# Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2019 Meeting

The proposed agenda for the August 2019 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 July 16, 2019

| ID | Laboratory Test Name | Proposed Test Description |
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| 100316 | NPDX ASD Energy Metabolism | Neurology (autism), 6 central carbon metabolites from energy metabolism and mitochondrial function by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder (ASD) |
| 100321 | CareViewRx | Prescription Drug Monitoring, 120 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100322 | Pigmented Lesion Assay (PLA) - DELETE 0089U | Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) |
| 100342 | IBSchek – DELETE 0085U | Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA) |
| 100343 | ePlex BCID Gram Positive Panel | Bloodstream potentially pathogenic gram-positive bacterial organisms detection by nucleic acid (DNA), 20 bacterial targets, 4 resistance genes, 1 pan gram-negative target, 1 pan Candida target, amplified probe technique, each analyte reported as detected or not detected |
| 100344 | ePlex BCID Fungal Pathogens Panel | Bloodstream potentially pathogenic fungal organisms detection by nucleic acid (DNA), 15 fungal targets, amplified probe technique, each analyte reported as detected or not detected |
| 100345 | ePlex BCID Gram Negative Panel | Bloodstream potentially pathogenic gram-negative bacterial organisms detection by nucleic acid (DNA), 21 bacterial targets and 6 resistance genes, 1 pan gram-positive target, 1 pan Candida target amplified probe technique, each analyte reported as detected or not detected |
| 100347 | DecisionDx-UM - DELETE 0081U | Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis |

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| 100348 | CareViewRx Plus | Prescription Drug Monitoring, 160 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, with presumptive screen, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100349 | PainViewRx | Prescription Drug Monitoring, 65 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100350 | PainViewRx Plus | Prescription Drug Monitoring, 80 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100351 | RiskViewRx | Prescription Drug Monitoring, 85 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100352 | RiskViewRx Plus | Prescription Drug Monitoring, 100 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |

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| 100353 | PsychViewRx | Prescription Drug Monitoring, 60 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100354 | PsychViewRx Plus | Prescription Drug Monitoring, 120 or more drugs, or metabolites, definitive liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM) and quantitative analysis with specimen validity, Urine, report of Detected or Not Detected of each drug with Quantitative Concentration within analyte measuring range, drug or metabolite with description, comments, and relevant information, per date of service |
| 100360 | BioFire FilmArray® Pneumonia Panel | Infectious disease (bacterial or viral lower respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 Targets, real-time semi-quantitative PCR, Bronchoalveolar Lavage (including mini-BAL) and Sputum (including endotracheal aspirate), diagnostic, Reports detections of 33 organismal and antibiotic resistance gene targets as well as semi-quantitative results (10^4, 10^5, 10^6, 10^7 copies/mL) when 15 of the bacteria are detected |
| 100361 | Insight TNBCtype | Insight TNBCtype, Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a TNBC clinical subtype and a immunomodulatory modifier |
| 100362 | Karius Test | Infectious Disease, testing microbial cell-free DNA with Next Generation Sequencing using a blood sample to identify bacterial, virial, fungal or parasite infections in patients with acute infection |
| 100364 | therascreen® FGFR RGQ RT-PCR Kit | Oncology (urothelial cancer), RNA, gene analysis by RT-PCR of FGFR3 genes (9 content and 4 housekeeping alterations), utilizing formalin-fixed paraffin- embedded (FFPE) urothelial cancer tumor tissue, reported as FGFR alteration status |

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| 100367 | SMASH | Constitutional (genome-wide) analysis; interrogation of genomic regions for copy number variants by SMASH (short multiply aggregated sequence homologies) for the diagnosis of specific conditions using blood, buccal or saliva specimens |
| 100368 | CustomNext + RNA: APC | Hereditary colon cancer disorder (familial adenomatosis polyposis); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated |
| 100369 | CustomNext + RNA: MLH1 | Hereditary colon cancer disorder (Lynch syndrome); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated |
| 100370 | CustomNext + RNA: MSH2 | Hereditary colon cancer disorder (Lynch syndrome); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated |
| 100371 | CustomNext + RNA: MSH6 | Hereditary colon cancer disorder (Lynch syndrome); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated |
| 100372 | CustomNext + RNA: PMS2 | Hereditary colon cancer disorder (Lynch syndrome); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated |
| 100373 | CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2) | Hereditary colon cancer disorder (Lynch syndrome); RNA analysis to screen for abnormal RNA transcripts and to resolve DNA variants of unknown significance when indicated |
| 100374 | therascreen PIK3CA RGQ PCR Kit | Oncology (breast cancer) gene analysis by RT-PCR of 11 mutations in the phosphatidylinositol 3-kinase catalytic subunit alpha (PIK3CA) gene using genomic DNA (gDNA) extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue or circulating tumor DNA (ctDNA) from plasma derived from K2EDTA anticoagulated peripheral whole blood, reported as PIK3CA alteration status |