# Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - November 2021 Meeting

The proposed agenda for the November 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 |
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| 100843 | Invitae PCM MRD Monitoring | Oncology, cell-free DNA, next generation targeted sequencing analysis of patient specific panels, with report of minimal residual disease (MRD) status |
| 100855 | AllerGenis Peanut Diagnostic and Reactivity Threshold Assay | Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of peanut allergy status, includes report of reactivity threshold level when performed |
| 100860 | BioFire FilmArray® Pneumonia Panel<br><br>**DELETE 0151U** | ~~0151U Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 Targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes, with limited semi-quantitative results~~ |
| 100861 | FilmArray® Gastrointestinal (GI) Panel<br><br>**DELETE 0097U** | ~~0097U Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter [C. jejuni/C. coli/C. upsaliensis], Clostridium difficile [C. difficile] toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio [V. parahaemolyticus/V. vulnificus/ V. cholerae], including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli [EAEC], Enteropathogenic Escherichia coli [EPEC], Enterotoxigenic Escherichia coli [ETEC] lt/st, Shiga-like toxin-producing Escherichia coli [STEC] stx1/stx2 [including specific identification of the E. coli O157 serogroup within STEC], Shigella/ Enteroinvasive Escherichia coli [EIEC], Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia [also known as G. intestinalis and G. duodenalis], adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus [Genogroups I, II, IV, and V])~~ |
| 100862 | HART CADhs® | Cardiology, (coronary artery disease) analysis of three proteins (high sensitivity [hs] troponin, adiponectin, Kidney Injury Molecule-1 [KIM-1]), using immunoassays, utilizing plasma, combined with 3 patient specific EMR values (age, sex, history of percutaneous coronary intervention), diagnostic algorithm reported as a risk score |
| 100880 | Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease Diagnostics | Infectious diseases, metagenomic next generation sequencing, sterile body fluids, eg. cerebrospinal fluid, diagnostic |
| 100883 | Xpert® Xpress CoV2/Flu/RSV plus (all targets)<br><br>**REVISE 0241U – Test name only** | Proposed test name: Xpert® Xpress ~~SARS-~~CoV-2/Flu/RSV plus (all targets) |

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| 100884 | Accelerate PhenoTest BC kit, AST configuration | Infectious disease (bacterial), blood culture, morphokinetic cellular analysis method to determine phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility |
| 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 |
| 100902 | Avise® Lupus | Auto-immune disease, autoantibody levels of 10 biomarkers using solid phase immunoassays, including two cell bound EC4d and BC4d using enzyme linked immunosorbent assay (ELISA), flow cytometry for complement C4d fragment, and ANA determined by indirect immunofluorescence from a blood sample run through a diagnostic algorithm yielding a negative, tier-2 positive or tier-1 positive result |
| 100904 | PancreaSeq Genomic Classifier | Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result, Negative, low probability of neoplasia, or Positive, high probability of neoplasia. |
| 100905 | DecisionDx DiffDx-Melanoma | Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant) |
| 100906 | Invitae PCM Tissue Profiling and MRD Baseline Assay | Oncology, tumor tissue and normal tissue profiling, by whole exome sequencing (WES), development of patient specific monitoring panel, followed by cell-free DNA next generation targeted sequencing analysis of patient specific panel, with report of minimal residual disease (MRD) status |
| 100907 | HART CVE® | Cardiology, (myocardial infarction, stroke, or cardiovascular death 1-year risk) analysis of four proteins (NT-proBNP, osteopontin, tissue of metalloproteinase-1 [TIMP-1], kidney injury molecule-1 [KIM-1]), using immunoassays, utilizing plasma, prognostic algorithm reported as a risk score |
| 100908 | HART KD® | Cardiology, (Kawasaki disease diagnostic) of three proteins (NT-proBNP, C-reactive protein, T-uptake), using immunoassays, utilizing plasma, diagnostic algorithm reported as a risk score |
| 100909 | Lyme Borrelia Nanotrap Urine Antigen Test | Infectious disease (bacterial), Borreliosis, OspA protein by Nanotrap® capture and antigen detection, urine, reported as detected or not detected |
| 100910 | Invitae Oncology, Germline Testing, Supplemental RNA Analysis | Oncology, Germline Testing, Supplemental RNA Analysis, Multi-Cancer Panel (84 genes) and Common Hereditary Cancers Panel (47 genes) |

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| 100912 | CareViewRx DDI | Prescription Monitoring, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with Drug-Drug Interaction Analysis, Contraindications, Black Box Warnings, drug or metabolite description, comments, including sample validation, per date of service |
| 100913 | DecisionDx-SCC | Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B) |
| 100914 | Xpert® Xpress CoV2/Flu/RSV plus (SARS-CoV-2 and Flu targets)<br><br>**REVISE 0240U – Test name only** | Proposed test name: Xpert® Xpress ~~SARS-~~CoV2/Flu/RSV plus (SARS-CoV-2 and~~&~~ Flu targets) |
| 100916 | Oncomine Dx Target Test<br><br>**REVISE 0022U** | ▲0022U Targeted genomic sequence analysis panel, cholangiocarcinoma and non-small cell lung neoplasia, DNA and RNA analysis, 1 - 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider |
| 100917 | LungLB® | Oncology (lung cancer), 4 probe FISH (3q29, 3p22.1, 10q22.3 and 10cen) assay using whole blood (white blood cells) as a predictive marker reported as decreased or increased risk for lung cancer |
| 100920 | EpiSign Complete | Congenital epigenetic disorders, DNA, 50 or more conditions with identified epigenetic signatures or imprinting abnormalities, whole genome methylation analysis by microarray, blood, diagnostic clinical report |
| 100921 | EpiSign Variant | Congenital epigenetic disorders, DNA, targeted analysis for specific disorder with identified epigenetic signature or imprinting abnormality, whole genome methylation analysis by microarray, blood, diagnostic clinical report |
| 100922 | Clarava™ | Transplantation medicine, RNA expression profiling by whole transcriptome next - generation sequencing on multiple genes from pre-transplant peripheral blood, algorithm reported as a risk score for predicting early acute rejection (EAR) in the first six months post-transplant |
| 100923 | Tuteva™ | Transplantation medicine (kidney), RNA expression profiling by whole transcriptome next - generation sequencing on multiple genes from peripheral blood collected post-transplant, algorithm reported as a risk score to predict clinical and subclinical acute cellular rejection |

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| 100924 | UTI with ABR Detection Assay | Urinary tract infections, Infectious agent detected by nucleic acid, amplified probe technique, (each organism, Acinetobacter baumannii, Candida albicans, Candida glabrata, Citrobacter freundii ,Coagulase Negative Staph, Enterobacter aerogenes ,Enterobacter cloacae ,Enterococcus faecalis ,Enterococcus faecium ,Escherichia coli ,Klebsiella oxytoca ,Klebsiella pneumoniae , Morganella morganii , Pantoea agglomerans, Proteus mirabilis ,Proteus vulgaris ,Pseudomonas aeruginosa ,Serratia marcescens ,Staphylococcus aureus ,Streptococcus agalactiae and the presence of associated antibiotic resistant genes (CTX-M group 1, 2, 9, 8/25, TEM, mecA, QnrA, QnrS, Qnr B, vanA1, vanA2, vanB, dfrA5, dfrA1, Sul1, Sul2, nfsA, SHV, KPC). Bridge Diagnostics UTI with ABR Detection Assay |
| 100925 | NPDX ASD Test Panel III | Neurology (autism spectrum disorder, ASD), quantitative measurements of 14 metabolites related to acyl carnitines, microbiome derived metabolites and a steroid hormone (ie, 3-Indoxyl Sulfate, 4-Ethylphenyl Sulfate, CMPF, Cortisone, Decanoylcarnitine, Dodecanedioic Acid, Glutarylcarnitine, Hexanoylcarnitine, Hydroxybutyrylcarnitine, Indoleacetic Acid, Indolelactic Acid, Octanoylcarnitine, Palmitoylcarnitine, and p-Cresol Sulfate) , LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive for risk of metabolic subtypes associated with ASD requiring additional testing |
| 100926 | Women's Health by Molecular Assay | 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 |