

Investigational and Experimental Laboratory Testing

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Introduction

Investigational and experimental (I&E) laboratory testing is addressed by this guideline.

Procedures Addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

Procedures address by this guideline	Procedure codes
3D Predict Glioma	0248U
4q25-AF Risk Genotype	81479
9p21 Genotype	81479
13C-Spirulina Gastric Emptying Breath Test (GEBT)	0106U
Accelerate PhenoTest BC kit	0086U
Adrenal Mass Panel	0015M
ADEXUSDx hCG Test	0167U
AlloSure Heart	81479
AlloSure Lung	81479
Anti-dsDNA, High Salt/Avidity	0039U
Apifyny	0021U
Apolipoprotein E Genotype (APOE)	81401
ARISk Autism Risk Assessment Test	81479
AssureMDx	81479
Bacterial Typing by Whole Genome Sequencing	0010U
BBDRisk Dx	0067U
BDX-XL2	0080U
BeScreened-CRC	0163U
BioPlex 2200 RPR Assay	0065U

Procedures address by this guideline	Procedure codes
BioPlex 2200 RPR Assay – Quantitative	0210U
BioPlex 2200 Syphilis Total & RPR Assay	0064U
BluePrint Molecular Subtyping Profile	81479
ChemoFX	81535 81536
Clarifi ASD	0170U
Clarifi Imaging System	0061U
clonoSEQ	81479
CNGnome	0209U
ColonSentry	81479
Colvera	0229U
Crohn's Prognostic Test	81401
Decipher Bladder TURBT	0016M
DecisionDx Cutaneous Melanoma	81529
DEPArray	0009U
DISCERN	0206U 0207U
Enhanced Liver Fibrosis	0014M
Envisia Genomic Classifier	81554
ERA (Endometrial Receptivity Analysis)	0253U
EsoGuard	0114U
ExoDx®Prostate(IntelliScore)	0005U
Fetal RHD genotyping using maternal plasma (e.g. SensiGene)	81403
FirstSightCRC	0091U
Flow Adhesion of Whole Blood on VCAM-1	0121U
Flow Adhesion of Whole Blood to P-SELECTIN	0122U
Foundation PISM	0117U
HERmark Breast Cancer Assay	84999
IBD sgi Diagnostic	81479, 82397, 83520, 86140, 86255, 88346, 88350

Procedures address by this guideline	Procedure codes
IBSchek	0176U
ibs-smart	0164U
Insight TNBCtype	0153U
Intrinsic Hecpidin IDx Test	0251U
Karius Test	0152U
KidneyIntelX	0105U
KIF6 Genotype	81479
Know error	81479, 84999, 81265, 81266
LactoTYPE	81400
LC-MS/MS Targeted Proteomic Assay	0174U
LiverFASt	0166U
LPA-Aspirin Genotype	81479
LPA-Intron 25 Genotype	81479
Lymph2Cx Lymphoma Molecular Subtyping Assay	0017M
Lymph3Cx Lymphoma Molecular Subtyping Assay	0120U
M-Protein Detection and Isotyping my MALDI-TOF	0077U
MatePair Acute Myeloid Leukemia	0056U
MatePair Targeted Rearrangements, Hematologic	0014U
MatePair Targeted Rearrangements, Oncology	0013U
Mechanical Fragility, RBC by Shear Stress Profiling and Spectral Analysis	0123U
MicroGenDX qPCR & NGS For Infection	0112U
MiPS (Mi-Prostate Score)	0113U
miR-31now	0069U
Molecular Microscope MMDx—Heart	0087U
Molecular Microscope MMDx—Kidney	0088U
Multianalyte Assays with Algorithmic Analyses for Predicting Risk of Type 2 Diabetes	81506

Procedures address by this guideline	Procedure codes
MycoDART Dual Amplification Real Time PCR Panel for 4 Aspergillus species	0109U
myPath Melanoma	0090U
myPRS Myeloma Prognostic Risk Signature	81479
myTAIHEART	0055U
NPDX ASD ASM Panel I	0063U
NPDX ASD Energy Metabolism	0139U
Onco4D	0083U
Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells	0564T
OncoTarget/OncoTreat	0019U
OncotypeDx AR-V7 Nucleus Detect	81479
Oral Oncolytic AssuranceRX	0110U
PAI-1 Testing for Cardiovascular Disease Risk Assessment	81400, 85415
PanGIA Prostate	0228U
PartoSure Test	0066U
Pathway Fit	81291, 81401, 81479
Pathway Cardiac DNA Insight	81225, 81226, 81227, 81240, 81241, 81291, 81355, 81400, 81401, 81479
PCR Fungal Screen for Onychomycosis	87481, 87798
Percepta Bronchial Genomic Classifier	81479
PIGF Preeclampsia	0243U
POC (Products of Conception)	0252U
PolypDX	0002U
PreciseDx Breast Cancer Test	0220U
PredictSURE IBD Test	0203U
PreTRM	0247U
Prospera	81479
Prostate Cancer Risk Panel	0053U
RetnaGene AMD	81401, 81405, 81408, 81479, 81599
REVEAL Lung Nodule Characterization	0092U

Procedures address by this guideline	Procedure codes
ROMA Risk of Ovarian Malignancy Algorithm	81500
Signatera	81479
Singulex Clarity C. diff toxins A/B Assay	0107U
SLE-key Rule Out	0062U
SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy)	0254U
SMASH	0156U
Statin Induced Myopathy Genotype (SLCO1B1)	81328
Theralink Reverse Phase Protein Array (RPPA)	0249U
TissueCypher Barrett's Esophagus Assay	0108U
ToxLok	0079U
Twin Zygosity, cell free fetal DNA	0060U
UrSure	0025U
VectraDA	81490
Viracor TRAC dd-cfDNA	0118U
Vita Risk	0205U
Investigational and experimental tests that make use of molecular and genomic technologies	81479, 84999, 81599, and others

What Is I&E Laboratory Testing

Definition

An investigational and experimental (I&E) procedure is a service, supply, drug, or device that is not recognized as standard medical care for a condition, disease, illness, or injury diagnosis in question. These include laboratory tests regardless of whether they use molecular or genomic markers. Treatment is determined by the health plan based on an independent assessment of the peer-reviewed literature and scientific data. I&E laboratory testing refers to any assays performed in the laboratory for the purposes of disease diagnosis or health assessment that have insufficient data to determine the net health impact or data that demonstrates lack of an impact on health outcomes.

Investigational and Experimental Determinations

Laboratory tests are routinely released to market that make use of novel technologies or have a novel clinical application. These tests are often available on a clinical basis before the required evidence to support clinical validity and clinical utility are established. Typically, there is insufficient data to support that the test

- accurately assesses the outcome of interest, analytical and clinical validity
- significantly improves health outcomes, clinical utility, and
- performs better than an existing standard of care medical management option.

Because these tests are often proprietary, there may be no independent test evaluation data available in the early stages to support the laboratory's claims regarding test performance and utility.

As new tests become commercially available, the evidence base is reviewed. Tests determined to be I&E by the Health Plan are addressed by this guideline or a test-specific guideline and are not eligible for reimbursement.

FDA clearance

In the case of laboratory testing, FDA clearance is not a suitable standard given that the clearance assessment does not require evidence to support clinical utility. In addition, while the FDA has stated that it has the discretion to regulate laboratory developed tests (LDTs), it is currently only selectively exercising that discretion to take action against egregious practices.

Criteria

Introduction

This section catalogues some, but not all, laboratory assays that have been determined to be investigational and experimental (I&E). I&E tests may also be addressed in test-specific guidelines. Please refer to those documents for additional information. New I&E tests may not yet be specifically listed in this guideline, but such decisions will be made using the following criteria

Criteria: General Coverage Guidance

Medical laboratory assays are only eligible for reimbursement when ALL of the following conditions are met:

- Technical and clinical validity: The test must be accurate, sensitive and specific, based on sufficient, quality scientific evidence to support the claims of the test.
- Clinical utility: Healthcare providers can use the test results to provide significantly better medical care for the individual.

- Reasonable use: The usefulness of the test is not significantly offset by negative factors, such as expense, clinical risk, or social or ethical challenges.

Cardiovascular Assays

The following tests used to predict cardiovascular disease and/or direct therapy do not meet the above criteria and are not eligible for reimbursement.

- 4q25-AF Risk Genotype Test (rs2200733 allele) CPT: 81479
- 9p21 Genotype Test (rs10757278 and rs1333049 alleles) CPT: 81479
- Apolipoprotein E Genotype (APOE) CPT: 81401
- KIF6 Genotype Test CPT: 81479
- LPA-Aspirin Genotype Test (4399Met allele) CPT: 81479
- LPA-Intron 25 Genotype Test CPT: 81479
- myTAIHEART CPT: 0055U
- PAI-1 Testing for Cardiovascular Disease Risk Assessment CPT: 81400, 85415
- Statin Induced Myopathy Genotype (SLCO1B1) CPT: 81328

Hematology/oncology Assays

The following tests used in the screening, diagnosis, prognostication, and treatment decision-making for various neoplasms do not meet the above criteria and are not eligible for reimbursement.

Gene Expression Assays

- BluePrint Molecular Subtyping Profile [Proprietary 80-gene expression signature to classify Basal-type, Luminal-type and ERBB2-type breast cancers from Agendia] CPT: 81479
- ColonSentry [Proprietary 7-gene signature to detect colorectal cancer from StageZero Life Sciences] CPT: 81479
- Decipher Bladder TURBT [Oncology (bladder), mRNA, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)] CPT: 0016M
- DecisionDx - Cutaneous Melanoma assay [Proprietary 31-gene signature to assess melanoma metastatic risk from Castle Biosciences] CPT: 81529
- Envisia Genomic Classifier [Proprietary gene expression assay designed to aid in the diagnosis of idiopathic pulmonary fibrosis from Veracyte] CPT: 81554
- ExoDx®Prostate(IntelliScore) [Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score from Exosome Diagnostics, Inc.] CPT: 0005U

- Insight TNBCtype [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 from Insight Molecular Labs] CPT: 0153U
- Lymph2Cx Lymphoma Molecular Subtyping Assay, [Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin embedded tissue, algorithm reported as cell of origin from Mayo Clinic] CPT: 0017M
- Lymph3Cx Lymphoma Molecular Subtyping Assay, [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 from Mayo Clinic] CPT: 0120U
- miR-31now [Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin fixed paraffin-embedded tissue, algorithm reported as an expression score from GoPath Laboratories] CPT: 0069U
- myPath Melanoma [Proprietary 23-gene expression assay to assess the risk of malignant melanoma when a result cannot be obtained by clinical assessment and/or histopathology alone from Myriad Genetics] CPT: 0090U
- Myeloma Prognostic Risk Signature (myPRS) [Proprietary gene expression assay that is designed to predict an individual's risk of early relapse of multiple myeloma from Quest Diagnostics] CPT: 81479
- OncoTarget/OncoTreat [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 from Columbia University Department of Pathology and Cell Biology, Darwin Health] CPT: 0019U
- Percepta Bronchial Genomic Classifier [Proprietary gene expression assay designed to assess the risk of malignancy of lung nodules from Veracyte] CPT: 81479

Other Novel Assays

- 3D Predict Glioma [Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug from KIYATEC, Inc] CPT: 0248U
- Adrenal Mass Panel [Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy from Mayo Clinic Laboratories] CPT: 0015M

- AssureMDx [Proprietary non-invasive assay that analyzes tumor markers in the urine of individuals with hematuria to identify those at low risk and high risk for bladder cancer by MDx Health] CPT: 81479
- BBDRisk Dx [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 from Silbiotech, Inc] CPT: 0067U
- BDX-XL2 [Oncology (lung), mass spectrometric analysis of galentin-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 from Biodesix] CPT: 0080U
- ChemoFX [Proprietary test from Helomics to assess chemosensitivity] CPT: 81535, 81536
- clonoSEQ [Proprietary test that determines measurable residual disease (MRD) in the form of residual clonal cells to monitor changes in the disease burden during and post-treatment from Adaptive Biotechnologies] CPT: 81479
- Colvera [BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis from Colvera] CPT: 0229U
- DEPArray [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 from PacificDx] CPT: 0009U
- HERmark Breast Cancer Assay [Proprietary test designed to evaluate Her-2 total proteins in formalin-fixed, paraffin-embedded (FFPE) tissue specimens from LabCorp] CPT: 84999
- Know error [Proprietary test for DNA based specimen provenance confirmation from Strand Diagnostics] CPT: 81479, 84999, 81265, 81266
- MatePair Acute Myeloid Leukemia Panel, [Hematology (acute myelogenous leukemia), DNA, whole genome next generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s) from Mayo Clinic] CPT: 0056U
- MatePair Targeted Rearrangements, Oncology, [Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s) from Mayo Clinic] CPT: 0013U
- MatePair Targeted Rearrangements, Hematologic, [Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next generation

- sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s) from Mayo Clinic] CPT: 0014U
- MiPS (Mi-Prostate Score), [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 from MLabs] CPT: 0113U
 - Mitomic Prostate Test [Proprietary test using mitochondrial DNA to detect prostate cancer not identified by standard biopsy pathology from MDNA Life Sciences] CPT: none; research use only
 - Onco4D [Proprietary test to determine response to chemotherapy drugs using motility contrast tomography from Animated Dynamics] CPT: 0083U
 - OncotypeDx AR-V7 Nucleus Detect [Proprietary test designed to detect AR-V7 proteins in the nucleus of CTCs to determine response to AR-targeted therapies from Genomic Health] CPT: 81479
 - PanGIA Prostate [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 from Genetics Institute of America] CPT: 0228U
 - PAULA [Proprietary panel of four proteins designed to detect lung cancer in asymptomatic individuals at high risk from Genesys Biolabs] CPT: none; no insurance billing
 - PreciseDx Breast Cancer Test [Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score from PreciseDx] CPT: 0220U
 - Prostate Cancer Risk Panel [FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade from Mayo Clinic] CPT: 0053U
 - ROMA Risk of Ovarian Malignancy Algorithm [Proprietary test using the combination of CA125 + HE4 antigens to assess the likelihood of malignancy before surgery; test kit from Fujirebio Diagnostics, Inc. and offered by several reference laboratories] CPT: 81500
 - Signatera [Proprietary targeted “individual-specific assay” that uses multiple-PCR (mPCR) next generation sequencing (NGS) technology to detect ctDNA in the plasma of patients previously diagnosed with cancer. Tumor tissue and matched-normal whole exome sequencing (WES) are used to identify the individual-specific mutation signature to detect ctDNA and assess MRD from Natera] CPT: 81479
 - Theralink Reverse Phase Protein Array (RPPA) [Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report from Theralink Technologies] CPT: 0249U

- ToxLok [Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification from InSource Diagnostics] CPT: 0079U

Infectious Disease Assays

- Accelerate PhenoTest BC kit, [Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility from Accelerate Diagnostics, Inc] CPT: 0086U
- Bacterial Typing by Whole Genome Sequencing, [Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate from Mayo Clinic] CPT: 0010U
- BioPlex 2200 RPR Assay [Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR) from Bio-Rad Laboratories] CPT: 0065U
- BioPlex 2200 RPR Assay – Quantitative [Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR) from Bio-Rad Laboratories] CPT: 0210U
- BioPlex 2200 Syphilis Total & RPR Assay [Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative from Bio-Rad Laboratories] CPT: 0064U
- Karius Test [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 from Karius Inc] CPT: 0152U
- MicroGenDX qPCR & NGS For Infection, [Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene from MicroGenDX] CPT: 0112U
- MycoDART Dual Amplification Real Time PCR Panel for 4 Aspergillus species, [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 from RealTime Laboratories, Inc/MycoDART, Inc] CPT: 0109U
- PCR Fungal Screen for Onychomycosis, [Molecular tests for onychomycosis (e.g. Bako Diagnostics Onychodystrophy DNA Test)] CPT: 87481, 87798
- Singulex Clarity C. diff toxins A/B Assay [Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method from Singulex] CPT: 0107U

Non-cancer Gene Expression Assays

- Molecular Microscope MMDx—Heart, [Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection from Kashi Clinical Laboratories] CPT: 0087U

- Molecular Microscope MMDx—Kidney, [Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection from Kashi Clinical Laboratories] CPT: 0088U
- PredictSURE IBD Test [Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness from KSL Diagnostics, PredictImmune Ltd] CPT: 0203U
- VectraDA [Proprietary panel of 12 biomarkers that yields a rheumatoid arthritis disease activity score from Crescendo Bioscience] CPT: 81490

Non-molecular or Genomic Tests

The following non-molecular or genomic tests represented by Proprietary Laboratory Analyses (PLA) codes do not meet the above criteria and are not eligible for reimbursement.

- ADEXUSDx hCG Test [Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood from NOW Diagnostics] CPT: 0167U
- Anti-dsDNA, High Salt/Avidity [Deoxyribonucleic acid (DNA), antibody, double stranded, high avidity from University of Washington, Department of Laboratory Medicine] CPT: 0039U
- Apifyny [Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'UTR-BMI1, CEP 164, 3'-UTR Ropporin, Desmocollin, AURKAIP1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score from Armune BioScience Inc] CPT: 0021U
- BeScreened CRC [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 from Beacon Biomedical Inc] CPT: 0163U
- FirstSight CRC [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 from CellMax Life] CPT: 0091U
- Flow Adhesion of Whole Blood to P-SELECTIN [Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood from Functional Fluidics] CPT: 0122U
- Flow Adhesion of Whole Blood on VCAM-1 [Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood from Functional Fluidics] CPT: 0121U
- Foundation PISM [Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate,

- 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain from Ethos Laboratories] CPT: 0117U
- IBSchek [Cytotoxic distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA) from Commonwealth Diagnostics International, Inc] CPT: 0176U
 - ibs-smart [Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti- vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results from Gemelli Biotech] CPT: 0164U
 - Intrinsic Hecpudin IDx Test [Hecpudin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma from Intrinsic LifeSciences LLC] CPT: 0251U
 - KidneyIntelX [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, algorithm reported as probability score for rapid kidney function decline (RKFD) from RenalytixAI] CPT: 0105U
 - LC-MS/MS Targeted Proteomic Assay [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 from OncoOmicDx Laboratory] CPT: 0174U
 - LiverFASt [Liver disease, 10 biochemical assays (α 2-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 from Fibronostics] CPT: 0166U
 - Mechanical Fragility, RBC by shear stress profiling and spectral analysis [Mechanical fragility, RBC, shear stress and spectral analysis profiling from Functional Fluidics] CPT: 0123U
 - M-Protein Detection and Isotyping by MALDI-TOF [Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype from Mayo Clinic] CPT: 0077U
 - NPDX ASD ADM Panel I [Neurology (autism), 32 amines by LCMS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder from Stemina Biomarker Discovery, Inc] CPT: 0063U
 - NPDX ASD Energy Metabolism [Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α -ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD) from Stemina Biomarker Discovery, Inc] CPT: 0139U

- Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations CPT: 0564T
- Oral Oncolytic AssuranceRX [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 from Firstox Laboratories, LLC] CPT: 0110U
- PartoSure Test [Placental alpha-micro globulin-1 (PAMG1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen from Parsagen Diagnostics, Inc] CPT: 0066U
- PolypDX [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 from Atlantic Diagnostic Laboratories] CPT: 0002U
- REVEAL lung [Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy from MagArray, Inc] CPT: 0092U
- SLE-key Rule Out [Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score from Veracis Inc] CPT: 0062U
- Clarifi Imaging System [Transcutaneous measurement of five biomarkers using spatial frequency domain imaging (SFDI) and multi-spectral analysis from Modulim] CPT: 0061U
- UrSure Tenofovir Quantification Test [Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative from Synergy Medical Laboratories] CPT: 0025U

Risk Assessment Assays

The following tests that assess disease risk, prognosis, or subtyping do not meet the above criteria and are not eligible for reimbursement.

- ¹³C-Spirulina Gastric Emptying Breath Test (GEBT) [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 from Cairn Diagnostics] CPT: 0106U
- AlloSure Heart, [Proprietary non-invasive assay to screen for organ injury and rejection in heart transplant recipients through measurement of donor-derived cell-free DNA in recipient blood sample from CareDx] CPT: 81479

- AlloSure Lung, [Proprietary non-invasive assay to screen for organ injury and rejection in lung transplant recipients through measurement of donor-derived cell-free DNA in recipient blood sample from CareDx] CPT: 81479
- ARISk Autism Risk Assessment Test [Proprietary test from IntegraGen] CPT: 81479
- Cardiac DNA Insight [Proprietary test from Pathway Genomics that assesses genetic markers for cardiac-related conditions] CPT: 81225, 81226, 81227, 81240, 81241, 81291, 81355, 81400, 81401, 81479
- Clarifi ASD [Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis from Quadrant Biosciences] CPT: 0170U
- CNGnome [Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities from PerkinElmer Genomics] CPT: 0209U
- Crohn's prognostic test [NOD2/CARD15 gene variant testing] CPT: 81401
- DISCERN [Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amyloospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease from NeuroDiagnostics] CPT: 0206U
- DISCERN [Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure) from NeuroDiagnostics] CPT: 0207U
- Enhanced Liver Fibrosis [Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years from Siemens Healthcare Diagnostics] CPT: 0014M
- ERA (Endometrial Receptivity Analysis) [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) from Igenomix] CPT: 0253U
- EsoGuard, [Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus from Lucid Diagnostics] CPT: 0114U
- Fetal RHD genotyping using maternal plasma (e.g. SensiGene) CPT: 81403
- IBD sgi Diagnostic [Proprietary test from Prometheus with genomic components including ATG16L1, STAT3, NKX2-3, and ECM1 gene variants.] CPT: 81479, 82397, 83520, 86140, 86255, 88346, 88350

- LactoTYPE [Proprietary test from Prometheus that assesses the hypolactasia C/T genetic variant] CPT: 81400
- MethylDetox Profile [The MethylDetox Profile test is a testing panel that assesses genes in the methylation pathway to provide “more actionable information than MTHFR testing alone” and provides “suggestions for specific nutrient needs” based on test findings from Cell Science Systems] CPT: none; no insurance billing
- Multianalyte Assays with Algorithmic Analyses for Predicting Risk of Type 2 Diabetes CPT: 81506
- Pathway Fit [Proprietary test from Pathway Genomics that focuses on metabolism, diet, and exercise traits] CPT: 81291, 81401, 81479
- PIGF Preeclampsia [Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia from PerkinElmer Genetics] CPT: 0243U
- POC (Products of Conception) [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 from Igenomix] CPT: 0252U
- PreTRM [Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth from Sera Prognostics] CPT: 0247U
- Prospera [Proprietary non-invasive assay that uses a single-nucleotide polymorphism (SNP)-based technology to evaluate active allograft rejection by measuring the DNA derived from transplanted donor kidneys; from Natera] CPT: 81479
- RetnaGene AMD [Proprietary test from Sequenom CMM to predict risk of wet AMD progression] CPT: 81401, 81405, 81408, 81479, 81599
- SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy) [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 from Igenomix] CPT: 0254U
- SMASH [Copy number (eg, intellectual disability, dysmorphology), sequence analysis from Marvel Genomics] CPT: 0156U
- TissueCypher Barrett's Esophagus Assay [Gastroenterology (Barrett's esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-

embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer from Cernostics] CPT 0108U

- Twin zygosity [genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood from Natera] CPT: 0060U
- Viracor TRAC dd-cfDNA, [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 from Viracor Eurofins] CPT:0118U
- Vita Risk [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 from Arctic Medical Laboratories] CPT: 0205U