Proposed Proprietary Laboratory Analyses Panel Meeting Agenda – February 2026 Meeting

The proposed agenda for the February 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 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
101631	UNITY Fetal RhD NIPT	Obstetrics (fetal RhD noninvasive prenatal test), next-generation sequencing analysis of cell-free DNA for detection of fetal presence or absence of RhD antigen in RhD-negative pregnant individuals, reported as detected or not detected
101910	MMDx Lung	Transplant rejection (lung), mRNA, analysis of 9 pathogenesis-based transcripts (QCAT, DSAST,

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		NKB, ABMR RAT, GRIT, IRRAT30, FICOL, IRITD3, IRITD5) by microarray, formalin-fixed paraffin embedded lung biopsy tissue, algorithmic risk stratification, reported as quantitative risk score
102026	Fetal Focus	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA NGS analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and to determine fetal inheritance of maternal mutation, utilizing a maternal blood sample, algorithm reported as a fetal risk score
102143	Genomind NeuroPsych Report **Delete 0423U**	~~*Psychiatry (eg, depression, anxiety), genomic analysis panel, includes variant analysis of 26 genes buccal swab, report including metabolizer status and risk of drug toxicity by condition*~~
102144	GeneStrat ESR1	Oncology (breast cancer), DNA, evaluation of 11 gene variants (*E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D*) using droplet digital polymerase chain reaction (ddPCR), circulating cell free DNA, initial detection and monitoring estrogen receptor 1 (ESR1), reported as ESR1 gene positive or negative mutation status
102145	Proofer ’7 HPV mRNA E6 and E7 Biomarker Test **Revise 0463U**	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker, triage test for positive HPV screening results, can be used reflexively
102146	OncoAssure Prostate **Revise Lab Name Only 0497U**	Oncology (prostate), mRNA gene-expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer
102147	Alcohol T-Score(TM) (Blood)	Behavioral (Alcohol Use Disorder), DNA, analysis of four DNA methylation markers (cg02583484, cg04987734, cg09935388 and cg04583842), methylation sensitive digital PCR, whole blood, algorithm reported as a summed T-score of methylation at the four loci tested indicating probability of continued alcohol use
102148	Alcohol T-Score(TM) (Saliva)	Behavioral (Alcohol Use Disorder), DNA, analysis of five DNA methylation markers (four content: cg02583484, cg04987734, cg09935388, cg04583842, and one normalizing: cg08141395), methylation sensitive digital PCR, saliva, algorithm results reported as a summed T score of DNA methylation in the white blood cell component of saliva determining likelihood of continued alcohol use

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102150	AdvanceAD-Tx	Autoimmune (atopic dermatitis) mRNA, next generation sequencing, gene expression profiling of 487 genes, non-invasive skin-surface collection using curette, algorithm reported as likelihood of response to atopic dermatitis systemic therapy
102161	Bartonella ImmunoBlot IgM Test	Bartonella species (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM
102162	Bartonella ImmunoBlot IgG Test	Bartonella ~~species~~ (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG
102163	Babesia ImmunoBlot IgM Test	Babesia species (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM
102164	Babesia ImmunoBlot IgG Test	Babesia species (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG
102167	Smoke Signature(c) (Blood)	Addiction medicine (tobacco use), DNA, analysis of one methylation marker (cg05575921 [AHRR]), methylation-sensitive digital polymerase chain reaction (dPCR), utilizing whole blood, algorithm reported as quantitative percent methylation and estimated average cigarette use per day
102168	Smoke Signature(c) (Saliva)	Addiction medicine (tobacco use), DNA, analysis of two DNA methylation markers (one content: cg05575921 [AHRR] and one normalizing: cg08141395), methylation-sensitive digital polymerase chain reaction (dPCR), utilizing the white blood cell component of saliva, algorithm reported as quantitative percent methylation and estimated average cigarette use per day
102169	Smoke Signature(c) Lung CA(TM) (Blood)	Oncology (Lung Cancer), DNA, analysis of DNA methylation marker (cg05575921), methylation sensitive digital PCR, whole blood, algorithm results reported as the 20-year hazard ratio for lung cancer
102170	Smoke Signature(c) Lung CA(TM) (Saliva)	Oncology (Lung Cancer), DNA, analysis of DNA 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
102171	Focused Pharmacogenomics Panel **Delete 0029U**	~~*Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823)*~~

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102173	Vesta Bladder Risk Stratify	Oncology (bladder), autonomous algorithmic analysis of histologic features from hematoxylin and eosin stained tissue slides for recurrence and progression risks, formalin-fixed paraffin embedded (FFPE) tissue, prognostic, reported as recurrence and progression risk scores
102174	CNSide CSF Tumor Cell Enumeration (TCE)	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential (MUC1/CA15-3/EMA/CD227), (EPCAMTrop1/CD326), Trop2, (CD318/CDCP1), (CD340/erB2/HER-2), MSC/SUSD2, FOLR1/FBP, HFGR/c-MET, EGFR, N Cadherin protein biomarkers, cerebrospinal fluid, report as detection and quantification of tumor cells
102175	PredicineBEACON Baseline	Oncology (minimal residual disease (MRD)), tumor DNA, next-generation sequencing, using FFPE and blood samples, initial (baseline) assessment for design and construction of a patient-specific panel for future comparisons to evaluate for MRD. The test consists of whole exome sequencing and customized assay design with a single plasma test
102177	Vesta Bladder BCG Predict	Oncology (bladder), autonomous algorithmic analysis of histologic features from hematoxylin and eosin stained tissue slides for non-response to Bacillus Calmette-Guerin (BCG) formalin-fixed paraffin embedded (FFPE) tissue, reported as presence or absence of biomarker for non-response to BCG
102179	PredicineCARE Urine Assay	Oncology (Genitourinary (GU) cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden (TMB), urine, mutations with clinical actionability reported as actionable variant
102180	MRD for Personalized Measurable Residual Disease for Leukemia associated Gene Fusion	Oncology (hematologic neoplasm), analysis of patient-specific oncogenic gene fusion RNA biomarker(s) as indicated by results of genomic sequencing results for patient's cancer, up to 5 RNA biomarkers per patient, digital PCR, peripheral blood or bone marrow, algorithm reported as positive or negative for measurable residual disease (MRD) with disease burden quantification if positive
102181	Personalized Measurable Residual Disease test set up for Leukemia associated Gene Fusion	Oncology (hematologic neoplasm), assay design and analysis of patient-specific oncogenic gene fusion RNA biomarker(s) as indicated by results of genomic sequencing results for patient's cancer, up to 5 RNA biomarkers per patient, digital polymerase chain reaction, peripheral blood or bone marrow, algorithm reported as positive or negative for measurable residual disease (MRD) with disease burden quantification if positive
102182	PredicineBEACON MRD (Longitudinal)	Oncology (minimal residual disease (MRD)), tumor DNA, next-generation sequencing, using whole

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		blood samples, subsequent assessment with comparison to initial assessment to evaluate for MRD in cancer patients. The test consists of a single plasma test.
102183	inFoods IBS **Revise 0598U**	Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by ~~microarray-based immunoassay~~ enzyme-linked immunosorbent assay (ELISA), whole blood or serum, report as elevated (positive) or normal (negative) antibody levels
102184	Northstar CH Plus	Oncology (solid tumor), leukocyte derived genomic DNA, sequence analysis of 15 or more genes including BRCA1 and BRCA2 for identification of single nucleotide variants and small insertions/deletions, reported as negative or positive with the identity of specific variant detected
102185	Plasma Detect Genome MRD - Baseline	Oncology (molecular residual disease [MRD]), whole genome sequence analysis, cell-free DNA, whole blood and tumor tissue DNA, baseline assessment for design of a personalized variant profile to evaluate current MRD and for comparison to subsequent MRD assessments
102186	Plasma Detect Genome MRD - Monitoring	Oncology (molecular residual disease [MRD]), whole genome sequence analysis, cell-free DNA, whole blood, assessment utilizing patient-specific tumor information for persistence, recurrence or clearance
102188	Oncomine Dx Express Test	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes, from DNA and RNA extracted from formalin-fixed, paraffin-embedded (FFPE) tissue
102189	GenomeDx Rapid, Proband	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing for single-nucleotide variants, insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, blood or buccal sample, identification and categorization of genetic variants
102190	SAGE Reveal	Oncology (solid tumors), drug resistance assay, intact viable tumor tissue from surgical biopsy, core needle biopsy, or malignant bodily fluid, quantification of intracellular adenosine triphosphate, algorithm reported as drug cytotoxic efficacy score for response and non-response to targeted and chemotherapeutic agents and combinations
102191	OptRx	Oncology (solid tumor), autonomous extraction and quantification of tumor microenvironment (TME) biomarkers from digitized whole-slide imaging of the patient's tissue specimen, reported as individualized recurrence-risk estimates and potential treatment-benefit identification correlated

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		to disease-free and/or overall survival, if appropriate
102192	Tempus xT CDx **Revise 0473U**	Oncology (solid tumor), next-generation sequencing (NGS) of DNA from ~~FFPE tissue with comparative sequence analysis from a matched normal specimen (blood or saliva)~~formalin-fixed paraffin-embedded (FFPE) tissue, 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden, with comparative sequence analysis from a matched normal specimen (blood or saliva), if available
102193	MAP-AD Test	Neurology (Alzheimer Disease), methylated DNA, targeted sequencing of AD-1 and AD2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status
102194	Tissue Specific Markers for Ealy Diagnosis of Sjogren's Disease **Revise 0522U**	Carbonic anhydrase VI, parotid specific/secretory protein and salivary protein 1 (SP1), IgG, IgM, and IgA antibodies, ~~chemiluminescence~~ immunoassay, semiqualitative, blood
102195	Cytochrome P450 1A2 Genotype **Delete 0031U**	~~*CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)*~~
102197	OncoDx (TM) (Hereditary Germline Cancer Genetics Panel)	Oncology, genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing with integrated exon-level CNV detection (digital MLPA for SNVs, small indels <40 bp) from saliva, whole blood or nail, diagnostic and risk-assessment result type, interpretive clinical variants reported with classification
102198	RenaXome (TM) (Renal Disease Whole Exome Sequencing)	Nephrology (kidney disease-related genetic conditions); germline DNA; ~20,000 protein-coding genes; whole-exome sequencing using paired-end NGS with bioinformatic analysis on ; specimen: whole blood or saliva; diagnostic result type for inherited kidney disorders, variants reported with classifications detected with ; interpretive clinical report classifying pathogenic/likely pathogenic variants and medically actionable secondary findings
102199	SAGE Prevail	Oncology (solid tumors), drug resistance assay, intact viable tumor tissue from surgical biopsy, core needle biopsy, or malignant bodily fluid, quantification of proliferating cells with 5-Ethynyl-2-deoxyuridine (EdU) incorporation, algorithm reported as drug antiproliferative efficacy score for response and non-response to targeted and chemotherapeutic agents and combinations

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102200	RenaPGx (TM) (Renal Pharmacogenetic Test)	Nephrology and/or Transplant Nephrology; DNA; 13 genes; real-time PCR and targeted genotyping; specimen: saliva or buccal swab; predictive pharmacogenetic profile for drug selection, dose optimization, and toxicity risk in kidney disease and transplant management; interpretive clinical report classifying pharmacogenetic variants with recommendations based on guideline-supported clinical dosing frameworks
102201	GlycoKnow Ovarian **Delete 0577U**	~~*Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy*~~
102202	Pyruvate Dehydrogenase (PDH) Enzyme Assay	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of one enzyme complex by radioactive activity assay, cultured skin fibroblasts, diagnostic quantitative result
102203	Complex I Assembly Western Blot Assay	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of one enzyme complex by western blot analysis, cultured skin fibroblast, diagnostic qualitative result
102204	Complex V Hydrolysis Enzyme Assay	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of one enzyme complex by spectrophotometric kinetic assay, cultured skin fibroblasts, diagnostic quantitative result
102205	Fecal Immunochemical Test, Quantitative	Oncology, screening for colorectal cancer, Fecal immunochemical test, quantitative determination of hemoglobin, by automated immunoassay, using automated analyzer, stool, includes sample preparation and analysis, reporting hemoglobin concentration
102207	Valar Pancreas ChemoPredict	Oncology (pancreas), autonomous algorithmic analysis of histologic features from hematoxylin and eosin stained tissue slides for chemotherapy regimen response, formalin-fixed paraffin embedded (FFPE) tissue, predictive, reported as a chemotherapy regimen response biomarker for 5-Fluororuracil or Gemcitabine based chemotherapy
102208	CKM PGx (TM) Panel (Hypertension and Cardiovascular-kidney-metabolic pharmacogenetic panel)	Cardiology Nephrology, Endocrinology; DNA; nine genes (CYP2D6, CYP2C19, NAT2, SLCO1B1, HLA-B*58:01, CYP2C9, VKORC1, ABCG2, G6PD); real-time PCR and targeted genotyping; specimen: buccal swab or saliva; predictive pharmacogenetic profile for drug metabolism, efficacy, and toxicity risk; interpretive clinical report classifying pharmacogenetic variants with recommendations to guide drug selection and dose optimization.
102209	DecisionDx-SCC ART	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by rt-pcr of 40

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		genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result for ART therapy guidance
102210	DecisionDx-SCC Plus	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by rt-pcr of 20 genes (14 content and 6 housekeeping) with 4 clinicopathologic factors, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result for metastatic and local recurrence risks
102212	Ataraxis Breast RISK	Oncology (breast cancer), immunoassay nucleic acid biomarker staining and image analysis with artificial intelligence assessment of at least 256 morphological features and clinical factors, prognostic algorithm determining risk of metastasis, reported as a recurrence score
102213	Ataraxis Breast CTX	Oncology (breast cancer), immunoassay biomarker staining and image analysis with artificial intelligence assessment of at least 256 morphological features and clinical factors, predictive algorithm to chemotherapy response, reported as absolute benefit of chemotherapy
102214	Ataraxis Breast NEO	Oncology (breast cancer), immunoassay biomarker staining and image analysis with artificial intelligence assessment of at least 256 morphological features and clinical factors, predictive algorithm of response to neoadjuvant therapy, reported as likelihood of pathologic complete response
102215	GenomeDx Rapid, Comparator	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by next-generation sequencing, blood or buccal sample, relevant variants reported with proband results
102216	GenomeDx ultraRapid, Proband	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing for single-nucleotide variants, insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, blood or buccal sample, identification and categorization of genetic variants