Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2023 Meeting

The proposed agenda for the August 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 via email for a copy of the application and associated materials. **Only requests submitted via email to Caitlin.Mora@ama-assn.org will be accepted.** 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 following relevant deadlines for provision of written comments on the agenda to ensure comment review by all parties. The applicant(s) who submitted the original code change application is automatically considered an interested party and are notified by AMA staff of any request for review submitted by another party.

Verbal comments may be made publicly at the meeting following a statement of conflict of interest.

*Interested party requests will not be processed until the interested party submits a signed confidentiality agreement and disclosure of interest form.

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
101313	Cxbladder Detect+	Oncology (bladder), mRNA expression profiling by real time quantitative PCR of 5 genes (MDK, HOXA13, CDC2, IGFBP5, and CXCR2) in combination with ddPCR analysis of 6 single nucleotide polymorphisms in two genes (TERT and FGFR3) utilizing a midstream voided urine sample, algorithm reported as a risk score of having urothelial carcinoma
101399	Colosense	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, and EGLN2) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
101400	Guardant360 Response	Oncology (pan-cancer), analysis of DNA biomarker response to anti-cancer therapy using cell-free circulating DNA, biomarker comparison to a previous baseline pre-treatment cell-free circulating DNA analysis using next-generation sequencing, algorithm reported as a quantitative change from baseline, including specific alterations, if appropriate
101420	Genomind NeuroPsych Report	Gene analysis panel for detection of variants in 26 genes associated with psychiatric and other pharmaceutical treatment (eg, depression, anxiety), genomic analysis panel, variant analysis of 26 genes
101441	miR Sentinel Prostate Cancer Test	Oncology (prostate) analysis of 53 small noncoding RNAs (sncRNAs), extracted from urinary exosomes, by quantitative real time polymerase chain reaction (rt-qPCR), reported as no molecular evidence, low-, moderate- or elevated-risk of prostate cancer
101442	Qlear Wound Pathogen Panel	Infectious agent detection by nucleic acid (DNA or RNA), wound pathogen, semiquantitative identification of DNA from 28 pathogen targets and 18 ABR gene targets, reported as an antimicrobial stewardship risk score, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), swab
101443	CardioRisk+	Cardiology (Coronary Heart Disease [CAD], Polygenic risk score based on 564,856 SNPs, targeted variant genotyping, buccal swab, algorithm reported as polygenic risk to acquired heart disease
101444	RCIGM Rapid Whole Genome Sequencing, Comparator Genome	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis, each comparator genome (eg, parents, siblings)
101445	RCIGM Ultra-Rapid Whole Genome Sequencing	Genome (eg, unexplained constitutional or heritable disorder or syndrome), ultra-rapid sequence analysis
101446	Early Sepsis Indicator	+Monocyte distribution width, whole blood (List separately in addition to code for primary procedure) (Use XXXXU in conjunction with 85004 or 85025)
101447	Epic Sciences ctDNA Metastatic Breast Cancer Panel	Oncology (Breast), targeted hybrid capture genomic sequence analysis panel, circulating tumor DNA analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden
101460	Omnipathology Oropharyngeal HPV PCR Test	Infectious disease (viral), real-time PCR testing for 14 high-risk HPV types using oropharyngeal swab

101463	Malabsorption Evaluation Panel	Gastroenterology, malabsorption evaluation of alpha-1-antitrypsin, calprotectin, pancreatic elastase and reducing substances, feces, quantitative
101464	Glycine Receptor Alpha1 IgG	Glycine Receptor Alpha1 IgG, serum or cerebrospinal fluid (CSF), live Cell-Binding Assay (LCBA), qualitative
101465	Kelch-Like Protein 11 Antibody	Kelch-Like Protein 11 (KLHL11) Antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative
101466	NavDx Revise 0356U	▲0356U Oncology (oropharyngeal or anal), ~~evaluation~~ cell-free DNA, droplet digital PCR to profile the fragmentation pattern of tumor tissue modified viral (TTMV) HPV DNA using 17 DNA biomarkers ~~using droplet~~, weighted fragment size distribution algorithmic analysis, ~~digital PCR (ddPCR), cell-free DNA~~, whole blood, algorithm reported as a prognostic TTMV risk score for cancer recurrence
101468	EpiSwitch® Prostate Screening Test	Oncology, DNA, 3D Genetic Profiling; five (5) DNA regulatory (epigenetic) markers called chromosome conformation signatures (CCS), extracted from whole blood and measured by quantitative PCR (qPCR), an algorithm stratifies patients based on their likelihood of prostate cancer, in combination with prostate-specific antigen (PSA) measurement
101469	BluePrint 80-gene molecular subtyping profile	Oncology (breast), mRNA, gene-expression profiling by micro-array of 80 content genes and 465 housekeeping genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as Index diagnostic of molecular subtype (Basal, Luminal, Her2)
101470	RightMed Exclude F2 and F5 Gene Report	Drug processing/Drug metabolism (multiple conditions), whole blood or buccal, DNA analysis, 25 genes, with variant analysis including impacted gene-drug interactions and reported phenotypes
101471	ChemoID	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (cscs), from cultured cscs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 10 drugs or drug combinations
101472	PROphet® NSCLC Test	Oncology (lung), plasma analysis of 388 proteins, using aptamer-based proteomics technology, predictive algorithm reported as clinical benefit (CB) from immune checkpoint inhibitor therapy.
101473	MindX Blood Test- Anxiety Report	Psychiatry (anxiety disorders), blood, RNA sequencing, algorithm reported as current and future anxiety disorder risk and recommended treatment.
101474	MeMed BV® Revise 0351U	▲0351U Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, or venous whole blood, algorithm reported as likelihood of bacterial infection
101475	EffectiveRX Comprehensive Panel	Drug Metabolism or processing (multiple conditions), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted gene-drug interactions