Proposed Proprietary Laboratory Analyses Panel Meeting Agenda- February 2019 Meeting

The proposed agenda for the February 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 January 16, 2019

ID	Laboratory Test Name	Proposed Test Description
100239	BLOODchip® ID CORE XT™ test	Blood group genotyping and antigen prediction panel. The test interrogates 29 polymorphic positions in genomic DNA to determine the genotype of 10 blood groups and predict the phenotype of 37 red blood cell antigens.
100240	IBSchek	A semi-quantitative Enzyme-linked Immunosorbent Assay (ELISA) diagnostic test for Functional Gastrointestinal Disorder which measures two IgG antibodies, An IgG antibody directed against Cytolethal Distending Toxin Subunit B (CdtB), a toxin secreted by a common gut bacteria Campylobacter jejuni and An IgG antibody directed against human vinculin, a protein found in the lining of the gut, in Human venous blood or capillary blood.
100241	Accelerate PhenoTest™ BC kit	Infectious disease (Bacteremia and fungemia), positive blood culture, identification of causative organisms by rRNA FISH, 6 or more organism targets identified, identification results reported as positive or negative for organism targets, and antimicrobial susceptibility by changes in bacterial cell morphology, antimicrobial susceptibility reported as both minimum inhibitory concentration (MIC) and corresponding categorical interpretations (susceptible, intermediate, or resistant).
100242	Molecular Microscope ® MMDx—Kidney	Tissue rejection (allograft organ kidney), mRNA gene expression analysis of 1,494 genes utilizing microarray, measuring mRNA transcript levels in transplant kidney biopsy tissue, with allograft rejection and injury algorithm reported as a probability score.
100243	Molecular Microscope ® MMDx—Heart	Tissue rejection (allograft organ heart), mRNA gene expression analysis of 1,283 genes utilizing microarray, measuring mRNA transcript levels in transplant heart biopsy tissue, with allograft rejection and injury algorithm reported as a probability score.
100244	RNA-Sequencing by NGS – Request to delete code 0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank
100245	Pigmented Lesion Assay (PLA)	Oncology, Melanoma; PRAME and LINC00518 gene expression analysis by RTqPCR on pigmented lesion skin cells aiding diagnostic purposes.
100246	myPath Melanoma	Oncology (cutaneous melanoma) mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a categorical result (Eg benign, indeterminate, or malignant)
100247	FirstSight	Oncology (colorectal cancer screening), circulating tumor cell assay, whole blood, algorithm reported as binary result, positive or negative, for likelihood of colorectal cancer or pre-cancer (adenoma)

100248	Reveal Lung Nodule Characterization	Oncology (lung), multiple protein biomarkers by magnetic nanosensor technology, plasma, algorithm reported as risk score
100249	FilmArray® Respiratory Panel (RP)	Infectious disease testing to aid in the diagnosis of respiratory infections, fully automated multiplexed nucleic acid test (DNA and RNA) for detection of 20 respiratory pathogens from nasopharyngeal swabs (NPS) samples, automated DNA melt curve analysis with each pathogen reported as either detected or non-detected in about one hour
100250	ComplyRX	Disease/Patient type: Patients with long term drug therapy, Polypharmacy, Intentional/Unintentional underdosing, Noncompliance Chemical(s) analyzed: small molecules and metabolites (Prescription medication) Number of markers: 65 Methodology: High pressure liquid chromatography tandem mass spectrometry (HPLC-MS/MS) Specimen type: Urine Result type: Detected, Not-Detected
100251	RCIGM Rapid Whole Genome Sequencing	Pediatric genetic disease (e.g. neonatal intensive care), DNA, whole genome next generation sequencing by rapid methods (<7 days), blood or other DNA source, sequence analysis
100252	Esophageal String Test (EST)	Eosinophilic Esophagitis, 2 protein biomarkers (Eotaxin-3, Major Basic Protein-1), enzyme-linked immunosorbent assays (ELISA), specimen obtained by Esophageal String Test (EST) using capsule-based device-the EnteroTracker(TM), algorithm reported as predictive probability index for active Eosinophilic Esophagitis. Proprietary Names/Manufacturer: Esophageal String Test (EST), EnteroTracker(TM)/EnteroTrack, LLC.
100253	HPV, High Risk Male Urine	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) Specimen type Urine, Male
100254	FilmArray® Gastrointestinal (GI) Panel	Infectious disease testing to aid in the diagnosis of infectious gastroenteritis, fully automated multiplexed nucleic acid test (DNA and RNA) for detection of 22 gastrointestinal pathogens from stool samples in Cary Blair transport media, automated DNA melt curve analysis with each pathogen reported as either detected or non-detected in about one hour
100255	FilmArray® Respiratory Panel 2 (RP2)	Infectious disease testing to aid in the diagnosis of respiratory infections, fully automated multiplexed nucleic acid test (DNA and RNA) for detection of 21 respiratory pathogens from nasopharyngeal swabs (NPS) samples, automated DNA melt curve analysis with each pathogen reported as either detected or non-detected in about one hour

100256	FilmArray Respiratory Panel (RP) EZ	Infectious disease testing to aid in the diagnosis of respiratory infections, fully automated multiplexed nucleic acid test (DNA and RNA) for detection of 14 respiratory pathogens from nasopharyngeal swabs (NPS) samples, automated DNA melt curve analysis with each pathogen reported as either detected or non-detected in about one hour
100257	ColoNext, Ambry Genetics	Oncology (colon 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 17 genes, interrogation for sequence and copy number variants by a combination of next generation sequencing, sanger sequencing, MLPA, array CGH, and qPCR, diagnostic algorithm, report of clinically relevant variants
100258	BreastNext, Ambry Genetics	Oncology (hereditary breast and ovarian 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 17 genes, interrogation for sequence and copy number variants by a combination of next generation sequencing, sanger sequencing, MLPA, array CGH, and qPCR, diagnostic algorithm, report of clinically relevant variants
100259	OvaNext, Ambry Genetics	Oncology (hereditary breast, ovarian and uterine 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 25 genes, interrogation for sequence and copy number variants by a combination of next generation sequencing, sanger sequencing,MLPA, array CGH, and qPCR, diagnostic algorithm, report of clinically relevant variants
100260	CancerNext, 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 34 genes, interrogation for sequence and copy number variants by a combination of next generation sequencing, sanger sequencing, MLPA, array CGH, and qPCR, diagnostic algorithm, report of clinically relevant variants