Proposed Proprietary Laboratory Analyses Panel Meeting Agenda- February 2018 Meeting

The proposed agenda for the February 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 January 16, 2018

ID	Laboratory Test Name	Proposed Test Description
100118	Lyme ImmunoBlots IgM and IgG	Infectious disease (bacterial), antibodies detection to 17-19 Borrelia burgdorferi sensu lato recombinant proteins, by ImmunoBlots in serum or plasma, diagnostic (provide supportive evidence of infection), reported as positive or negative with protein bands detected.
100120	Anti-Merkel Cell Panel	Oncology (Merkel cell carcinoma), detection of antibodies to two proteins (oncoprotein and capsid protein), multiplex bead assay, serum, reported as presence/absence of capsid protein and detection with titer of oncoprotein for therapeutic decision making
100121	Tick-Borne Relapsing Fever Borrelia (TBRF) ImmunoBlots IgM and IgG Tests	Infectious disease (bacterial), antibodies detection to 14 Tick-Borne Relapsing Fever (TBRF) Borrelia group recombinant proteins, by ImmunoBlots in serum or plasma, diagnostic (provide supportive evidence of infection), reported as positive or negative.
100126	Real-time quaking-induced conversion for prion detection (RT-QuIC)	Neurological disorder (eg prion disease), protein, pathogenic prion protein, real-time quaking-induced conversion, CSF, diagnostic, report result as positive or negative
100128	EXaCT-1 Whole Exome Testing	Oncology (somatic mutations). Whole Exome 22,000 genes by Next Generation Sequencing. DNA extracted and analyzed from formalin fixed paraffin embedded tissue and Whole Blood. Algorithm result type is predictive and prognostic. Report of specific gene mutations, alterations as targets for therapeutic agents.
100130	FoundationOne CDx™ (F1CDx)	Broad next generation sequencing in vitro diagnostic device, solid malignant neoplasms, DNA analysis, 324 genes, detection of substitutions, insertion and deletion alterations (indels), copy number alterations (CNAs), and select gene rearrangements as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB), reported as presence/absence of variants and discrete levels of MSI and TMB, and associated therapy(ies) including multiple FDA-approved companion diagnostics, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens.
100131	ToxLok – Revision to existing PLA code 0020U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, ~~with~~includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service. Proprietary name: ToxLok by

		InSource Diagnostics
100132	SensievaTM Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay	25OH Vitamin D2, 25OH Vitamin D3, and total 25OH Vitamin D, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), blood, quantitative, micro-volume assay.
100134	OmniSeq Comprehensive	Oncology targeted genomic sequence analysis panel by next generation sequencing, solid tumors, DNA and RNA analysis, 144 genes, interrogation for sequence variants and rearrangements, formalin-fixed paraffin embedded block, reported as presence/absence of variants and associates therapy(ies) to consider.
100135	Immune Report Card	Multimodal immune-oncology analysis panel, advanced stage solid tumors, DNA-seq for mutational burden (MuB) 409 oncogenes, RNA-seq for tumor infiltrating lymphocytes (TILs) of 11 genes and T-cell receptor signaling (TCRS) for 43 genes, protein expression by IHC of 3 genes, tumor infiltrating lymphocytes (TILs) by IHC, microsatellite instability by PCR, PD-L1/L2 copy number gain by FISH, formalin-fixed paraffin embedded, report identifies targetable immune markers.
100136	Anti-dsDNA, High Salt/Avidity	Autoimmunity (Systemic Lupus Erythematosus, SLE), detection of high avidity anti-dsDNA antibodies, ELISA assay, serum, reported as quantitative number for therapeutic decision making
100138	Panorama Twins Zygosity	Fetal twin zygosity testing (e.g., monozygous, dizygous) genotypic analysis, circulating cell-free fetal DNA in maternal blood, must include determination of twin zygosity with risk-predictive algorithm result type
100139	MRDx BCR-ABL Test	Oncology (hematolymphoid neoplasia), mRNA, BCR-ABL1, major breakpoint fusion transcript, quantitative RT-PCR amplification, blood, report of molecular response (MR) and BCR-ABL ratio %IS