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Owner	
Area	Medical Policy
Lines Of Business	All Lines of Business

Proprietary Laboratory Testing

PURPOSE:

This policy addresses emerging technology surrounding proprietary laboratory testing. Providers are encouraged to check eligibility and benefits prior to submitting any request for proprietary lab work as some plans limit certain types of testing, such as genetic testing.

DEFINITIONS:

NCCN- National Comprehensive Cancer Network. It is a non profit organization focusing on research, patient care, and education. The organization develops resources, expert recommendations, and guidelines related to cancer care.

NCCN as a Category 1, 2A or 2B Level of Evidence and Consensus

- Category 1: Based upon high-level evidence there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence without a uniform consensus but with no major disagreement that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

CLIA- The Clinical Laboratory Improvement Amendments

COVERAGE POLICY:

At the time of the initial release of Proprietary Laboratory Testing (PLA) codes where there is insufficient peer review literature or evidence based guidelines available to determine the value of the testing regarding clinical efficacy, safety, or applicability to clinical practice, and to what extent a specific test supports clinical decision making, or has demonstrated a definitive positive impact on clinical outcomes, those tests will be considered

experimental and investigational. Proprietary Laboratory Test Codes that have a status of experimental/ investigational are excluded from coverage.

The listings below are not intended to be all inclusive. Please check with The Health Plan regarding precertification requirements if a Proprietary Lab test is not found listed in this policy or on the Prior Authorization List on the Internet.

Providers are reminded to use correct coding for requested tests for the appropriate date of service.

For any of the allowed tests to be covered:

- The specific test is a covered benefit per specific line of business and/or plan design.
- Overly broad multi-gene panels may not be covered under certain lines of business.
- Some tests are only allowed once per lifetime.
- Tests, whether single or part of a panel, will not be covered if duplicative. Providers should be aware if the member has undergone previous genetic testing in order to avoid denials.
- Most tests are not covered when used as a screening tool in the general population. There must be specific signs and/or symptoms or an existing diagnosis indicating a clinical need for the test.
- The lab providing the test is responsible for clearly indicating to treating physicians the population and indication(s) for test use.
- Tests must be performed in CLIA-certified laboratory.
- The testing must be approved by the US Food and Drug Administration and indication(s) for the test must be supported based on published, peer-reviewed prospective evidence.
- The test will provide information that will impact plan of care and guide therapy.
- If applicable, the testing is using molecular biomarkers that has not been previously performed for predictive therapy selection.
- Testing is performed according to the intended use of the test in the intended patient population for which the test was developed and validated.
- If specific criteria is not indicated here for individual tests, The Health Plan will utilize InterQual Criteria or the appropriate Medicare NCD/LCD depending on product line.

Proprietary Lab Tests Requiring Precertification:

- **Precertification Requirements do not imply coverage as some tests may not be covered for all lines of business. Please check corresponding fee schedules and plan documents for line of business prior to requesting review.**

Abbott Alinity™ m HSV 1&2/VZV Assay (Abbott Molecular, Inc)

Abbott Alinity™ m STI CT/NG/TV/MG and CT/NG/TV Assays (Abbott Molecular, Inc)

AlloSure® (CareDx® Laboratory, CareDx®, Inc)

Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping (Quest Diagnostics®)

Augusta Hematology Optical Genome Mapping (Georgia Esoteric and Molecular Labs, Augusta University, Bionano)

Augusta Optical Genome Mapping (Georgia Esoteric and Molecular (GEM) Laboratory, LLC)

Avantect™ Pancreatic Cancer Test (ClearNote™ Health)

Aventa FusionPlus™ (Aventa Genomics, LLC)

Barontella ddPCR (Galaxy Diagnostics, Inc)

Barontella Digital ePCR™ (Galaxy Diagnostics, Inc)

BCRAplus (Ambry Genetics)

BioFire® Respiratory Panel 2.1(RP2.1) and BioFire® FilmArray Pneumonia (PN) Panel (bioMérieux)

- Covered for members with signs/symptoms of respiratory infection and are immunocompromised and considered high risk for complications.
- May not be covered for all LOB.

BIOFIRE® SPOTFIRE® Respiratory/Sore Throat(R/ST) Panel – Respiratory Menu (bioMérieux)

BIOFIRE® SPOTFIRE® Respiratory/Sore Throat(R/ST) Panel – Sore Throat Menu (bioMérieux)

BreastNext® (Ambry Genetics®) Deleted 01/01/2026

BTG Early Detection of Pancreatic Cancer (Breakthrough Genomics)- Currently may only be covered for certain Medicare plans.

CARDIO inCode-Score (CIC-SCORE) (GENinCode U.S. Inc)

CardioRisk+ (Gene by Gene, LTD) (OpenDNA, LTD)

Caris Assure™ (Caris MPI, Inc d/b/a Caris Life Sciences®)

CELLSEARCH® HER2 Circulating Tumor Cell (CTC- HER2) Test (Menarini Silicon Biosystems, Inc)- May not be covered for all lines of business

Chromosome Genome Mapping (UR Medicine Labs, Bioano Genomics, Inc)

Ciprofloxacin Susceptibility of Neisseria Gonorrhea (MedArbor Diagnostics, SpeeDx, Inc)

Clarifi™ (Quadrant Biosciences, Inc)

CNT (CEP72, TPMT, and NUDT15) genotyping panel (RPRD Diagnostics)

ColoScape™ Colorectal Cancer Detection (DiaCarta Clinical Lab, DiaCarta , Inc) - May only be covered for Medicare plans

ColoNext® (Ambry Genetics®)

clonoSEQ® Assay (Adaptive Biotechnologies)

Comprehensive Screen (Aspenti Health) - Covered only for certain Medicare plans at this time

CRCdx® RAS Mutation Detection Kit (EntroGen, Inc)

- This test is the analysis of variants of the KRAS and NRAS genes.
- Considered medically necessary when used to aid in the identification of colorectal cancer patients for treatment with Vectibix® (panitumumab). As of the date of this policy origination, this is the only approved indication.

DecisionDx® DiffDx™- Melanoma (Castle Biosciences, Inc)

DH Optical Genome Mapping/Digital Karyotyping Assay (The Clinical Genomics and Advanced Technology

(CGAT) Laboratory at Dartmouth Health, Bionano Genomics)

Elecsys® PhosphoTau (181P) CSF(pTau181) and B- Amyloid (1-42) CSF II (Abeta 42) Ratio (Roche Diagnostics Operations)

Elecsys® Total-Tau CSF (tTau) and B- Amyloid(1-42) CFS II (Abeta 42) (Roche Diagnostics Operations)

- Elecsys® PhosphoTau (181P) CSF(pTau181) and B -Amyloid (1-42) CSF II (Abeta 42) Ratio or Elecsys® Total-Tau CSF (tTau) and B- Amyloid(1-42) CFS II (Abeta 42) may be covered for members with a diagnosis of Alzheimer's disease where treatment with amyloid beta targeting therapy (e. g. lecanemab-irmb [Leqembi™] or idonanemab-azbt [Kisunla]) is being considered.
- Not covered for any other indication at this time.

Epi+gene CHD™ (CardioDiagnostics, Inc)

EpiSign Complete (Greenwood Genetic Center)

Episwitch® CiRT (Checkpoint-Inhibitor response Test) (Next Bio-Research Services, LLC. Oxford Biodynamics, PLC)

EpiSwitch® Prostate Screening Test (Oxford Biodynamics, Inc)

ERA® Endometrial Receptivity Analysis (Igenomix® USA)

ESOPREDICT® Barrett's Esophagus Risk Classifier Assay (Capsulomics, Inc d/b/a Previse) - Currently only covered for certain Medicare plans at this time.

Eurofins TRAC™ dd-cfDNA (Transplant Genomics, Inc)

ExaCT-1 Whole Exome Testing (Lab of Oncology- Molecular Detection, Weill Cornell Medicine-Clinical Genomics Laboratory)

Foundation One CDx™ (F1CDx) (Foundation Medicine ,Inc)

Foundation®One Liquid CDx (Foundation Medicine, Inc)

Genomic Prostate Score® (GPS) Test (MDxHealth, Inc)

Genomic Unity® 2.0, (Variantyx Inc)

Genomic Unity® Ataxia and Comprehensive Repeat Expansion and Sequence Analysis (Variantyx Inc)

Genomic Unity® Comprehensive Mitochondrial Disorders Analysis (Variantyx Inc)

Genomic Unity® DMD Analysis (Variantyx Inc)

Genomic Unity® Whole Genome Analysis- Proband, Comparator (Variantyx Inc)

Genomic Unity® Exome Plus Analysis- Proband, Comparator (Variantyx Inc)

Genomind® Pharmacogenetics Report (Genomind®, Inc) May only be covered for certain Medicare plans

Genomind® Professional PGx Express™ CORE (Genomind®, Inc) May only be covered for certain Medicare plans

GeneticsNow® Comprehensive Germline Panel (GoPath Diagnostics, Inc)

GeneSight® Psychotropic and ADHD tests (Assurex Health, Inc, Myriad Genetics, Inc) 0345U must be billed for all LOB for these tests.

Genesys Carrier Panel (Genesys Diagnostics, Inc)

Guardant360®, Guardant360 Response™, Guardant360® CDx , and Guardant360 Tissue Next™ Tests (Guardant Health, Inc)

IDgenetix® (Castle Biosciences, Inc)

IDH1, IDH2, and TERT Mutation Analysis, (NGS), Tumor (IDTRT) (Mayo Clinic)

Insight TNBCtype™ (Insight Molecular Labs)

InVisionFirst®-Lung Liquid Biopsy (Inivata, Inc)- May only be covered for Medicare plans

Invitae PCM MRD Monitoring (Invitae Corportation)

Invitae PCM Tissue Profiling and MRD baseline Assay (Invitae Corporation)

IriSight™ Prenatal Analysis- Proband and Comparator Tests (Variantyx, Inc)

IsoPSA® (Cleveland Diagnostics, Inc)

Karius® Test (Karius Inc)

KawasakiDx (OncoOmicsDx Laboratory, mProbe)

kidneyintelX (Renalytix, Inc, NYC, NY) - Test is not covered as a screening or standalone diagnostic

kidneyintelX.dkd™ (Renalytix, Inc, NYC, NY)- Test is not covered as a screening or standalone diagnostic

Lifetime Genomics Risk Assessment (GenomicMD, Inc)

LiquidHALLMARK® (Lucence Health) both codes 0409U and 0530U

LiquidHALLMARK® ctDNA and ctRNA, (Lucence Health, Inc) 0571U.

Lung HDPCR™ (Protean BioDiagnostics)

LungLB® (LungLife AI®)

Lymph3Cx Lymphoma Molecular Subtyping Assay (Mayo Clinic)

Macrolide Resistance of Mycoplasma Genitalium (MedArbor Diagnostics, SpeeDx, Inc)

Medication Management Neuropsychiatric Panel (RCA Laboratory Services LLC d/b/a GENETWORx)

MI Cancer Seek™ NGS Analysis (Caris MPI d/b/a Caris Life Sciences)

MindX Blood Test™- Memory/Alzheimers, Mood, Pain, Stress, Suicidality, and Longevity (MindX™ Sciences)

Mind Px (Mindera Corporation) -Limited coverage

miR-31 now™ (GoPath Laboratories)

miR Sentinel™ Prostate Cancer Test (miR Scientific, LLC) Codes 0343U and 0424U

Molecular Microscope® MMDx-Heart (Kashi Clinical Laboratories)

Molecular Microscope® MMDx-Kidney (Kashi Clinical Laboratories)

M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry (Mayo Clinic)

- Covered for evaluation and management of plasma cell dyscrasias.

MSK-IMPACT Integrated Mutation Profiling of Actionable Cancer Targets (Memorial Sloan Kettering Cancer Center)

MyAML, NGS Panel (LabPMM, LLC)

myChoice® CDx (Myriad Genetics)

MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 4 Aspergillus species (RealTime Laboratories, Inc/MycoDART, Inc)

MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 6 Candida species (RealTime Laboratories, Inc/MycoDART, Inc)

MyGenVar Pharmacogenomics Test (Geisinger Medical Laboratories)

MyMRD® NGS Panel (Laboratory for Personalized Molecular Medicine)

myPath® Melanoma (Castle Biosciences, Inc)

MyProstateScore and MyProstateScore 2.0 (LynxDX)

myTAIHEART (TAI Diagnostics, INC)

mRNA CancerDetect™ (Viome Life Sciences, Inc)

NavDx® (Naveris, Inc)

NextGen Precision™ Testing (Precision Diagnostics LBN Precision Toxocology, LLC)

NorthStar Response™ (cell-free circulating DNA) (BillionToOne, Inc)

NorthStar Select™ (cell-free circulating DNA) (BillionToOne, Inc)

NT (NUDT15 and TPMT) genotyping panel (RPRD Diagnostics)

Oncomap™ ExTra (Exact Sciences, Inc, Genomic Health Inc)

Oncomine™ DX Target Test (Thermo Fisher Scientific)

OncoReveal™ CDx (Pillar Biosciences, Inc)

Oncotype MAP™ Pan-Cancer Tissue Test (Paradigm Diagnostics)

OvaNext® (Ambry Genetics®)

OncoSignal 7 Pathway Signal (Protean BioDiagnostics)

OncoTarget/OncoTreat (Columbia University Department of Pathology and Cell Biology, Darwin Health) - May only be covered for Medicare plans

Oncotype DX® Breast DCIS Score™ Test (Genomic Health, Inc)

PancreaSeq® Genomic Classifier (Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center) - Potential Experimental and Investigational

PGDx elio™ tissue complete (Personal Genome Diagnostics, Inc)

PGT-M, Igenomix® (Part of Vitrolife Group™ Igenomix®)

Praxis Optical Genome Mapping, (Praxis Genomics, LLC)- May only be covered for certain Medicare plans

Praxis Whole Genome and Somatic Whole Genome Sequencing tests (Praxis Genomics LLC) - May only be covered for certain Medicare plans

Praxis Transcriptome and Somatic Transcriptome (PraxisGenomics LLC)- May only be covered for certain Medicare plans

Praxis Combined Whole and Somatic Combined Whole Genome Sequencing and Optical and Somatic Optical Genome Mapping (Praxis Genomics) - May only be covered for certain Medicare plans

PreciseType® HEA Test (Immucor, Inc)

PrecisionCHD™ (Cardio Diagnostics, Inc)

ProstateNow™ Prostate Germline Panel (GoPath Diagnostics, Inc)

QClamp® Plex VEXAS UBA1 Mutation Test (DiaCarta, Inc)

Qlear UTI and Qlear UTI – Reflex ABR (Lifescan Labs of Illinois, Thermo Fisher Scientific)- May only be covered for certain Medicare plans

QuantiVirus™ HPV E6/E7 mRNA tests for Cervical Cancer (DiaCarta, Inc)

RadTox™ cfDNA test ((DiaCarta Inc)

Rapid Genome Sequencing Test (University of California San Francisco Genomic Medicine Laboratory)

Rapid Whole Genome Sequencing (Mayo Clinic)

Rapid Genome Sequencing Family Member Comparator (Mayo Clinic) - use with code 0582U.

RCIGM Rapid Whole Genome Sequencing (Rady Children's Institute for Genomic Medicine)

RCIGM Ultra-Rapid Whole Genome Sequencing (Rady Children's Institute for Genomic Medicine)

Rh Test (Natera™)- All of the following indications must be met for coverage:

- Pregnancy may be at risk for alloimmunization due to maternal RhD status or the presence of red cell antigen antibodies; *and*
- Paternal antigen typing is unavailable or heterozygous; *and*
- Amniocentesis is declined or contraindicated.

RightMed® Mental Health Gene Report and Mental Health Medication Report (OneOme LLC)

RightMed ® Comprehensive Test and Comprehensive Test Exclude F2 and F5 (OneOme LLC)- May only be covered for Medicare plans

RightMed® Gene Test Exclude F2 and F5 (OneOme® LLC)

RightMed® Oncology Gene and Oncology Medication Reports (OneOme® LLC)

RightMed® PGx16 Test and Gene Report (OneOme®, LLC)

Risk Reveal™ (Razor Genomics)

Salimetrics® Salivary Melatonin Profile (Salimetrics® LLC)

- May be covered to R/O Cushings Syndrome.

- Include signs, symptoms, or clinical support why the member is being tested for Cushing's Syndrome.
- **Note:** Salivary cortisol collected in the evening for the diagnosis of Cushing's Syndrome is currently the only covered application of hormone measurement in salivary fluid. Any other request of salivary hormones measurements will be denied as experimental and investigational.

SelectMDx® for Prostate Cancer (MDx Health®, Inc)

Sentosa® SQ HIV-1 Genotyping Assay (Vela Operations Singapore Pte, Ltd)- Covered for Medicare members only

Signatera™ (Natera, Inc)- Only covered for Medicare plans

SMASH™ (New York Genome Center, Marvel Genomics)

Solid Tumor Expanded Panel (Quest Diagnostics®)

Strata Select™ (Strata Oncology, Inc)

Tempus nP (Tempus Labs, Inc) May only be covered for certain Medicare plans

ThyGeNEXT® Thyroid Oncogene Panel (Interspace Diagnostics)

ThyraMIR™ (Interspace Diagnostics)

Thyroid GuidePx® (Protean BioDiagnostics, Qualisure Diagnostics)

ThyroSeq® CRC (CBLPath, Inc, University of Pittsburgh Medical Center)- Potential Experimental and Investigational

Thyroseq Genomic Classifier (CBL Path, Inc)

ToxLok™ (inSource Diagnostics)

TruSight™ Oncology Comprehensive (Illumina, Inc)

Tuteva™ (Verici Dx, Inc)

UCGSL RFC1 Repeat Expansion Test (University of Chicago Genetic Services Laboratories)

Unity Carrier Screen™ (BillionToOne, Inc)

UCSF Pharmacogenomics Panel (University of California San Francisco Genomic Medicine Laboratory)

Vasistera™ (Natera, Inc)

Versiti™ aHUS Genetic Evaluation (Versiti™ Diagnostic Laboratories)

Versiti™ Autosomal Dominant Thrombocytopenia, Inherited Thrombocytopenia, Thrombosis, Coagulation Disorder Panels (Versiti™ Diagnostic Laboratories)

Versiti™ Congenital Neutropenia, Comprehensive Bleeding, Fibrinolytic, Comprehensive Platelet Disorder Panels (Versiti™ Diagnostic Laboratories)

Versiti™ VWD Type 2B Evaluation Tests (Versiti™ Diagnostic Laboratories)

Versiti™ VWF Collagen III and IV, and VWF Type 2N Binding Tests (Versiti™ Diagnostic Laboratories)

Versiti™ VWF Propeptide Antigen (Versiti™ Diagnostic Laboratories)

Versiti™ Red Cell Genotyping Panel (Versiti™ Diagnostic Laboratories)

VitaGraft™ Kidney 2.0 (Oncocyte Corporation) Deleted 01/01/2026

VitaGraft™ Kidney Baseline + 1st Plasma Test (Oncocyte Corporation) Deleted 01/01/2026

VitaGraft™ Kidney Subsequent (Oncocyte Corporation) Deleted 01/01/2026

xT CDx (Tempus AI, Inc)

Proprietary Lab Tests Not Requiring Precertification

Providers should be aware that although the following tests do not require precertification, the codes listed in this section may not be covered for all lines of business. Coverage and benefit criteria still apply. For example; services ordered and or performed by out-of network providers may require precertification for certain plan types. Confirm coverage guidelines with CMS, BMS, or plan documents and The Health Plan.

Accelerate PhenoTest™ BC Kit (Accelerate Diagnostics) 0086U- May not be covered for all lines of business

AmHPR® H. pylori Antibiotic Resistance Panel (American Molecular Laboratories)

Bacterial Typing by Whole Genome Sequencing (Mayo Clinic)

BCR-ABL1 major and minor breakpoint fusion transcripts (University of Iowa, Department of Pathology, Asuragen)

BDX-XL2 (Biodesix®, Inc)

- Covered for individuals >40 yrs of age, and
- Pulmonary nodule of diameter 8-30mm, and
- Pre-test risk of cancer 50% or less.

BioPlex 2200 Syphilis Total & RPR Assay (Bio-Rad Laboratories), and

BioPlex 2200 RPR Assay (Bio-Rad Laboratories)

- Covered as a screening of all pregnant women, and persons who are at risk of syphilis infection.
- Diagnostic testing of individuals with signs and symptoms of syphilis.

BLOODchip® ID CORE XT™ (Grifols Diagnostic Solutions Inc)

- Covered Pre-transfusion molecular testing (red blood cells, platelets, or white blood cells) with one or all of the following,
- Longterm frequent transfusions anticipated and risk for developing antibodies,
- Autoantibodies or other serologic reactivity interferes with the exclusion of clinically significant alloantibodies,
- Suspected antibody against an antigen for which typing sera is not available,
- Laboratory discrepancies on serological typing,
- The individual has not previously been tested for blood cell antigen.

Cap-Score™ Test (Androvia Life Sciences)- Plans with infertility benefits may cover based on plan design. Those benefits may be limited to certain services only.

Catechol-O-Methyltransferase (COMT) genotype (Mayo Clinic)

CNGnome™ (PerkinElmer Genomics)

Cologuard Plus™ (Exact Science Laboratories, LLC, Exact Science Corporation) 0464U. As of 2/1/2025 .

Colvera® (Clinical Genomics Pathology Inc) -Currently only covered for Medicare plans

Cordant CORE™ (Cordant Health Solutions)

CustomNext +RNA: APC, MLH1, MSH2, MSH6, PMS2, Lynch (Ambry Genetics)

- Covered targeted multi-gene panel for hereditary colon cancer syndromes (APC, BMPR1A, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, SMAD4, STK11, TP53) that meet guidelines .

CYP2D6 Common Variants and Copy Number, Full Genome Sequencing, Hybrid Gene Targeted Sequence Analysis (2D6 and 2D7), Trans-duplication/gene duplication/multiplication tests. Codes 0070U-+0076U (Mayo Clinic). Include any add on codes.

- Above tests are covered for members who have been prescribed doses of tetrabenazine (Xenazine) greater than 50 mg per day.
- Covered fo DX Gaucher disease type 1 who are being considered for treatment with eliglustat (Cerdelga).
- Covered for indications listed in Medicare LCD *MOLDX: Pharmacogenomics Testing (L38394)*
- Repeat CYP2D6 genotyping has no proven value and will not be reimbursed.

Cytochrome P450 1A2 Genotype (Mayo Clinic)

DEPArray™ HER2 (PacificDx)

DISCERN™(NeuroDiagnostics) Codes 0206U and 0207U- Covered for Medicare plans only

Ektacytometry (BioChip Labs™)

- Covered for the diagnosis of red blood cell (RBC) cytoskeleton and hydration disorders (e.g., hereditary spherocytosis, pyro-poikilocytosis, stomatocytosis, ovalocytosis, elliptocytosis and xerocytosis) when RBC morphology does not provide a clear diagnosis.

ePlex Respiratory Pathogen (RP) Panel and ePlex Respiratory Pathogen Panel 2 (GenMark Diagnostics, Inc)

- Covered for the indications listed in Palmetto and CGS LCD's Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988 and L39038 and Article A58710 and A58747).

ePlex® BCID Fungal Pathogens Panel (GenMark Diagnostics, Inc)

ePlex® BCID Gram- Positive Panel (GenMark Diagnostics, Inc)

- Covered for the indications listed in Palmetto and CGS's LCD's Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988 and L39038 and Article A58710 and A58747).

ePlex® BCID Gram- Negative Panel (GenMark Diagnostics, Inc)

- Covered for the indications listed in Palmetto and CGS LCD's Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988 and L39038 and Article A58710and A58747).

ExosomeDX® Prostate (IntelliScore) (Exosome Diagnostics, Inc)

- Does not have established diagnosis of prostate cancer.
- Test ordered by physician specialist (e.g. urologist and oncologist) for treatment and management decision

FLT3 ITD MRD (NGS, Lab PMM LLC, an Invivoscribe Technologies, Inc Company)

Focused Pharmacogenomics Panel (Mayo Clinic)

FRAT® (Folate Receptor Antibody Test) (Religen Inc)

- Covered for evaluation of individuals with cerebral folate deficiency syndrome.

Genomic Unity ® AR, CACNA1A, CSTB, FXN, MECP2, PTEN, and SMN1/2 Analysis Tests (Variantyx Inc)

Genomic Unity ® Cardiac Ion Channelopathies Analysis and Lynch Syndrome Analysis Tests (Variantyx Inc)

HPV, High-Risk, Male Urine (Molecular Testing Labs)

HPV-SEQ Test (Sysmex Inostics, Inc)- Currently only covered for certain Medicare plans upon claim review.

JAK2 Mutation (University of Iowa, Department of Pathology)

JAK2 Exons 12 to 15 Sequencing (Mayo Clinic)

LeukoStrat®CDx FLT3 Mutation Assay (LabPMM LLC, an Invivoscribe Technologies, Inc Company)

Lumipulse® G ß-Amyloid Ratio (1-42/1-40) Test (Fujirebio Diagnostics, Inc)

- Covered for individuals with a confirmed diagnosis of Alzheimer's disease for selecting therapy based on β-amyloid (Aβ) status and tau staging and in identifying individuals likely to benefit the most from anti-Aβ treatments.

Lyme ImmunoBlot IgG and IgM tests (IgeneX Inc, ID-FISH Technology Inc (ASR))

Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgM Test and IgG Test (IgeneX Inc, ID-FISH Technology Inc)

- Lyme ImmunoBlot and Tick-Borne Relapsing Fever tests are covered for determination of definitive Diagnosis of Lyme Disease to support initial IV antibiotic therapy.
- The CDC recommends a 2-test approach using a sensitive enzyme immunoassay (EIA) or IFA followed by a Western immunoblot. All specimens positive or equivocal by a sensitive EIA or IFA should be tested by a standardized Western immunoblot.
- The CDC states when Western immunoblot is used during the first 4 weeks of disease onset (early LD), both immunoglobulin M (IgM) and immunoglobulin G (IgG) procedures should be performed.
- Tests performed outside of recommended parameters will not be covered.

MicroGenDX qPCR & NGS For Infection (MicroGenDX)- Currently only covered for Medicare plans.

MRDx BCR-ABL test (MolecularMD)

Navigator ABO, Rh Blood Group NGS (Grifols Immunohematology Center) - Currently only covered for Medicare plans.

Navigator ABO, CO, CROM, DI, DO, FUTI, FUT2, FY, GE, GYPA, GYPB, IN, JK, JR, KEL, KLF1, and LU Sequencing tests (Grifols Immunohematology Center)

Navigator LW, RHD/CE, SC, XK, YT Sequencing Tests (Grifols Immunohematology Center)

NPM1 MRD by NGS (LabPMM LLC, an Invivoscribe Technologies, Inc Company)

Omnia™ SARSCoV-2 Antigen Test (Qorvo Biotechnologies)

Pigmented Lesion Assay (PLA) (DermTech)

POC (Products of Conception) (Igenomix® USA)

Praxis™ Extended RAS Panel (Illumina)

- Covered for recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer or breast and/or ovarian cancer based on coverage guidelines indicated in Medicare's National Coverage Determination on Next Gen Sequencing *(90.2)*.
- Covered for prognostic and predictive testing in colorectal cancer when guidelines are met.

PrecisionBlood™ (San Diego Blood Bank)- Currently only covered for Medicare plans

PredictSURE IBD™ Test (KSL Diagnostics, PredictImmune Ltd)- Currently only covered for Medicare plans upon claims review

Psych HealthPGxPanel (RPRD Diagnostics)- May only be covered for Medicare plans upon claims review .

QIAstat-Dx Respiratory SARS coV-2 Panel (QIAGEN Sciences)

Real-time quaking-induced conversion for prior detection (RT-QuIC) (National Prion Disease Pathology Surveillance Center)

+RNAinsight™ for ATM, BRCA 1/2, CancerNext® ColoNext®, PALB2, ProstateNext®, (Ambry Genetics)
May not be covered for all lines of business. Confirm Coverage CMS, BMS or plan documents.

Serotonin Receptor Genotype (HTR2A and HTR 2 C) (Mayo Clinic)- Deleted 01/01/2026

Shield ™(Guardant Health)

- Blood based biomarker test covered for colorectal screening for members at least 45 years of age and asymptomatic, and
- Initial test, or at least 3 years since last test.

Singulex Clarity C. diff toxins A/B assay (Singulex)

- Covered to detect the presence of Clostridium difficile toxins in a stool sample due to signs/symptoms C-difficile.

SMART PGT-A (Pre-implantation Genetic Testing- Aneuploidy) (Igenomix® USA)

Smart PGT-A Plus, Igenomix®, Smart PGT-SR, Igenomix®, and Smart PGT-SR Plus (Igenomix®, Part of Vitrolife Group™, Thermo Fisher Scientific)

- **Covered for pre-implantation genetic diseases (PGD) if one or more biological parents has a known translocation in chromosome 13, 18, or 21**
- **Not covered for any other indication**
- **Support must be submitted with claim.**

Therascreen® FGFR RGQ RT-PCR Kit (Qiagen)

Therascreen® PIK3CA RGQ RT-PCR Kit (Qiagen)

Therascreen® PIK3CA RGQ PCR Kit (Qiagen)

Thiopurine Methyltransferase (TPMT) and Nudix hydrolase (NUDT15) (Mayo Clinic)

ToxProtect (Genotx Laboratories)

- Billing unit limits may apply.
- Refer to Clinical Drug Testing in Addiction Treatment Programs and Pain Management Programs Policy.

Trimethylamine (TMA) and TMA N-Oxide (Children's Hospital Colorado Laboratories)

- Measurement of urinary trimethylamine (TMA) and TMA-N-oxide (TMAO) is considered medically necessary for diagnosing individuals with foul smelling urine suspected of having trimethylaminuria (fish odor syndrome).

Twins Zygosity PLA (Natera Inc)

Vita Risk® (Artic Medical Laboratories)- Currently only covered for Medicare plans.

VeriMap™ Peanut DX Bead-Based Epitope Assay (AllerGenis™ Clinical Clinical Laboratory, AllerGenis™, LLC)- Only covered for Medicare plans

VeriMap™ Peanut Reactivity Bead-Based Epitope Assay (AllerGenis™ Clinical Clinical Laboratory, AllerGenis™, LLC)- Only covered for Medicare plans

Warfarin Response Genotype (Mayo Clinic)

Not Currently Covered or Excluded:

FDA approval and/or clearance alone is not an indication of coverage. The following tests are considered experimental or investigational as of the release or update of this policy, there is insufficient evidence from current peer review literature or Medicare coverage guidelines to support the use of these tests. Not an all inclusive list.

Evidence does not support the use of comprehensive multi-gene panels for predictive or prognostic testing in CRC.

There is limited evidence to support the use of liquid biopsy testing for plasma cell-free DNA (cfDNA) or circulating tumor DNA (ctDNA) to predict recurrence of CRC or monitor response to CRC therapy in postoperative settings. Literature review of current evidence does not support the used of liquid biopsy testing in other clinical settings.

- **13C-Spirulina Gastric Emptying Breath Test (GEBT) (Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC)**
- **3D Predict Glioma (KIYATEC®, Inc)-** Non-covered indications for chemosensitivity and chemoresistance assay.
- **3D Predict™ Ovarian (KIYATEC®, Inc)**
- **Accelerate PhenoTest® BC Kit, AST configuration (Accelerate Diagnostics, Inc) 0311U**
- **AChR Live Cell-Based Assay (Neurocode USA, Inc)**
- **AidaBreast™ (PreludeDx™Prelude Corporation)**
- **aiSLE® DX Disease Activity Index (Progentec Diagnostics, Inc)**
- **aiSLE® DX Flare Risk Index (Progentec Diagnostics, Inc)**
- **ALICE (Analysis of Infectious Chronic Endometritis) (Igenomix® USA)**
- **ALZpath pTau217 (Neurocode USA, Inc, Quanterix/ALZpath)**
- **AMBLor® Melanoma Prognostic Test (Avero® Diagnostics)**
- **Amplified Sciences PanCystPro™ (Amplified Sciences, Inc)**

- **Anti-dsDNA, High Salt/Avidity (University of Washington, Department of Laboratory Medicine, Bio-Rad)**
- **Apifiny® (Armune BioScience, Inc)**
- **ArteraAI Prostate Test (Artera Inc®)**
- **AssureMDx™ (Vesica Health® Inc)**
- **AssuranceRx (Micro Serum, Firstox Laboratories, LLC)**
- **Auria® (Namida Lab, Inc)**
- **Aventa Lymphoma, (Aventa Genomics, LLC)**
- **Avantect Ovarian Cancer Test (Clear Note® Health)**
- **Avise® Lupus (Exagen, Inc)**
- **Bacteria, Viruses, Fungus, and Parasite Metagenomic Sequencing, Spinal Fluid (MSCSF) (Mayo Clinic Laboratory)**
- **BBDRiskDx™ (Silbiotech, Inc)**
- **Bescreened™-CRC (Beacon Biomedical Inc)**
- **BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel, (bioMérieux)**
- **BIOTIA-ID™ Urine NGS Assay, (Biotia, Inc)**
- **Bladder CARE™ (Pangea Laboratory, LLC)**
- **Bradykinin Quantitative (Virant Diagnostics)**
- **Branched-Chain Amino Acids, Self-Collect, Blood Spot (Mayo Clinic, Laboratory Developed Test)**
- **Bridge Urinary Tract Infection Detection and Resistance Test (Bridge Diagnostics)**
- **Bridge Women's Health Infectious Disease Detection Test (Bridge Diagnostics, Thermo Fisher and Hologic Test Kit on Panther Instrument)**
- **CareView360 (Newstar Medical Laboratories, LLC)**
- **CELLSEARCH® Circulating Melanoma Cell (CMC) Test (Menarini Silicon Biosystems, Inc)**
- **CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC) Test (Menarini Silicon Biosystems, Inc)**
- **CELLSEARCH® ER Circulating Tumor Cell (CTC-ER) Test (Menarini Silicon Biosystems, Inc)**
- **CELLSEARCH® PDL1 Circulating Tumor Cell (CTCPD-L1) Test (Menarini Silicon Biosystems, Inc)**
- **ChemoID® (ChemoID® Lab, Cordgenics, LLC)**
- **Clarava™ (Verici Dx, Inc)**
- **ClarityDx Prostate (Protean BioDiagnostics)** Deleted 01/01/2026 possibly being recoded 1/1/2026 as code 0609U with updated description change
- **ColonAiQ (Breakthrough Genomics, Singlera Genomics, Inc)**
- **Coloscape™PLUS (DiCarta,Inc)**
- **Colosense™ (Geneoscopy, Inc)**
- **ComplyRX (Claro Labs)**
- **Covid-19 Antibody Test (Mt Sinai Laboratory)**
- **Cxbladder™ Triage (Pacific Edge Diagnostics USA, Ltd)-** May be covered for Medicare members upon claim review
- **Cxbladder Triage Plus ((Pacific Edge Diagnostics USA, Ltd)-** May be covered for Medicare members upon claim review
- **CXCL10 Urine test (One Lambda™ Inc)**

- **CyPath® Lung (Precision Pathology Services, bioAffinity Technologies, Inc)**
- **DCISionRT® (PreludeDx™, Prelude Corporation)**
- **DecisionDx™ -SCC (Castle Biosciences, Inc)**
- **DiviTum®TKa (Biovica Inc)**
- **EarlyDx MethylScan™ HCC (EarlyDiagnostics Laboratory)**
- **Early Sepsis Indicator (Beckman Coulter Inc.)**
- **Early Sjören's Syndrom Profile (Immco Diagnostics, Inc)**
- **EarlyTect® Bladder Cancer Detection (EarlyTect® BCD), (Promis Diagnostics, Inc)**
- **EffectiveRX™ Comprehensive Panel (RCA laboratory Services LLC d/b/a GENETWORx)**
- **EMMA (Endometrial Microbiome Metagenomic Analysis), (Igenomix® USA)**
- **Endosign® Barrett's Esophagus Test (Cyted Health, Inc)**
- **Epignostix CNS Tumor Methylation Classifier (Heidelberg Epignostix GmbH)**
- **EPISEEK™ MPE (Malignant Pleural Effusion Detection Test) (Precision Epigenomics, Inc)**
- **EsoGuard™ (Lucid Diagnostics)**
- **Esophageal String Test™(EST) (EnteroTrackTM Labs, EnteroTrack, LLC)**
- **FebriDx® Bacterial/NonBacterial Point-of Care Assay (Lumos Diagnostics LLC)**
- **FidaLab Molecular Wound Infection Test (FidaLab LLC)**
- **FirstSightCRC™ (CellMax Life)**
- **Flow Adhesion of Whole Blood on VCAM-1 (FAB-V) (Functional Fluidics)**
- **Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL) (Functional Fluidics)**
- **Foundation PI™ (Ethos Laboratories)**
- **GeneSight Analgesic, GeneSight MTHFR-W**ould use 81479 or 81291respectively and may not be covered depending on reason for test and line of business.
- **Glial Fibrillary Acidic Protein Blood Test (Neurocode USA, Inc) (Fujirebio Diagnostics, Inc)**
- **GFR by NMR (Labtech™ Diagnotics)**
- **GlycA (Laboratory Corporation of America)**
- **Glycine receptor alpha1 IgG, serum or cerebrospinal fluid(CSF), live cell-binding assay(LCBA), qualitative (Glycine Receptor Alpha1 IgG) (Mayo Clinic/Mayo Clinic Laboratories)**
- **GlycoKnow ™ Ovarian (InterVenn Biosciences)**
- **Guardant Reveal™, Guardant Health, Inc-** Code 0569U may be covered for Medicare plans upon claims review
- **HART CADhs®, CVE®, and KD® Tests (Atlas Genomics, Prevencio, Inc)**
- **Haystack MRD™ Baseline (Quest Diagnostics®)**
- **Haystack MRD™ Monitoring (Quest Diagnostics®)**
- **HealthTrackRx Bronchitis (HealthTrackRx, Thermo Fisher Scientific)**
- **HealthTrackRx Vaginitis (HealthTrackRx, Thermo Fisher Scientific)**
- **HepatoTrack™ (LuminoDx Laboratory)**
- **HDL Reverse Cholesterol Transport Panel with pCAD Score (Quest Diagnostics®)**
- **HelioHCC™Strat and HelioHCC™Trace, (Helio Genomics®)**
- **HelioLiver™ Test (Fulgent Genetics, LLC, Helio Health, Inc)-** May be covered for Medicare plans upon

claims review

- **Hypoxic BioChip Adhesion (BioChip Labs™)**
- **IBSchek® (Commonwealth Diagnostics International, Inc)**
- **ibs-smart™ (Germelli Biotech)**
- **IGoCheck™ (Blood-Based Colorectal Cancer Test) (Milagen, Inc)**
- **IVD CAPSULE PSP (Rapid Sepsis Test, Abionic SA)**
- **IMMray® PanCan-d (Immunovia, Inc)**
- **Immunoscore® (HalioDx)**
- **inFoods® IBS, (Ethos Laboratories)**
- **IntelliSep® Test, (Cytovale®)**
- **Intrinsic Hepcidin IDx™ Test (IntrinsicDx)**
- **IriSight CNV Analysis (Variantyx Inc)**
- **i-STAT TBI (Abbott Point of Care)**
- **Johns Hopkins Metagenomic Next- Generation Sequencing Assay for Infectious Disease Diagnostics (Johns Hopkins Medical Microbiology Laboratory)**
- **Kelch-Like Protein Screening Test (PSE) (Mayo Clinic)**
- **Diabetes Risk Test (Kihealth Inc®)**
- **Labcorp® Plasma Complete™ (Labcorp)**
- **LC-MS/MS Targeted Proteomic Assay (OncoOmicDX Laboratory, LDT)**
- **LifeScale Gram Negative Kit (LSGN) with Lifescale AST system, (Affinity Biosensors, LLC)**
- **Lyme Borrelia Nanotrap® Urine Antigen Test (Galaxy Diagnostics, Inc)**
- **Liposcale® (CIMA Sciences, LLC)**
- **LiverFAST™ (Fibronostics)**
- **LRP4 Cell-Based Assay (Neurocode USA, Inc)**
- **LucentAD™ Complete (Quanterix Corporation)**
- **LucentAD p-Tau 217 (Quanterix Corporation)** Deleted 01/01/2026
- **LungOI (Imagene)**
- **Malasorption Evaluation Panel (Mayo Clinic)**
- **MammoCheck™ (Blood-Based Breast Cancer Test) (Milagen, Inc)**
- **MCED Tests (multi-cancer early detection tests). Example: GRAIL Test (Galleri) Currently in review by Medicare. Not FDA approved. Current coding (81479, 81599). Cancerguard ™(Exact Science) MCED (multicancer detection test) under development- clinical trial and not FDA approved.**
- **Mechanical Fragility, RBC by shear stress profiling and spectral analysis (Functional Fluidics)**
- **MeMed BV® (MeMed Diagnostics, Ltd)**
- **Merlin™ Test (SkylineDx USA, Inc)**
- **MI-HEART Ceramides, Plasma (Mayo Clinic) -** May be covered for Medicare plans depending on jurisdiction
- **M-InSight Patient Definition Assay (Corgenix Clinical Laboratory)** Being deleted as of 10/01/2025.
- **M-inSight Patient Follow-Up Assessment (Corgenix Clinical Laboratory)** Being deleted as of 01/01/2025.
- **Merkel SmT Oncoprotein Antibody Titer (University of Washington, Department of Laboratory**

Medicine)

- **Merkel Virus VP1 Capsid Antibody (University of Washington, Department of Laboratory Medicine)**
- **MiCheck® Prostate (Minomic®, Inc)**
- **MindX One™ Blood Test - Anxiety (MindX Sciences)**
- **myOLARIS™-KTdx (Olaris®, Inc)**
- **NanoDetect-TB™ (NanoPin Technologies, Inc)**
- **NASHnext™ (NIS4TM) (Labcorp)**
- **NaviDKD™ Predictive Diagnostic Screening for Kidney Health (Journey Biosciences, Inc)**
- **Neurofilament Light Blood Test (Neurocode USA, Inc) (Fujirebio Diagnostics, Inc)**
- **Neurofilament Light Chain(Nfl), digital immunoassay (Neuromuscular Clinical Lab at Washington University in St Louis School of Medicine)-** Code Deleted 1/1/2026
- **Neurofilament Light Chain(Nfl), ultra-sensitive immunoassay (Neuromuscular Clinical Lab at Washington University in St Louis School of Medicine)**
- **NeXGenTM Fungal/AFB NGS Assay (Eurofins Viracor, LLC)**
- **Nodify CDT® (Biodesix, Inc)**
- **Normoxic BioChip Adhesion (BioChip Labs™)**
- **NPDX ASD ADM Panel I and ASD Panel III Tests (Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX)**
- **NPDX ASD and Central Carbon Energy Metabolism (Stemina Biomarker Discovery, Inc)**
- **OmniGraf® (EurofinsTransplant Genomics, LLC)**
- **Omnipathology Orophayngeal HPV PCR Test (OmniPathology Solutions)**
- **OncoAssure™ Prostate (DiCarta, Inc)**
- **Oncuria® Detect, Oncuria® Monitor and Oncuria® Predict tests (DiaCarta Clinical Lab, Diacarta, Inc)**
- **OptiSeq™ Colorectal Cancer NGS Panel (DiaCarta, Inc)**
- **OptiSeq™ Dual Cancer Panel Kit (DiaCarta, Inc)**
- **Onco4D™ (Animated Dynamics, Inc)**
- **OncobiotaLUNG (Micronoma™)**
- **Oral Oncolytic Assurance RX (Firstox Laboratories, LLC)**
- **Osmotic Gradient Ektacytometry (Cincinnati Children's Clinical Laboratories)**
- **OvaWatch℠ (Aspira Women's Health™, Aspira Labs, Inc)**
- **OVERA® (OVA1 Next Generation) (Aspira Labs, Inc, Vermillion, Inc)**
- **OWLiver® (CIMA Sciences, LLC)**
- **PanGIA Prostate (Genetics Institute of America)**
- **PancreaSure™ (Immunovia, Inc)**
- **Paris (Tempus AI, Inc)**
- **PEPredictDx (OncoOmicsDx Laboratory, mProbe)**
- **PFAS, Panel 2-24 (Forever Chemicals, Quest Diagnostics)**
- **PFAS 9-Panel (Forever Chemicals)**
- **PFAS Testing & PFASure™ (National Medical Services, NMS Labs, Inc)**
- **PFAS Testing &PFASure® FT (National Medical Services, NMS Labs)**

- **PGDx elio™ plasma focus Dx (Personal Genome Diagnostics, Inc)**
- **Phenylalanine and Tyrosine, Self-Collect, Blood Spot (Mayo Clinic, Laboratory Developed Test)**
- **PIGF Preeclampsia Screen (PerkinElmer Genetics, Inc)**
- **Preeclampsia sFlt1/PIGF Ratio (PERA) (Mayo Clinic)**
- **PreciseDx™ Breast Biopsy Test (PreciseDx)**
- **PreciseDX™ Breast Cancer Test (PreciseDx)**
- **PrecisView® CNS (Phenomics Health inc™)**
- **PrecivityAD® and PrecivityAD2™® (C2N Diagnostics, LLC)**
- **Precivity-ApoE™ (C2N Diagnostics, LLC)**
- **PredicineATLAS™ Assay (Predicine Inc)**
- **PredicineCARE™ Assay (Predicine Inc)**
- **Prenatal Detect RhD (Devyser Genomic Laboratories)**
- **PreTRM® (Sera Prognostics, Inc®)**
- **Procise ADL™ (ProciseDx, Inc))**
- **Procise IFFX™ (ProciseDx, Inc)**
- **PolyDX™ (Atlantic Diagnostic Laboratories)**
- **PromarkerD (Sonic Reference Laboratory, Proteomics International Pty Ltd)**
- **Proofer '7HPVMRNA E6 & E7 Biomarker Test (Global Diagnostic Labs, LLC, PrecTect as a Mel-Mount Medical, Inc subsidiary)**
- **PROphet® NSCLC Test (OncoHost, Inc)**
- **Prospera™ (Natera™)**
- **ProsTAV® (Life Length S.L.)**
- **PROSTOX™ ultra (MiraDx, Inc)**
- **PurISTSM (Tempus AI, Inc)**
- **QuantiDNA™ Colorectal Cancer Triage Test (DiaCarta, Inc)**
- **REVEAL Lung Nodule Characterization (MagArray, Inc)**
- **Resolution ctDx Lung™ (Resolution Bioscience, Inc)**
- **RNA Salah Targeted Expression Panel (Moffitt Cancer Center Advanced Diagnostics Laboratory)**
- **SafeDrugs (Astraeus Lab, LLC)**
- **Sensieva™ Droplet 250H Vitamin D2/D3 Microvolume LC/MS Assay (Insource Diagnostics)**
- **Seronegative Rheumatoid Arthritis Panel (KSL Diagnostics-Beutner Laboratories Inc, KSL Diagnostics Inc)**
- **PreClara™ Ratio (sFlt-1/PIGF) (Thermo Fisher Scientific)**
- **Single Cell Prenatal Diagnosis (SCPD) Test (Luna Genetics, Inc)**
- **SLE-key® Rule Out (Veracis, Inc)**
- **SmartHealth Vascular Dx™ (Morningstar Laboratories, LLC, SmartHealth DX)**
- **Snapshot Oral Fluid Compliance (Ethos Laboratories)**
- **Spatial Frequency Domain Imaging (SFDI) (Modulated Imaging, Inc.)**
- **Stockholm3 (BioAgilytix Diagnostics)**
- **SAAmplify™ Test (Amprion Clinical Laboratory)**

- **SLL Comprehensive Drug Anaalysis (Soft Landing Labs)**
- **Synovasure® Comprehensive PJI test Panel with SYN Tuition™ (CD Laboratories Inc)**
- **SyncView® Pain (Phenomics Health™, Inc)**
- **SyncView® PainPlus (Phenomics Health™, Inc)**
- **SyncView® Rx (Phenomics Health™, Inc)**
- **Taq Array Card Urinary Tract Infection PCR Panel, (SoftCell Laboratories, LLC)**
- **Tempus p-MSI (Tempus AI, Inc)**
- **Tempus p-Prostate (Tempus AI, Inc)**
- **Theralink® Reverse Phase Protein Array (RPPA) (Theralink® Technologies, Inc)**
- **Tissue Specific Markers for Early Diagnosis of Sjogren's Disease (KSL Diagnostics Inc)**
- **TissueCypher® Barrett's Esophagus Assay (Ceranostics)**
- **TriVerity™ (Inflammatix™, Inc)**
- **Tryptase Gene Copy Number Analysis (Virant Diagnostics, Inc)**
- **Tru-Immune™ (Ethos Laboratories)**
- **Tyrosinemia Follow-Up Panel, Self-Collect, Blood Spot (Mayo Clinic, Laboratory Developed Test)**
- **UncompliDx (Elite Medical Laboratory Solution LLC)**
- **UNITY Fetal Antigen™ NIPT (BillionToOne Laboratory, BillionToOne Inc)**
- **Unity Fetal Risk Screen™ (BillionToOne Laboratory, BillionToOne Inc)**
- **Urinary Tract Infection Testing (NxGen MDx LLC)**
- **UriFind® Urothelial Carcinoma Assay (DiCatra, Inc)**
- **UroAMP MRD (Convergent Genomics, Inc)**
- **UrSure Tenofovir Quantification Test**: **(Synergy Medical Laboratories) -** Check for Medicare coverage
- **Vaginal Infection Testing (NxGen MDx LLC)**
- **VAP Cholesterol Test, (VAP Diagnostics Laboratory, Inc)**
- **Very-Long Chain AcylCoA Dehydrogenase (VLCAD) Enzyme Activity (Children's Hospital Colorado Laboratory)**
- **Versiti™ Heparin-Induced Thrombocytopenia Evaluation-PEA, Versiti™ Diagnostic Laboratories**

CODING GUIDELINES:

This list of codes is not intended to be all-inclusive as the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) update and release code information occur more frequently than The Health Plan policy updates. Codes that are not active on date of service may not be eligible for reimbursement.

0020M	Oncology (central nervous system), analysis of 30000 DNA methylation loci by methylation array, utilizing DNA extracted from tumor tissue, diagnostic algorithm reported as probability of matching a reference tumor subclass	Epignostix CNS Tumor Methylation Classifier, Heidelberg Epignostix GmbH
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	PreciseType® HEA Test, Immucor, 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.	PolypDX™ , Atlantic Diagnostic Laboratories, LLC, Metabolomic Technologies, 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 Medicare requires providers to bill 81500 for ROMA™ Medicare requires providers to bill 81503 for OVA1®	Overa (OVA1 Next Generation), Aspira Labs, Inc, Vermillion, 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	ExosomeDx® Prostate (IntelliScore) , Exosome Diagnostics, Inc
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	ToxProtect, Genotox Laboratories LTD
0008U	Helicobacter pylori detection and antibiotic resistance, dna, 16s and 23s rrna, gyra, pbp1, rdxa and rpob, next generation sequencing, formalin-fixed paraffin-embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin	AmHPR® H. pylori Antibiotic Resistance Panel, American Molecular Laboratories, Inc
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	DEPArray™ HER2, PacificDx
0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogeneticbased report of strain relatedness, per submitted isolate	Bacterial Typing by Whole Genome Sequencing, Mayo Clinic
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	Cordant CORE™ , Cordant Health Solutions
0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood	BCR-ABL1 major and minor breakpoint fusion transcripts , University of Iowa, Department of Pathology, Asuragen

	or bone marrow, report of fusion not detected or detected with quantitation	
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	JAK2 Mutation, University of Iowa, Department of Pathology
0018U	Transplantation medicine (allograft rejection, renal), measurement of donor and third-partyinduced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	ThyraMIR™, Interpace Diagnostics
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	OncoTarget/OncoTreat, Columbia University Department of Pathology and Cell Biology, Darwin Health
0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTRBMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score;	Apifiny®, Armune BioScience, Inc
0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider	Oncomine™ Dx Target Test, Thermo Fisher Scientific
0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or nondetection of FLT3 mutation and indication for or against the use of midostaurin	LeukoStrat®CDx FLT3 Mutation Assay, LabPMM LLC, an Invivoscribe Technologies, Inc Company,
0024U	Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative	GlycA, Laboratory Corporation of America
0025U	Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative	UrSure Tenofovir Quantification Test, Synergy Medical Laboratories, UrSure Inc
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") (For the Thyroseq Genomic Classifier, by CBL Path Inc.)	Thyroseq Genomic Classifier, CBLPath, Inc, University of Pittsburgh Medical Center

0027U	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15	JAK2 Exons 12 to 15 Sequencing, 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)	Focused Pharmacogenomics Panel, Mayo Clinic
0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823)	Warfarin Response Genotype, Mayo Clinic
0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)	Cytochrome P450 1A2 Genotype, Mayo Clinic
0032U	COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant	Catechol-O- Methyltransferase (COMT) Genotype, Mayo Clinic
0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.6142211T>C], HTR2C rs3813929 [c.- 759C>T] and rs1414334 [c.551-3008C>G])	Serotonin Receptor Genotype (HTR2A and HTR 2C), Mayo Clinic Deleted 01/01/2026
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)	Thiopurine Methyltransferase (TPMT) and Nudix Hydrolase (NUDT15), Mayo Clinic
0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking induced conformational conversion, qualitative For additional PLA code with identical clinical descriptor, see 0584U.	Real-time quaking- induced conversion for prion detection (RT-QuIC), National Prion Disease Pathology Surveillance Center
0036U	Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses	ExaCT-1 Whole Exome Testing, Lab of Oncology- Molecular Detection, Weill Cornell Medicine-Clinical Genomics Laboratory
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	FoundationOne CDx™ (F1CDx), Foundation Medicine, Inc
0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative	Sensieva™ Droplet 25OH Vitamin D2/ D3 Microvolume LC/MS Assay, InSource Diagnostics

0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	Anti-dsDNA, High Salt/ Avidity, University of Washington, Department of Laboratory Medicine, Bio-Rad
0040U	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative	MRDx BCR-ABL Test, MolecularMD
0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	Lyme ImmunoBlot IgM, IgeneX Inc, ID-FISH Technology Inc (ASR) (Lyme ImmunoBlot IgM Strips Only)
0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	Lyme ImmunoBlot IgG, IgeneX Inc, ID-FISH Technology Inc (ASR) (Lyme ImmunoBlot IgG Strips Only)
0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups by immunoblot, IgM	Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgM Test , IgeneX Inc, ID-FISH Technology Inc (Provides TBRF ImmunoBlot IgM Strips)
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups by immunoblot, IgG	Tick-Borne Relapsing Fever (TBRF) Borrelia ImmunoBlots IgG Test, IgeneX Inc, ID-FISH Technology Inc (Provides TBRF ImmunoBlot IgG Strips)
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by realtime RTPCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score	The Oncotype DX® Breast DCIS Score™ Test, Genomic Health, Inc
0046U	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative	FLT3 ITD MRD by NGS, LabPMM LLC, an Invivoscribe Technologies, Inc Company
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	Genomic Prostate Score® (GPS) Test, MDxHealth, Inc.
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)	MSK-IMPACT, Integrated Mutation Profiling of Actionable Cancer Targets, Memorial Sloan Kettering Cancer Center
0049U	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative	NPM1 MRD by NGS, 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	MyAML NGS Panel, LabPMM LLC, an Invivoscribe Technologies, Inc Company
0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service	UcompliDx, Elite Medical Laboratory Solutions, LLC
0052U	Measurement of all five major lipoprotein classes and subclasses in blood	VAP Cholesterol Test, VAP Diagnostics Laboratory, Inc
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	AssuranceRx Micro Serum, Firstox Laboratories, LLC
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma	myTAIHEART, TAI Diagnostics, Inc
0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative	Merkel SmT Oncoprotein Antibody Titer, 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	Merkel Virus VP1 Capsid Antibody, University of Washington, Department of Laboratory Medicine
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood. Not covered as a screening tool in the general population	Twins Zygosity PLA, Natera, Inc
0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin	Spatial Frequency Domain Imaging (SFDI) by Modulated Imaging, Inc.
0062U	Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score	SLE-key® Rule Out, Veracis Inc
0063U	Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder [metabolomic analysis of blood samples]	NPDX ASD ADM Panel I, Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX
0064U	Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative	BioPlex 2200 Syphilis Total & RPR Assay, Bio-Rad Laboratories

0065U	Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)	BioPlex 2200 RPR Assay, Bio-Rad Laboratories
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	BBDRisk Dx™ , Silbiotech, 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	MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 6 Candida species, RealTime Laboratories, Inc/ MycoDART, Inc
0069U	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score	miR-31now ™, GoPath Laboratories
0070U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, common and select rare variants (ie, *2, *3, *4, 5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xN)	CYP2D6 Common Variants and Copy Number, 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) Code first 0070U	CYP2D6 Full Gene Sequencing, 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) Code first 0070U	CYP2D6-2D7 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) Code first 0070U	CYP2D7-2D6 Hybrid 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	CYP2D6 trans- duplication/ multiplication nonduplicated gene targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

	is trans) (List separately in addition to code for primary procedure) Code first 0070U	
+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) Code first 0070U	CYP2D6 5' 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) Code first 0070U	CYP2D6 3' gene duplication/ multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test
0077U	Immunoglobulin paraprotein (m-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype	M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry, Mayo Clinic, Laboratory Developed Test
0079U	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (snps), urine and buccal DNA, for specimen identity verification	ToxLok™ , InSource Diagnostics
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	BDX-XL2, Biodesix®, Inc,
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	Next Gen Precision™ Testing, Precision Diagnostics LBN Precision Toxicology, LLC
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 combination	Onco4D™, Animated Dynamics, Inc
0084U	Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens	BLOODchip® ID CORE XT™, Grifols Diagnostic Solutions 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	Accelerate PhenoTest™ BC kit, Accelerate Diagnostics, Inc Do not confuse with CPT 0311U

	inhibitory concentration (MIC)-based antimicrobial susceptibility	Accelerate PhenoTest ® BC kit, AST configuration
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-Heart, 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	Molecular Microscope® MMDx-Kidney, Kashi Clinical Laboratories
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)	Pigmented Lesion Assay DermTech Melanoma Test, DERM-JES Holdings, LLC d/b/a DermTech, LLC
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)	myPath® Melanoma, Castle Biosciences, Inc
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	FirstSightCRC™, CellMax Life
0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy	REVEAL Lung Nodule Characterization, MagArray, Inc
0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected	ComplyRX, Claro Labs
0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis	RCIGM Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine (RCIGM) Broad panel for 0425U
0095U	Eosinophilic esophagitis, 2 protein biomarkers (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	Esophageal String Test™(EST), EnteroTrack™ Labs, EnteroTrack, LLC

0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine	HPV, High-Risk, Male Urine, Molecular Testing Labs
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])	ColoNext®, 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])	BreastNext®, 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])	OvaNext®, Ambry Genetics®
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)	KidneyIntel (Renalytix Inc, NYC, NY)
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	13C-Spirulina Gastric Emptying Breath Test (GEBT), Cairn Diagnostics d/b/a Advanced Breath Diagnostics, LLC
0107U	Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple- step method	Singulex Clarity C. diff toxins A/B assay, Singulex
0108U	Gastroenterology (Barrett's esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative	TissueCypher® Barrett's Esophagus Assay, Ceranostics

	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	
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	MYCODART- PCR™ Dual Amplification Real Time PCR Panel for 4 Aspergillus species, RealTime Laboratories, Inc/ MycoDART, Inc
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	Oral OncolyticAssuranceRX, Firstox Laboratories, LLC
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	Praxis™ Extended RAS Panel, Illumina
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene	MicroGenDX qPCR & NGS For Infection, MicroGenDX
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	MyProstateScore, Lynx DX
0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus	EsoGuard™, Lucid Diagnostics
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	ePlex Respiratory Pathogen (RP) Panel, GenMark Diagnostics, Inc
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	Snapshot Oral Fluid Compliance, Ethos Laboratories
0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate,	Foundation PI℠ , Ethos Laboratories

	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	
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	Eurofins TRAC™ dd- cfDNA, Transplant Genomics Inc,
0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events	MI-HEART Ceramides, Plasma, 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	Lymph3Cx Lymphoma Molecular Subtyping Assay, Mayo Clinic, Laboratory Developed Test
0121U	Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood	Flow Adhesion of Whole Blood on VCAM-1 (FAB-V), Functional Fluidics
0122U	Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood	Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL), Functional Fluidics
0123U	Mechanical fragility, RBC, shear stress and spectral analysis profiling	Mechanical Fragility, RBC by shear stress profiling and spectral analysis, Functional Fluidics
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)	BRCAplus, 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) Code first 81435, 0101U	+RNAinsight™ for ColoNext®, 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) Code first 81435, 0101U	RNAinsight™ for BreastNext®, Ambry Genetics Deleted as of 01/01/2026
+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) Code first 81162, 81432, 0103U	RNAinsight™ for OvaNext®, Ambry Genetics Deleted as of 01/01/2026
+0133U	Hereditary prostate cancer-related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure) Code first 81162	RNAinsight™ for ProstateNext®, 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) Code first 81162, 81432, 81435	RNAinsight™ for CancerNext®, 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) Code first 81162	RNAinsight™ for GYNPlus®, Ambry Genetics Deleted 01/01/2026
+0136U	ATM (ataxia telangiectasia mutated) (eg, ataxia telangiectasia) mRNA sequence analysis (List separately in addition to code for primary procedure) Code first 81408	RNAinsight™ for ATM, 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) Code first 81307	RNAinsight™ for PALB2, 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) Code first 81162	RNAinsight™ for BRCA1/2, Ambry Genetics
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 Fungal Pathogens Panel, 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- Positive Panel, 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	ePlex® BCID Gram- Negative Panel, GenMark Diagnostics, Inc
0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens	Karius® Test, Karius Inc
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	Insight TNBCtype™, Insight Molecular Labs
0154U	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 FGFR3TACC3v3)	therascreen® FGFR RGQ RT-PCR Kit, QIAGEN QIAGEN GmbH
0155U	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)	therascreen® PIK3CA RGQ RT-PCR Kit, QIAGEN QIAGEN GmbH

0156U	Copy number (eg, intellectual disability, dysmorphology), sequence analysis	SMASH™ , New York Genome Center, Marvel Genomics™
+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) Code first 81201	CustomNext + RNA: APC, 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) Code first 81292	CustomNext + RNA: MLH1, Ambry Genetics®
+0159U	MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis s (List separately in addition to code for primary procedure) Code first 81295	CustomNext + RNA: MSH2, 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) Code first 81298	CustomNext + RNA: MSH6, Ambry Genetics®
+0161U	PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary nonpolyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) Code first 81317	CustomNext + RNA: PMS2, 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) Code first 81292, 81295, 81298, 81317, 81435	CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2), Ambry Genetics®
0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto1], 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	BeScreened™-CRC, Beacon Biomedical Inc

0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	ibs-smart™, Gemelli Biotech
0165U	Peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope result and interpretation	VeriMAP™ Peanut Dx – Bead-based Epitope Assay, AllerGenis™ Clinical Laboratory, AllerGenis™ LLC
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	LiverFASt™, Fibronostics
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	NT (NUDT15 and TPMT) genotyping panel, RPRD Diagnostics
0170U	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	Clarifi™, Quadrant Biosciences, Inc
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	MyMRD® NGS Panel, Laboratory for Personalized Molecular Medicine
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	myChoice® CDx, Myriad Genetics Laboratories, Inc
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	Psych HealthPGx Panel, RPRD Diagnostics
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	LC-MS/MS Targeted Proteomic Assay, OncoOmicDx Laboratory, LDT

0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	Genomind® Professional PGx Express™ CORE, Genomind, Inc
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (i.e., ELISA)	IBSchek®, Commonwealth Diagnostics International, Inc
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	therascreen® PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH
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	VeriMAP™ Peanut Reactivity ThresholdBead Based Epitope Assay, AllerGenis™ Clinical Laboratory, AllerGenis™ LLC
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)	Resolution ctDx Lung™, Resolution Bioscience, Inc
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 ABO Sequencing, Grifols Immunohematology Center
0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	Navigator CO Sequencing, Grifols Immunohematology Center
0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	Navigator CROM Sequencing, 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 DI Sequencing, Grifols Immunohematology Center
0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	Navigator DO Sequencing, Grifols Immunohematology Center
0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	Navigator FUT1 Sequencing, Grifols Immunohematology Center

0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	Navigator FUT2 Sequencing, 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 FY Sequencing, Grifols Immunohematology Center
0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	Navigator GE Sequencing, 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 GYPA Sequencing, 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 GYPB Sequencing, Grifols Immunohematology Cente
0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	Navigator IN Sequencing, 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 JK Sequencing, 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 JR Sequencing, Grifols Immunohematology Center
0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	Navigator KEL Sequencing, Grifols Immunohematology Center
0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (i.e., exon 13)	Navigator KLF1 Sequencing, 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 LU Sequencing, 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 LW Sequencing, 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 RHD/CE Sequencing, 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 SC Sequencing, Grifols Immunohematology Center
0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	Navigator XK Sequencing, Grifols Immunohematology Center
0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	Navigator YT Sequencing, Grifols Immunohematology Center
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	BioFire® Respiratory Panel 2.1 (RP2.1), BioFire® Diagnostics, LLC
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	PredictSURE IBD™ Test, KSL Diagnostics, PredictImmune Ltd
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	Vita Risk®, Arctic Medical Laboratories
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	DISCERN™, NeuroDiagnostics
+0207U	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) Code first 0206U	DISCERN™, NeuroDiagnostics
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities	CNGnome™, PerkinElmer Genomics
0210U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	BioPlex 2200 RPR Assay – Quantitative, Bio-Rad Laboratories

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	MI Cancer Seek™ - NGS Analysis, Caris MPI d/b/a Caris Life Sciences
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 Excludes 81425	Genomic Unity® Whole Genome Analysis – Proband, 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) Excludes 81426	Genomic Unity® Whole Genome Analysis – Comparator, 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 Excludes 81415	Genomic Unity® Exome Plus Analysis – Proband,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) Excludes 81416	Genomic Unity® Exome Plus Analysis – Comparator, 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® Ataxia Repeat Expansion and Sequence Analysis, 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® Comprehensive Ataxia Repeat Expansion and Sequence Analysis, 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	Genomic Unity® DMD Analysis, Variantyx Inc
0219U	Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (i.e., protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility	Sentosa ® SQ HIV-1 Genotyping Assay, Vela Operations Singapore Pte Ltd
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	PreciseDX™, Breast Cancer Test, PreciseDx
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	Navigator ABO Blood Group NGS, 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	Navigator Rh Blood Group NGS, Grifols Immunohematology Center
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	QIAstat-Dx Respiratory SARS CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed	COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory
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	ePlex® Respiratory Pathogen Panel 2, GenMark Dx, GenMark Diagnostics, Inc

0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum	Tru-Immune™ , Ethos Laboratories, GenScript® USA Inc
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	Comprehensive Screen, Aspenti Health
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	PanGIA Prostate, Genetics Institute of America, Entopsis, LLC
0229U	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis	Colvera®, Clinical Genomics Pathology 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® AR Analysis, 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® CACNA1A Analysis, 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® CSTB Analysis, 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® FXN Analysis, 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	Genomic Unity® MECP2 Analysis, 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® PTEN Analysis, Variantyx Inc
0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions	Genomic Unity® SMN1/2 Analysis, 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® Cardiac Ion Channelopathies Analysis, 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	Genomic Unity® Lynch Syndrome Analysis, Variantyx 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	FoundationOne® Liquid CDx, Foundation Medicine, 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	Guardant360® CDx, Guardant Health Inc
0243U	Time-resolved fluorescence immunoassay of placental-growth factor in maternal serum to evaluate risk of preeclampsia	PlGF Preeclampsia Screen, PerkinElmer Genetics, Inc

0244U	Gene analysis of 257 genes associated with solid organ cancer in tumor tissue sample, comprehensive genomic profiling	Oncotype MAP™ Pan-Cancer Tissue Test, Paradigm Diagnostics, Inc
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	ThyGeNEXT® Thyroid Oncogene Panel, Interpace Diagnostics
0246U	Red blood cell antigen typing, DNA, genotyping for 16 or more blood groups with phenotype prediction of 51 or more red blood cell antigens	PrecisionBlood™ , San Diego Blood Bank
0247U	Quantitative measurement of insulin-like growth factor-binding protein 4 and sex hormone-binding globulin (SHBG) in maternal serum by LC-MS/MS to evaluate risk of premature birth	PreTRM®, Sera Prognostics, Inc®
0248U	Oncology, spheroid cell culture in a 3D microenvironment, 12 drug panel, brain- or brain metastasis-response prediction for each drug	3D Predict Glioma, KIYATEC®, Inc
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	Theralink® Reverse Phase Protein Array (RPPA), Theralink® Technologies, 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	PGDx elio™ tissue complete, Personal Genome Diagnostics, Inc
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	Intrinsic Hepcidin IDx™ Test, IntrinsicDx, Intrinsic LifeSciences™ LLC
0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/ duplications, mosaicism, and segmental aneuploidy	POC (Products of Conception), 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)	ERA® (Endometrial Receptivity Analysis), 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/ duplications, mosaicism, and segmental aneuploidy, per embryo tested	SMART PGT-A (Pre-implantation Genetic Testing – Aneuploidy), Igenomix® USA
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	Cap-Score™ Test, Androvia LifeSciences, Avantor Clinical Services (previously known as Therapak)
0256U	Trimethylamine/trimethylamine N-oxide (TMA/ TMAO) profile, tandem mass spectrometry (MS/ MS), urine, with algorithmic analysis and interpretive report	Trimethylamine (TMA) and TMA N-Oxide, Children's Hospital Colorado Laboratory
0257U	Very long chain acyl-coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood	Very-Long Chain AcylCoA Dehydrogenase (VLCAD) Enzyme Activity, Children's Hospital Colorado Laboratory
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	Mind.Px, Mindera Corporation
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	GFR by NMR, Labtech™ Diagnostics
0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping *Has an identical descriptor	Augusta Optical Genome Mapping, Georgia Esoteric and Molecular (GEM) Laboratory, LLC, Bionano Genomics Inc
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	Immunoscore®, HalioDx

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	OncoSignal 7 Pathway Signal, Protean BioDiagnostics, Philips Electronics Nederland BV
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 (LCMS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	NPDX ASD and Central Carbon Energy Metabolism, Stemina Biomarker Discovery, Inc
0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping. *Has an identical descriptor	Praxis Optical Genome Mapping, 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 Whole Genome Sequencing, 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 Transcriptome, 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	Praxis Combined Whole Genome Sequencing and Optical Genome Mapping, Praxis Genomics LLC
0268U	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	Versiti™ aHUS Genetic Evaluation, Versiti™ Diagnostic Laboratories, Versiti™
0269U	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 22 genes, blood, buccal swab, or amniotic fluid	Versiti™ Autosomal Dominant Thrombocytopenia Panel, Versiti™ Diagnostic Laboratories, Versiti™

0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid	Versiti™ Coagulation Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™
0271U	Hematology (congenital neutropenia), genomic sequence analysis of 24 genes, blood, buccal swab, or amniotic fluid	Versiti™ Congenital Neutropenia Panel, Versiti™ Diagnostic Laboratories, Versiti™
0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 60 genes and duplications/deletion of *PLAU*, blood, buccal swab, or amniotic fluid, comprehensive	Versiti™ Comprehensive Bleeding Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™
0273U	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU), blood, buccal swab, or amniotic fluid	Versiti™ Fibrinolytic 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™ Comprehensive Platelet Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™
0275U	Hematology (heparin-induced thrombocytopenia), platelet antibody reactivity by flow cytometry, serum	Versiti™ Heparin- Induced Thrombocytopenia Evaluation – PEA, Versiti™ Diagnostic Laboratories, Versiti™
0276U	Hematology (inherited thrombocytopenia), genomic sequence analysis of 42 genes, blood, buccal swab, or amniotic fluid	Versiti™ Inherited Thrombocytopenia Panel, Versiti™ Diagnostic Laboratories, Versiti™
0277U	Hematology (genetic platelet function disorder), genomic sequence analysis of 40 genes and duplication/detection of *PLAU*, blood, buccal swab, or amniotic fluid	Versiti Platelet Function Disorder Panel, Versiti™Diagnostic Laboratories, Versiti™
0278U	Hematology (genetic thrombosis), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	Versiti™ Thrombosis Panel, 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 III 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 Collagen IV Binding, 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™ VWF Propeptide Antigen, 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™ Red Cell Genotyping Panel, Versiti™ Diagnostic Laboratories, Versiti™
0283U	von Willebrand factor (VWF), type 2B, platelet-binding evaluation, radioimmunoassay, plasma	Versiti™ VWD Type 2B Evaluation, Versiti™ Diagnostic Laboratories, Versiti™
0284U	von Willebrand factor (VWF), type 2N, factor VIII and VWF binding evaluation, enzyme linked immunosorbent assays (ELISA), plasma	Versiti™VWF Type 2N Binding, Versiti™ Diagnostic Laboratories, Versiti™
0285U	Oncology, disease progression and response monitoring to radiation, chemotherapy, or other systematic cancer treatments, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported in ng/mL	RadTox™ cfDNA test, DiaCarta Clinical Lab, DiaCarta Inc
0286U	CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	CNT (CEP72, TPMT and NUDT15) genotyping panel, RPRD Diagnostics
0287U	Oncology (thyroid), DNA and mRNA, nextgeneration sequencing analysis of 112 genes, fine needle aspirate or formalinfixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)	ThyroSeq® CRC, CBLPath, Inc, University of Pittsburgh Medical Center
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	RiskReveal™, Razor Genomics
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™ Memory/ Alzheimer's, 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™ - Pain, 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™ - Mood, 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	MindX Blood Test™ - Stress, 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™ - Suicidality, 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	MindX Blood Test™ - Longevity, MindX Sciences™ Laboratory, MindX Sciences™ In
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	DCISionRT®, PreludeDx™, Prelude Corporation
0296U	Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy	mRNA CancerDetect™, Viome Life Sciences, Inc
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 Whole Genome Sequencing, 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 Transcriptome, 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 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	Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping, Praxis Genomics LLC
0301U	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR)	Bartonella ddPCR, 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	Bartonella Digital ePCR™, Galaxy Diagnostics, Inc
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	Hypoxic BioChip Adhesion, 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	Normoxic BioChip Adhesion, 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	Ektacytometry, BioChip Labs™
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	Invitae PCM Tissue Profiling and MRD Baseline Assay, 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	Invitae PCM MRD Monitoring, Invitae Corporation
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 CADhs®, Complete Omics, Inc, 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 CVE®, Complete Omics, Prevencio, Inc

0310U	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NTproBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD	HART KD®, Complete Omics, Prevencio, Inc
0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility for each organ identified	Accelerate PhenoTest® BC kit, AST configuration, Accelerate Diagnostics, Inc Do not confuse with CPT code 0086U.
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	Avise® Lupus, Exagen Inc
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)	PancreaSeq® Genomic Classifier, Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center
0314U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-nfixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)	DecisionDx® DiffDx™-Melanoma, 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)	DecisionDx®-SCC, Castle Biosciences, Inc
0316U	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine	Lyme Borrelia Nanotrap® Urine Antigen Test, Galaxy Diagnostics Inc
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	LungLB®, LungLife AI®
0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood	EpiSign Complete, Greenwood Genetic Center

0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection	Clarava™, Verici Dx, Verici Dx, Inc
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using post transplant peripheral blood, algorithm reported as a risk score for acute cellular rejection	Tuteva™ , Verici Dx, Verici Dx, Inc
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.	Bridge Urinary Tract Infection Detection and Resistance Test, Bridge Diagnostics
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	NPDX ASD Test Panel III, Stemina Biomarker Discovery d/b/a NeuroPointDX
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	Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics, Johns Hopkins Medical Microbiology Laboratory
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	Guardant360®, Guardant Health, 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	Vasistera™ , Natera, Inc
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	CareView360, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, icrosatellite instability and tumor mutational burden utilizing DNA and RNA from	Oncomap™ ExTra, Exact Sciences, Inc, Genomic Health Inc

	tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations	
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab	Bridge Women's Health Infectious Disease Detection Test, Bridge Diagnostics, Thermo Fisher and Hologic Test Kit on Panther Instrument
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	Augusta Hematology Optical Genome Mapping, Georgia Esoteric and Molecular Labs, Augusta University, Bionano
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	EpiSwitch® CiRT (Checkpoint-inhibitor Response Test), Next Bio-Research Services, LLC, Oxford BioDynamics, PLC
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	HelioLiver™ Test, Helio Genomics®
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	Guardant360 Tissue Next™, Guardant Health, 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 – Proband, 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	IriSight™ Prenatal Analysis – Comparator, Variantyx, Inc

	repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent)	
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® Circulating Multiple Myeloma Cell (CMMC) Test, 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	CELLSEARCH® HER2 Circulating Tumor Cell (CTC- HER2) Test, Menarini Silicon Biosystems, 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	SelectMDx® for Prostate Cancer, MDxHealth®, 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	Signatera™, Natera, 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	Single Cell Prenatal Diagnosis (SCPD) Test, Luna Genetics, 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	IMMray® PanCan-d, Immunovia, Inc
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	miR Sentinel™ Prostate Cancer Test, miR Scientific, LLC
0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid	OWLiver®, CIMA Sciences, LLC

	markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis	
0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	GeneSight® Psychotropic, Assurex Health, Inc, Myriad Genetics, Inc
0347U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 16 gene report, with variant analysis and reported phenotypes	RightMed® PGx16 Test, 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 Exclude F2 and F5, 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® Comprehensive Test, 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	RightMed® Gene Report, OneOme®, LLC
0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, or venous whole blood, algorithm reported as likelihood of bacterial infection	MeMed BV®, MeMed Diagnostics, Ltd
0355U	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)	Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping, Quest Diagnostics®
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	NavDx®, Naveris, Inc
0358U	Neurology (mild cognitive impairment), analysis of B-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative	Lumipulse® G ß-Amyloid Ratio (1-42/ 1-40) Test, Fujirebio 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	IsoPSA®, Cleveland Diagnostics, 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	Nodify CDT®, Biodesix, Inc
0361U	Neurofilament light chain, digital immunoassay, plasma, quantitative	Neurofilament Light Chain (NfL), Mayo Clinic Deleted 01/01/2026
0362U	Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture–enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes	Thyroid GuidePx®, Protean BioDiagnostics, Qualisure Diagnostics
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	Cxbladder™ Triage, Pacific Edge Diagnostics USA, Ltd
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	clonoSEQ® Assay , Adaptive Biotechnologies
0365U	Oncology (bladder), 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA), by immunoassays, urine, diagnostic algorithm, including patients age, race, and gender, reported as a probability of harboring urothelial cancer	Oncuria® Detect, 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® Monitor, 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	Oncuria® Predict, 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	ColoScape™ Colorectal Cancer Detection, DiaCarta Clinical Lab, DiaCarta, Inc
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, Lifescan Labs of Illinois, Thermo Fisher Scientific
0372U	Infectious disease (genitourinary detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score	Qlear UTI – Reflex ABR, Lifescan Labs of Illinois, Thermo Fisher Scientific
0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [i.e., transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score	OvaWatch℠ , Aspira Women's Health℠, Aspira Labs, 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	ArteraAI Prostate Test, Artera Inc®
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)	Liposcale®, CIMA Sciences, LLC
0378U	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat -primed PCR, blood, saliva, or buccal swab	UCGSL RFC1 Repeat Expansion Test, University of Chicago Genetic Services Laboratories
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	Solid Tumor Expanded Panel, Quest Diagnostics®

0381U	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement oa allo-isoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry(LC-MS/MS)	Branched-Chain Amino Acids, 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)	Phenylalanine and Tyrosine, 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	Tyrosinemia Follow-Up Panel, Self-Collect, Blood Spot, Mayo Clinic, Laboratory Developed Test
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	NaviDKD™ Predictive Diagnostic Screening for Kidney Health, Journey Biosciences, Inc
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	PromarkerD, Sonic Reference Laboratory, Proteomics International Pty Ltd
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	AMBLor® melanoma prognostic test, Avero® Diagnostics
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	InVisionFirst®-Lung Liquid Biopsy, Inivata, Inc
0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha-inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD	KawasakiDx, 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	PEPredictDx, OncoOmicsDx Laboratory, mProbe
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	Strata Select™, Strata Oncology, Inc
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	Medication Management Neuropsychiatric Panel, RCA Laboratory Services LLC d/b/a GENETWORx, GENETWORx
0393U	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative	SAAmplify™-aSYNT, Amprion® Clinical Laboratory
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	PFAS Testing & PFASure™, National Medical Services, NMS Labs, Inc
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	OncobiotaLUNG, Micronoma™
0398U	Gastroenterology (Barrett 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	ESOPREDICT® Barrett's Esophagus Risk Classifier Assay, Capsulomics, Inc d/b/a Previse
0399U	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgGbinding 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	FRAT® (Folate Receptor Antibody Test, Religen 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	Genesys Carrier Panel, Genesys Diagnostics, Inc
0401U	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event	CARDIO inCode-Score (CIC-SCORE), GENinCode U.S. 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	Abbott Alinity™ m STI Assay, Abbott Molecular, Inc CT/NG/TV/MG
0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch urine, algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer	MyProstateScore 2.0, LynxDX
0404U	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression	DiviTum®TKa, Biovica Inc, Biovica International AB
0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected	BTG Early Detection of Pancreatic Cancer, Breakthrough Genomics providence NC
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	CyPath® Lung, Precision Pathology Services, bioAffinity Technologies, Inc
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	KidneyintelX.dkd™, Renalytix Inc, NYC, NY
0408U	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrode	Omnia™ SARSCoV-2 Antigen Test, Qorvo Biotechnologies,

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	LiquidHALLMARK®, Lucence Health, Inc Analyzes circulating cell-free DNA and RNA from plasma specimens. This is not 0530U.
0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected	Avantect™ Pancreatic Cancer Test, ClearNote™ Health
0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	IDgenetix®, Castle Biosciences, Inc
0412U	Beta amyloid, AB42/40 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	PrecivityAD® blood test, C2N Diagnostics LLC
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	DH Optical Genome Mapping/Digital Karyotyping Assay, The Clinical Genomics and Advanced Technology (CGAT) Laboratory at Dartmouth Health, Bionano Genomics
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	LungOI, Imagene
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 [SmartVascular Dx]	SmartHealth Vascular Dx™, Morningstar Laboratories, LLC, SmartHealth DX

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	Genomic Unity® Comprehensive Mitochondrial Disorders Analysis, Variantyx Inc
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	PreciseDx Breast Biopsy Test, PreciseDx, Inc NYC,NY
0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype	Tempus nP, Tempus Labs, Inc
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) of genes TERT and FGFR3, urine, algorithm reported as a risk score for urothelial carcinoma	Cxbladder Triage Plus, Pacific Edge Diagnostics USA LTD
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	Colosense™, Geneoscopy, 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	Guardant 360 Response™, Guardant Health, 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	Genomind® Pharmacogenetics Report – Full, Genomind®, Inc
0424U	Oncology (prostate), exosome- based analysis of 53 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RTqPCR), urine, reported as no molecular evidence, low-,moderate-, or elevated-risk of prostate cancer	miR Sentinel™ Prostate Cancer Test, miR Scientific®, LLC
0425U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings)	RCIGM Rapid Whole Genome Sequencing, Comparator Genome, Rady Children's Institute for Genomic Medicine
0426U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis	RCIGM Ultra-Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine
+0427U	Monocyte distribution width, whole blood (List separately in addition to code for primary procedure). (Use 0427U in conjunction with 85004, 85025)	Early Sepsis Indicator, Beckman Coulter, Inc
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) Use G0476 (Cervical cancer screening, all-inclusive HPV co-test with cytology (Pap smear) allowed once every 5 years . Females ages 30-65 years.	Omnipathology Oropharyngeal HPV PCR Test, OmniPathology Solutions, Medical Corporation
0430U	Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase and reducing substances, feces, quantitative	Malabsorption Evaluation Panel, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic
0431U	Glycine receptor alpha1 IgG, serum or cerebrospinal fluid (CSF), live cell-binding assay (LCBA), qualitative	Glycine Receptor Alpha1 IgG, Mayo Clinic/Mayo Clinic Laboratories
0432U	Kelch-like protein 11 (KLHL11) antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative	Kelch-Like Protein 11 Antibody, Mayo Clinic/Mayo Clinic Laboratories, Mayo Clinic

0433U	Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer	EpiSwitch® Prostate Screening Test (PSE), Oxford BioDynamics Inc, Oxford BioDynamics PLC
0434U	Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes	RightMed® Gene Test Exclude F2 and F5, OneOme® 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	ChemoID®, ChemoID® Lab, Cordgenics, LLC
0436U	Oncology (lung), plasma analysis of 388 proteins, using aptamer-based proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy	PROphet® NSCLC Test, OncoHost, Inc
0437U	Psychiatry(anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers,whole blood, algorithm reported as predictive risk score	MindX One™ Blood Test – Anxiety, MindX Sciences
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	EffectiveRX™ Comprehensive Panel, RCA Laboratory Services LLC d/b/a d/b/a GENETWORx
0439U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/ LOC107986769], rs6820447 [intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD	Epi+Gen CHD™, Cardio Diagnostics, Inc
0440U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) (rs710987 [LINC010019], rs1333048 [CDKN2B-AS1],	PrecisionCHD™, Cardio Diagnostics, Inc

	rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1], cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRR], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported as detected or not detected for CHD	
0441U	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index	IntelliSep® Test, Cytovale®
0442U	Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent	FebriDx® Bacterial/NonBacterial Point-of Care Assay, Lumos Diagnostics, LLC
0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid	Neurofilament Light Chain (NfL), Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine
0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-hyphenfixed paraffin-hyphenembedded (FFPE) tumor tissue, report of clinically significant variant(s)	Aventa FusionPlus™, Aventa Genomics, LLC
0445U	β-amyloid (Abeta42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology	Elecsys® PhosphoTau (181P) CSF (pTau181) and βAmyloid (1-42) CSF II (Abeta 42) Ratio, Roche Diagnostics Operations, Inc (US owner/operator)
0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity	aisle® DX Disease Activity Index, Progentec Diagnostics, Inc

0447U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare	aisle® DX Flare Risk Index, Progentec Diagnostics, Inc
0449U	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (CFTR, SMN1, HBB, HBA1, HBA2)	UNITY Carrier Screen™, BillionToOne Laboratory
0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides Being Deleted 10/01/2025	M-inSight® Patient Definition Assay, Corgenix Clinical Laboratory, Sebia
0451U	Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance Being deleted 10/01/2025	M-inSight® Patient Follow-Up Assessment, Corgenix Clinical Laboratory, Sebia
0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer	EarlyTect® Bladder Cancer Detection (EarlyTect® BCD), Promis Diagnostics, Inc
0453U	Oncology (colorectal cancer), cell-free DNA (cfDNA), methylation based quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)	ColonAiQ®, Breakthrough Genomics, Singlera Genomics, Inc
0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping. *Has an identical descriptor 0260U, 0264U	Chromosome Genome Mapping, UR Medicine Labs, Bionano Genomics, Inc
0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal,	Abbott Alinity™ m STI Assay, Abbott Molecular, Inc CT/NG/TV

	endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected	
0457U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative	PFAS 9- Panel, Quest Diagnostics® Forever Chemicals
0458U	Oncology (breast cancer), S100A8 and S100A9, by enzyme linked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score	Auria®, Namida Lab, Inc
0459U	β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology	Elecsys® Total Tau CSF (tTau) and βAmyloid (1-42) CSF II (Abeta 42) Ratio, Roche Diagnostics Operations, Inc
0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes	RightMed® Oncology Gene Report, OneOme® LLC
0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes	RightMed® Oncology Medication Report, OneOme® LLC
0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary	Salimetrics® Salivary Melatonin Profile (Circadian Phase Assessment), Salimetrics® Clinical Laboratory, Salimetrics®, LLC
0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker	Proofer '7 HPV mRNA E6 and E7 Biomarker Test, Global Diagnostics Labs, LLC, PreTect AS, a Mel-Mont Medical, Inc, wholly owned subsidiary
0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal	Cologuard Plus™, Exact Sciences Laboratories, LLC, Exact Sciences Corporation

	hemoglobin), utilizing stool, algorithm reported as a positive or negative result	
0465U	Oncology (urothelial carcinoma), DNA, quantitative methylation specific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative	UriFind® Urothelial Carcinoma Assay, DiaCarta, Inc, AnchorDx
0466U	Cardiology (coronary artery disease [CAD]), DNA, genome wide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease	CardioRisk+, Gene by Gene, Ltd, OpenDNA, Ltd
0467U	Oncology (bladder), DNA, next generation sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden	UroAmp MRD, Convergent Genomics, Inc
0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis	NASHnext™ (NIS4TM), Labcorp
0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination	IriSight™ CNV Analysis, Variantyx Inc,
0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from	HPV-SEQ Test, Sysmex Inostics, Inc

	plasma	
0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin fixed paraffin-embedded (FFPE), predictive, identification of detected mutations	CRCdx® RAS Mutation Detection Kit, EntroGen, Inc
0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semi-qualitative, blood, reported as predictive evidence of early Sjogren's syndrome	Early Sjögren's Syndrome Profile, Immco Diagnostics, Inc
0473U	Oncology (solid tumor), next generation sequencing (NGS) of DNA from formalin-fixed paraffin embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden	xT CDx, Tempus AI, Inc
0474U	Hereditary pan-cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using next generation sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene	GeneticsNow® Comprehensive Germline Panel, GoPath Diagnostics, Inc
0475U	Hereditary prostate cancer related disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/ deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer	ProstateNow™ Prostate Germline Panel, GoPath Diagnostics, Inc
0476U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder	RightMed® Mental Health Gene Report, OneOme, LLC

0477U	Drug metabolism, psychiatry (eg, major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder [ADHD], schizophrenia), whole blood, buccal swab, and pharmacogenomic genotyping of 14 genes and CYP2D6 copy number variant analysis, including impacted gene-drug interactions and reported phenotypes	RightMed® Mental Health Medication Report, OneOme, LLC
0478U	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) informalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection	Lung HDPCR™, Protean BioDiagnostics
0479U	Tau, phosphorylated, pTau217	ALZpath pTau217, Neurocode USA, Inc, Quanterix/ALZpath
0480U	Infectious disease (bacteria, viruses, fungi, and parasites), cerebrospinal fluid (CSF), metagenomic next-generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification	Bacteria, Viruses, Fungus, and Parasite Metagenomic Sequencing, Spinal Fluid (MSCSF), Mayo Clinic, Laboratory Developed Test
0481U	IDH1 (isocitrate dehydrogenase 1 [NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions)	IDH1, IDH2, and TERT Mutation Analysis, NextGeneration Sequencing, Tumor (IDTRT), Mayo Clinic, Laboratory Developed Test
0482U	Obstetrics (preeclampsia), biochemical assay of soluble fms-like tyrosine kinase 1 (sFlt-1) and placental growth factor (PlGF), serum, ratio reported for sFlt1/PlGF, with risk of progression for preeclampsia with severe features within 2 weeks	Preeclampsia sFlt1/PlGF Ratio (PERA), Mayo Clinic, Laboratory Developed Test
0483U	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance	Ciprofloxacin Susceptibility of Neisseria gonorrhoeae, MedArbor Diagnostics, SpeeDx, Inc

0484U	Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance	Macrolide Resistance of Mycoplasma genitalium, MedArbor Diagnostics, SpeeDx, Inc
0485U	Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden	Caris Assure™, Caris MPI, Inc d/b/a Caris Life Sciences®
0486U	Oncology (pan-solid tumor), next generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction	Northstar Response™, BillionToOne Laboratory, BillionToOne, Inc
0487U	Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidy corrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability	Northstar Select™, BillionToOne Laboratory, BillionToOne, Inc
0488U	Obstetrics (fetal antigen noninvasive prenatal test), cellfree DNA sequence analysis for detection of fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya), or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected	UNITY Fetal Antigen™ NIPT, BillionToOne
0489U	Obstetrics (single-gene noninvasive prenatal test), cellfree DNA sequence analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and relative mutation-dosage analysis based on molecular counts to determine fetal inheritance of maternal mutation, algorithm reported as a fetal risk score for the condition (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)	UNITY Fetal Risk Screen™, BillionToOne Laboratory, BillionToOne, Inc

0490U	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, high molecular–weight melanoma associated antigen, CD34 and CD45 protein biomarkers, peripheral blood	CELLSEARCH® Circulating Melanoma Cell (CMC) Test, Menarini Silicon Biosystems Inc
0491U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker–expressing cells, peripheral blood	CELLSEARCH® ER Circulating Tumor Cell (CTC-ER) Test, Menarini Silicon Biosystems Inc
0492U	Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of PD-L1 protein biomarker expressing cells, peripheral blood	CELLSEARCH® PDL1 Circulating Tumor Cell (CTCPD-L1) Test, Menarini Silicon Biosystems Inc
0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next generation sequencing, plasma, reported as percentage of donor derived cell-free DNA	Prospera™, Natera™
0494U	Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative	Rh Test, Natera™
0495U	Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer	Stockholm3, BioAgilytix Diagnostics
0496U	Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk	ColoScape™ PLUS, DiaCarta, Inc

0497U	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA), utilizing formalin fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer	OncoAssure™ Prostate, DiaCarta, Inc
0498U	Oncology (colorectal), next generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation	OptiSeq™ Colorectal Cancer NGS Panel, DiaCarta, Inc
0499U	Oncology (colorectal and lung), DNA from formalin-fixed paraffin embedded (FFPE) tissue, next generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection	OptiSeq™ Dual Cancer Panel Kit, DiaCarta, Inc
0500U	Autoinflammatory disease (VEXAS syndrome), DNA, UBA1 gene mutations, targeted variant analysis (M41T, M41V, M41L, c.118-2A>C, c.118-1G>C, c.1189_118-2del, S56F, S621C)	QClamp® Plex VEXAS UBA1 Mutation Test, DiaCarta, Inc
0501U	Oncology (colorectal), blood, quantitative measurement of cell free DNA (cfDNA)	QuantiDNA™ Colorectal Cancer Triage Test, DiaCarta, Inc
0502U	Human papillomavirus (HPV), E6/E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV	QuantiVirus™ HPV E6/E7 mRNA Test for Cervical Cancer, DiaCarta, Inc
0503U	Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (pTau217, np-tau217, pTau217/nptau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as likelihood of positive or negative for amyloid plaques	PrecivityAD2™, C2N Diagnostics, LLC
0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, realtime PCR, reported as positive or negative for each organism	Urinary Tract Infection Testing, NxGen MDx LLC
0505U	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or	Vaginal Infection Testing, NxGen MDx LLC

	negative for each organism	
0506U	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus	EndoSign® Barrett's Esophagus Test, Cyted Health Inc
0507U	Oncology (ovarian), DNA, whole genome sequencing with 5hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected	Avantect Ovarian Cancer Test, ClearNote® Health
0508U	Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell free DNA with risk for active rejection	VitaGraft™ Kidney Baseline + 1st Plasma Test, Oncocyte Corporation Deleted 01/01/2026
0509U	Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphisms (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection	VitaGraft™ Kidney Subsequent, Oncocyte Corporation Deleted 01/01/2026
0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole transcriptome data, reported as probability of predicted molecular subtype	PurISTSM, Tempus AI, Inc
0511U	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug	PARIS, Tempus AI, Inc, Tempus AI, Inc (by its wholly owned subsidiary SEngine Precision Medicine, LLC)
0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffinembedded (FFPE) tissue, reported as increased or decreased probability of MSI-high (MSI-H)	Tempus p-MSI, Tempus AI, Inc
0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency	Tempus p-Prostate, Tempus AI, Inc

	(HRD) status, formalin fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker	
0514U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)	Procise ADLTM, ProciseDx Inc
0515U	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of infliximab (IFX) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (µg/mL)	Procise IFX™, ProciseDx Inc
0516U	Drug metabolism, whole blood, pharmacogenomic genotyping of 40 genes and CYP2D6 copy number variant analysis, reported as metabolizer status	MyGenVar Pharmacogenomics Test, Geisinger Medical Laboratories
0517U	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications	PrecisView® CNS, Phenomics Health™ Inc
0518U	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications	SyncView® Pain, Phenomics Health™ Inc
0519U	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LCMS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic minimally effective range of prescribed, non-prescribed, and illicit medications in circulation	SyncView® PainPlus, Phenomics Health™ Inc
0520U	Therapeutic drug monitoring, 200 or more drugs or substances, LCMS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications	SyncView® Rx, Phenomics Health™ Inc

0521U	Rheumatoid factor IgA and IgM, cyclic citrullinated peptide (CCP) antibodies, and scavenger receptor A (SR-A) by immunoassay, blood Effective 01/01/2025	Seronegative Rheumatoid Arthritis Panel, KSL Diagnostics-Beutner Laboratories, Inc, KSL Biomedical, Inc
0522U	Carbonic anhydrase VI, parotid specific/ secretory protein and salivary protein 1 (SP1), IgG, IgM, and IgA antibodies, chemiluminescence, semiqualitative, blood Effective 01/25/25	Tissue Specific Markers for Early Diagnosis of Sjogren's Disease, KSL Diagnostics, Inc
0523U	Oncology (solid tumor), DNA, qualitative, next-generation sequencing (NGS) of single-nucleotide variants (SNV) and insertion/deletions in 22 genes utilizing formalin-fixed paraffin-embedded tissue, reported as presence or absence of mutation(s), location of mutation(s), nucleotide change, and amino acid change	oncoReveal™ CDx, Pillar Biosciences, Inc
0524U	Obstetrics (preeclampsia), sFlt1/PlGF ratio, immunoassay, utilizing serum or plasma, reported as a value	PreClara™ Ratio sFlt-1/PlGF, Thermo Fisher Scientific
0525U	Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug	3D Predict ™Ovarian, KIYATEC®, Inc
0526U	Nephrology (renal transplant), quantification of CXCL10 chemokines, flow cytometry, urine, reported as pg/mL creatinine baseline and monitoring over time	CXCL10 Urine Test, One Lambda™, Inc
0527U	Herpes simplex virus (HSV) types 1 and 2 and Varicella zoster virus (VZV), amplified probe technique, each pathogen reported as detected or not detected	Abbott Alinity™ m HSV 1 & 2 / VZV Assay, Abbott Molecular, Inc
0528U	Lower respiratory tract infectious agent detection, 18 bacteria, 8 viruses, and 7 antimicrobial resistance genes, amplified probe technique, including reverse transcription for RNA targets, each analyte reported as detected or not detected with semiquantitative results for 15 bacteria	BIOFIRE® FILMARRAY® Pneumonia (PN) Panel, bioMérieux
0529U	Hematology (venous thromboembolism [VTE]), genome-wide single-nucleotide polymorphism variants, including F2 and F5 gene analysis, and Leiden variant, by microarray analysis, saliva, report as risk score for VTE	Lifetime Genomics Risk Assessment, VTE, GenomicMD, Inc

0530U	Oncology (pan-solid tumor), ctDNA, utilizing plasma, next generation sequencing (NGS) of 77 genes, 8 fusions, microsatellite instability, and tumor mutation burden, interpretative report for single-nucleotide variants, copy number alterations, with therapy association	LiquidHALLMARK®, Lucence Health, Inc Considered a broad molecular profiling panel test. This is not 0409U.
0531U	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma	NeXGen™ Fungal/AFB NGS Assay, Eurofins Viracor, LLC, Eurofins Viracor, LLC
0532U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome and mitochondrial DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, peripheral blood, buffy coat, saliva, buccal or tissue sample, results reported as positive or negative	Rapid Genome Sequencing Test, University of California San Francisco Genomic Medicine Laboratory
0533U	Drug metabolism (adverse drug reactions and drug response), genotyping of 16 genes (ie, ABCG2, CYP2B6, CYP2C9, CYP2C19, CYP2C, CYP2D6, CYP3A5, CYP4F2, DPYD, G6PD, GGCX, NUDT15, SLCO1B1, TPMT, UGT1A1, VKORC1), reported as metabolizer status and transporter function	UCSF Pharmacogenomics Panel, University of California San Francisco Genomic Medicine Laboratory
0534U	Oncology (prostate), microRNA, single-nucleotide polymorphisms (SNPs) analysis by RT-PCR of 32 variants, using buccal swab, algorithm reported as a risk score	PROSTOX™ ultra, MiraDx, Inc
0535U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative	PFAS Testing & PFASure®FT, National Medical Services (NMS Labs), Laboratory Developed Test
0536U	Red blood cell antigen (fetal RhD), PCR analysis of exon 4 of RHD gene and housekeeping control gene GAPDH from whole blood in pregnant individuals at 10+ weeks gestation known to be RhD negative, reported as fetal RhD status	Prenatal Detect RhD, Devyser Genomic Laboratories, Devyser AB
0537U	Oncology (colorectal cancer), analysis of cell-free DNA for epigenomic patterns, next-generation sequencing, >2500 differentially methylated regions (DMRs), plasma, algorithm reported as positive or negative	Shield™, Guardant Health, Inc
0538U	Oncology (solid tumor), next-generation targeted sequencing analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis of 600 genes, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations,	PredicineATLAS™ Assay, Predicine Inc

	microsatellite instability, tumor mutation burden, reported as actionable variant	
0539U	Oncology (solid tumor), cell-free circulating tumor DNA (ctDNA), 152 genes, next-generation sequencing, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and microsatellite instability, using whole-blood samples, mutations with clinical actionability reported as actionable variant	PredicineCARE™ Assay, Predicine Inc
0540U	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor-derived cell-free DNA to determine probability of rejection	AlloSure®, CareDx® Laboratory, CareDx®, Inc
0541U	Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), serum, algorithm reported as prediction of coronary artery disease (pCAD) score	HDL Reverse Cholesterol Transport Panel with pCAD Score, Quest Diagnostics®
0542U	Nephrology (renal transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus (human polyomavirus 1) using real-time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status	myOLARIS™-KTdx, Olaris®, Inc
0543U	Oncology (solid tumor), next-generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single-nucleotide variants, multi-nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden	TruSight™ Oncology Comprehensive, Illumina, Inc
0544U	Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA, percentage reported as risk for rejection	VitaGraft™ Kidney 2.0, Oncocyte Corporation 01/01/2026
0545U	Acetylcholine receptor (AChR), antibody identification by immunofluorescence, using live cells, reported as positive or negative	AChR Live Cell-Based Assay, Neurocode USA
0546U	Low-density lipoprotein receptor-related protein 4 (LRP4), antibody identification by immunofluorescence, using live cells, reported as positive or negative	LRP4 Cell-Based Assay, Neurocode USA, Inc

0547U	Neurofilament light chain (NfL), chemiluminescent enzyme immunoassay, plasma, quantitative	Neurofilament Light Blood Test, Neurocode USA, Inc, Fujirebio Diagnostics, Inc
0548U	Glial fibrillary acidic protein (GFAP), chemiluminescent enzyme immunoassay, using plasma	Glial Fibrillary Acidic Protein Blood Test, Neurocode USA, Inc, Fujirebio Diagnostics, Inc
0549U	Oncology (urothelial), DNA, quantitative methylated real-time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC)	Bladder CARE™, Pangea Laboratory LLC
0550U	Oncology (prostate), enzyme-linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer	ClarityDx Prostate, Protean BioDiagnostics Deleted 01/01/2026
0551U	Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma	LucentAD p-Tau 217, Quanterix Corporation Deleted 01/01/2026
0552U	Reproductive medicine (preimplantation genetic assessment), analysis for known genetic disorders from trophectoderm biopsy, linkage analysis of disease-causing locus, and when possible, targeted mutation analysis for known familial variant, reported as low-risk or high-risk for familial genetic disorder	PGT-M, Igenomix®, Part of Vitrolife Group™, Igenomix®
0553U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, and a mitochondrial DNA score, results reported as normal/balanced (euploidy/ balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, or mosaic, per embryo tested	Smart PGT-A Plus, Igenomix®,Part of Vitrolife Group, Thermo™, Fisher Scientific
0554U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from trophectoderm biopsy for aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal (euploidy), monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or	Smart PGT-SR , Igenomix®,Part of Vitrolife Group, Thermo™, Fisher Scientific

	inconsistent cohort when applicable, per embryo tested	
0555U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested	Smart PGT-SR Plus, Igenomix®,Part of Vitrolife Group, Thermo™, Fisher Scientific
0556U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	HealthTrackRx Bronchitis, HealthTrackRx, Thermo Fisher Scientific
0557U	Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis, Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism	HealthTrackRx Vaginitis, HealthTrackRx, Thermo Fisher Scientific
0558U	Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression	IGoCheck™ (Blood-Based Colorectal Cancer Test), Milagen,Inc
0559U	Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression	MammoCheck™ (Blood-Based Breast Cancer Test), Milagen, Inc
0560U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood and tumor tissue, baseline assessment for design and construction of a personalized variant panel to evaluate current MRD and for comparison to subsequent MRD assessments	Haystack MRD™ Baseline, Quest Diagnostics®

0561U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to initial assessment to evaluate for MRD	Haystack MRD™ Monitoring, Quest Diagnostics®
0562U	Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (SNVs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free DNA, plasma, reported as presence of actionable variants	PGDx elio™ plasma focus Dx, Personal Genome Diagnostics Inc
0563U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative	BIOFIRE® SPOTFIRE® Respiratory/ Sore Throat (R/ST) Panel – Respiratory Menu, bioMérieux
0564U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative	BIOFIRE® SPOTFIRE® Respiratory/ Sore Throat (R/ST) Panel – Sore Throat Menu, bioMérieux
0565U	Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cell-free DNA, plasma, algorithm reported as cancer signal detected or not detected	EarlyDx MethylScan™ HCC, EarlyDiagnostics Laboratory, EarlyDiagnostics, Inc
0566U	Oncology (lung), qPCR-based analysis of 13 differentially methylated regions (CCDC181, HOXA7, LRRC8A, MARCHF11, MIR129-2, NCOR2, PANTR1, PRKCB, SLC9A3, TBR1_2, TRAP1, VWC2, ZNF781), pleural fluid, algorithm reported as a qualitative result	EPISEEK™ MPE (Malignant Pleural Effusion Detection Test), Precision Epigenomics Inc,
0567U	Rare diseases (constitutional/heritable disorders), whole-genome sequence analysis combination of short and long reads, for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variants	Genomic Unity® 2.0, Variantyx, Inc
0568U	Neurology (dementia), beta amyloid (AB40, AB42, AB42/40 ratio), tau-protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by	LucentAD™ Complete, Quanterix Corporation

	ultra-high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology	
0569U	Oncology (solid tumor), next-generation sequencing analysis of tumor methylation markers (>20000 differentially methylated regions) present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction, if appropriate May be covered for Medicare plans if guidelines are met	Guardant Reveal™, Guardant Health, Inc
0570U	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison	i-STAT TBI, Abbott Point of Care
0571U	Oncology (solid tumor), DNA (80 genes) and RNA (10 genes), by next-generation sequencing, plasma, including single-nucleotide variants, insertions/deletions, copy-number alterations, microsatellite instability, and fusions, reported as clinically actionable variants	LiquidHALLMARK® ctDNA and ctRNA, Lucence Health, Inc
0572U	Oncology (prostate), high-throughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer	ProsTAV®, Life Length S.L.
0573U	Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous	Amplified Sciences PanCystPro™, Amplified Sciences, Inc
0574U	Mycobacterium tuberculosis, culture filtrate protein-10-kDa (CFP-10), serum or plasma, liquid chromatography mass spectrometry (LC-MS)	NanoDetect-TB™, NanoPin Technologies, Inc
0575U	Transplantation medicine (liver allograft rejection), miRNA gene expression profiling by RT-PCR of 4 genes (miR-122, miR-885, miR-23a housekeeping, spike-in control), serum, algorithm reported as risk of liver allograft rejection Effective 10/01/2025	HepatoTrack™, LuminoDx Laboratory,

0576U	Transplantation medicine (liver allograft rejection), quantitative donor-derived cell-free DNA (cfDNA) by whole genome next generation sequencing, plasma and mRNA gene expression profiling by multiplex real-time PCR of 56 genes, whole blood, combined algorithm reported as a rejection risk score Effective 10/01/2025	OmniGraf® Liver, Eurofins Transplant Genomics, LLC
0577U	Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy Effective 10/01/2025	GlycoKnow™ Ovarian, InterVenn Biosciences
0578U	Oncology (cutaneous melanoma), RNA, gene expression profiling by realtime qPCR of 10 genes (8 content and 2 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reports a binary result, either low-risk or high-risk for sentinel lymph node metastasis and recurrence 10/01/2025	Merlin™ Test, SkylineDx USA, Inc,
0579U	Nephrology (diabetic chronic kidney disease), enzyme linked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline 10/01/2025	Promarker®D, Proteomics International USA, Proteomics International Pty Ltd
0580U	Borrelia burgdorferi, antibody detection of 24 recombinant protein groups, by immunoassay, IgG Effective 10/01/2025	iDart™Lyme IgG ImmunoBlot Kit, ID-FISH Technology, Inc
0581U	Transplantation medicine, antibody to non-human leukocyte antigens (non- HLA), blood specimen, flow cytometry, single-antigen bead technology, 39 targets, individual positive antibodies reported 10/01/2025	Autoantibody to Non- Human Leukocyte Antigen (non-HLA), Mayo Clinic Jacksonville
0582U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome DNA sequencing for single nucleotide variants, insertions/ deletions, copy number variations, blood, saliva, tissue sample, variants reported 10/01/2025	Rapid Whole Genome Sequencing, Mayo Clinic

0583U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome comparator DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, blood, saliva, tissue sample, variants reported with proband results(List separately in addition to code for primary procedure) Add-on. Use in conjunction with 0582U Effective 10/01/2025	Rapid Genome Sequencing Family Member Comparator, Mayo Clinic
0584U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking induced conformational conversion, qualitative Code with identical clinical descriptor, see 0035U Effective 10/01/2025	RT-QuIC Prion, CSF, Mayo Clinic
0585U	Targeted genomic sequence analysis panel, solid organ neoplasm, circulating cell-free DNA (cfDNA) analysis from plasma of 521 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, and microsatellite instability, report shows identified mutations, including variants with clinical actionability	Labcorp® Plasma Complete™, Labcorp, Laboratory Developed Test
0586U	Oncology, mRNA, gene expression profiling of 216 genes (204 targeted and 12 housekeeping genes), RNA expression analysis, formalin fixed paraffin-embedded (FFPE) tissue, quantitative, reported as log2 ratio per gene	RNA Salah Targeted Expression Panel, Moffitt Cancer Center Advanced Diagnostics Laboratory
0587U	Therapeutic drug monitoring, 60-150 drugs and metabolites, urine, saliva, quantitative liquid chromatography with tandem mass spectrometry (LCMS/ MS), specimen validity, and algorithmic analyses for presence or absence of drug or metabolite, risk score predicted for adverse drug effects Effective 10/01/2025	SafeDrugs, Astraeus Lab, LLC, Quantlio Technologies
0588U	Infectious disease (bacterial or viral), 32 genes (29 informative and 3 housekeeping), immune response mRNA, gene expression profiling by split-well multiplex reverse transcription loop-mediated isothermal amplification (RTLAMP), whole blood, reported as continuous risk scores for likelihood of bacterial and viral infection and likelihood of severe illness within the next 7 days	TriVerity™, Inflammatix™, Inc

0589U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by high-performance liquid chromatography with tandem mass spectrometry (LCMS/ MS), plasma or serum, quantitative Effective 10/01/2025	PFAS (Forever Chemicals) Panel 2 – 24 PFAS, Quest Diagnostics®
0590U	Infectious disease (bacterial and fungal), DNA of 44 organisms (34 bacteria, 10 fungi), urine, next-generation sequencing, reported as positive or negative for each organism Effective 10/01/2025	BIOTIA-ID™ Urine NGS Assay, Biotia Inc
0591U	Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), plasma, serum, prognostic algorithm incorporating 3 proteins and digital rectal examination, results reported as a probability score for clinically significant prostate cancer Effective 10/01/2025	MiCheck® Prostate, Minomic®, Inc
0592U	Oncology (hematolymphoid neoplasms), DNA, targeted genomic sequence of 417 genes, interrogation for gene fusions, translocations, rearrangements, utilizing formalin-fixed paraffin embedded(FFPE) tumor tissue, results report clinically significant variant(s) Effective 10/01/2025	Aventa Lymphoma, Aventa Genomics, LLC
0593U	Infectious disease (genitourinary pathogens), DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, urine, each analyte reported as detected or not detected Effective 10/01/2025	Taq Array Card Urinary Tract Infection PCR Panel, SoftCell Laboratories LLC, Doc Lab Inc
0594U	Infectious disease (sepsis), semiquantitative measurement of pancreatic stone protein concentration, whole blood, reported as risk of sepsis Effective 10/01/2025	IVD CAPSULE PSP – Rapid Sepsis Test, Abionic SA
0595U	Infectious disease (tropical fever pathogens), vectorborne and zoonotic pathogens, including 2 viruses (Chikungunya virus and Dengue virus serotypes 1, 2, 3, and 4), 1 bacterium (Leptospira species), and 1 parasite with species differentiation (Plasmodium species, Plasmodium falciparum, and Plasmodium vivax/ovale), real-time RTPCR, whole blood, each pathogen reported	BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel, bioMérieux

	as detected or not detected Effective 10/01/2025	
0596U	Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography with tandem mass spectrometry (LCMS/ MS), reported as an APOE proteotype Effective 10/01/2025	Precivity-ApoE™, C2N Diagnostics, LLC
0597U	Oncology (breast), RNA expression profiling of 329 genes by targeted next generation sequencing and 20 proteins by multiplex immunofluorescence, formalin-fixed paraffin embedded (FFPE) tissue, algorithmic analyses to determine tumor-recurrence risk score Effective 10/01/2025	AidaBreast™, PreludeDx™, Prelude Corporation
0598U	Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by microarray-based immunoassay, whole blood or serum, report as elevated (positive) or normal (negative) antibody levels Effective 10/01/2025	inFoods® IBS, Ethos Laboratories, Biomerica
0599U	Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative Effective 10/01/2025	PancreaSure™, Immunovia, Inc
0600U	Infectious disease (wound infection), identification of 65 organisms and 30 antibiotic resistance genes, wound swab, real-time PCR, reported as positive or negative for each organism Effective 01/01/2026	FidaLab Molecular Wound Infection Test, FidaLab LLC
0601U	Infectious disease (periprosthetic joint infection), analysis of 11 biomarkers (alpha defensins 1–3, Creactive protein, microbial antigens for Staphylococcus [SPA, SPB], Enterococcus, Candida, and C. acnes, total nucleated cell count, percent neutrophils, RBC count, and absorbance at 280 nm) using immunoassays, hematology, clinical chemistry, synovial fluid, and diagnostic algorithm reported as a probability score Effective 01/01/2026	Synovasure® Comprehensive PJI Test Panel with Syn Tuition™,CD Laboratories, Inc, division of Zimmer Biomet, CD Diagnostics, Inc, a division of Zimmer Biomet

0602U	Endocrinology (diabetes),insulin (INS) gene methylation using digital droplet PCR, insulin, and Cpeptide immunoassay, serum, Hemoglobin A1c immunoassay, whole blood, algorithm reported as diabetes-risk score Effective 01/01/2026	Diabetes Risk Test, Kihealth Inc® Laboratory
0603U	Drug assay, presumptive, 77 drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS), results reported as positive or negative Effective 01/01/2026	SLL Comprehensive Drug Analysis, Soft Landing Labs, Soft Landing Labs
0604U	Allergy and immunology (chronic recurrent angioedema), 4 bradykinin peptides, liquid chromatography and tandem mass spectrometry (LC-MS/ MS), whole blood, quantitative Effective 01/01/2026	Bradykinin, Quantitative, by LC-MS/MS, Virant Diagnostics, Inc
0605U	Allergy and immunology (hereditary alpha tryptasemia), DNA, analysis of TPSAB1 gene copy number variation using digital PCR, whole blood, results reported with genotype specific interpretation of alpha-tryptase copy number and algorithmic classification as normal or abnormal Effective 01/01/2026	Tryptase Gene Copy Number Analysis by dPCR, Virant Diagnostics, Inc
0606U	Hematology (red cell membrane disorders), RBCs, osmotic gradient ektacytometry, whole blood quantitative Effective 01/01/2026	Osmotic Gradient Ektacytometry, Cincinnati Children's Clinical Laboratories, RR Mechatronics
0607U	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 31 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations Effective 01/01/2026	EMMA (Endometrial Microbiome Metagenomic Analysis), Igenomix®, Igenomix® USA
0608U	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 10 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations (Do not report 0608U in conjunction with 0607U) Effective 01/01/2026	ALICE (Analysis of Infectious Chronic Endometritis), Igenomix®, Igenomix® USA

0609U	Oncology (prostate), immunoassay for total prostate-specific antigen (PSA) and free PSA, serum or plasma, combined with clinical features, algorithm reported as a probability score for clinically significant prostate cancer Effective 01/01/2026	ClarityDX Prostate, Protean BioDiagnostics, Nanostics Inc
0610U	Infectious disease (antimicrobial susceptibility), phenotypic antimicrobial susceptibility testing of positive blood culture using microfluidic sensor technology to quantify bacterial growth response to multiple antibiotic types, reporting categorical susceptibility (susceptible, susceptible dose dependent, intermediate, resistant), minimum inhibitory concentration, and interpretive comments Effective 01/01/2026	LifeScale Gram Negative Kit (LSGN) with the LifeScale AST system, Affinity Biosensors, LLC
0611U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result Code with identical clinical descriptor, is 0612U Effective 0/01/2026	HelioHCC™ Strat, Helio Genomics®
0612U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result Code with identical clinical descriptor, see 0611U. Effective 01/01/2026	HelioHCC™ Trace, Helio Genomics®
0613U	Oncology (urothelial carcinoma), DNA methylation and mutation analysis of 6 biomarkers (TWIST1, OTX1, ONECUT2, FGFR3, HRAS, TERT promoter region), methylation-specific PCR and targeted next-generation sequencing, urine, algorithm reported as a probability index for bladder cancer and upper tract urothelial carcinoma Effective 01/01/2026	AssureMDx™, Vesica Health® Inc

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RELATED POLICIES:

Clinical Drug Testing in Addiction Treatment Programs and Pain Management Programs ID 17249930

Experimental/Investigational Services Policy Stat ID 14533046

Genetic Testing for Hereditary Cancers: Breast, Ovarian, and Pancreatic ID 16843290

Non-invasive Prenatal Testing (NIPT) - Cell-Free DNA ID 14949798

Vaginitis Diagnostic Testing ID 14533208

POLICY HISTORY:

11/05/2024 New

01/01/2025 Coding Guidelines section updated to add additional Proprietary Lab codes 0001U-0046U, 0048U-0094U, 0096U-0103U, 0106U-0117U, 0119U-0247U, 0249U-0259U, 0261U-0263U, 0265U-0301U, 0303U-0350U, 0352U-0355U, 0358U-0364U, 0366U-0402U, 0404U- 0406U, 0408U-0419U, 0428U. Deleted codes 0478U as deactivated as of 10/01/2024 and 0456U, as code deactivated 01/01/2025.Revised code descriptions for the following: 0351U, 0356U, 0403U. Changed CPT 0528U from not requiring precertification to requiring precertification in order to match PAL and CPT TOOL. Coverage policy section added the following notation: *If specific criteria is not indicated here for individual tests, The Health Plan will utilize InterQual Criteria or the appropriate Medicare NCD/LCD depending on product line*. Updated References section. Updated Precertification sections and Exclusion sections with the additional codes.

06/01/2025 Updated 0080U to no precertification required. Added the new April 2025 codes 0531U-0551U. Added 0478U back to policy. Added coverage criteria for Rh Test by Natera, 0494U. Revised Proprietary names to the following codes: 0089U, 0095U, 0220U, 0288U, 0308U, 0309U, 0310U, 0393U, 0420U. Revised descriptions to the following codes: 0285U and 0365U. Moved the following codes from the exclusion section to the tests requiring precertification section: 0527U, 0331U, 0444U, 0454U, 0227U, 0439U, 0318U, 0332U,

0433U, 0047U, 0335U, 0336U, 0105U, 0407U, 0529U, 0409U, 0430U, 0119U, 0069U, 0068U, 0486U, 0487U, 0169U, 0523U, 0019U, 0313U, 0440U, 0494U, 0434U, 0460U, 0461U, 0339U, 0219U, 0449U, 0165U, 0178U. Noted the following codes are deleted: 0240U, 0241U, 0352U-as it is replaced by 81515, 0369U, 0370U, 0373U, 0374U, 0380U, 0428U. Removed reference to Somatic Mutation CRC and Xt testing as coding has been changed to 81445,81449. etc..

07/28/ 2025 Added July 1, 2025 codes 0552U-0574U. Noted code deletion for Codes being deleted as of 7/1/ 2025. Noted codes being deleted for 10/01/2025 0450U, 0451U. Added 81599 and 81479 in regards to MCED (multicancer early detection) testing being not covered. Added note as to Cancerguard™ by Exact Sciences as not covered as currently in clinical trial. 2025 revisions to descriptions completed. As presented in MDOC 7/23/2025.

10/13/2025 for 1/1/2026 policy update. Added language: *"Covered only for certain Medicare plans at this time."* for codes 0178U, 0227U, 0423U, 0175U, 0333U, 0388U, 0419U. Moved code 0025U, 0119U, 0179U, 0261U, 0263U, 0275U, 0287U, 0313U, 0341U to Exclusions/Not Covered section . Added may be covered for Medicare plans only language for 0119U. Moved code 0320U and 0552U, 0563U, 0564U, 0567U, 0571U, 0582U, and 0583U to Requires Precertification section. Moved code 0256U, 0399U to No Precertification Required section. Added language for that code 0345U must be billed for all lines of business for GeneSight® Psychotropic test. Added info for GeneSight ADHD, GeneSight Analgesic, GeneSight MTHFR would use 81479 or 81291respectively and may not be covered depending on reason for test and line of business. Added for code 0569U Guardant Reveal that it may be covered for Medicare plans providing guidelines are met. Added language under Coverage Guidelines requiring providers to bill the appropriate code for the appropriate tests as assigned by CMS and AMA. Added the new codes for October 2025 and January 2026, 0575U-0613U. Noted codes being deleted for October 2025 and January 2026: 0033U, 0131U, 0132U, 0135U, 0361U, 0508U, 0509U, 0544U, 0550U, 0551U. Removed the codes deleted back in July 2025: 0240U, 0241U, 0369U, 0370U, 0373U, 0374U.

12/3/2025 UM Committee removed Cologuard Plus 0464U from requiring precertification for 2/1/2025.

DISCLAIMER:

The services listed in this policy is not meant to be an all-inclusive list of Proprietary Lab services available. Proprietary Laboratory codes not found in this policy does not necessarily imply coverage or non-coverage of a service.

This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy is intended to address medical necessity guidelines that are suitable for most individuals. Each individual's unique clinical situation may warrant individual consideration based on medical records. Individual claims may be affected by other factors, including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgment. Reimbursement for any services shall be subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification, and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and

application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health care services provided in any particular case.

All Revision Dates

1/23/2026, 1/22/2026, 9/15/2025, 6/3/2025, 3/3/2025, 11/28/2024

Approval Signatures

Step Description	Approver	Date
Medical Directors Oversight Committee		1/27/2026
	Authorization & Medical Policy Manager	