Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2020 Meeting

The proposed agenda for the May 2020 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 April 7, 2020

ID	Laboratory Test Name	Proposed Test Description
100414	PredictSURE IBD Test	Autoimmune disease, mRNA, gene expression profiling by quantitative polymerase chain reaction with reverse transcription (RT-qPCR) of 17 different genes (15 target genes and 2 reference genes), utilizes mRNA extracted from whole blood stored in PAXgene tubes, a continuous risk score classified into a high- or low-prognostic risk category of patients with recent diagnosis of inflammatory bowel disease from PredictSURE algorithm.
100500	Afirma Xpression Atlas	Oncology (thyroid) mRNA sequencing analysis panel, utilizing fine needle aspirate, interrogation of 593 genes for expressed sequence variants and rearrangements, must include sequencing of BRAF, RAS, RET, PAX8 and NTRK, reported as detected/not detected. (Afirma Xpression Atlas, Veracyte, Inc.)
100521	Vita Risk	Disease Type: Degenerative retina disease: age related macular degeneration. Chemicals Analysed: DNA Number of Markers: 3 Methodology: PCR+ MOLDI-TOF. Agena Mass Array system to determine specific sites of genetic polymorphism based on size/charge difference of PCR-amplified gene segments. 4 genomic sites are measured. Specimen type: buccal swab Algorithm result: Predictive Report Type: binomial: "Positive" or "Negative"
100522	DISCERN Morphological Image	Neurology (Alzheimer disease) by morphometric imaging, using cultured skin fibroblasts, reported as Alzheimer disease or non-Alzheimer dementia
100523	DISCERN Human Protein Kinase C Epsilon (PKCe)	Neurology (Alzheimer disease), fibroblast cells protein kinase C-epsilon (PKCe) concentration will be measured by immunoassay, utilizing skin biopsy tissue, reported as diagnostic probability index for Alzheimer disease
100524	DISCERN AD Index	Neurology (Alzheimer disease) quantitative imaging of phosphorylated Erk1 and Erk2 biomarkers, using cultured skin fibroblasts, reported as probably index for Alzheimer disease
100526	Afirma Medullary Thyroid Carcinoma (MTC) Classifier	Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, positive or negative for MTC) Afirma Medullary Thyroid Carcinoma (MTC) Classifier

		offered by Veracyte, Inc
100527	Discern Fibroblast Culture	Neurology (Alzheimer disease) skin fibroblast culture. Use this code in conjunction with AD index, MI and CKCe codes
100528	CNGnome	CNGnome from PerkinElmer Genomics detects chromosomal (structural) and cytogenomic constitutional copy number (genome-wide), AOH and UPD analysis using low pass whole genome sequencing from genomic DNA extracted from blood or saliva samples; Diagnostic testing; Intellectual disability or global developmental delay, multiple congenital anomalies, autism spectrum disorders, chromosomal imbalances including micro-deletion syndromes, uniparental isodisomy, autosomal recessive conditions due to consanguinity, previously negative karyotyping and/or chromosomal microarray results; Report pathogenic, likely pathogenic variants and variants of uncertain significance based on ACMG variant classification guidelines
100529	LEVL breath acetone test	Acetone, by nanosensor detection, exhaled breath
100530	BioPlex 2200 RPR assay - Quantitative	Quantitative RPR titer: Syphilis test, Non-treponemal reagin antibodies in a two-step fully automated immunoassay format, using serum or plasma, diagnostic, reported as quantitative titer
100532	MI Cancer Seek™ – NGS analysis	Oncology, pan-tumor, solid tumor, DNA & RNA, whole exome and transcriptome panel, by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, algorithms for DNA results determine SNVs, INDELs, copy number alterations, tumor mutational burden, microsatellite instability and therapy assoc. algorithms for RNA results determine fusions, transcript variants, SNVs, INDELs and therapy association
100533	SnapshotNIR (a.k.a. Kent Camera)	Non-invasive measurement of three biomarkers, deoxygenated hemoglobin (Hb), oxygenated hemoglobin (HbO2), and resultant oxygenation ratio of tissue oxygenation (St02) in superficial tissue using multispectral near infrared analysis.
100535	Genomic Unity® Whole Genome Analysis - Proband	Unexplained constitutional or heritable disorder or syndrome, comprehensive whole genome and mitochondrial DNA sequence analysis including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-

		uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
100536	Genomic Unity® Whole Genome Analysis - Comparator	Unexplained constitutional or heritable disorder or syndrome, comprehensive whole genome and mitochondrial DNA sequence analysis including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (e.g., parent, sibling)
100537	Genomic Unity® Exome Plus Analysis - Proband	Unexplained constitutional or heritable disorder or syndrome, comprehensive whole exome and mitochondrial DNA sequence analysis including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
100538	Genomic Unity® Exome Plus Analysis - Comparator	Unexplained constitutional or heritable disorder or syndrome, comprehensive whole exome and mitochondrial DNA sequence analysis including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (e.g., parent, sibling)
100539	Genomic Unity® Ataxia Repeat Expansion Analysis	Autosomal dominant and recessive hereditary ataxias, 12 gene sequence analysis including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100540	Genomic Unity® Ataxia Analysis	Autosomal dominant and recessive hereditary ataxias, 51 gene sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
100541	Genomic Unity® DMD Analysis	Duchenne and Becker muscular dystrophy, DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic

		variants
100542	Sentosa® SQ HIV-1 Genotyping Assay	Disease type (Infectious agent), Chemical(s) analyzed (viral RNA), Number of markers (3 viral genes), Methodology(s) (Next Generation Sequencing (NGS)), Number of functional domains (if indicated), Specimen type (plasma), Algorithm result type (phenotypic prediction of antiviral drug susceptibility using bioinformatics and interpretive algorithm), Report type (predictive)
100543	BioFire® Respiratory Panel 2.1 (RP2.1)	Infectious disease testing to aid in the diagnosis of respiratory infections (including COVID-19), fully automated multiplexed nucleic acid test (DNA and RNA) for detection of 22 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
100545	Melody™	Breast cancer screening quantitative assessment of protein biomarkers by ELISA in combination with a prognostic algorithm, using lacrimal gland fluid, result reported as presence or absence of clinical significant findings indicating a need for further evaluation by imaging
100546	PreciseDx Breast Cancer Test	Oncology (breast cancer), H&E digital images processed with AI-image analysis software; Clinical and histologic 12 feature algorithm reported as a recurrence score (PDxBR™, PreciseDx)
100547	Navigator ABO Blood Group NGS	Red cell antigen (ABO Blood Group) genotyping (ABO), gene analysis cis vs. trans arrangement of variants, NGS, ABO gene
100548	Navigator Rh Blood Group NGS	Red cell antigen (Rh Blood Group) genotyping (D, C, c, E, e and others), gene analysis cis vs. trans arrangement of variants, RHD and RHCE genes