Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2024 Meeting

The proposed agenda for the August 2024 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
101705	~~PersonalisedRX, Lab Genomics LLC, Agena Bioscience, Inc~~ **DELETE** 0380U	~~0380U Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype~~
101706	Shield™	Oncology (eg, colorectal) screening, analysis of multiple biomarkers from plasma including methylation using next generation sequencing, algorithm reported with a categorical result (e.g. normal signal detected or abnormal signal detected)
101720	Tissue Specific Markers for Ealy Diagnosis of Sjogren's Disease	Utilizing chemiluminescence methodology, semi-quantitative measurement of antibodies to isotypes IgG, IgA, and IgM of Salivary Protein 1, Parotid Secretory Protein and Carbonic Anhydrase VI is carried out in serum
101722	Oncuria® Detect, DiaCarta Clinical Lab, DiaCarta, Inc **REVISE** 0365U	▲0365U Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1, and VEGFA) ~~by~~ using immunoassays, utilizing voided urine~~,~~ sample with diagnostic~~,~~ algorithm which includes patient's age, race and gender reported as a probability of harboring urothelial ~~bladder~~ cancer
101725	~~oncoReveal™ DX Lung and Colon Cancer Assay, Pillar® Biosciences, Pillar® Biosciences~~ **DELETE** 0448U	~~0448U Oncology (lung and colon cancer), DNA, qualitative, next-generation sequencing detection of single-nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffin-embedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options~~
101726	oncoReveal™ CDx	Oncology, (solid tumor pan-cancer) DNA, qualitative, next generation sequencing based detection of single nucleotide variants and deletions in 22 genes, formalin-fixed paraffin-embedded solid tumor, reported as presence or absence of mutation(s), location of mutation, nucleotide change, amino acid change, and therapeutic options
101727	sFlt-1/PlGF	Hypertensive disorder of pregnancy (chronic hypertension with superimposed preeclampsia, chronic hypertension without superimposed preeclampsia, gestational hypertension, and preeclampsia) between the gestational ages of weeks 23 and 34+6. Biomarker test, protein, TRACE Technology to analyze the sflt-1 and PlGF biomarkers, serum or plasma specimens, prognostic, test reported as ratio for risk assessment
101729	Seronegative Rheumatoid Arthritis Panel	An autoimmune disease marker panel for seronegative rheumatoid arthritis measuring four autoantibodies by flour immunoassay and enzyme linked immunosorbent assays in serum. An interpretative report (positive or negative) is provided
101730	3D Predict Ovarian	Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or

		peritoneal tumor response prediction for each drug
101731	QUEST AD-Detect™, Beta-Amyloid 42/40 Ratio, Plasma, Quest Diagnostics **DELETE** 0346U	~~0346U Beta amyloid, Aß40 and Aß42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma~~
101742	~~PrismRA®, Scipher Medicine®, Scipher Medicine®~~ **DELETE** 0456U	~~0456U Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anticyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy~~
101745	CXCL10 Urine Test	Transplantation Medicine Nephrology (tissue rejection), quantification of CXCL10 chemokines from urine utilizing flow cytometry, reported as pg/mg creatinine; analysis of increases from baseline used to monitor for subclinical tissue rejection and need for biopsy
101747	Allelica Multi-Ancestry Breast Cancer PRS Test	Polygenic risk score (breast cancer), Genome-wide analysis to determine ancestry followed by analysis of 530,000 - 690,000 ancestry-specific single nucleotide polymorphisms (SNPs), algorithm personalized to genetic ancestry and reported as lifetime, 5- and 10- year risk of breast cancer, utilizes saliva or blood samples
101748	Allelica Multi-Ancestry CAD PRS Test	Polygenic risk score (CAD), Genome-wide analysis to determine ancestry followed by DNA sequence analysis of 648 - 6.6 million ancestry-specific single nucleotide polymorphisms (SNPs), algorithm personalized to genetic ancestry and reported as relative risk of CAD, utilizes saliva or blood samples
101749	Abbott Alinity m HSV 1 & 2 / VZV Assay	Infectious agent (viral), Herpes simplex virus type 1, Herpes simplex virus type 2, Varicella zoster virus, multiplex amplified probe technique, cutaneous or mucocutaneous lesion, each pathogen reported as detected or not detected
101750	BIOFIRE FILMARRAY Pneumonia Panel	Infectious agent detection by multiplexed amplified probe technique including multiplexed reverse transcription, pathogen-specific nucleic acid (DNA or RNA), bacterial or viral lower respiratory tract infection, identification of 18 bacteria, 8 viruses, and 7 antimicrobial resistance genes, lower respiratory tract specimens, qualitative RT-PCR, semi-quantitative results for 15 bacterial organisms, each pathogen reported as detected or not detected
101751	Lifetime Genomics Risk Assessment, VTE	Hematology, venous thromboembolism (VTE), genome-wide single nucleotide polymorphism (snp) variants, including coagulation factor ii and v (F2 and F5) gene analysis, and Leiden variant, by microarray analysis, saliva, report as risk score for VTE
101752	Epic Sciences ctDNA Metastatic Breast Cancer Pan **DELETE** 0428U	~~0428U Oncology (Breast), targeted hybrid capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden~~
101761	LiquidHALLMARK	Next generation sequencing (NGS) to evaluate cell-free DNA from a blood specimen for 80 genes associated with solid-organ tumors

101763	Esophageal String Test (EST) **REVISE** 0095U	▲0095U Eosinophilic esophagitis, 2 protein biomarkers (Eotaxin-3 ~~[CCL26 {C-C motif chemokine ligand 26}]~~ and major ~~b~~Basic ~~protein [PRG2 {proteoglycan 2, pro eosinophil major basic protein}]~~ 1), enzyme-linked immunosorbent assays (ELISA), specimen obtained by esophageal string test device, algorithm reported as probability of active or inactive eosinophilic esophagitis