Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2022 Meeting

The proposed agenda for the August 2022 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
100525	ColoScape Colorectal Cancer Mutation Detection Test	Oncology (Colorectal Cancer, Solid organ neoplasia), multiplex real-time PCR based Xenonucleic acid (XNA) mediated PCR clamping technology, cfDNA, Plasma or formalin-fixed paraffin-embedded tissue, report of colorectal cancer-associated mutations in genes including APC (codons 1309, 1367, 1450 and 876), BRAF (codon 600), CTNNB1 (codons 41 and 45), KRAS (codons 12 and 13), NRAS (codons 12 and 13), PIK3CA (codon 545), SMAD4 (codon 361) and TP53 (codons 175, 248 and 273) and the methylation genes (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1)
101002	Apolipoprotein L1 (APOL1) Renal Risk Variant Genotyping	Apolipoprotein L1 exon 6, G1 variant and G2 deletion analysis by Sanger sequencing
101096	Opioid Use Disorder Genetic Risk Test (OUD-GRT)	Genetic Risk test (Cheek tissue), DNA, PCR genotype analysis of 3 genes COMT, OPRM1, DAT1A, reported as risk status for OUD
101120	NavDx	Oncology (oropharyngeal), cell-free DNA, droplet digital PCR to profile the fragmentation pattern of tumor tissue modified viral (TTMV) HPV DNA using 17 DNA biomarkers, weighted fragment size distribution algorithmic analysis, whole blood, algorithm reported as a prognostic TTMV risk score for cancer recurrence
101122	Dawn IO Melanoma	Oncology (melanoma), liquid chromatography, 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 to immunotherapy agents
101126	Lumipulse® G β-Amyloid Ratio (1-42/1-40) Test	Neurology (Mild Cognitive Impairment related to Alzheimer's disease and other forms of dementia); Protein analysis of β-Amyloid 1-42 and β-Amyloid 1-40; Two proteins; Chemiluminescence enzyme immunoassay (CLEIA); Cerebral spinal fluid (CSF); Diagnostic; Reported as a positive or negative result as determined by the cutoff of the ratio
101127	Esophageal String Test (EST)	▲0095U ~~Inflammation (e~~Eosinophilic esophagitis~~), ELISA analysis of~~ 2 protein biomarkers (~~e~~otaxin-3 (CCL26 [C-C motif chemokine ligand 26]) and major basic protein (PRG2 [proteoglycan 2, pro eosinophil major basic protein]), enzyme-linked immunosorbent assays (ELISA), specimen obtained by ~~swallowed nylon~~ esophageal string test device, algorithm reported as ~~predictive~~ probability ~~index for~~ of active or inactive ~~e~~Eosinophilic esophagitis

101140	Oncuria® Detect	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) using immunoassays, utilizing voided urine sample with diagnostic algorithm which includes patient's age, race and gender reported as a probability of harboring cancer
101141	Oncuria® Monitor	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) using immunoassays, utilizing voided urine sample with diagnostic algorithm which includes patient's age, race and gender reported as a probability of a recurring cancer
101142	Oncuria® Predict	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) using immunoassays, utilizing voided urine sample with diagnostic algorithm reported as a risk score
101143	IsoPSA®	Oncology (high-grade prostate cancer),analysis of all PSA structural isoforms by phase separation and immunoassay, utilizing plasma, algorithm index depicting risk of cancer
101144	Nodify CDT	Oncology (lung) enzyme-linked immunosorbent assay measurement of seven autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), utilizing plasma, algorithm reported as a categorical result (e.g., No Significant Level of Autoantibodies Detected (NSLAD), Moderate Level (Moderate) or High Level (High))
101145	Neurofilament Light Chain (NfL)	Neurology biomarker, neurofilament light chain, plasma, digital immunoassay, quantitative
101147	AvaGen Keratoconus Test	Ophthalmology (Keratoconus), DNA, Next generation sequencing (NGS) of over 25 genes, buccal swab, algorithm reported as a prognostic polygenic risk score (Do not report with CPT 81333)
101148	Thyroid GuidePx	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 formalin-fixed paraffin embedded tissue, algorithm reported as one of three molecular subtypes
101151	Cxbladder® Triage	Oncology (urothelial), mRNA, gene expression profiling by realtime quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm incorporating age, sex, smoking history and macrohematuria frequency, reported as a risk score for having urothelial carcinoma