Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - February 2025 Meeting

The proposed agenda for the February 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
101785	PGT-M	Selecting low-risk embryos or HLA matching embryos in couples 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
101787	Preimplantation Genetic Testing (PGT) for aneuploidy, ploidy, and additional quality controls	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as euploid (normal), monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with QC results reported as contamination detected or inconsistent cohort when applicable, per embryo tested
	RadTox cfDNA test 0285U	▲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 as ng/ml ~~a radiation toxicity score~~
101827	Preimplantation Genetic Testing (PGT) for structural rearrangements (SR) and aneuploidy	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for structural rearrangements, aneuploidy, and a mitochondrial DNA score, results reported as euploid/balanced (normal/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, or mosaic, per embryo tested
101828	Preimplantation Genetic Testing (PGT) for structural rearrangements (SR), aneuploidy, ploidy, and additional quality controls	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for structural rearrangements, aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as euploid/balanced (normal/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with QC results reported as contamination detected or inconsistent cohort when applicable, per embryo tested
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
101856	Minimal Residual Disease, Baseline	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 comparisons to subsequent MRD assessments

101858	Minimal Residual Diseases, Monitoring	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to previously designed and constructed personalized variant panel to evaluate for MRD
101859	~~Lesion Infection (Wound), Lab Genomics LLC, Thermo Fisher Scientific~~ **DELETE 0370U**	~~0370U Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibiotic resistance genes, multiplex amplified probe technique, wound swab~~
101860	~~GI assay (Gastrointestinal Pathogen with ABR), Lab Genomics LLC, Thermo Fisher Scientific~~ **DELETE 0369U**	~~0369U Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic resistance genes, multiplex amplified probe technique~~
101861	~~Respiratory Pathogen with ABR (RPX), Lab Genomics LLC, Thermo Fisher Scientific~~ **DELETE 0373U**	~~0373U Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen~~
101862	Urogenital Pathogen with Rx Panel (UPX), Lab Genomics LLC, Thermo Fisher Scientific **DELETE 0374U**	~~0374U Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic resistance genes, multiplex amplified probe technique, urine~~
101886	PGDx elio plasma focus Dx	Targeted genomic sequence analysis panel, solid malignant neoplasm analysis of 33 genes, detection of single nucleotide variants (SNVs), insertions and deletions (indels), copy number amplifications (CNAs), and translocations in human genomic circulating cell-free DNA (cfDNA)
101888	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel - Respiratory Menu	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets including Adenovirus, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Coronavirus (seasonal), Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A virus with 2 subtypes, Influenza B virus, Parainfluenza virus, and Respiratory syncytial virus, and 4 bacterial targets including Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative

101890	PreciseBreast™ ~~PreciseDx™ Breast Cancer Test~~, PreciseDx, PreciseDx **REVISE 0220U TEST NAME ONLY**	*0220U Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score*
101892	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel - Sore Throat Menu	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets including Adenovirus, Coronavirus (seasonal), Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A virus with 2 subtypes, Influenza B virus, Parainfluenza virus, and Respiratory syncytial virus and 4 bacterial targets including Chlamydia pneumoniae, Mycoplasma pneumoniae, Streptococcus dysgalactiae (Group C/G Strep), and Streptococcus pyogenes (Group A Strep), qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
101893	MethylScan HCC	Oncology (hepatocellular carcinoma), NGS methylation pattern assay to detect epigenetic alterations (6626 markers) using cell-free DNA (cfDNA) extracted from plasma using a predictive algorithm reported as "cancer signal detected" or "cancer signal not detected"
101894	Bronchitis	Infectious disease, respiratory tract infection, real-time PCR amplification of DNA/RNA markers for B pertussis/parapertussis/bronchiseptica, C pneumoniae, M pneumoniae reported as low, moderate, or high, and Adenovirus, Coronaviruses, COVID-19, Enterovirus D68, Metapneumovirus, Influenza A/B, Parainfluenza, RSV, Rhino/Enterovirus reported as positive or negative, utilizing nasopharyngeal or oropharyngeal swabs
101895	Vaginitis	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis , Bacterial Vaginosis Associated Bacteria-2&3 (BVAB-2, BVAB-3), Mobiluncus species, Megasphaera 1&2, reported as low, moderate, or high, and Candida species (C. albicans, C. tropicalis, C. parapsilosis), Candida krusei, Candida glabrata, Herpes simplex virus 1&2, Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, reported as positive or negative, utilizing vaginal-fluid specimens
101900	~~Xpert® Xpress CoV-2/Flu/RSV plus (all targets), Cepheid®~~ **DELETE 0241U**	~~0241U Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected~~
101901	~~Xpert® Xpress CoV-2/Flu/RSV plus (SARS-CoV-2 and Flu targets), Cepheid®~~ **DELETE 0240U**	~~0240U Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected~~

101902	EPISEEK-MPE (Malignant Pleural Effusion Detection Test)	Oncology (lung), qPCR-based analysis of 13 differentially methylated regions, utilizing pleural fluid, algorithm reported as a qualitative result
101903	Pigmented Lesion Assay (PLA), ~~DermTech~~DERM-JES Holdings, LLC **REVISE 0089U LAB NAME ONLY**	*0089U Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)*
101905	Genomic Unity 2.0	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, combination of short and long reads; genomic sequence analysis (single nucleotide variants, deletions/insertions and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy and inversions; mitochondrial DNA sequence and deletions, analysis short tandem repeat genes, methylation status of selected regions, gDNA isolated from blood, saliva, amniocentesis, CVS and tissue, identification and categorization of genetic variants
101906	Cxbladder Triage Plus~~Cxbladder Detect+~~, Pacific Edge Diagnostics USA LTD, Pacific Edge Diagnostics USA LTD **REVISE 0420U TEST NAME ONLY**	*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*
101907	LucentAD Complete	Blood Plasma beta amyloid (AB40, AB42, AB42/40 ratio), tau-protein phosphorylated at residue (eg, pTau 217), Neurofilament light chain (Nf-L), and GFAP (glial fibrillary acidic protein), by ultra-high sensitivity molecule detection (e.g. SIMOA), combined into an algorithm reported as positive, intermediate, or negative for Alzheimer pathology
101908	Guardant Reveal	Oncology (solid tumor) next-generation sequencing analysis of tumor methylation markers (>20,000 Differentially Methylated Regions) present in cell-free circulating tumor DNA (ctDNA), algorithm reported as presence or absence of ctDNA, with disease-burden correlation, if appropriate
101909	i-STAT TBI	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 overall result of elevated or not elevated based on threshold comparison
101911	LiquidHALLMARK ctDNA and ctRNA	Oncology (solid tumor), DNA (80 genes) and RNA (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

101912	SAAmplify-aSYN Test, ~~SYNTap® Biomarker Test,~~ Amprion Clinical Laboratory, Amprion Clinical Laboratory **REVISE 0393U and TEST NAME**	0393U Neurology (~~eg, Parkinson's disease, dementia, wi~~proteinopath ~~Lewy bodies~~), cerebrospinal fluid ~~(CSF)~~, detection of misfolded ~~α~~alpha-synuclein protein by seed amplification assay (also known as real-time quaking-induced conformational conversion or RT-QuIC), qualitative, with diagnostic algorithm
101913	FibroSIGHT™	Liver Disease (Metabolic dysfunction associated steatohepatitis [MASH]), digital imaging of unstained formalin-fixed paraffin-embedded (FFPE) liver tissue by second harmonic generation (SHG) microscopy to visualize fibrillar collagen and fibrosis, reporting liver staging of fibrosis with a summary pathologist interpretation
101914	ProsTAV	Oncology (Prostate), HT-QFISH, Telomeres and clinical variables (DRE, PSA, free PSA and age), blood, algorithm reported as risk score
101915	Amplified Sciences PanCystPro Test	Oncology (pancreas), Raman spectroscopic analysis of a protein, immunodetection of a protein and electrochemical detection of a metabolic marker, utilizing pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous, indicative of potential for malignancy
101916	NanoDetect-TB	Tuberculosis test, pulmonary and extrapulmonary tuberculosis, non-sputum, antigen, serum or plasma samples, analyzes a biomarker peptide derived from the Mtb virulence factor CFP-10 using a liquid chromatography-coupled mass spectrometry (LC-MS) system
101920	LiquidHALLMARK **REVISE 0530U**	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