Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - November 2024 Meeting

The proposed agenda for the November 2024 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
100834	Guardant Reveal	Oncology (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
101753	NeXGen Fungal/AFB NGS Assay	Invasive fungal disease and Acid-Fast Bacteria identification using next-generation sequencing as a diagnostic approach which employs advanced genetic sequencing technologies to detect and identify pathogens in clinical samples
101784	Rapid whole genome sequencing	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings)
101785	PGT-M	Select low-risk embryos or HLA matching embryos with a high risk for a specific genetic condition utilizing fluorescent PCR and, if applies, minisequencing or restriction fragment length polymorphism, trophectoderm embryo biopsies, low-risk familial haplotypes and, if applies familial genetic variants, report if embryos are low-risk or at-risk for the familial condition
101786	EMMA / ALICE	Optimal microbiome to improve pregnancy probabilities, real-time PCR to detect bacterial DNA in endometrial biopsy sample, 30 bacterial targets, report if DNA from each target has been detected or not and if it is within a reference range or not
101787	Preimplantation Genetic Testing (PGT) for aneuploidy, ploidy, and additional quality controls	Next-generation sequencing (NGS) and single nucleotide polymorphisms (SNPs) test applied to preimplantation embryo biopsies to determine aneuploidy of any chromosome and/or ploidy abnormalities, detection of external DNA contamination, and lack of expected genetic relatedness between samples originating from a cohort of embryos, diagnostic, algorithm result
101800	PROSTOX ultra	Oncology (prostate), mRNA, gene expression profiling by RT-PCR of 32 genes, utilizing a noninvasive buccal swab to determine if patient has a genetically higher risk of late grade greater or equal to 2 genitourinary toxicity following radiation therapy, algorithm result type is predictive and the report type is a risk score (High or Low)
101802	PFASure (R) FT, Serum/Plasma (Perfluoroalkyl Substances)	Toxicology, Perfluoroalkyl Substances, (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), LCMS/MS, quantitative
101803	PrenatalDetect RHD	RhD feto-maternal blood group incompatibility test (RHD), cell-free circulating fetal DNA, real-time PCR, RHD (Rh blood group D antigen) exon 4, housekeeping control gene GAPDH
101804	Shield™	Oncology (eg, colorectal) next-generation sequence analysis of cfDNA for epigenomic patterns, utilizing plasma, algorithm reported as positive or negative
101805	PredicineCARE Assay	Oncology (solid tumor), circulating tumor DNA analysis of 152 plus genes, including *EGFR, BRAF, PIK3CA, FGFR3, AR, ALK, KRAS, ERBB2, ROS1, NTRK1,* by next-generation sequencing, interrogation for single nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and microsatellite instability (MSI), utilizing whole blood samples, report showing mutations with clinical actionability

101821	PredicineATLAS Assay	Oncology (solid tumor), Formalin-Fixed Paraffine-Embedded (FFPE) tumor tissue, DNA analysis of 600 genes, including *EGFR, BRAF, PIK3CA, FGFR3, AR, ALK, KRAS, ERBB2, ROS1, NTRK1*, by next-generation sequencing, interrogation for single nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations, microsatellite instability (MSI), tumor mutation burden (TMB), report showing mutations with clinical actionability
101822	AlloSure	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA (cfDNA)
101823	HDL Reverse Cholesterol Transport Panel with pCAD Score	Cardiovascular Disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of five distinct HDL-bound apolipoproteins, serum, proprietary algorithm reported as HDL reverse cholesterol transport panel with pCAD score
101824	HART CADhs®, ~~Atlas Genomics~~ Complete Omics, Inc, Prevencio, Inc **REVISE Laboratory name only**	*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*
101826	myOLARIS-KTdx	Nephrology (kidney transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus using real time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status
101827	Preimplantation Genetic Testing (PGT) for structural rearrangements (SR) and aneuploidy	Next-generation sequencing (NGS) applied to preimplantation embryo biopsies to determine aneuploidy of any chromosome and/or structural imbalances in chromosomes, genomic DNA from the embryo biopsies is the analyte, diagnostic, algorithm result
101828	Preimplantation Genetic Testing (PGT) for structural rearrangements (SR), aneuploidy, ploidy, and additional quality controls	Next-generation sequencing (NGS) and single nucleotide polymorphisms (SNPs) test applied to preimplantation embryo biopsies to determine aneuploidy of any chromosome and/or structural imbalances in chromosomes for which the patient carries a balanced structural rearrangement, ploidy abnormalities, detection of external DNA contamination, and lack of expected genetic relatedness between samples originating from a cohort of embryos, diagnostic, algorithm result
101830	Alice (Analysis of Infectious Chronic Endometritis)	Optimal microbiome to improve pregnancy probabilities, real-time PCR to detect bacterial DNA in an endometrial biopsy sample, 10 bacterial pathogens, report if DNA from each target has been detected or not and if it is within a reference range or not
101831	TruSight Oncology Comprehensive	Oncology (solid tumor), next-generation sequencing (NGS) of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of over 500 genes, interrogation for sequence variants, insertion and deletion alterations, rearrangements, and tumor-mutation burden
101832	VitaGraft Kidney 2.0	Donor-derived cell free DNA (dd-cfDNA) in plasma, droplet-digital PCR, 48 SNPs with high minor allelic frequencies, average of 19 SNPs will be informative and are used to quantify dd-cfDNA as percentage of total cfDNA and as concentration in copies/mL of plasma, algorithm, quantitative report high or low

		risk for active rejection
101833	CNSide	Oncology (Leptomeningeal Metastases), cerebrospinal fluid-derived tumor cell isolation using a combination of an antibody capture cocktail consisting of 10 different antibodies, and a streptavidin-coated microfluidic channel that allows for the detection, quantification, and characterization of clinically-relevant biomarkers expressed by the cerebrospinal fluid-derived tumor cells via Fluorescent In Situ Hybridization (FISH)
101834	Preimplantation Genetic Testing (PGT) for aneuploidy	Next-generation sequencing (NGS) test applied to preimplantation embryo biopsies to determine if the embryo has aneuploidy of any chromosome, genomic DNA from the embryo biopsies is the analyte, diagnostic, algorithm result
101835	Acetylcholine receptor (AChR) antibody, live-CBA	Immunology (neurology), acetylcholine receptor (AChR) antibody identification by live cell-based immunofluorescence assay (CBA)
101836	LRP4 antibody by cell-based assay	Immunology (neurology), low-density lipoprotein receptor-related protein 4 (LRP4) antibody identification by cell-based immunofluorescence assay (CBA)
101837	UCSF Pharmacogenomics Panel	Drug metabolism, whole blood, pharmacogenomic genotyping of 15 genes, reported as metabolizer status and transporter function
101838	Neurocode plasma GFAP	Neurology, analysis of glial fibrillary acidic protein (GFAP) by chemiluminescent enzyme immunoassay, plasma, normal reference range provided
101839	~~DetermaRx™, Oncocyte Corporation~~ RiskReveal, Razor Genomics **REVISE Test name and Laboratory name only**	*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*
101840	HART CVE®, ~~Atlas Genomics~~ Complete Omics, Inc, Prevencio, Inc **REVISE Laboratory name only**	*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*
101841	HART KD®, ~~Atlas Genomics~~ Complete Omics, Inc, Prevencio, Inc **REVISE Laboratory name only**	*0310U Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD*
101842	Bladder CARE	Oncology (urothelial), quantitative epigenetic profiling by real-time PCR of three DNA methylated cancer markers, TRNA-Cys, SIM2, and NKX1-1, urine, diagnostic algorithm reported as an index value, which is a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC)
101843	Neurocode blood NfL	Neurology, analysis of neurofilament light chain (NfL) by chemiluminescent enzyme immunoassay, plasma or serum, normal reference range provided

101844	MammoCheck (Blood-Based Breast Cancer Biomarker test)	Oncology, breast cancer, serum, measures level of secreted breast cancer protein marker (BF9 antigen) by enzyme-linked immunoassay (ELISA), quantitative, result reported as indicative of response/no response to therapy or disease progression/regression
101845	IgoCheck (Blood-Based Colorectal Cancer Biomarker test)	Oncology, colorectal cancer, serum, measures level of secreted colorectal cancer protein marker (BF7 antigen) by enzyme-linked immunoassay (ELISA), quantitative, result reported as indicative of response/no response to therapy or disease progression/regression
101846	CDX Prostate	Oncology, prostate cancer, immunochemistry measurements of total prostate specific antigen (PSA) and free PSA in blood combined with up to five specific clinical parameters with a machine learning software predictive algorithm to provide a risk score for the presence of high-grade prostate cancer
101847	LucentAD p-Tau 217	Phosphorylated Tau 217 (pTau-217), by ultra-high sensitivity molecule detection (SIMOA), plasma, reported as positive, intermediate, or negative for Alzheimer pathology
101852	Emily's Care Nourish Test System (Model 1)	Quantitative analysis of human milk for macronutrient content, including protein, fat, and carbohydrate levels, utilizing colorimetric methodology, performed at the point of care, using a reusable device (iPhone, and lightbox) with disposable test strips
101857	LiquidHALLMARK ctDNA and ctRNA **REVISE 0409U**	▲0409U Oncology (solid tumor), DNA (80 genes) and RNA (~~36~~10 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