Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - February 2022 Meeting

The proposed agenda for the February 2022 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
100880	Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics	Infectious disease (bacterial, viral, fungal, parasitic), pathogen detection by metagenomic next generation sequencing, DNA and RNA, sterile body fluids, (e.g. cerebrospinal fluid), diagnostic, reported as organism detected (e.g. human herpes virus 6)
100900	3D Predict™ Ovarian Doublet Panel	Oncology (ovarian), spheroid cell culture, 4 drug panel, tumor response prediction for each drug
100901	3D Predict™ Ovarian PARP Panel	Oncology (ovarian), spheroid cell culture, 4 drug panel comprised of poly (ADP-ribose) polymerase (PARP) inhibitors, tumor response prediction for each drug
100941	Guardant360	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
100961	Vasistera	Single nucleotide polymorphism (SNP)-based noninvasive prenatal test (NIPT) for fetal chromosome abnormalities in maternal blood, Cell free DNA is analyzed using targeted PCR and sequencing of SNPs, risk assessment for trisomy 21, trisomy 18, and trisomy 13, only
100983	CareViewRx DDI	Comprehensive medication assessment including drug-drug interaction analysis, contraindication and black-box warning evaluation, and quantitation of more than 120 drugs and metabolites by liquid chromatography with tandem mass spectrometry from urine, with algorithmic analysis reported as presence or absence of significant patient adverse event
100984	LIVERFASt™ **REVISE 0166U – Deletion of Laboratory name only**	**Clinical Laboratory** - ~~Fibronostics~~ **Test Manufacturer** - Fibronostics
100986	Oncomap™ ExTra	Oncology (solid and liquid tumor), whole exome (DNA) and whole transcriptome (RNA) next-generation sequencing, with paired tumor-normal subtraction for comprehensive tumor profiling, utilizing formalin-fixed paraffin-embedded tissue, fresh frozen tissue, and peripheral blood, reports clinically actionable somatic mutations, single nucleotide variants, copy number alterations, transcript variants, fusions, tumor mutational burden, and microsatellite instability, with therapy association
100987	Women's Health by Molecular Assay, Bridge Diagnostics	Custom OpenArray assay for the detection of microorganisms (Atopobium vaginae, BVAB2, Chlamydia trachomatis, Enterococcus faecalis, Escherichia coli, Gardnerella vaginalis, Haemophilus ducreyi, Lactobacillus crispatus, Lactobacillus jensenii, Megasphaera Species (Type 1), Mobiluncus curtisii, Mobiluncus mulieris, Mycoplasma genitalium, Mycoplasma hominis, Neisseria gonorrhoeae, Staphylococcus aureus, Streptococcus agalactiae (GBS), Treponema pallidum (Syphilis), Candida albicans,

		Candida glabrata, Candida krusei, Candida parapsilosis Candida tropicalis, Trichomonas vaginalis, Herpes Simplex Virus type 1 (HSV-1), Herpes Simplex Virus type 2 (HSV-2)) involved in bacterial vaginosis (BV), aerobic vaginitis (AV), vaginal candidiasis, and sexually transmitted infections (STIs) using Real-Time PCR technology on the OpenArray platform
100988	Augusta Hematology optical genome mapping	Hematology Optical Genome Mapping of individuals with hematological malignancies, such myeloid and lymphoid cancers, detects structural variations, including copy number variations in the cancer genome that are causative for a specific malignancy
100989	COLVERA **REVISE 0229U**	BCAT1 (Branched chain amino acid transaminase 1) ~~or~~and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis