Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - February 2021 Meeting

The proposed agenda for the February 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
100681	Product of Conception (POC)	Fetal aneuploidy DNA genomic sequence analysis, sequencer and bioinformatics analysis, utilizing fetal DNA in product of conception tissue, includes STR analysis of 3 dissection sites and fetal DNA analysis of 24 chromosomes from one site with application of bioinformatics algorithm, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, segmental aneuploidy and the presence of maternal cell contamination (MCC)
100682	3D Predict Glioma	Oncology (brain), ex vivo 3D cell culture drug response panel by cell viability, utilizing live tissue, reported as an individualized tumor response prediction for therapies approved by the FDA or used in clinical trials as per guidelines
100683	MindX SX Prevent Blood Test	Psychiatry (suicidality), blood, RNA sequencing plus risk emotional/behavioral assessment results, algorithm reported as current and future suicide risk and recommended treatment
100700	Theralink® Reverse Phase Protein Array (RPPA) Assay	Oncology assay which analyzes proteins and activated protein pathways, measures a minimum of 32 phosphoproteins and protein analytes. Laser Capture Microdissection (LCM) is combined with Reverse Phase Protein Array (RPPA). The assay is run on tumor samples and is a predictive test. The report indicates relative levels of total protein or activated (phosphorylated) protein
100701	VeriMAP™ Peanut Reactivity Threshold - Bead Based Epitope Assay – Revise test name 0178U	VeriMAP™ Peanut ~~Sensitivity~~ Reactivity Threshold – Bead Based Epitope Assay
100703	MindX Memory AD Prevent Blood Test	Psychiatry (memory), blood, RNA sequencing plus risk emotional/behavioral assessment results, algorithm reported as current and future memory disorders/exacerbation risk (Alzheimer's disease) and recommended treatment
100704	MindX Pain Blood Test	Psychiatry (pain), blood, RNA sequencing plus risk emotional/behavioral assessment results, algorithm reported as current and future pain disorder/exacerbation risk (chronic pain) and recommended treatment
100705	MindX Mood Disorders Blood Test	Psychiatry (mood), blood, RNA sequencing plus risk emotional/behavioral assessment results, algorithm reported as current and future mood disorder risk (depression, mania) and recommended treatment
100706	MindX Stress Disorders Blood Test	Psychiatry (pain), blood, RNA sequencing plus risk emotional/behavioral assessment results, algorithm reported as current and future pain disorder/exacerbation risk (chronic pain) and recommended treatment
100707	MindX Longevity Blood Test	Health assessment (longevity), blood, RNA sequencing plus risk emotional/behavioral assessment results, algorithm reported as current and future risk of dying and recommended treatment
100708	PGDx elio tissue complete	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 505 genes, interrogation for somatic alterations (SNVs, small insertions and deletions, one

		amplification and four translocations), microsatellite instability and tumor mutation burden
100709	Intrinsic Hepcidin IDx(TM) Test	Iron deficiency, anemia, autoimmune, inflammation, oncology, peptide, hepcidin, quantitative enzyme linked immunosorbent assays (ELISA), blood, serum, plasma, diagnostic
100710	Oncosignal 4-Pathway version for Breast Cancer	Oncology (breast cancer), mRNA expression profiling by RT-qPCR for 4 signal pathways (ER, AR, PI3K, MAPK) from formalin-fixed paraffin-embedded tissue, diagnostic algorithm reported as activity score on a scale from 0 to 100
100712	Endometrial Receptivity Analysis (ERA)	Reproductive Endocrinology and Infertility (REI), Endometrial Receptivity Analysis (ERA), next -generation sequencing, RNA, analysis of the transcriptomic signature from 238 genes differentially expressed by stages of endometrial cycle (hormone replacement therapy (HRT) or natural cycle), utilizing fresh tissue, with bioinformatics predictive algorithm to identify the endometrial Window of Implantation (WOI) to guide personalized embryo transfer (pET), reported by endometrial stage as Receptive, Early Receptive, Late Receptive, Pre-receptive, Post-receptive, Proliferative or no RNA detected with an associated diagnostic probability
100713	SMART PGT-A (Pre-implantation Genetic Testing - Aneuploidy)	Embryo aneuploidy, DNA genomic sequence analysis, utilizing embryo tissue, includes analysis of 24 chromosomes and application of bioinformatics algorithm, reported as the presence of uniform aneuploidies, high or low degree of mosaicism, presence of segmental aneuploidy and a MitoScore, a score based on a quantification of mitochondrial DNA in the cell and embryo to yield a score indicating energy status of an embryo and implantation potential