# Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - February 2023 Meeting

The proposed agenda for the February 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 |
|---|---|---|
| 100881 | IntelliSep test | Infectious disease (bacterial, fungal or viral infection), semi-quantitative, whole blood sample, biomechanical assessment (via deformability cytometry) with algorithmic analysis and result reported as an index |
| 101191 | AMBLor® melanoma prognostic test | Melanoma, whole-slide imaging, including morphometric analysis of two protein biomarkers, AMBRA1 and loricrin, from formalin-fixed paraffin- embedded tissue, reporting progression risk |
| 101221 | Prostate Cancer Risk Panel<br><br>**DELETE 0053U** | ~~0053U Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade~~ |
| 101240 | InVisionFirst®-Lung Liquid Biopsy | Oncology (non-small cell lung cancer), SNV, Indel, Fusion, and CNV detection by next-generation sequencing, ctDNA, whole blood, report of genetic alteration(s) |
| 101241 | CareViewRx<br><br>**DELETE 0143U** | ~~)(0143U Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid Chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101242 | CareViewRx Plus<br><br>**DELETE 0144U** | ~~0144U Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid Chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101243 | PainViewRx<br><br>**DELETE 0145U** | ~~0145U Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid Chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101244 | PainViewRx Plus<br><br>**DELETE 0146U** | ~~0146U Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LCMS/ MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101245 | RiskViewRx<br><br>**DELETE 0147U** | ~~0147U Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid Chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |

| | | |
|---|---|---|
| 101246 | RiskViewRx Plus<br><br>**DELETE 0148U** | ~~0148U Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid Chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101247 | PsychViewRx<br><br>**DELETE 0149U** | ~~0149U Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101248 | PsychViewRx Plus<br><br>**DELETE 0150U** | ~~)(0150U Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid Chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service~~ |
| 101261 | HART CVE®<br><br>**REVISE 0309U – Revision of Laboratory name only** | **Clinical Laboratory** - ~~Prevencio, Inc~~ Atlas Genomics<br><br>**Test Manufacturer** – Prevencio, Inc |
| 101262 | My Prostate Score<br><br>**REVISE 0113U – Revision of Test name, Laboratory name, Manufacturer name only** | **Test name** - ~~MiPS(Mi-Prostate Score)~~ MyProstateScore<br><br>**Clinical Laboratory** - ~~MLabs~~ Lynx DX<br><br>**Test Manufacturer** - ~~MLabs~~ Lynx DX |
| 101263 | KawasakiDx | Diagnostic assay to determine the risk score for Kawasaki disease, a vasculitis disease, assay quantifies the RNA of 2 gene markers, IFI27 and MCEMP1, through RT-qPCR of RNA extracted from blood samples |
| 101280 | HART KD®<br><br>**REVISE 0310U – Revision of Laboratory name only** | **Clinical Laboratory** - ~~Prevencio, Inc~~ Atlas Genomics<br><br>**Test Manufacturer** – Prevencio, Inc |
| 101281 | Strata Select | Oncology (pan-tumor), DNA and RNA by next generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, 437 genes, interpretative report for single nucleotide variants, splice site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability with therapy association, algorithm quantifying immunotherapy response score |

| | | |
|---|---|---|
| 101282 | Medication Management Neuropsychiatric Panel | Psychiatry (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes (58 variants), including impacted gene-drug interactions, and deletion/duplication analysis of CYP2D6 |
| 101284 | SYNTap® Biomarker Test | Neurology (proteinopathy), cerebrospinal fluid, detection of misfolded α-synuclein protein by seed amplification assay (also known as real-time quaking-induced conformational conversion or RT-QuIC), qualitative, with diagnostic algorithm |
| 101286 | HART CADhs®<br><br>**REVISE 0308U – Revision of Laboratory name and Code Descriptor** | **Clinical Laboratory** - ~~Prevencio~~, Inc Atlas Genomics<br><br>**Test Manufacturer** – Prevencio, Inc<br><br>▲0308U Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) <u>with 3 clinical parameters (age, sex, history of cardiac intervention)</u>, plasma, algorithm reported as a risk score for obstructive CAD |
| 101301 | PEPredictDx | Obstetrics and Gynecology, serum proteins, serum protein profiling of 3 protein biomarker concentrations, utilizing patient blood serum, algorithm reported as a pre-eclampsia (PE) risk score to identify high-risk PE patients |
| 101302 | Athelas Home Assay | Mental disorders/Oncology/Hematology, blood cells, image analysis using machine learning, utilizing whole blood, algorithm result reported as a concentration |
| 101303 | Perfluoroalkyl Substances (PFAS) | Toxicology, Perfluoroalkyl Substances, (eg. perfluorooctanoic acid, perfluorooctane sulfonic acid), LC-MS/MS, quantitative |
| 101304 | OncobiotaLUNG | Oncology (Lung), multiomics (microbial DNA analyzed by shotgun NGS and 2 proteins), Shotgun Next Gen Sequencing [NGS] and bead-based immunoassays for protein analytes from plasma, algorithm-based malignancy risk category of lung nodules for early-stage lung cancer diagnostic |
| 101305 | Spectrum PGT-M | Single gene inherited conditions 300,000 DNA SNPs markers analyzed, Microarray, Embryo biopsy, Probability report |
| 101306 | IntelxDKD™<br><br>**REVISE 0105U – Revision of Test name, Laboratory name,** | **Test name** – ~~KidneyIntelX™~~ <u>IntelxDKD™</u><br><br>**Clinical Laboratory -** ~~RenalytixAI~~ <u>Renalytix Inc.</u> |

| | | |
|---|---|---|
| | **Manufacturer name and Code Descriptor** | **Test manufacturer** – ~~RenalytixAI~~ Renalytix. Inc, NYC, NY<br><br>▲0105U 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 ~~longitudinal~~ clinical data, ~~including APOL1 genotype if available, and~~ utilizing plasma (isolated fresh or frozen), algorithm reported as ~~probability score~~ risk for ~~rapid~~ progressive decline in kidney function ~~decline (RKFD)~~ |
| 101307 | Agilent Resolution ctDx FIRST | Targeted genomic sequence analysis panel, oncology (non-small cell lung cancer), cell-free DNA, analysis of 109 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations |
| 101308 | ESOPREDICT® Barrett's Esophagus Risk Classifier Assay | Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded tissue, with prognostic and predictive algorithm reported as risk score for progression to high-grade dysplasia or esophageal cancer |
| 101309 | LIVERFASt GP+ | Liver disease, analysis of 7 biochemical assays (triglycerides, total cholesterol, fasting glucose, total bilirubin, AST, ALT, GGT) combined with 4 anthropometrics (age, weight, height, sex), utilizing serum, algorithm reported as clinical category (stage) of nonalcoholic fatty liver disease (NAFLD) from normal (N0), fatty liver (N1), NASH with mild fibrosis (N2) to NASH with bridging fibrosis (N3) with a summary interpretation |
| 101310 | FRAT® (Folate Receptor Antibody Test) | Neurology (autism spectrum disorder), folate receptor auto antibody detection by using enzyme linked immunosorbent assays [ELISA]) for binding auto antibodies, in patient serum samples , report of presence or absence of binding auto antibodies |
| 101311 | Genesys Carrier Panel | NGS, Fragment Analysis, MLPA, DNA, 145 genes in total, inherited disorder, utilizing buccal swab |
| 101312 | CARDIO inCode-SCORE (CiC SCORE) | Molecular assay for the in vitro identification of single nucleotide polymorphism (SNP) variants associated with Coronary Heart Disease (CHD) in genomic DNA extracted from blood or saliva. Based on the SNP results, a genetic risk score (GRS) is calculated and used in conjunction with clinical evaluation to assess the risk of CHD for individuals with no prior history of cardiovascular events. |