Proposed Proprietary Laboratory Analyses Panel Meeting Agenda- May 2019 Meeting

The proposed agenda for the May 2019 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.**

Upon review of this agenda, if the reviewer believes that they will need to provide comment on an issue, they should send a request for a copy of the application and associated materials to Michael Pellegrino. This request for review of the application 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.

Updated April 10, 2019

ID	Laboratory Test Name	Proposed Test Description
100026	KidneyIntelX	Chronic Kidney Disease (Type II Diabetes), protein profile by electrochemiluminescence of 3 proteins (TNFR-1, TNFR-2, and KIM-1), plasma, prognostic algorithm reported as a probability (risk) score
100281	Snapshot Oral Fluid Compliance	Prescription drug monitoring, 35 or more analytes confirmed with liquid chromatography/tandem mass spectrometry, urine, results reported as a patient compliance measurement, either: "Consistent" for compliant or "Review Results" for potential noncompliance with prescribed medications and risk of drug to drug interactions
100282	Foundation PI	Pain Management (long term drug use), analysis of 11 endogenous analytes (Methylmalonic acid; Xanthurenic acid; Homocysteine; Pyroglutamic acid; Vanilmandelate; 5-hydroxyindoleacetic acid; Hydroxymethylglutarate; Ethylmalonate; 3-hydroxypropyl mercapturic acid (3-HPMA); Quinolinic acid; Kynurenic acid) in urine, by chromatography with tandem mass spectrometry, using urine, algorithm reported as likelihood of atypical biochemical function as cause of pain
100283	Placental Growth Factor	Placental Growth Factor (PlGF), maternal serum, by Dissociation Enhanced Lanthanide Fluorescent Immunoassay (DELFIA)
100284	Y Chromosome Detection	Y chromosome, maternal plasma, cfDNA, single probe,qualitative, Y chromosome detected by endpoint PCR, predictive algorithm
100285	TissueCypher® Barrett's Esophagus Assay	Oncology (Barrett's Esophagus), whole slide digital imaging including morphometric analysis, immunolabeling (Quantitative) using computer-assisted technology including 9 protein biomarkers and morphology using formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high grade dysplasia or cancer
100286	MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species	Aspergillus Species Panel (A. fumigatus, A. terreus, A. niger and A. flavus), amplified probe technique with qualitative report of the presence or absence of each species

100287	First Trimester Screen | Fß	Fetal congenital abnormalities, biochemical assays of three analytes (Free Beta hCG, PAPP-A, AFP), utilizing maternal dried blood spot, Dissociation-Enhanced Lanthanide Fluorescence immunoassay(DELFIA), algorithm reported as a risk score
100288	Maternal Fetal Screen | T1	Fetal congenital abnormalities and perinatal complications, biochemical assays of five analytes (Free Beta hCG, PAPP-A, AFP, PlGF and Inhibin-A), maternal serum, Dissociation Enhanced Lanthanide Fluroescence Immuno Assays (DELFIA), algorithm reported as a risk scores
100289	Maternal Fetal Screen | T1 + Y Chromosome	Fetal congenital abnormalities and perinatal complications, biochemical assays of five maternal serum analytes (Free Beta hCG, PAPP-A, AFP, PlGF and Inhibin-A), Dissociation Enhanced Lanthanide Fluroescence Immuno Assays (DELFIA), additionally qualitative assessment of Y chromosome in maternal plasma by endpoint PCR, cfDNA, single probe, predictive algorithm. algorithm reported as a risk scores
100290	Preeclampsia Screen | T1	Maternal complications of pregnancy, biochemical assays of three maternal serum analytes (PAPP-A, AFP and PlGF), Dissociation Enhanced Lanthanide Fluroescence Immuno Assays (DELFIA), predictive algorithm. algorithm reported as a risk score
100291	Preeclampsia Screen | T1 + Y Chromosome	Preinatal complications, biochemical assays of three maternal serum analytes (PAPP-A, AFP and PlGF) utilizing Dissociation Enhanced Lanthanide Fluroescence Immuno Assays (DELFIA) and qualitative endpoint PCR detection of Y chromosome in maternal plasma, cfDNA, single probe, predictive algorithm, algorithm reported as a risk score for preeclampsia
100292	Flow Adhesion of Whole Blood on VCAM-1 (FAB-V)	Sickle Cell Disease, erythrocytes adhering to immobilized VCAM-1 substrate using a flow adhesion assay, whole blood sample, diagnostic result, report as an adhesion index relative to reference range for healthy vs patients with SCD
100293	Singulex Clarity C. diff Toxins A/B assay	Infectious disease (bacterial), C. difficile toxins detected by Single Molecule Counting technology, per tested stool sample

100294	Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL)	Sickle Cell Disease, WBCs adhering to immobilized VCAM-1 substrate using a flow adhesion assay, blood sample, prognostic result as steady state levels directly correlate to timing of future pain crises, report as an adhesion index relative to reference range for healthy vs patients with SCD
100295	Mechanical Fragility (MF)	Sickle Cell Disease (SCD), red blood cell (RBC) membrane stability by means of induced hemolysis of RBCs due to varying levels of shear stress, as represented by RBC Mechanical Fragility Profile, functional assay with hemolysis, both initial and induced by mechanical shear stress, assessed using proprietary spectrophotometric method. Induced hemolysis is expressed as a fraction of free hemoglobin (HBF) relative to total hemoglobin concentration (HbT), whole blood sample, predictive biomarker with lower levels of induced hemolysis, corresponding to higher RBC stability, signaling a both short and long-term survival rate of transfused or patient's RBCs, report based upon the percentage of induced hemolysis as a function of stress duration. Results reported as area under the curve relative to reference range for healthy individuals
100296	13C-Spirulina Gastric Emptying Breath Test (GEBT)	Gastrointestinal; measurement of solid phase gastric emptying and identification of gastroparesis; uses 13C-labeled Spirulina substrate; breath analysis (7 specimens); chromatographic separation of CO2 and subsequent determination of carbon-13 excretion rate by rate Gas Isotope Ratio Mass Spectrometry (GIRMS); reports gastric emptying rate using 13CO2 excretion rate metric at 45, 90, 120, 150, 180 and 240 minutes; diagnostic
100297	Viracor TRAC Kidney dd-cfDNA	Kidney transplant donor derived cell free DNA quantified from plasma with whole genome next generation sequencing, reported as percentage of donor derived cell free DNA
100298	MiPS (Mi-Prostate Score)	Oncology (prostate), urine PCA3 and TMPRSS2:ERG and serum PSA following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score for high grade prostate cancer (Gleason 7+).
100299	EsoGuard	Oncology (Barrett's Esophagus), sequencing to detect mVIM and mCCNA1 methylation signatures, esophageal tissue, results reported as positive or negative for Barrett's Esophagus

100300	Viracor TRAC Lung dd-cfDNA	Lung transplant donor derived cell free DNA quantified from plasma with whole genome next generation sequencing, reported as percentage of donor derived cell free DNA.
100301	Viracor TRAC Heart dd-cfDNA	Heart transplant donor derived cell free DNA quantified from plasma with whole genome next generation sequencing, reported as percentage of donor derived cell free DNA
100302	Illumina Praxis (TM) Extended RAS Panel	Targeted genomic analysis panel, non-small cell lung neoplasia, DNA, 2 genes (KRAS, NRAS), interrogation by next generation sequencing for clinically actionable variants in 6 codons (56 variants reported), utilizing formalin-fixed paraffin-embedded tumor tissue
100303	MicroGenDX Comprehensive Infectious Disease qPCR and NGS Test	Microbial infectious disease (eg, chronic wound, urinary tract, sinus, bacterial prostatitis, respiratory, joint (PJI) and closed space infections), genomic sequence analysis utilizing a combination of qPCR and NGS, using two target genes (16S amd ITS) for amplicon sequencing, numerous target species (including but not limited to Enterococcus faecalis, Klebsiella pneumoniae, Streptococcus agalactiae, Streptococcus pyogenes, Enterococcus faecium, Pseudomonas aeruginosa, Staphylococcus aureus, Trichophyton rubrum, Candida albicans, Haemophilus influenzae, Moraxella catarrhalis, Streptococcus pneumoniae, Mobiluncus curtisii, Mobiluncus mulieris, Ureaplasma urealyticum, Ureaplasma parvum, Staphylococcus saprophyticus)
100304	Lymph3Cx Lymphoma Molecular Subtyping Assay	Oncology (B-cell lymphoma), mRNA, gene-expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as risk scores for primary mediastinal and diffuse large B-cell lymphoma with cell of origin subtyping in the latter
100305	CancerNext, Ambry Genetics – Request to delete code 0104U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], *EPCAM* and *GREM1* [deletion/duplication only])

100306	BRCAPlus, Ambry Genetics	Oncology (pan cancer), DNA and in vitro mRNA analytics to resolve variants of unknown significance, as required, from whole blood/saliva/cultured cells, genomic sequence analysis of eight genes (BRCA 1/2, ATM, CDH1, CHEK2, PALB2, PTEN, TP53), interrogation for sequence and copy number variants by a combination of next generation sequencing, sanger sequencing, MLPA, and array CGH, diagnostic algorithm, report of clinically relevant variants
100307	ColoNext® +RNAinsight™	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [10 genes]
100308	BreastNext® +RNAinsight™	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [13 genes]
100309	OvaNext® +RNAinsight™	Hereditary ovarian cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [17 genes]
100310	ProstateNext® +RNAinsight™	Hereditary prostate cancer; RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [11 genes]
100311	CancerNext® +RNAinsight™	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [18 genes]
100312	GYNPlus® +RNAinsight™	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, or colon cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [12 genes].

100313	CustomNext® +RNAinsight™ for ATM	Hereditary ATM breast cancer-related disorders (eg, hereditary breast cancer, hereditary pancreatic cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [1 gene]
100314	CustomNext® +RNAinsight™ for PALB2	Hereditary PALB2 breast cancer-related disorders (eg, hereditary breast cancer, ovarian cancer, pancreatic cancer and male breast cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [1 gene]
100315	CustomNext® +RNAinsight™ for BRCA 1/2	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated [2 genes]
100317	MI-HEART Ceramides, Plasma	Ceramides, plasma, liquid chromatography-tandem mass spectrometry, quantitative and risk score
100318	ePlex Respiratory Pathogen (RP) Panel	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 19 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus A, respiratory syncytial virus B, Chlamydophila pneumonia, Mycoplasma pneumoniae)
100319	Oral OncolyticAssuranceRX	Prescription drug monitoring, one or more oral oncolytic drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood, quantitative report with steady-state range for the prescribed dose when detected, per date of service