Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2021 Meeting

The proposed agenda for the May 2021 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
100714	Cap-Score™ Test	Male infertility, sperm capacitation assessment (SCA), distribution patterns of the ganglioside GM1, fluorescent microscopy, fresh or frozen semen samples, diagnosis is based on the percent of capacitation competent sperm (Cap-Score™), a man's fertility is reported as his probability of generating a pregnancy (PGP)
100720	Trimethylamine (TMA)	TMA/TMAO (Trimethylamine/Trimethylamine N-oxide) profile, ion pairs 146/118, 155/127, 76/58, and 85/66, tandem mass spectrometry (MS/MS), urine
100721	VLCAD	VLCAD (Very long chain acyle-CoA dehydrogenase), Enzyme activity in leukocytes, mutation analysis of ACADVL
100722	UCompliDx **Revise 0051U**	▲0051U Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine and blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service
100747	Mind.Px	Autoimmune disease (psoriasis), mRNA, Next Generation Sequencing, gene expression profiling of 50-100 genes, surface collection using adhesive patch, algorithm reported as likelihood of response to various therapeutic classes
100769	Vanadis® NIPT **Delete 0168U**	0168U ~~Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy~~
100772	SYNTap-CSF	Neurology (neurodegenerative disease), cerebrospinal fluid, detection of protein misfolding by cyclic protein amplification, qualitative
100773	GFR(NMR)	Using NMR, GFR(NMR) quantifies myo-inositol, valine, and Nephrology (chronic kidney disease), glomerular filtration rate, using myo-inositol, valine, creatinine, by nuclear magnetic resonance spectroscopy, serum, combined with cystatin C (by immunoassay), age, sex, quantitative
100774	Praxis Optical Genome Mapping	Optical Genome Mapping Analysis of high molecular weight genomic DNA utilizing Bionano Optical Genome Mapping technologies from blood, frozen tissue and cell lines. This diagnostic test assesses the entire nuclear genome. Report contains annotated structural variants believed to be associated with patient's condition.
100775	Praxis Whole Genome Sequencing	Whole Genome Sequencing and Analysis of DNA from blood, frozen and FFPE tissue, saliva, buccal swabs and cell lines. The report contains single nucleotide and copy number variants in the nuclear and mitochondrial genome and changes in repeat sizes in the nuclear genome that are thought to contribute to the patient's condition.
100776	Praxis Transcriptome	Whole Transcriptome Sequencing and Analysis from RNA extracted from blood, frozen and FFPE tissue and cell lines utilizing Next-Generation Sequencing. Diagnostic test reports transcript level and processing changes believed to be causative of the patient's condition.
100777	Praxis Combined Whole Genome Sequencing and Optical Genome	Whole Genome Sequencing and Optical Mapping Analysis is performed on genomic DNA from blood, frozen tissue and cell lines utilizing Next-Generation Sequencing and

	Mapping	Bionano Optical Genome Mapping. This is a diagnostic test that reports out relevant variants with annotation.
100782	Heparin-Induced Thrombocytopenia Evaluation - PEA	Immune (Heparin Induced Thrombocytopenia), Antibody, Flow Cytometry, Serum, diagnostic report of antibody reactivity
100783	VWF Collagen IV Binding	von Willebrand Disease, protein, Two proteins:von Willebrand factor and collagen IV, enzyme linked immunosorbent assays [ELISA], Citrated plasma, diagnostic report
100784	VWF Propeptide Antigen	von Willebrand Disease, protein, one protein:von Willebrand propeptide, enzyme linked immunosorbent assays [ELISA], Citrated plasma, diagnostic report
100785	VWD Type 2B Evaluation	von Willebrand Disease Type 2B, protein, one protein:von Willebrand factor, enzyme linked immunosorbent assays [ELISA], Citrated plasma, diagnostic report
100786	VWD Type 2N Binding	von Willebrand Disease Type 2N, protein, one protein:von Willebrand factor, enzyme linked immunosorbent assays [ELISA], Citrated plasma, diagnostic report
100790	Immunoscore®	Oncology (colorectal cancer), tissue, slide preparation and image analysis with artificial intelligence assessment of four histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), reported as immune response and recurrence risk score
100791	Oncosignal 7-Pathway version for Breast Cancer and Other Cancers	Oncology (breast cancer and other cancers), mRNA expression profiling by RT-qPCR for 7 signal pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch) from formalin-fixed paraffin-embedded tissue, diagnostic algorithm reported as activity score on a scale from 0 to 100
100792	Augusta Optical Genome Mapping	Constitutional disorders (developmental delay, autism spectrum disorder, multiple congenital anomalies, dysmorphic features, intellectual disability, Facioscapulohumeral muscular dystrophy, fragile X and other congenital anomalies). Augusta Optical Genome Mapping, utilizes DNA isolated from fresh/frozen blood and/or cells for whole genome analysis to detect structural variants causative of a genetic syndrome
100793	aHUS Genetic Evaluation	Germline, sequence variants, Next-Generation DNA sequencing, 15 genes, DNA, diagnostic report of specific sequence variants
100794	Autosomal Dominant Thrombocytopenia Panel	Germline, sequence variants, Next-Generation DNA sequencing, 22 genes, DNA, diagnostic report of specific sequence variants
100795	Coagulation Disorder Panel	Germline, sequence variants, Next-Generation DNA sequencing, 19 genes, DNA, diagnostic report of specific sequence variants
100796	Comprehensive Bleeding Disorder Panel	Germline, sequence variants, Next-Generation DNA sequencing, 60 genes, DNA, diagnostic report of specific sequence variants
100797	NPDX ASD Energy Metabolism **Revise 0139U**	▲0139U Neurology (autism spectrum disorder, ASD), quantitative measurements of 16 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumerate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), LC-MS/MS, plasma, algorithmic analysis with result reported as

		negative or positive (with metabolic subtypes of ASD).
100798	Comprehensive Platelet Disorder Panel	Germline, sequence variants, Next-Generation DNA sequencing, 63 genes, DNA, diagnostic report of specific seq
100799	Congenital Neutropenia Panel	Germline, sequence variants, Next-Generation DNA sequencing, 23 genes, DNA, diagnostic report of specific sequence variants
100800	Fibrinolytic Disorder Panel	Germline, sequence variants, Next-Generation DNA sequencing, 9 genes, DNA, diagnostic report of specific sequence variants
100801	Inherited Thrombocytopenia Panel	Germline, sequence variants, Next-Generation DNA sequencing, 23 genes, DNA, diagnostic report of specific sequence variants
100802	Platelet Function Disorder Panel	Germline, sequence variants, Next-Generation DNA sequencing, 31 genes, DNA, diagnostic report of specific sequence variants
100803	Thrombosis Panel	Germline, sequence variants, Next-Generation DNA sequencing, 12 genes, DNA, diagnostic report of specific sequence variants
100804	Versiti Red Cell Genotyping Panel	Germline, sequence variants, Real-Time PCR, 72 SNP's, EDTA whole blood or DNA, Report of predicted red cell phenotype from sequence variants
100805	VWF Collagen III Binding	von Willebrand Disease, protein, Two proteins, von Willebrand factor and collagen III, enzyme linked immunosorbent assays [ELISA], Citrated plasma, diagnostic report