Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - February 2024 Meeting

The proposed agenda for the February 2024 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.**

NOTICE –INTERESTED PARTY PROCESS

Upon review of this agenda, if the reviewer believes that they will need to provide comment on an issue, they must seek Interested Party status by submitting a request for a copy of the application and associated materials. Under your email, please select *Proprietary Laboratory Analysis (PLA) requests* from the dropdown. **Only requests submitted through Zendesk will be approved.** This request for review of the agenda 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
101392	RightMed Oncology Medication Report	Oncology, whole blood or buccal, DNA SNP genotyping by real time PCR of 24 genes, with variant analysis including impacted gene-drug interactions and reported phenotypes
101461	M-inSight® Patient Definition Assay	Oncology (minimal residual disease [MRD]), serum liquid chromatographic tandem mass spectrometry (MS/MS) peptide sequencing analysis initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for MRD
101501	M-inSight® Follow Up Assessment Assay	Oncology (minimal residual disease [MRD]), serum liquid chromatographic mass spectrometry (MS) peptide quantitative analysis of patient specific peptide panel subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD
101505	EarlyTect® Bladder Cancer Detection (EarlyTect® BCD)	Oncology (bladder), a single analyte, methylated PENK DNA detection by real-time PCR with a linear target enrichment step (LTE-qMSP), urine, reported as likelihood of bladder cancer
101532	Early Detection of Molecular Residual Disease and Risk Stratification for stage 1 to 3 Colo rectal Cancer	Methylation based real-time PCR analysis of colon cancer specific methylation markers - 9 specific targets
101533	Chromosome Genome Mapping	Cytogenomic, (genome wide analysis) for constitutional chromosomal abnormalities, including structural variations, copy number variations and loss-of-heterozygosity variants, optical genome mapping (OGM)
101540	Delve Neuro	Agnostic infectious disease pathogen detection and identification by DNA and RNA metagenomic next-generation sequencing (bacteria, fungi, RNA viruses, DNA viruses, parasites) including specimen stabilization, specimen shipping, cellular lysis, nucleic acid extraction, separate RNA and DNA library preparation with reverse transcriptase PCR and PCR, next generation sequencing, bioinformatic alignment of sequencing data to curated pathogen database, cerebrospinal fluid, identification of pathogenic microbial organisms with clinical interpretation and report
101541	ALINITY m STI Assay	Infectious agents (sexually transmitted infection) includes Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female urine and male urine, each pathogen reported as detected or not detected
101542	PrismRA	Autoimmune (Rheumatoid Arthritis), next generation sequencing, gene expression of 19 genes, whole blood, with analysis of anti-CCP levels, combined with sex, patient global assessment and BMI, algorithm reported as a score that predicts non-response to TNFi therapy
101543	Afirma Xpression Atlas **DELETE 0204U**	~~**0204U** Oncology (thyroid) mRNA gene expression analysis of 593 genes for sequence variants and rearrangements, including BRAF, RAS, RET, PAX8 and NTRK, utilizing fine needle aspirate, reported as detected/not detected~~

101544	Perfluoroalkyl substances (PFAS)	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
101545	Auria	Oncology (Breast Cancer) Biochemical ELISA Assay of two proteins (S100 A8 and S100 A9) utilizing tear fluid with age algorithm reported as a risk score
101546	Elecsys® Total Tau CSF (tTau) and β-Amyloid (1-42) CSF II (Abeta 42) Ratio	βamyloid (Abeta42) and Total-Tau (tTau), electrochemiluminescence immunoassay, cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
101547	RightMed Oncology Gene Report	Oncology, Whole blood or buccal, DNA SNP genotyping by real time PCR of 24 genes, with variant analysis and reported phenotypes
101548	Circadian Phase Assessment	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional); ELISA, saliva, screening/preliminary
101549	Proofer 7 HPV mRNA E6 and E7 Biomarker	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk HPV types: 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification, cervical exo or endo epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker
101550	Cologuard Plus™	Oncology (colorectal) screening, quantitative real-time target and signal amplification with a minimum of 3 DNA markers (e.g., mutations, promoter methylation markers) and protein marker(s) (eg, fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result

101551	~~Oncotype DX Genomic Prostate Score, Genomic Health, Inc, Genomic Health, Inc~~ Genomic Prostate Score® (GPS) Test, MDxHealth, Inc, MDxHealth, Inc **Revise 0047U** **Revisions to Test Name, Laboratory and Manufacturer only**	**0047U** Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
101552	UriFind Bladder Cancer Assay	Oncology (Bladder cancer), methylation-specific quantitative PCR (qPCR), gDNA, voided urine, reported as binary diagnostic (positive or negative) result based on the methylation status of ONECUT2 and VIM genes
101553	CardioRisk+	Cardiology (coronary heart disease [CAD]), Polygenic risk score based on 564,856 SNPs, targeted variant genotyping, buccal swab, algorithm reported as polygenic risk to acquired heart disease

101554	UroAmp MRD	Oncology (bladder), analysis of minimal residual disease, somatic DNA analysis of urinary tumor DNA by next generation sequencing of 60 genes and whole genome aneuploidy, algorithms reported as minimal residual disease status positive or negative and quantitative disease burden
101555	VitaGraft Kidney	Donor-derived cell free DNA (dd-cfDNA) in plasma for kidney recipients using dd-cfDNA. 36 SNPs with high minor allelic frequencies are inferred for being different between the donor and the recipient, where the recipient shall be homozygous
101556	Alzpath pTau217	Neurology (mild cognitive impairment or Alzheimer's disease), analysis of Phospho-Tau (pTau217), by ultra-high sensitivity molecule detection (eg, SIMOA), plasma, reported as positive, intermediate, or negative for Alzheimer pathology
101557	NASHnext™ (NIS4)™	Hepatology (non-alcoholic steatohepatitis [NASH]), four individual biomarkers (miR-34a-5p, alpha 2-macroglobulin, YKL40, HbA1c), using serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis
101563	Acetylcholine receptor (AChR) antibody, live-CBA	Immunology (neurology), acetylcholine receptor (AChR) antibody identification by live cell-based immunofluorescence assay (CBA)
101564	Xpert® CT/NG **DELETE 0353U**	~~**0353U** Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae,multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected~~
101566	IriSight™ CNV Analysis - duo /trio	Reproductive medicine (Fetal constitutional heritable disorders), whole genome analysis for detection of chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicates uniparental disomy (UPD), and aneuploidy; Amniotic fluid (or chorionic villus sample) or products of conception, identification and categorization of genetic variants, diagnostic report, fetus, including maternal cell contamination, backup cell culture, blood and/or saliva identification, and categorization of genetic variants, each comparator (parent)
101568	HPV-SEQ	Oncology (oropharyngeal), detection of minimal residual disease by NGS-based evaluation of 8 DNA targets for quantification of cell-free HPV 16 and 18 DNA (cfHPV-DNA)
101570	LiquidHALLMARK® **REVISE 0409U**	▲**0409U** Oncology (solid tumor), DNA (80 genes) and ~~RNA (36 genes)~~, by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability
101571	CRCdx RAS Mutation Detection Kit	Oncology, DNA, 35 targets in 2 genes, qualitative real-time PCR, formalin-fixed paraffin embedded, predictive, mutation detected
101572	Early Sjogren's Syndrome Panel	Autoimmune, Antibody ELISA based assay for IgG,M,A each against 3 distinct protein targets in blood, including dried blood spots. Providence predictive evidence of early Sjogren's Syndrome. Qualitative output of presence absence of each antibody isotype and target (i.e. 9 results)
101574	xT CDx	Oncology (solid organ neoplasm), next-generation sequencing, DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from matched normal specimen (blood

		or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor mutational burden
101575	ProstateNow	Hereditary prostate cancer-related disorders (eg, hereditary prostate cancer), genomic sequence analysis panel utilizing a combination of ngs, sanger, mlpa, and array cgh, with mmrna analytics and genetic risk score to resolve variants of unknown significance when indicated (23 genes [sequencing, and deletion/duplication in 15 of the 23 genes])
101576	GeneticsNow	Hereditary pan cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel utilizing a combination of ngs and sanger (88 genes [sequencing, and deletion/duplication in 20 of the 88 genes])
101580	ProsTAV PSA test	Prostate cancer, blood, sample is processed to isolate the peripheral blood mononucleated cells (PBMCs), reports come back, negative or positive, to be used to determine patient care, prostate biopsy or monitoring of PSA levels that will occur according to normal clinical practice