



# Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2026 Meeting

The proposed agenda for the May 2026 CPT® Proprietary Laboratory Analyses Panel meeting identifies the test names and requested descriptions for each test. The laboratory test name and test description detailed in this document are extracted from Applications submitted for discussion at this meeting. **Until such time as the Technical Advisory Group acts on these requests, the information that appears in this Proposed Agenda is provided for informational purposes only.**

## NOTICE –INTERESTED PARTY PROCESS

Upon review of this agenda, if the reviewer believes that they may want to provide written comments on an application, the reviewer must seek Interested Party status by submitting a request form. The form requires identification of the potential Interested Party, a brief summary of the basis for the request (e.g., associated vendor/ industry representative), and signature of the confidentiality agreement and disclosure of interest forms. For more information, [please visit our website](#).

**The deadline to submit comments for the upcoming May 2026 Panel meeting is April 21, 2026. Only requests submitted via the CPT Smart App’s [Interested Party Portal](#) will be considered.** Any recognized Interested Party who provides written comments must do so no later than the deadlines below and in the Interested Party Portal. Should you miss the comment deadline, verbal comments can be provided in person at the Panel meeting.

App ID	Laboratory Test name	Code Request	Proposed Test Descriptor
a007155_1	HealthTrackRx Vaginitis	D0557U	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
a007155_2	HealthTrackRx Bronchitis	D0556U	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
a010685	MMDx Lung	NEW	Pulmonology (lung transplant) mRNA, gene expression profiling by microarray measuring of 19,462 genes, in fresh transplant biopsy tissue, allograft rejection and injury algorithm reported as quantitative risk score

a011771	Genomic Unity® Whole Genome Analysis - Duo	NEW	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat gene expansions, blood, saliva or gDNA, identification and categorization of genetic variants, proband and comparator
a033807	Human Papillomavirus (HPV) Types 18, 31, 33, and 35, Droplet Digital PCR, Blood	NEW	Human papillomavirus (HPV), genotypes 18, 31, 33, and 35, cell free DNA ,whole blood, multiplex digital droplet polymerase chain reaction (ddPCR), quantitative
a083860	Exosome Kidney Transplant Report (EkTRA)	NEW	Nephrology (kidney transplant), mRNA, gene expression profiling by real-time quantitative PCR of up to 12 genes (11 content and 1 housekeeping), utilizing urine, algorithm reported as a rejection risk score
a088184	GraftAssure	NEW	Transplantation medicine, quantification of donor-derived cell-free DNA (dd-cfDNA) using digital PCR analysis of plasma, reported as quantity of dd-cfDNA in plasma to determine the probability of allograft rejection
a129880	OncoAlly® Hereditary Hematologic Cancer Analysis	NEW	Oncology (hereditary hematologic cancer), genomic DNA, whole genome sequencing (WGS) platform, (single nucleotide variants, deletions/insertions and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, analysis of over 105 genes, gDNA isolated from blood, saliva, cultured skin fibroblasts (skin biopsy) or extracted genomic DNA, diagnostic, identification and categorization of genetic variants
a131938	Genomic Unity® Whole Exome Plus Analysis - Duo	NEW	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 and comparator
a140592	UNITY Platelet Fetal Antigen™ NIPT	NEW	Obstetrics (fetal platelet antigen noninvasive prenatal test), cell-free DNA sequence analysis for detection of fetal presence or absence of 1 or more human platelet antigens (HPA-1a, HPA-1b, HPA-3a, HPA-5b, and others), in pregnancies for management of fetal and neonatal alloimmune thrombocytopenia (FNAIT), reported as maternal/fetal incompatibility detected or not detected per selected antigen
a144522	Protega	NEW	Transplantation medicine, RNA expression transcriptome by next generation sequencing, profiling of a select set of biomarkers (e.g. transcripts) from post-transplant peripheral blood, algorithm reported as a risk score for predicting progressive fibrosis in the kidney allograft

a162061	Know Error	NEW	DNA, short tandem repeat (STR) analysis of multiple loci ( $\geq 10$ STR markers), polymerase chain reaction (PCR) amplification with fragment analysis (e.g., capillary electrophoresis), buccal swab and prostate biopsy tissue (fresh or formalin-fixed paraffin-embedded), specimen identity/provenance assessment, qualitative reporting of match or mismatch between reference and tissue DNA
a166593	OncoAssure Prostate  <i>Change of Lab Name Only</i>	▲0497U	Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes ( <i>FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA</i> ), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer
a196018	xT CDx	▲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 ( <del>blood or saliva</del> ), <u>when available</u> , 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and <u>tumor mutational burden</u> <del>tumor mutation burden</del>
a209757	NIS2+™	NEW	Hepatology (metabolic dysfunction-associated steatohepatitis [MASH]), miR-34a-5p, YKL40, serum, algorithm reported as a single score for MASH activity and fibrosis
a233058	H14	NEW	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia, fragile X), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include sequencing analysis of 14 genes ( <i>CFTR, SMN1, HBB, HBA1, HBA2, ASPA, DMD, IKBKAP, GALT, GBA, ACADM, PKHD1, DHCR7, HEXA</i> )
a239360	Smoke Signature© (Saliva)	NEW	Addiction medicine (tobacco use), DNA, analysis of two methylation markers (one content: cg05575921 [AHRR] and one normalizing: cg08141395), methylation-sensitive digital polymerase chain reaction (dPCR), saliva, algorithm reported as quantitative percent methylation and estimated average cigarette use per day
a243364	LymphDetect Head & Neck (TM)	NEW	Oncology (head and neck), circulating tumor DNA (ctDNA), tumor-informed next-generation sequencing (NGS) analysis of patient-specific somatic variants identified from primary tumor tissue, utilizing post-operative lymphatic exudate specimen, algorithm reported as presence or absence of molecular residual disease
a270083	Smoke Signature© (Blood)	NEW	Addiction medicine (tobacco use), DNA, analysis of one methylation marker (cg05575921 [AHRR]), methylation-sensitive digital polymerase chain reaction (dPCR), whole blood, algorithm reported as quantitative percent methylation and estimated average cigarette use per day

a272013	Wound Panel	NEW	Infectious disease (wound infection), identification of 27 organisms and 28 antibiotic resistance genes, wound swab, real-time PCR, reported as positive or negative for each organism
a316656	Alcohol T-Score™ (Blood)	NEW	Behavioral (Alcohol Use Disorder), DNA, analysis of four methylation markers (cg02583484, cg04987734, cg09935388 and cg04583842), methylation sensitive digital PCR, whole blood, algorithm reported as a summed T-score
a330269	Fibroblast Growth Factor 21 (FGF21)	NEW	Inborn error of metabolism (primary mitochondrial disease), determination of FGF21 concentration by ELISA, serum or plasma, diagnostic quantitative result
a334081	OvasomDx	NEW	Oncology (ovarian), exosome-based biochemical analysis of three proteins (CA125, HE4, C5a) extracted from human serum, algorithm reported as an Ovarian Cancer Score
a341236	Decipher Prostate Genomic Classifier	NEW	Oncology (prostate), mRNA, next-generation sequencing gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
a408472	MiCheck® Prostate	▲0591U	Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), <del>plasma</del> , serum, prognostic algorithm incorporating 3 proteins and digital rectal examination, results reported as a probability score for clinically significant prostate cancer
a413214	Immunoglobulin Isotypes (GAM) for the EXENT Analyser	NEW	Immunoglobulin paraprotein (m-protein), semi-quantitative, serial immunoprecipitation and MALDI-TOF mass spectrometry, blood, automated identification of intact monoclonal immunoglobulin isotypes (IgG, IgA, IgM, total kappa, total lambda) using proprietary software, reported in g/L and m/z, total immunoglobulin concentrations (IgG, IgA, IgM) determined by turbidimetry, reported in g/L, and interpretive comments for detection of therapeutic monoclonal antibodies
a425249	Quantitative Fecal Immunochemical Test for Hemoglobin in Stool	NEW	Oncology, screening for colorectal cancer, fecal latex agglutination test, quantitative determination of hemoglobin, by immunoassay, using automated analyzer, stool, includes sample preparation and analysis, reporting hemoglobin concentration in nanograms hemoglobin per milliliter buffer
a429285	Genomic Unity® 2.0 - Duo	NEW	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 variant, proband and comparator
a449476	Genomic Unity® Whole Genome Analysis - Trio	NEW	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat gene expansions, blood, saliva or gDNA, identification and categorization of genetic variants proband and two comparators
a455612	Smoke Signature© Lung CA™	NEW	Oncology (lung cancer), DNA, analysis of one methylation marker (cg05575921), methylation sensitive digital PCR, whole blood, algorithm results reported as the 20-year hazard ratio for lung cancer
a508105	Ascent	NEW	Oncology, suspected or confirmed central nervous system tumors, low-pass whole genome sequencing analysis of cerebrospinal fluid, interrogation for chromosome arm-level and focal losses and gains
a510909_1 a599632	FLT3	▲0046U	<i>FLT3</i> ( <i>fms-related tyrosine kinase 3</i> ) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
a510909_2	NPM1	▲0049U	<i>NPM1</i> ( <i>nucleophosmin</i> ) (eg, acute myeloid leukemia) gene analysis, quantitative
a528992	Promarker®Eso	NEW	Gastroenterology (esophageal adenocarcinoma), mass spectrometry (LC-MS/MS) analysis of 4 serum glycoprotein biomarkers (alpha-1-antitrypsin, alpha-1-antichymotrypsin, complement C9 and plasma kallikrein) combined with clinical factors (age, sex and body mass index), algorithm reported as a probability for esophageal adenocarcinoma
a535240	HepatoTrack	▲0575U	Transplantation medicine (liver allograft rejection), miRNA gene expression profiling by RT-PCR of 4 genes ( <i>miR-122</i> , <i>miR-885</i> , <i>miR-23a</i> housekeeping, spike-in control), serum, <u>plasma or whole blood</u> , algorithm reported as risk of liver allograft rejection
a539346	CancerVision	NEW	Oncology (solid tumor), targeted enhanced whole genome sequence analysis (TE-WGS), including whole genome sequencing of tumor and matched normal DNA with targeted panel sequencing of 526 genes, utilizing formalin-fixed paraffin-embedded (FFPE) or fresh frozen tumor tissue and matched normal blood or buccal swab, identifying somatic variants (SNVs, indels, CNAs), genomic instability markers (TMB, MSI, HRD), and select germline variants, reported with clinically significant mutations and therapy associations

a542633	Labcorp® Plasma Complete™	D0585U	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
a542635	Oncodetect	NEW	Oncology (pan-cancer), analysis of molecular residual disease (MRD), next generation sequencing (NGS), circulating tumor DNA (ctDNA) analysis in whole blood and tumor for baseline assessment to determine personalized panel to evaluate current MRD status and for comparisons to subsequent MRD assessments.
a570199	H5	NEW	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)
a592021	OncoAlly® Comprehensive Hereditary Cancer Analysis	NEW	Oncology (hereditary cancer), genomic DNA, whole genome sequencing (WGS) platform, (single nucleotide variants, deletions/insertions and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, analysis of over 115 genes. gDNA isolated from blood, saliva, cultured skin fibroblasts (skin biopsy) or extracted genomic DNA, diagnostic, identification and categorization of genetic variants.
a604537	Avantect Pancreatic Cancer Test	NEW	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment and glycan biomarker analysis, whole blood or plasma, algorithm reported as cancer detected or not detected
a612506	Human Papillomavirus (HPV) Type 16, Droplet Digital PCR, Blood	NEW	Human papillomavirus (HPV), genotype 16, cell free DNA, whole blood, digital droplet polymerase chain reaction (ddPCR), quantitative
a653296	Horizon Expanded Panel	NEW	Genetic testing for severe inherited conditions (eg, cystic fibrosis, ashkenazi jewish-associated disorders [eg, bloom syndrome, canavan disease, fanconi anemia type c, mucopolidosis type vi, gaucher disease, tay-sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, from a blood sample, must include sequencing of at least 15 genes (eg, <i>acadm</i> , <i>arsa</i> , <i>aspa</i> , <i>atp7b</i> , <i>bckdha</i> , <i>bckdhb</i> , <i>blm</i> , <i>cftr</i> , <i>dhcr7</i> , <i>fancc</i> , <i>g6pc</i> , <i>gaa</i> , <i>galt</i> , <i>gba</i> , <i>gbe1</i> , <i>hbb</i> , <i>hexa</i> , <i>ikbkap</i> , <i>mcoln1</i> , <i>pah</i> )
a658478	PreTRM	▲0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, blood and blood derivatives, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth

a661292	IriSight® Comprehensive Analysis - Prenatal Duo	NEW	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, proband and comparator
a664608	Smoke Signature© Lung CA™ (Saliva)	NEW	Oncology (lung cancer), DNA, analysis of two methylation markers (one content: cg05575921 and one normalizing: cg08141395), methylation sensitive digital PCR, saliva, algorithm results reported as the 20-year hazard ratio for lung cancer
a681561	BBB Direct Detect Multiplex	NEW	Infectious disease ( <i>Bartonella</i> species, <i>Borrelia</i> species and <i>Babesia</i> species), multiplex digital PCR (dPCR) for detection of DNA at the genus level for each species, from blood, qualitative reporting of presence or absence of each pathogen at the genus level
a686743	Delve Detect Cerebral Spinal Fluid	NEW	Agnostic infectious disease pathogen detection and identification by DNA and RNA metagenomic next-generation sequencing (bacteria, fungi, RNA viruses, DNA viruses, parasites) including specimen stabilization, specimen shipping, cellular lysis, nucleic acid extraction, separate RNA and DNA library preparation with reverse transcriptase PCR and PCR, next generation sequencing, bioinformatic alignment of sequencing data to curated pathogen database, cerebrospinal fluid, identification of pathogenic microbial organisms with clinical interpretation and report
a703606	SyncViewRx	NEW	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
a773106	OncoAlly® Common Hereditary Cancers Analysis	NEW	Oncology (hereditary cancer), genomic DNA, whole genome sequencing (WGS) platform, (single nucleotide variants, deletions/insertions and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, analysis of over 60 genes, gDNA isolated from blood, saliva, cultured skin fibroblasts (skin biopsy) or extracted genomic DNA, diagnostic, identification and categorization of genetic variants
a792729	IriSight® Comprehensive Analysis - Prenatal Trio	NEW	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, proband and two comparators
a803110	HART PAD	NEW	Cardiology (peripheral artery disease [PAD]), analysis of 3 proteins (midkine, angiopoietin-1, and kidney injury molecule-1 [KIM-1]) by immunoassays combined with a clinical parameter (history of hypertension), plasma, algorithm reported as a risk score for obstructive peripheral artery disease
a839695	Alcohol T-Score™ (Saliva)	NEW	Behavioral (Alcohol Use Disorder), DNA, analysis of four methylation markers (four content: cg02583484, cg04987734, cg09935388, cg04583842, and one normalizing: cg08141395), methylation sensitive digital PCR, whole blood or saliva, algorithm reported as a summed T-score
a856324	Oncodetect	NEW	Oncology (pan-cancer), analysis of molecular residual disease (MRD) next generation sequencing (NGS), circulating tumor DNA (ctDNA) analysis in whole blood for subsequent assessment with comparison to previously analyzed patient specimens to evaluate MRD status
a857256	Guardant360 Tissue RNA	NEW	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, RNA analysis, 350 or more genes, interrogation RNA alterations (e.g gene rearrangements and splice isoforms)
a857437	HerResolve	NEW	Reproductive medicine (endometriosis), micro RNA , analysis or 3 mRNAs by qPCR and 3 proteins, using blood, algorithm reported as endometriosis detected/not-decteced
a865749	Panorama	NEW	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
a875142	MyPhenomeRx	NEW	Obesity, DNA genotyping, analysis of up to 41 genes, buccal swab or blood specimen, patient biometrics, risk score algorithm to identify a predisposition to up to four phenotypes, reported as likelihood to benefit from therapeutics
a890116	22Q	NEW	Genetic testing, fetal chromosomal microdeletion(s), genomic sequence analysis, analysis of microdeletion(s) (eg. DeGeorge syndrome), using circulating cell-free fetal DNA in maternal blood
a892274	Alinity i TBI	NEW	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl terminal hydrolase L1 (UCH-L1), immunoassay, serum or plasma, individual components reported with the overall result of positive or negative based on threshold comparison

a896207	Latitude	NEW	Oncology (solid tumor), next-generation sequencing analysis of genome-wide tumor methylation markers present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction
a954786	Genomic Unity® 2.0 - Trio	NEW	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 variant, proband and two comparators
a975723	Genomic Unity® Exome Plus Analysis - Trio	NEW	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 and two comparators