo Clinic/Mayo Clinic Laboratories	**0432U**	Kelch-like protein 11 (KLHL11) antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative
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
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
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
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
MindX OneTM 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
EffectiveRXTM 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

This page intentionally left blank