Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2021 Meeting

The proposed agenda for the August 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
100502	RADTOX cfDNA test	Oncology and Radiation Toxicity, cfDNA, one marker, nucleic acid probe hybridization assay that uses branched DNA (bDNA) technology, whole Blood, prognostic, Probability Index
100814	CNT (CEP72, NUDT15 and TPMT) Genotyping Panel	CEP72 (Centrosomal Protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) gene analysis, common variants (e.g. drug metabolism)
100821 **REVISE** 0090U **REVISE** Laboratory name ~~Myriad Genetic Laboratories~~ Castle Biosciences, Inc.	myPath Melanoma	▲0090U 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 (ie, benign, in~~de~~termedi~~n~~ate, malignant)
100822	ThyroSeq Cancer Risk Classifier	Oncology (thyroid cancer), DNA and mRNA next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin embedded tissue from thyroid cancer, algorithmic prediction of cancer risk recurrence, reported as a categorical result ("Low Risk", "Intermediate Risk " or "High Risk")
100823	DetermaRX™	Oncology, (lung), mRNA, algorithmic interpretation by quantitative PCR analysis on surgically resected formalin-fixed, paraffin embedded lung cancer tissue on RNA from 11 cancer-related target genes (*BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A)* and 3 reference genes (*ESD, TBP, YAP1)* with risk of occurrence score
100824	MindX Blood Test- Memory and Alzheimer's Disease	Psychiatry, Neurology, Memory Disorders/Alzheimer Disease, mRNA, gene expression profiling by RNA sequencing of 24 genes (biomarkers), utilizing whole blood, algorithm reported as predictive risk score
100825	MindX Blood Test-Suicidality	Psychiatry, Suicidality, mRNA, gene expression profiling by RNA sequencing of 54 genes (biomarkers), utilizing whole blood, algorithm reported as predictive risk score
100826	MindX Blood Test Pain Report	Neurology, Psychiatry, Pain, mRNA, 36 Biomarkers, RNA sequencing, Whole blood, Predictive, Risk Score
100827	MindX Blood Test- Mood Disorders	Psychiatry, Mood Disorders (depression, mania, bipolar disorder), mRNA, gene expression profiling by RNA sequencing of 144 genes (biomarkers), utilizing whole blood, algorithm reported as predictive risk score
100828	MindX Blood Test- Stress Disorders	Psychiatry, Stress Disorders (PTSD), mRNA, gene expression profiling by RNA sequencing of 72 genes (biomarkers), utilizing whole blood, algorithm reported as predictive risk score

100829	MindX Blood Test-Longevity	Medicine, Gerontology, Longevity, mRNA, gene expression profiling by RNA sequencing of 18 genes (biomarkers), utilizing whole blood, algorithm reported as predictive risk score
100832	DCISionRT®	Oncology (breast ductal carcinoma in situ), DNA, protein expression profiling by immunohistochemistry of seven proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, and SIAH2), with four clinicopathologic factors (size, age, margin status and palpability), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
100835	Adhesion BioChip Normoxic	Hematology, red blood cell adhesion to endothelial/subendothelial adhesion molecules (eg, laminin, fibronectin, VCAM-1, ICAM-1, E-selectin, P-selectin) normoxic condition, functional assessment through microchannels subjected to micro-physiologic flow conditions at shear stress range from 1 dyne/cm2 to 10 dyne/cm2, whole blood, with algorithmic analysis and result reported as Red Blood Cell Adhesion Index
100837	Gene SCN1A	Drug - Gene Test, DNA, Multiplex Real-time (RT)-PCR of one gene (SCN1A - g.25606G>A), Buccal swab and Saliva, diagnostic, presumptive results/recommendations related to medication classes
100838	Gene ABCG2	Drug - Gene Test, DNA, Multiplex Real-time (RT)-PCR of one gene (Gene ABCG2 - c.421C>A, c.421C>G), Buccal swab and Saliva, diagnostic, presumptive results/recommendations related to medication classes
100839	Gene CYP4F2	Drug - Gene Test, DNA, Multiplex Real-time (RT)-PCR of one gene (Gene CYP4F2 - CYP4F2*3, c.1297C>A), Buccal swab and Saliva, diagnostic, presumptive results/recommendations related to medication classes
100841	Invitae PCM Tissue Profiling and MRD Baseline Assay	Oncology, tumor tissue and normal tissue profiling, by whole exome sequencing (WES); development of patient specific monitoring panel, followed by cell-free DNA next generation targeted sequencing analysis of patient specific panel, with report of minimal residual disease (MRD) status
100842	mRNA CancerDetect	Oncology (oral cavity cancer and/or oropharyngeal cancer), gene expression profiling by RNA sequencing of more than 20 molecular features (e.g., human and/or microbial mRNA), utilizing saliva samples, algorithm reported as positive or negative result
100843	Invitae PCM MRD Monitoring	Oncology, cell-free DNA, next generation targeted sequencing analysis of patient specific panels, with report of minimal residual disease (MRD) status
100844	Praxis Somatic Whole Genome Sequencing	Oncology, comparative analyzes DNA from normal and malignant cells, whole genome sequencing by Illumina Short Read sequencing (ISR), specimen types including peripheral blood, bone marrow aspirate and sorted cells as well as frozen or formalin fixed paraffin embedded (FFPE) tissue, diagnostic, prognostic and predictive information, report describes the malignancy tested and identifies pathways that can be targeted for treatment

100845	Praxis Somatic Transcriptome	Oncology, comparative analyzes RNA from normal and malignant cells, whole genome sequencing by Illumina Short Read sequencing (ISR), specimen types including peripheral blood, bone marrow aspirate and sorted cells as well as frozen or formalin fixed paraffin embedded (FFPE) tissue, diagnostic, prognostic and predictive information, report describes the identified cause(s) of the malignancy tested and identifies pathways that can be targeted for treatment
100846	Praxis Somatic Optical Genome Mapping	Oncology, comparative analysis of DNA from normal and malignant cells, whole genome sequencing by Bionano Optical genome mapping, specimen types including peripheral blood, bone marrow aspirate and sorted cells as well as frozen tissue, diagnostic, prognostic and predictive information, report describes the identified cause(s) of the malignancy tested and identifies pathways that can be targeted for treatment.
100847	Bartonella ddPCR	Infectious disease (bacterial), Bartonellosis, DNA (1 content target and 1 human housekeeping gene control), partitioning and nucleic acid amplification by droplet digital PCR (ddPCR), blood/body fluid, reported as binary result (positive/negative)
100848	Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping	Oncology, comparative analyzes DNA from normal and malignant cells, whole genome sequencing) by Illumina Short Read sequencing (ISR) and Optical Genome mapping (OGM), specimen types including peripheral blood, bone marrow aspirate and sorted cells as well as frozen tissue. Formalin fixed paraffin embedded (FFPE) tissue can only be analyzed by ISR, diagnostic, prognostic and predictive information about responsiveness to certain types of treatments, report describes the identified cause(s) of the malignancy tested and identifies pathways that can be targeted for treatment
100849	Lyme Nanotrap® Urine Antigen Test"	Infectious disease (bacterial), Borreliosis, OspA protein biomarker by Nanotrap® capture with antigen detection by Western Blot, urine, reported as detected or not detected
100850	Bartonella Digital ePCR™	Infectious disease (bacterial), Bartonellosis, DNA (1 content target and 1 human housekeeping gene control), pre and post BAPGM™ liquid sample enrichment confirmed by partitioning and nucleic acid amplification by droplet digital PCR (ddPCR), blood/body fluid, reported as binary result (positive/negative)
100851	Adhesion BioChip Hypoxic	Hematology, red blood cell adhesion to endothelial/subendothelial adhesion molecules (eg, laminin, fibronectin, VCAM-1, ICAM-1, E-selectin, P-selectin) hypoxic condition, functional assessment through microchannels subjected to micro-physiologic flow conditions at shear stress range from 1 dyne/cm2 to 10 dyne/cm2, whole blood, with algorithmic analysis and result reported as Red Blood Cell Adhesion Index
100852	Afirma Medullary Thyroid Carcinoma (MTC) Classifier **DELETE** 0208U	~~Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma~~

100853	StrandDx™ - ASD Autism Spectrum Disorder	Autism spectrum disorder (ASD), neurological condition, metallomics analysis using laser ablation-inductively coupled plasma-mass spectrometry analysis of a hair strand (15 metals). Machine learning analysis use data on metal profiles to generate the probability of disease risk
100854	Laser-Optical Rotational Red Cell Analyzer (Lorrca) Ektacytometry	Hematology, Laser-Optical Rotational Red Cell Analyzer (Lorrca) assessment of red blood cell (RBC) functionality and deformability as a function of shear stress, whole blood, reported as a Maximum Elongation Index