Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2018 Meeting

The proposed agenda for the August 2018 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 July 18, 2018

ID	Laboratory Test Name	Proposed Test Description
100119	SLE-key Rule Out	Autoimmune (Systemic Lupus Erythematosus), with classifier algorithm, based on 80 DNA, protein, oligonucleotide, lipid and carbohydrate antigens and detected as IgG and IgM isotypes for a total of 160 antibodies (3 IgG antibodies to DNA, Sm, and U1snRNP and 3 IgM antibodies to histone, U1snRNP and a synthetic oligonucleotide are content; 56 housekeeping; 98 other), using indirect ELISA on a protein microarray and serum specimen. Diagnostic results are expressed as a probability score with binary classification of SLE ruled out or SLE not ruled out
100137	NPDX ASD ADM Panel I	Autism spectrum disorder (ASD), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with ASD (NeuroPointDX: NPDX ASD ADM Panel I)
100182	BioPlex 2200 Syphilis Total & RPR Assay	Syphilis Test, dual/multiplex antibodies, treponemal and non-treponemal total (IgG/IgM) antibodies in a two-step automated immunoassay format, using serum or plasma, diagnostic, reported as reactive/non-reactive
100184	PartoSure Test	Preterm birth, placental alpha-micro globulin-1 (PAMG-1), detection by immunoassay with direct optical observation, cervico-vaginal fluid, risk of delivery within 7 days.
100196	BioPlex 2200 RPR Assay	RPR: Syphilis test, Non-treponemal reagin antibodies in a two-step fully automated immunoassay format, using serum or plasma, diagnostic, reported as reactive/non-reactive
100205	Onco4D Bio-dynamic Chemotherapy Selection Assay	Oncology, phenomic profiling of epistatic DNA, RNA, and protein expression as reflected by up to 40 bio-dynamic markers of cellular response to challenge drugs, using motility contrast tomography, fresh or frozen tissue or cells, prognostic, reported algorithmic classification as sensitive or resistant. (Onco4D™ bio-dynamic chemotherapy selection assay, Animated Dynamics, Inc.)
100206	BBDRisk Dx	Oncology (Breast), Protein expression profiling of four cancer biomarkers, Matrix Metalloproteinase-1 (MMP-1), Carcinoembryonic Antigen-related Cell Adhesion Molecule 6 (CEACAM6), Hyaluronoglucosaminidase (HYAL1), Highly Expressed in Cancer Protein (HEC1), by immunohistochemistry, utilizing formalin fixed paraffin embedded tissue (FFPE), algorithm reported as cancer risk score. Proprietary name: BBDRisk Dx
100208	MYCODART Dual Amplification Real Time PCR Panel for 6 Candida species	Infectious disease (fungal) species specific Candida typing by hydrolysis DNA probes , phylogenetically based report of species relatedness per submitted isolate, using RT-PCR and using Dual amplification PCR on tissue, plasma or serum. The final report states fungal DNA present or not present .This assay can identify low level infections in

		patients with conditions described above compared to blood culture or traditional PCR. Species specific hydrolysis probes used in MYCODART- PCR provides higher sensitivity and specificity (>95%)compared to blood culture (<50%)
100209	miR-31now	Oncology (metastatic colorectal cancer), microRNA, Expression profiling of miR-31-3p by real-time RT-PCR utilizing formalin-fixed, paraffin-embedded (FFPE) tissue. Results reported as low or high expression level based on validated cut-off which predicts response to anti-EGFR therapy
100210	Toxlok – Revise 0020U	▲0020U ~~Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, u~~Urine~~, withincludes~~ specimen verification ~~including~~by DNA authentication in comparison to buccal DNA, per date of service Proprietary name: ToxLok by InSource Diagnostics
100211	CYP2D6 Common Variants and Copy Number -Revise 0028U	▲0028U CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants ~~with reflex to targeted sequence analysis~~
100212	CYP2D6 DNA Sequence Analysis	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted DNA sequence analysis for specificity of phenotype (eg, CYP2D6-2D7, CYP2D6, CPY2D7-2D6, CYP2D6 duplication), each sequence
100213	Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry	Hematology and Oncology, protein, immunoprecipitation and mass spectrometry, blood or urine, report presence or absence of M-protein and isotype
100214	INFINITI Neural Response Panel	Determines risk of Opioid Use Disorder, DNA, target signal amplification by MicroArray BioFilmChip®, detection of 16 genetic variants in brain reward pathway, using buccal swab specimen, algorithm reported as predictive, qualitative result for risk of Opioid Use Disorder – Yes or No