Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2023 Meeting

The proposed agenda for the May 2023 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. **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
100584	Abbott Alinity m STI Assay	Infectious agent (sexually transmitted infection) pathogen-specific DNA or RNA, 4 targets (chlamydia trachomatis, neisseria gonorrhoeae, trichomonas vaginalis, mycoplasma genitalium), multiplex amplified probe technique, for use in the following sample types – vaginal, endocervical, and urine (male), each pathogen reported as detected or not detected
101036	Versiti™ Congenital Neutropenia Panel **REVISE** 0271U	▲0271U Hematology (congenital neutropenia), genomic sequence analysis of ~~23~~ 24 genes, blood, buccal swab, or amniotic fluid
101037	Versiti™ Thrombosis Panel **REVISE** 0278U	▲0278U Hematology (genetic thrombosis), genomic sequence analysis of ~~12~~ 14 genes, blood, buccal swab, or amniotic fluid
101038	Versiti™ Autosomal Dominant Thrombocytopenia Panel **REVISE** 0269U	▲0269U Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of ~~14~~ 22 genes, blood, buccal swab, or amniotic fluid
101039	Versiti™ Platelet Function Disorder Panel **REVISE** 0277U	▲0277U Hematology (genetic platelet function disorder), genomic sequence analysis of ~~31~~ 40 genes, blood, buccal swab, or amniotic fluid
101040	Versiti™ Comprehensive Bleeding Disorder Panel **REVISE** 0272U	▲0272U Hematology (genetic bleeding disorders), genomic sequence analysis of ~~51~~ 61 genes, blood, buccal swab, or amniotic fluid, comprehensive
101042	Versiti™ Comprehensive Platelet Disorder Panel **REVISE** 0274U	▲0274U Hematology (genetic platelet disorders), genomic sequence analysis of ~~43~~ 63 genes, blood, buccal swab, or amniotic fluid
101283	MyProstateScore 2.0	Oncology (Prostate), mRNA, gene expression profiling by real-time RT-PCR of 18 genes, utilizing first-catch urine (or processed first-catch urine), algorithm is reported as the MyProstateScore2.0 which predicts the percent likelihood of detecting clinically-significant prostate cancer (Grade Group [GG] ≥2) on biopsy

101285	Divitum® TKa	Oncology, semi-quantitative measurement of thymidine kinase activity, by immunoassay, serum, results reported as DiviTum® Unit Activity (DUA) to inform prognosis and/or monitor tumor progression or response to hormone and/or targeted therapy
101321	Noninvasive detection of pancreatic ductal adenocarcinoma	pancreatic ductal adenocarcinoma - cancer detection DNA 56 Methylation haplotype blocks markers (eg, TLX2, SFRP2, AGAP2) methylation status next generation sequencing method blood predictive positive or negative
101343	CyPath® Lung	Oncology (lung), flow cytometry analysis of fluorescence intensity (FVS510, CD206, CD66b, CD3, CD19, TCPP), cell types (CD206, CD66b, CD3, CD19) and clinical risk factors (age), utilizing sputum, algorithm outcome reported as a likelihood of malignancy
101344	DAWN™ IO Melanoma **DELETE** 0357U	~~● 0357U Oncology (melanoma), artificial intelligence (AI) enabled quantitative mass spectrometry analysis of 142 unique pairs of glycopeptide and product fragments, plasma, prognostic, and predictive algorithm reported as likely, unlikely, or uncertain benefit from immunotherapy agents~~
101345	IntelxDKD™	Nephrology (chronic [diabetic] kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with clinical data, utilizing plasma (isolated fresh or frozen), algorithm reported as risk for progressive decline in kidney function
101351	Omnia™ SARS-CoV-2 Antigen Test	Infectious agent antigen detection by bulk acoustic wave biosensor-based immunoassay with enzymatic enhancement, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
101353	LiquidHALLMARK	Oncology (solid tumor) liquid biopsy ctDNA analysis, via NGS, of somatic mutations of in 80 genes, fusions in 10 genes, and their variants to associate with FDA approved therapies, clinical trials or resistance to therapies that are commonly associated with multiple cancers, including lung, breast and colon cancer
101354	MDAnderson Cancer Center Hematopathology Optical Genome Mapping	Oncology (hematopathology neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alterations
101355	Avantect Pancreatic Cancer Test	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as a cancer detected or not detected
101356	IDgenetix	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
101358	PrecivityAD® blood test	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, utilizing plasma, algorithmically combined with age to determine presence or absence of brain amyloid pathology
101359	DH Optical Genome Mapping Assay	Digital Karyotyping with Optical Genome Mapping, utilizing ultra high molecular weight DNA derived from fresh blood or bone marrow

101360	miR Sentinel™ Prostate Cancer Test **REVISE** 0343U	▲0343U Oncology (prostate)~~, exosome-based~~ analysis of ~~442~~ 53 small noncoding RNAs (sncRNAs), extracted from urinary exosomes, by quantitative ~~reverse~~ ~~transcription~~ real time polymerase chain reaction (RT-qPCR), ~~urine,~~ reported as no molecular evidence ~~of no~~ -, low-~~, intermediate~~, moderate- or ~~high~~ elevated-risk of prostate cancer
101361	Envisage Barrett's Esophagus Risk Classifier Assay **DELETE** 0386U	~~0386U Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer~~
101380	LungOI	Oncology (lung), whole slide imaging analysis with artificial intelligence assessment of at least 8 genes (eg, ALK, BRAF, EGFR, ERBB2, RET, ROS1) for gene sequence variants and rearrangements, formalin-fixed paraffin-embedded tissue, algorithm analysis reported qualitatively as positive or negative
101381	Thyroid GuidePx **REVISE** 0362U	▲0362U Oncology (papillary thyroid cancer), Ribonucleic acid (RNA), gene-expression profiling via targeted hybrid capture–enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, utilizing fine needle aspirate (FNA) or formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes
101382	SmartVascular DX	Vascular endothelial test, a chemistry assay testing 7 protein biomarkers, IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN and MCP-3 and four global risk factors,(age, sex, family history, and personal history of diabetes) utilizing a blood sample and algorithm, diagnosing elevated vascular inflammation and providing a risk score of the patient's 5 year risk of acute coronary syndrome and stroke
101384	GENETWORx UTI with ABR	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 20 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
101385	Genomic Unity® Comprehensive Mitochondrial Disorders Analysis	Rare diseases (constitutional/ heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis, including sequence changes, deletions, insertions, and copy number variants analysis (including deletions, duplications, inversions and mobile element insertions) in a set of 335 nuclear genes associated with mitochondrial disorders, blood or saliva, identification and categorization of genetic variants
101386	PartoSure™ Test **DELETE** 0066U	~~0066U Placental alpha-micro globulin-1 (PAMG-1), immunoassay with direct optical observation, cervicovaginal fluid, each specimen~~
101388	CellSearch® PD-L1 Circulating Tumor Cell (CTC-PDL1) Test	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18 and 19, and CD45 protein biomarkers, and quantification of PD-L1 protein biomarker expressing cells, peripheral blood
101389	CellSearch® ER Circulating Tumor Cell (CTC-ER) Test	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18 and 19, and CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker expressing cells, peripheral blood

101394	PreciseDx Breast **REVISE** 0220U	▲0220U Oncology (breast cancer), image analysis of surgical or biopsy specimen with artificial intelligence assessment of 8-12 ~~histologic and immunohistochemical~~ digital morphologic features, algorithm combined with clinical data, reported as a recurrence score
101395	PreciseDx Breast Biopsy Test	Oncology (breast cancer),image analysis of biopsy specimen with AI assessment of 8 algorithm combined digital morphologic features, with clinical data, reported as a recurrence score
101396	CellSearch® Circulating Melanoma Cell (CMC) Test	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential CD146, high-molecular weight melanoma-associated antigen, CD34 and CD45 protein biomarkers, peripheral blood
101397	Tempus nP	Neuropsychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD], bipolar disorder, schizophrenia), genomic sequence analysis panel, variant analysis of at least 13 genes, including deletion/duplication analysis of CYP2D6
101398	Agilent Resolution ctDx FIRST **DELETE** 0397U	~~0397U Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations~~