Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2020 Meeting

The proposed agenda for the August 2020 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.

ID	Laboratory Test Name	Proposed Test Description
100581	Comprehensive Screen	A presumptive drugs of abuse toxicology screen that utilizes multiple reaction monitor methodology via tandem mass spectrometry. Substance Use Disorder, Substance Use Dependence (including substance use conditions in remission) or Prescription Drug Monitoring; clinical toxicology diagnostic and monitoring urine specimen testing panel deploying tandem mass spectrometry targeting 35-55 drug analytes; qualitative with medication matching; using LC-MS/MS to include two to three distinct compound identifiers for detection; includes sample validation when performed; per date of service
100585	PanGIA Prostate	Oncology (Prostate neoplasia), Bio-Molecular Profile, Multi-Analyte, using OpsisDx NUTEC Slides and Machine Learning Algorithm, First Morning Voided Urine, Diagnostic, report “CONSISTENT WITH” or “NOT CONSISTENT WITH” men who have Prostate Cancer, including CONFIDENCE SCORE
100600	Xpert® Xpress SARS-CoV-2/Flu/RSV (all targets)	Respiratory pathogen, multiplex amplified probe technique, multiplex reverse transcription, multiple types or subtypes, 4 targets (SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV))
100602	Karius Test	Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, ~~PCR and~~ plasma, untargeted next-generation sequencing, ~~plasma, detection of >1,000 potential microbial organisms~~ report for significant positive pathogens
100603	Colvera	Oncology (colorectal cancer), DNA, BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) promoter methylation analysis (i.e. detection of 10 differentially methylated CpG sites for BCAT1 and 11 sites for IKZF1) (eg, colorectal cancer), and ACTB (Beta-actin) as an assay control, detected by multiplexed real-time [RT]-PCR, utilizing plasma derived from venous whole blood, reported as a positive or negative diagnostic test result
100604	Genomic Unity® SMN1/2 Analysis	Neurology (spinal muscular atrophy), SMN1 and SMN2 gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, and mobile element insertions, blood or saliva, identification and characterization of genetic variants
100605	FoundationOne Liquid CDx	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions and deletions (indels) and select rearrangements and copy number losses using circulating cell-free (cfDNA)

100606	Genomic Unity® FXN Analysis	Neurology (Friedreich ataxia), FXN gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat expansions, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100607	Genomic Unity® CSTB Analysis	Neurology (e.g., progressive myoclonic epilepsy type 1A), CSTB gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat expansions, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100608	Genomic Unity® CACNA1A Analysis	Neurology (e.g., early infantile epileptic encephalopathy 42, episodic ataxia type 2, familial hemiplegic migraine 1, familial hemiplegic migraine 1 with progressive cerebellar ataxia, spinocerebellar ataxia 6), CACNA1A gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat gene expansions, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100609	ePlex Respiratory Pathogen Panel 2	Infectious agent detection by nucleic acid (DNA and RNA), 19 viral types and subtypes including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and two bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
100610	Genomic Unity® AR Analysis	Multiple rare diseases (e.g., androgen insensitivity syndrome, partial androgen insensitivity with or without breast cancer, hypospadias, spinal and bulbar muscular atrophy of Kennedy), AR gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat expansions, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100611	Genomic Unity® MECP2 Analysis	Neurology (Rett syndrome), MECP2 gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants

100612	Genomic Unity® PTEN Analysis	PTEN hamartoma tumor syndrome (e.g., Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome, PTEN-related Proteus syndrome, Proteus-like syndrome), PTEN gene sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100613	Guidance UTI	Infectious disease (bacterial and viral infection), pathogen-specific nucleic acid, 67 targets, PCR (41 bacterial and viral targets) antibiotic resistance genes (7 targets), and Pooled -Antibiotic Susceptibility Testing (P-AST) (19 targets) in urine with qualitative results
100614	Genomic Unity® Lynch Syndrome Analysis	Oncology (Lynch syndrome), genomic DNA sequence analysis of 5 common genes (i.e., MLH1, MSH2, MSH6, PMS2, and EPCAM) including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100615	Xpert® Xpress SARS-CoV-2/FLU/RSV (SARS-CoV-2 & Flu targets only)	Respiratory pathogen, multiplex amplified probe technique, includes multiplex reverse transcription, multiple types or subtypes, 3 targets (SARS-CoV-2, Influenza A, Influenza B)
100616	Tru Immune	Tru-Immune SARS-CoV-2 surrogate Viral Neutralization Test (sVNT) is a high throughput quantitative blocking ELISA assay for the detection of viral inhibition capacity of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
100617	Genomic Unity® Cardiac Ion Channelopathies Analysis	Cardiology (e.g., idiopathic ventricular fibrillation, atrial fibrillation, hypertrophic cardiomyopathy, long QT syndrome, short QT syndrome, Romano-Ward syndrome, Jervell and Lange-Nielsen syndrome, Brugada syndrome), genomic DNA sequence analysis of 10 common genes (i.e., ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A) including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants