Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - November 2025 Meeting

The proposed agenda for the November 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
100767	Blue Native Polyacrylamide Gel Electrophoresis (PAGE)	Inborn error of metabolism (primary mitochondrial disease), analysis of 4 enzyme complexes by BNPage with in-gel activity staining, frozen tissue (muscle, liver, heart, and cultured skin fibroblasts), diagnostic qualitative result comparison to in-assay control
101885	FibroSIGHT TM Plus	Hepatology (Metabolic Dysfunction Associated Steatohepatitis [MASH]), digital imaging of

		unstained formalin-fixed paraffin-embedded (FFPE) liver biopsy tissue by second harmonic generation (SHG) microscopy for fibrosis-related collagen detection, algorithmic analysis of collagen features in the SHG image, reported as a quantitative fibrosis score, corresponding categorical fibrosis stage and classification
102100	iDart Lyme IgG ImmunoBlot Kit **Revise 0580U**	*580U Borrelia burgdorferi, antibody detection of ~~24~~ 31 recombinant protein groups, by immunoassay, IgG*
102101	iDart Lyme IgM ImmunoBlot Kit	Borrelia burgdorferi, antibody detection of 26 recombinant protein groups, by immunoassay, IgM
102102	TruD MDS COPD	Pulmonary (chronic obstructive pulmonary disease), DNA methylation analysis of >18,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early COPD detection and diagnosis
102103	TruD MDS ASCVD	Cardiovascular (atherosclerotic cardiovascular disease), DNA methylation analysis of >20,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early ASCVD detection and diagnosis.
102104	TruD MDS Alzheimer's & MCI	Neurology (Alzheimer's disease and other dementias), DNA methylation analysis of >30,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early dementia detection and diagnosis.
102105	TruD MDS Major Depressive Disorder	Psychiatry (major depressive disorder), DNA methylation analysis of over 20,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early MDD detection and diagnosis
102107	TruD MDS Schizophrenia	Psychiatry (schizophrenia), DNA methylation analysis of >15,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early schizophrenia detection and diagnosis
102108	TruD MDS Bipolar	Psychiatry (bipolar disorder), DNA methylation analysis of >10,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early bipolar disorder detection and diagnosis
102109	TruD MDS Multiple Sclerosis	Autoimmune (multiple sclerosis), DNA methylation analysis of >5,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early MS detection and diagnosis
102110	TruD MDS Parkinson's	Neurology (Parkinson's disease - neurodegenerative), DNA methylation analysis of >20,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early Parkinson's disease detection and diagnosis

102111	TruD MDS NASH	Gastroenterology (non-alcoholic steatohepatitis - fatty liver disease), DNA methylation analysis of 5,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early NASH detection and diagnosis
102112	TruD MDS Osteoporosis	Endocrinology (osteoporosis - metabolic bone disease), DNA methylation analysis of >5,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early osteoporosis detection and diagnosis
102113	TruD MDS Lyme Disease	Infectious Disease (Lyme borreliosis), DNA methylation analysis of >10,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early Lyme disease detection and diagnosis
102114	TruD MDS Hepatocellular Carcinoma	Infectious Disease (Lyme borreliosis), DNA methylation analysis of >10,000 CpG sites, whole blood, genome-wide CpG analysis, algorithmic analysis, early Lyme disease detection and diagnosis
102121	CNSide CSF Tumor Cell Enumeration (TCE)	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, report as detection and/or quantification of tumor cells in cerebrospinal fluid
102123	SAGE Reveal	Oncology (solid tumors), analysis of tissue metabolic activity in patient-derived three-dimensional (3D) microtumor replicates retaining the native tumor microenvironment, validated metabolic analyte, fresh tissue, computational algorithm, prognostic, effectivity score for response and non-response to targeted and chemo therapeutic agents and combinations
102129	MeMed BV, MeMed Diagnostics Ltd and its licensees, MeMed Diagnostics Ltd and its licensees **REVISE LABORATORY & MANUFACTURER NAME ONLY 0351U**	*0351U Oncology (solid tumors), analysis of tissue metabolic activity in patient-derived three-dimensional (3D) microtumor replicates retaining the native tumor microenvironment, validated metabolic analyte, fresh tissue, computational algorithm, prognostic, effectivity score for response and non-response to targeted and chemo therapeutic agents and combinations*
102132	Vesta Bladder BCGPredict	Oncology (bladder), augmentative algorithmic analysis of histologic features from hemotoxylin and eosin stained tissue slides for Bacillus Calmette-Guerin (BCG) response, formalin-fixed paraffin embedded (FFPE) tissue, predictive, reported as a BCG unresponsiveness biomarker
102135	Vesta Bladder Risk Stratify	Oncology (bladder), augmentative algorithmic analysis of histologic features from hemotoxylin and eosin stained tissue slides for recurrence and progression risks, formalin-fixed paraffin

		embedded (FFPE) tissue, prognostic, reported as recurrence and progression risk scores
102136	Valar Pancreas ChemoPredict	Oncology (pancreas), augmentative algorithmic analysis of histologic features from hemotoxylin and eosin stained tissue slides for chemotherapy regimen response, formalin-fixed paraffin embedded (FFPE) tissue, predictive, reported as a chemotherapy regimen preference biomarker
102137	RenaDx- Renal Disease Comprehensive Panel	DNA is extracted from saliva samples and analyzed by next-generation sequencing targeting 449 genes associated with renal diseases. Sequence variants are identified and classified according to established professional guidelines. A board-certified laboratory director interprets the results and issues a clinical report that categorizes findings as pathogenic, likely pathogenic, variants of uncertain significance, or risk alleles, which is provided to the ordering clinician for use in patient care.
102138	CRISPR-TB Blood Test	Infectious disease (tuberculosis), DNA, analysis of 1 locus by polymerase chain reaction (PCR) with CRISPR-based probe detection, plasma or serum, reported qualitatively as detected or not detected for Mycobacterium tuberculosis complex DNA
102139	Trimethylamine (TMA), Children's Hospital Colorado Laboratory **Revise 0256U**	*0256U Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, liquid chromatography tandem mass spectrometry (LC-MS/MS), urine, with algorithmic analysis and interpretive report*
102140	PreTransplant Risk Assessment (PTRA) ~~Clarava™~~ **Revise test name only 0319U**	*0319U Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection*
102141	BluePRint 80-gene Molecular Subtyping Profile	Oncology (breast), mRNA, gene expression profiling by micro-array of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as Index which is diagnostic of a molecular subtype (luminal, basal, HER2)