Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2025 Meeting

The proposed agenda for the May 2025 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 will need to provide comment on an issue, they must seek Interested Party status by submitting a request for a copy of the application and associated materials. Under your email, please select *Proprietary Laboratory Analysis (PLA) requests* from the dropdown. **Only requests submitted through Zendesk will be approved.** This request for review of the agenda materials should contain the identity of the interested party seeking such and a brief summary of the basis for the request (e.g., associated vendor/ industry representative).

Any interested parties wishing to provide written comments on any agenda items should be aware of the relevant deadlines for reviewing and providing written comments to allow review by all parties (eg, Panel members, Technical Advisory Group reviewers, applicants, etc.). The applicant(s) who submitted the original code change application is automatically considered an interested party and is notified by AMA staff of any request for review submitted by another party. Interested parties should be advised of the expedited deadlines of the PLA code development process to facilitate quarterly submission, review and publication of Proprietary Laboratory Analyses Applications, in accordance with the timeframes defined in the Proprietary Laboratory Analyses (PLA) Calendar.

*Interested party requests will not be processed until the interested party submits a signed confidentiality agreement and disclosure of interest form. Interested party requests will be processed within 5 days of receipt of the requested forms. Written comments for these requests are due within 3 days upon receipt of materials, unless extenuating circumstances preclude the ability for interested parties to provide written comments for consideration within the defined timeframes.

During the time between now and the date of the meeting, the agenda will, most likely, be modified to reflect changes – additions, deletions or updates.

ID	Laboratory Test Name	Proposed Test Description
101123	HepatoTrack	Transplantation medicine (allograft liver rejection), miRNA gene expression profiling by RT-PCR of 4 genes (2 content, 1 housekeeping and 1 spike-in control), utilizing blood, algorithm reported as a rejection prediction score to assess acute cellular rejection
101765 0333U	HelioLiver™Test, ~~Fulgent Genetics, LLC, Helio Health, Inc~~ Helio Genomics®, Helio Genomics® **REVISE LABORATORY & MANUFACTURER NAME ONLY 0333U**	*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*
101786	EMMA / ALICE	Reproductive medicine (endometrial microbiome assessment), real time PCR analysis for 30 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations
101830	Alice (Analysis of Infectious Chronic Endometritis)	Reproductive medicine (endometrial microbiome assessment), real time PCR analysis for 10 bacterial DNA targets linked to Chronic Endometritis from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations
101880	Osmotic Gradient Ektacytometry (OGE)	Hematology, osmotic gradient ektacytometry (OGE), red blood cell (RBC) functionality and deformability as a function of increasing osmolality under continuous shear stress, whole blood, reported as hypotonic osmolality (Omin), elongation index (Elmax), and hypertonic osmolality (Ohyp) on the curve
101882	OmniGraf Liver	Transplantation medicine (allograft rejection, liver), quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, utilizing plasma, and mRNA, gene expression profiling by multiplex quantitative polymerase chain reaction (qPCR) of 56 genes, utilizing whole blood, combined algorithm reported as a rejection risk score
101921	Perfluoroalkyl Substances (PFAS) Panel 2 - 24 PFAS	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
101922	GlycoKnow Ovarian	Oncology (ovarian), serum, multianalyte glycoproteomic analysis by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring (MRM) mode, reported as predictive likelihood of malignancy
101923	Abnormal Prion Protein, Real-Time Quaking Induced Conversion (RT-QulC), Spinal Fluid	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion assay (RT-QulC), qualitative
101924	Merlin Test	Oncology (cutaneous melanoma), RNA, gene expression profiling by real-time qPCR of 10 genes (8 melanoma specific and 2 housekeeping), utilizing formalin-fixed paraffin-embedded

		tissue, algorithm reports a binary result: either Low Risk or High Risk for sentinel lymph node metastasis and recurrence
101925	Promarker®D	Nephrology (diabetes-related chronic kidney disease), enzyme-linked immunosorbent assay (ELISA) of Apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L) combined with clinical data estimated glomerular filtration rate (eGFR) and age, plasma, algorithm reported as a risk score for developing diabetic kidney disease or further kidney function decline
101940	Global MAPS (Global Metabolomic Assisted Pathway Screen - Plasma)	Inborn Errors of Metabolism (eg Creatine disorders, Bile acid disorders, Urea cycle disorder, Fatty acid oxidation disorders) metabolomic profiling by high-resolution mass spectrometry of >700 metabolites, plasma, semi-quantitative, reported as significantly altered analytes detected, rare analytes detected or common analytes absent
101941	iDart Lyme IgG ImmunoBlot Kit	Immunoblot test intended for the in vitro qualitative detection of IgG antibodies to Borrelia burgdorferi in human serum, positive results from the proposed test are supportive evidence for the presence of antibodies and exposure to B. burgdorferi.
101942	Rapid Genome Sequencing	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis
101943	Rapid Genome Sequencing Comparator	Rapid genome (eg, unexplained constitutional or heritable disorder or syndrome); each comparator genome (eg, parent, sibling)
101944	Labcorp Plasma Complete	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 521 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, and microsatellite instability, report showing identified mutations including variants with clinical actionability
101961	SafeDrugs	Polypharmacy drug safety panel, LCMS or GCMS, 60 or more prescribed and nonprescribed medications or substances in urine or saliva, including calculation and reporting of adverse event predictive risk score using test results and patient information, may also include therapeutic drug monitoring for specified patient prescriptions
101962	TriVerity	Infectious disease (bacterial infection, viral infection, illness severity), 32 genes (29 informative and 3 housekeeping), immune response mRNA, gene expression profiling by split-well multiplex quantitative rt-isothermal amplification, whole blood, reported as three continuous risk scores: likelihood of bacterial infection, likelihood of viral infection, and likelihood of severe illness (defined as the need for vasopressors, mechanical ventilation, or renal replacement therapy) within the next 7 days
101963	RNA Salah Targeted Expression Panel	Oncology, mRNA, gene expression profiling of 216 genes (204 targeted and 12 housekeeping genes), RNA expression analysis, formalin-fixed paraffin embedded tissue, quantitative
101964	AD-DetectTM ABeta 42/40 and p-tau217 Evaluation, Plasma	Neurology (Alzheimer disease and mild cognitive impairment), beta amyloid (AB40, AB42, AB42/40 ratio) and phosphorylated tau 217 (p-tau217) plasma algorithm reported as the likelihood of amyloid pathology consistent with Alzheimer's Disease
101965	Amyloid Beta 42/40 Ratio	Neurology (mild cognitive impairment),CSF or plasma analysis of Beta-amyloid 1-42 and 1-40, with ratio reported as positive, intermediate, or negative

101966	Neurofilament Light Chain (NfL)	Neurology (Neuronal Damage) Neurofilament light chain, electrochemiluminescence immunoassay, quantitative
101967	Delve Detect Cerebral Spinal Fluid	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
101968	AD-Detect(R)Phosphorylated tau217(p-tau217), Plasma	Neurology (mild cognitive impairment), analysis of Phosphorylated tau217(p-tau217), chemiluminescence enzyme immunoassay, reported as positive or negative
101969	miR Sentinel Prostate Cancer Test	Oncology (Prostate), RNA analysis of 224 sequences with algorithmic assessment of 42 prostate cancer-associated ncRNA targets, high-density RT-qPCR, non-DRE urine, algorithm reported as likelihood of prostate cancer with aggressiveness risk stratification when molecular evidence suggests increased risk
101970	BIOTIA-ID Urine NGS Assay	Infectious agent detection by nucleic acid (DNA), genitourinary pathogen, identification of at least 40 bacterial and/or fungal organisms, urine, next-generation sequencing (shotgun metagenomics) technique, reported as positive or negative for each organism
101971	MiCheck Prostate	Oncology (prostate cancer), biochemical analysis of three proteins (total psa, free psa, and HE4), utilizing plasma or serum, prognostic algorithm reported as a probability score of clinically significant prostate cancer
101972	Aventa FusionPlus Lymphoma	Oncology (hematolymphoid neoplasms), dna, targeted genomic sequence panel, at least 417 genes, interrogation for gene fusions, translocations, or other rearrangements, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant variant(s)
101973	Taq Array Card Urinary Tract Infection PCR Panel	Infectious disease (bacterial or fungal urinary tract infection), pathogen-specific and resistance gene DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, clean catch urine, each analyte reported qualitatively as detected or not detected
101974	Guardant360® Tissue ~~TissueNext™,~~ Guardant Health, Inc, Guardant Health, Inc **REVISE TEST NAME ONLY 0334U**	*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*
101975	Non-Human Leukocyte Antigen (HLA) Autoantibody	Transplantation medicine, antibody to non-human leukocyte antigens (HLA), blood specimen, flow cytometry, single-antigen bead technology, 39 targets, individual positive antibodies reported
101976	IVD CAPSULE PSP	Infectious disease, semiquantitative measurement of pancreatic stone protein concentration in whole blood for the assessment of sepsis risk
101977	BIOFIRE FILMARRAY Tropical Fever (TF) Panel	Infectious disease detection by nucleic acid (DNA or RNA); vector-borne and zoonotic pathogens, 2 viral targets (Chikungunya and Dengue serotypes (1,2,3, and 4)), 1 bacterial

		target (Leptospira spp.), and 3 parasitic targets (Plasmodium spp., Plasmodium falciparum, and Plasmodium vivax/ovale), qualitative RT-PCR, whole blood specimen, each pathogen reported as detected or not detected
101978	~~M-inSight® Patient Definition Assay, Corgenix Clinical Laboratory, Sebia~~ **DELETE 0450U**	~~0450U Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LC-MS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides~~
101979	~~M-inSight® Patient Follow-Up Assessment, Corgenix Clinical Laboratory, Sebia~~ **DELETE 0451U**	~~0451U Oncology (multiple myeloma), LC-MS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance~~
101980	Precivity-ApoE(TM)	Neurology (Alzheimer disease), multi-analyte analysis of plasma utilizing liquid chromatography with tandem mass spectrometry (LC-MS/MS); 4 distinct ApoE isoform-specific peptides analyzed to identify presence of ApoE2, ApoE3, and ApoE4 isoforms to qualitatively report one of the 6 ApoE proteotypes (ApoE2/ApoE2, ApoE2/ApoE3, ApoE2/ApoE4, ApoE3/ApoE3, ApoE3/ApoE4, ApoE4/ApoE4) that corresponds to the APOE genotype
101982	AidaBreast	Oncology (breast), multi-omic expression assay (Next-Gen Sequencing 400 or more genes and multiplex immuno- fluorescence 15 or more proteins) analysis of formalin- fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
101983	Global MAPS (Global Metabolomic Assisted Pathway Screen - Urine)	Inborn Errors of Metabolism (eg Creatine disorders, Bile acid disorders, Urea cycle disorder, Fatty acid oxidation disorders) metabolomic profiling by high-resolution mass spectrometry of >700 metabolites, urine, semi-quantitative, reported as significantly altered analytes detected, rare analytes detected or common analytes absent
101984	ArteraAI Breast Test	Oncology (breast cancer), image analysis with artificial intelligence of at least 128 histologic features and clinical factors, prognostic algorithm determining risk of recurrence
101985	Allelica Multi-Ancestry CAD PRS Test	Cardiology (coronary artery disease [CAD]), DNA, 648 - 6.6 million single nucleotide polymorphisms [SNPs] (depending on ancestry), genome-wide genotyping or sequencing, saliva or blood sample, prognostic algorithm reported as polygenic risk to acquired heart disease
101986	Pathlight	Oncology (multi-cancer), analysis for molecular residual disease (MRD) from plasma using digital polymerase chain reaction (dPCR)-based detection of patient-specific structural variants selected from prior next-generation sequencing of the patient's tumor and germline DNA, reported as the presence or absence of MRD, with tumor DNA level, if appropriate
101987	Allelica Multi-Ancestry Breast Cancer PRS Test	Oncology (breast cancer [BC]), DNA, 530,000 - 690,000 single nucleotide polymorphisms [SNPs] (depending on ancestry), genome-wide genotyping or sequencing, saliva or blood

		sample, prognostic algorithm personalized to genetic ancestry and reported as absolute risk of acquired breast cancer
101989	Allelica Absolute DxTM Breast Cancer Test	Oncology (breast cancer [BC]), DNA, 530,000 - 690,000 single nucleotide polymorphisms [SNPs] (depending on ancestry), targeted whole exome sequencing plus low coverage whole genome sequencing, saliva or blood sample, prognostic algorithm personalized to genetic ancestry and reported as absolute monogenic plus polygenic risk of acquired breast cancer
101991	inFoods IBS	Gastroenterology (irritable bowel syndrome), IgG antibody identification for 18 foods by microarray, blood (whole or serum), report of elevated or non-elevated (positive or negative)
101992	Tempus Homologous Recombination Deficiency	Oncology (solid tumor), homologous recombination deficiency (HRD) status from whole transcriptome RNA data obtained from prior analysis of formalin fixed paraffin embedded tumor tissue, algorithmic analysis reported as biomarker positive or not detected with a quantitative score
101993	Tempus Immune Profile Score	Oncology (solid tumor), analysis of immunotherapy response, RNA and DNA next-generation sequencing data obtained from prior analyses of formalin fixed paraffin embedded tumor tissue, algorithmic analysis reported as quantitative immune profile score with high/low biomarker classification
101994	Tempus p-NSCLC	Oncology (lung), augmentative algorithmic analysis, digitized hematoxylin and eosin stained slides from lung cancer formalin fixed paraffin embedded tumor tissue, whole slide imaging of histologic features for seven molecular biomarkers, including pathogenic or likely pathogenic alterations in ALK, BRAF, EGFR, ERBB2, MET, RET, ROS1, reported as increased or decreased probability for each biomarker
101995	Tempus p-Endometrial	Oncology (endometrial), augmentative algorithmic analysis, digitized hematoxylin and eosin stained slides from endometrial cancer formalin fixed paraffin embedded tumor tissue, whole slide imaging of histologic features for five molecular biomarkers, including MSI-High status and presence of pathogenic or likely pathogenic alterations in CTNNB1, POLE, PTEN, TP53, reported as increased or decreased probability for each biomarker
101996	PancreaSure™	Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative