Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - November 2023 Meeting

The proposed agenda for the November 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
101462	Epi+Gen CHD™	Cardiology (coronary heart disease [CHD]), DNA, analysis of five single nucleotide polymorphisms (SNPs) [rs11716050 (LOC105376934), rs6560711 (WDR37), rs3735222 (SCIN/LOC107986769), rs6820447 (intergenic) and rs9638144 (ESYT2)] and three DNA methylation markers [cg00300879 (transcription start site [TSS200] of CNKSR1), cg09552548 (intergenic) and cg14789911 (body of SPATC1L)], qPCR and digital PCR whole blood, algorithm reported as four tiered risk score (1 – low risk, 2 – borderline risk, 3- intermediate risk and 4 – high risk) of 3 year risk of symptomatic CHD
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 which is diagnostic of molecular subtype (Basal, Luminal, Her2)
101480	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
101483	Pre Tect HPV-Proofer' 7 **DELETE 0354U**	~~**0354U** Human papilloma virus (HPV), high risk types (i.e., 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by qPCR~~
101484	PrecisionCHD™	Cardiology (coronary heart disease [CHD]), DNA, analysis of ten single nucleotide polymorphisms (SNPs) (rs710987 (Gene body of LINC010019), rs1333048 (3' Intergenic region of CDKN2B), rs12129789 (Gene body of KCND3), rs942317 (Gene body of KTN1-AS1), rs1441433 (Gene body of PPP3CA), rs2869675 (Gene body of PREX1), rs4639796 (Gene body of ZBTB41), rs4376434 (Intergenic region near LINC00972), rs12714414 (Intergenic region near TMEM18) and rs7585056 (Intergenic region near TMEM18) and six DNA methylation markers [cg03725309 (Body of SARS1), cg12586707 (3' Intergenic region of CXCL1), cg04988978 (5' Promoter region of MPO), cg17901584 (Gene body of DHCR24-DT), cg21161138 (Gene body of AHRR) and cg12655112 (Gene body of EHD4)], qPCR and digital PCR whole blood, algorithm reported as binary result (detected/not detected) for the detection of CHD
101487	~~IntelxDKD™~~ kidneyintelX.dkd, Renalytix Inc, Renalytix Inc, NYC, NY **Revise 0407U - Test Name only**	**0407U** Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function

101488	Neurofilament Light Chain (NfL)	Neurology, protein, quantitation of a single neuronal protein (NfL), ultra-sensitive immunoassay (single molecular array), serum and cerebrospinal fluid, the test is utilized as a prognostic, diagnostic and therapeutic biomarker, quantitative assay reported as absolute value and designated as normal or abnormal based on age defined ranges
101500	Aventa™ FusionPlus	Oncology (solid organ neoplasia), dna, targeted genomic sequence panel, 361 genes, interrogation for gene fusions, translocations, or other rearrangements, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant variant(s)
101502	GENETWORx UTI with ABR **DELETE 0416U**	~~**0416U** Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic resistance genes, if performed, multiplex amplified probe technique, urine~~
101504	Elecsys® Phospho-Tau (181P) CSF (pTau181) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio	Neurology (mild cognitive impairment), analysis of βamyloid (Abeta42) and Phospho-Tau (181P) (pTau181), electrochemiluminescence immunoassay, cerebral spinal fluid, reported as positive or negative for amyloid pathology
101506	Venient Sx MCED (Female)	Oncology (multi cancer), female version, hematology (15 laboratory determinations), coagulation (2 laboratory determinations [PT, aPTT]), serum biochemistry and immunoassay (67 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), and urinalysis (11 laboratory determinations), utilizing peripheral blood, plasma, serum, urine, calculations and clinical data of the patient; algorithm reported as a likelihood score of having 47 different types of cancer in all stages (42 solid and 5 hematological tumors). Detection of 276 non-malignant diseases linked to the main body functions, systems and metabolisms
101508	aiSLE™ DX Flare Risk Index	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported along with an algorithmic prognostic risk score for developing a clinical flare
101509	oncoReveal Lung and Colon Cancer	Oncology (eg, lung and colon cancer), DNA, qualitative, next generation sequencing based detection of single nucleotide variants and deletions in 22 genes of interest across lung and colon cancers from formalin-fixed paraffin embedded solid tumor samples, to identify patients with non-small cell lung cancer or colorectal cancer who may benefit from treatment with cetuximab or panitumumab (CRC) or EGFR tyrosine kinase inhibitors
101510	Venient Cx Iron Function Comprehensive	Hematology (anemia, iron deficiency-related diseases and hemochromatosis), hematology (15 laboratory determinations), and serum biochemistry and immunoassay (24 laboratory determinations), utilizing peripheral blood, serum, calculations and clinical data of the patient, algorithm reported as a likelihood score of having an iron deficiency-related disease, such as microcytic, normocytic or macrocytic anemia, and its origin

101512	UNITY Carrier Screen™	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease] and alpha thalassemias) regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (CFTR, SMN1, HBB, HBA1, HBA2)
101513	aiSLE™ DX Disease Activity Index	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported along with an algorithmic risk score for current disease activity
101514	Venient Cx Cardiovascular Function Comprehensive	Cardiology (cardiovascular diseases), serum biochemistry and immunoassay (8 laboratory determinations [apolipoprotein A1, apolipoprotein B, lipoprotein (a), total cholesterol, HDL-cholesterol, triglycerides, bilirubin total, bilirubin direct]), utilizing serum, calculations and clinical data of the patient, algorithm reported as a likelihood score of developing cardiovascular disease and atherogenic disorders, such as coronary artery disease (CAD) or peripheral artery disease (PAD)
101515	Venient Cx Pancreatic Endocrine Function Comprehensive	Endocrinology (glucose metabolism, diabetes and insulin resistance), serum biochemistry and immunoassay (7 laboratory determinations [total cholesterol, HDL-c, triglycerides, insulin, serum creatinine, glucose, HbA1c]), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), and urinalysis (10 laboratory determinations), utilizing serum, urine, calculations and clinical data of the patient, algorithm reported as a likelihood score of having glucose related diseases such as pre-diabetes, all kinds of diabetes, and insulin resistance
101516	Venient Cx Thyroid Function Comprehensive	Endocrinology (thyroid diseases), serum biochemistry and immunoassay (9 laboratory determinations [anti-tg, anti-tpo, anti-tshr, thyroglobulin, tsh, t3 total, t3 free, t4 total, t4 free,]), utilizing serum, calculations, and clinical data of the patient, algorithm reported as a likelihood score of having a wide range of thyroid diseases and dysfunctions
101517	Venient Cx Parathyroid Function Comprehensive	Endocrinology (parathyroid diseases), serum biochemistry and immunoassay (4 laboratory determinations [calcium, albumin,, PTHi, vitamin d 25-OH total]), utilizing serum, calculations, and clinical data of the patient, algorithm reported as a likelihood score of having a parathyroid-related disease as well as calcium metabolism-related disfunction
101518	Venient Cx Hepatic Function Comprehensive	Hepatology (liver diseases), hematology (14 laboratory determinations), coagulation (2 laboratory determinations), serum biochemistry and immunoassay (17 laboratory determinations), utilizing peripheral blood, plasma, serum, calculations, and clinical data of the patient; algorithm reported as a likelihood score of developing any liver function disorder
101519	Venient Cx Renal Function Comprehensive	Nephrology (kidney diseases), serum biochemistry (10 laboratory determinations [e.g., electrolytes, proteins, other serum analytes]), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), and urinalysis (11 laboratory determinations), utilizing serum, urine, calculations, and clinical data of the patient; algorithm reported as a likelihood score of having any stage of kidney disease

101520	Venient Cx Hydroelectrolytic Metabolism Comprehensive	Nephrology (electrolytes imbalance-related disorders), serum biochemistry (9 laboratory determinations [bicarbonate, calcium, chloride, magnesium, phosphate, potassium, sodium, albumin, glucose]), utilizing serum, calculations, and clinical data of the patient; algorithm reported as a likelihood score of having any unbalanced ion-related diseases as well as nutrition deficits
101521	Venient Cx Prostate Function Comprehensive	Urology (prostate diseases), serum immunoassay (3 laboratory determinations [total PSA, free PSA, p2PSA]), utilizing serum, calculations, and clinical data of the patient; algorithm reported as a likelihood score of having prostate disease, by specifying the type
101522	Venient Cx Musculoskeletal System Comprehensive	Rheumatology (autoimmune connective tissue-related diseases), hematology (1 laboratory determination [ESR]), serum biochemistry and immunoassay (4 laboratory determinations [anti-CCP, rheumatoid factor, CRP-hs, CK]), utilizing peripheral blood, serum, calculations, clinical data of the patient; algorithm reported as a likelihood score of having an autoimmune inflammatory connective tissue-related disease
101523	Venient Cx Health Check Comprehensive (Female)	General Health (full medical), female version, hematology (15 laboratory determinations), coagulation (2 laboratory determinations [PT, aPTT]), serum biochemistry and immunoassay (45 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), and urinalysis (11 laboratory determinations), utilizing peripheral blood, plasma, serum, urine, calculations, and clinical data of the patient; algorithm reported as a likelihood score of detecting up to 276 diseases linked to the main body functions, systems and metabolisms
101524	Venient Cx Health Check Comprehensive (Male)	General Health (full medical), male version, hematology (15 laboratory determinations), coagulation (2 laboratory determinations [PT, aPTT]), serum biochemistry and immunoassay (45 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), and urianalysis (11 laboratory determinations), utilizing peripheral blood, plasma, serum, urine, calculations, and clinical data of the patient; algorithm reported as a likelihood score of detecting up to 276 diseases linked to the main body functions, systems and metabolisms
101525	Venient Sx Breast	Oncology (breast), hematology (14 laboratory determinations), serum biochemistry and immunoassay (16 analytes), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), utilizing peripheral blood, serum, urine, calculations and clinical data of the patient; algorithm reported as a likelihood score of having breast cancer in all stages
101526	Venient Sx Colon	Oncology (colon), hematology (14 laboratory determinations), serum biochemistry and immunoassay (17 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), utilizing peripheral blood, serum, urine, calculations and clinical data of the patient; algorithm reported as a likelihood score of having colon cancer
101527	Venient Sx Liver	Oncology (liver), serum biochemistry and immunoassay (15 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]) utilizing serum, urine, calculations and clinical data of the patient, algorithm reported as a likelihood score of having different types of liver cancer

101528	Venient Sx Ovarian	Oncology (ovarian), serum biochemistry and immunoassay (15 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), utilizing serum, urine and clinical data of the patient; algorithm reported as a likelihood score of having any type of ovarian cancer, including serous and mucinous epithelial, germ cell tumors and stromal tumors of the sex cords, in all stages
101529	Venient Sx Prostate	Oncology (prostate), serum biochemistry and immunoassay (12 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), utilizing serum, urine, calculations and clinical data of the patient; algorithm reported as a likelihood score of having prostate cancer in all stages.
101530	Venient Sx MCED (Male)	Oncology (multi cancer), male version, hematology (15 laboratory determinations), coagulation (2 laboratory determinations [PT, aPTT]), serum biochemistry and immunoassay (65 laboratory determinations), urine biochemistry (2 laboratory determinations [microalbumin, urine creatinine]), and urinalysis (11 laboratory determinations), utilizing peripheral blood, plasma, serum, urine, calculations and clinical data of the patient; algorithm reported as a likelihood score of having 47 different types of cancer in all stages (42 solid and 5 hematological tumors). Detection of 276 non-malignant diseases linked to the main body functions, systems and metabolisms