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| 11-0258 AMA electronic-chgo_lh | Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - November 2019 Meeting |

The proposed agenda for the November 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](https://www.ama-assn.org/practice-management/cpt-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.

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| **ID**  | **Laboratory Test Name** | **Proposed Test Description** |
| 100140 | BeScreened-CRC | Oncology (Colorectal Cancer Screen), biochemical ELISA assay of three plasma or serum based proteins (teratocarcinoma derived growth factor-1 (TDGF-1, Cripto-1), carcinoembryonic antigen (CEA), extracellular matrix protein(ECM) plus patient age, gender, history of CRC screening compliance utilizing a qualitative scoring indexed algorithm and a reported finding as negative or positive likely-hood to presence of CRC or advanced adenomas (polyps) |
| 100381 | ibs-smart™ | ibs-smart™, blood based immunosorbent assay (ELISA based test) for two antibodies, anti-CdtB and anti-vinculin, to diagnose diarrhea-predominant and mixed-type irritable bowel syndrome (IBS-D and IBS-M) |
| 100401 | VeriMAP Peanut Dx - Bead Based Epitope Assay | Immunology; Food Allergy Chemicals analyzed: Antibody Number of markers: 66 Methodology: Enzyme linked immunosorbent assay (ELISA) Specimen type: Blood Algorithm result: Diagnostic Report type: Probability index VeriMAP Peanut Dx - Bead Based Epitope Assay |
| 100402 | LiverFASt | Liver test, 10 protein biomarkers analyzed, with definitive confirmation of positive results, blood test, algorithm diagnostic, scoring liver fibrosis, activity and steatosis |
| 100403 | ADEXUSDx hCG Test | Gonadotropin, chorionic (hCG), by immunoassay with direct optical observation, capillary whole blood |
| 100404 | Vanadis NIPT | Fetal aneuploidy (trisomy 13, 18, 21) detection using cell-free DNA from maternal blood by rolling circle replication, without PCR and without excluding samples based on fetal fraction |
| 100405 | MediPines Gas Exchange Panel | Respiratory status determination providing 12 respiratory parameters, using galvanic O2 sensor and infrared spectrometric CO2 sensor and 2 wavelength pulse oximeter, from exhaled breath gas sampling method |
| 100406 | NT (NUDT15 and TPMT) genotyping panel | 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 |
| 100408 | Clarifi | Neurology, Autism Spectrum Disorder (ASD), biomarker panel of RNAs, next-generation sequencing, saliva, algorithmic analysis of patterns of abundances of the biomarker panel reported as a predictive probability of ASD diagnosis |
| 100409 | Drug-drug, Drug-substance Identification and Interaction – DELETE 0006U | Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified, per date of service |
| 100411 | MyMRD NGS Panel | targeted genomic sequence analysis panel, Acute Myeloid Leukemia, Myelodysplastic Syndrome and Myeloproliferative Neoplasms, DNA analysis of mutation hotspots of 23 genes (ASXL1 BRAF CALR CEBPA CSF3R DNMT3A FLT3 IDH1 IDH2 JAK2 KIT KRAS MPL NPM1 NRAS PTPN11 RUNX1 SF3B1 SRSF2 TP53 ZRSR2 CBFB-MYH11 KMT2A RUNX1-RUNX1T1), interrogation for single nucleotide variants, indels, deletions and structural variants by next generation sequencing from peripheral blood or bone marrow aspirate, analyzed for prognostic and/ or predictive pathologic variants and for the assessment of minimal residual disease |
| 100412 | therascreen® FGFR RGQ PCR Kit – REVISE 0154U | Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3), gene analysis [ie, p.R248C (c.742C>T), p.S249C (c.746C>G),p.G370C (c.1108G>T), p.Y373C (c.1118A>G), FGFR3-TACC3v1, and FGFR3-TACC3v3] utilizing formalin-fixed paraffin-embedded (FFPE) urothelial cancer tumor tissue, reported as FGFR gene alteration status |
| 100413 | therascreen® PIK3CA RGQ PCR Kit – REVISE 0155U | Oncology (breast cancer), DNA analysis by real-time PCR of the PIK3CA (phosphatidylinositol~~-4,5-bisphosphate~~ 3-kinase~~,~~ catalytic subunit alpha) ~~(eg, breast cancer),~~gene analysis (i.e. p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y) utilizing genomic DNA (gDNA) extracted from formalin-fixed paraffin-embedded (FFPE) breast tumor tissue or circulating tumor DNA (ctDNA) extracted from plasma derived from K2EDTA-anticoagulated peripheral whole blood, reported as PIK3CA gene mutation status |