Proposed Proprietary Laboratory Analyses Panel Meeting Agenda -November 2020 Meeting

The proposed agenda for the November 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.

ID	Laboratory Test Name	Proposed Test Description
100618	FilmArray Respiratory Panel (RP) EZ	**DELETE 0098U** ~~Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae)~~
100619	FilmArray® Respiratory Panel (RP)	**DELETE 0099U** ~~Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)~~
100620	FilmArray® Respiratory Panel 2 (RP2)	**DELETE 0100U** ~~Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 210 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)~~
100660	Guardant360®CDx	Targeted genomic sequence analysis, solid organ neoplasm using cell free DNA (cfDNA), DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements
100662	PIGF Preeclampsia Screen	Obstetrics (pre-eclampsia), biochemical assay (placental growth factor), time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for pre-eclampsia
100665	Oncotype MAP Pan-Cancer Tissue Test	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor mutational burden and microsatellite instability, utilizing formalin-fixed paraffin embedded tumor tissue.
100666	ThyGeNEXT Thyroid Oncogene Panel	Oncology (thyroid) Mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using Next Generation Sequencing; performed on cells collected from fine needle aspiration biopsy or cytology slides; reports include the associated risk of malignancy expressed as a percentage.

100667	PrecisionBlood(TM)	Red blood cell antigen typing, DNA, human erythrocyte antigen by genomic sequencing analysis of a minimum 51 antigens from a minimum of 16 blood groups, extracted from whole blood, validated RBC alleles reported
100668	PreTRM®	Obstetrics (Preterm birth risk predictor), quantitative measurement of two proteins from maternal serum measured by liquid chromatography-multiple reaction monitoring-mass spectrometry are combined with clinical data in an algorithmic analysis to report a predictive risk stratification result, and actionable threshold, compared to average population risk.