Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2024 Meeting

The proposed agenda for the May 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
101391	RightMed Mental Health Medication Report	Psychiatry, Drug processing/Drug metabolism, multiple conditions, including major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder, schizophrenia. Whole blood or buccal, DNA SNP and CYP2D6 copy number genotyping by real time PCR of 14 genes with variant analysis including reported phenotypes and impacted gene-drug interactions for a variety of medications
101584	SafeDrugs	Polypharmacy drug safety panel including laboratory test by LCMS or GCMS for more than 100 prescription and over-the-counter medications in urine, saliva, plasma, or serum, including calculation and reporting of adverse event predictive risk score using test results and patient information. May also include Therapeutic Drug Monitoring for specified patient prescriptions
101601	Lung HDPCR™	Oncology (Non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2 and MET) in FFPE tissue, interrogation for single nucleotide variants, insertions/deletions, gene rearrangements, and report of actionable detected variants for therapy selection
101602	Amyloid Protein Identification, Paraffin, Mass Spectrometry (AMPIP)	Amyloid typing, Congo red staining on paraffin sections, laser microdissection and sample processing (digestion), liquid chromatography tandem mass spectrometry (LC MS/MS) using shotgun proteomics (bioinformatic database analysis), semi-quantitative detection of amyloid proteins (minimum 42 amyloid and 3 signature), interpretation of proteome in conjunction with morphology and clinical history (when available). Additional mutation search on known hereditary types (when detected)
101606	ALZpathDx pTau217 (ALZPathDx)	Neurology (mild cognitive impairment or Alzheimer's disease), analysis of Phospho-Tau (pTau217), by ultra-high sensitivity molecule detection (e.g. SIMOA), plasma, reported as positive, intermediate, or negative for Alzheimer pathology
101608	Preeclampsia sFlt-1/PlGF Ratio	Obstetrics (preeclampsia), biochemical assay of sFlT-1 (soluble fms-like tyrosine kinase 1) and PIGF (placental growth factor), serum, ratio reported for SFlT-1/PIGF, with risk of progression for preeclampsia with severe features within 2 weeks
101612	RightMed Mental Health Gene Report	Psychiatry, Drug processing/Drug metabolism (multiple conditions, including major depressive disorder, general anxiety disorder, attention deficit hyperactivity disorder, schizophrenia). Whole blood or buccal, DNA SNP genotyping and CYP2D6 copy number by real time PCR of 14 genes, with variant analysis and reported phenotypes
101613	Fibronectin Glomerulopathy Confirmation, Mass Spectrometry (MSFNG)	Fibronectin glomerulopathy via laser microdissection of paraffin sections, sample processing (digestion), liquid chromatography tandem mass spectrometry (LC MS/MS) using shotgun proteomics (bioinformatic database analysis), semi-quantitative detection of fibronectin and fibulin-1 and internal control proteins, interpretation of proteome in conjunction with morphology and clinical history (when available)
101614	MyProstateScore 2.0, LynxDX,	▲0403U Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch ~~post-~~urine

	LynxDX **REVISE 0403U**	with or without a preceding digital rectal examination (DRE) ~~urine (or processed first-catch urine)~~, algorithm~~,~~ reported as percentage of likelihood of detecting clinically significant prostate cancer
101615	Bacteria, Viruses, Fungi, and Parasites Metagenomic Sequencing, Spinal Fluid	Infectious disease (bacteria, viruses, fungi and parasites), cerebrospinal fluid (CSF), metagenomic next generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification
101617	Neisseria gonorrhoeae gyrA	PCR based assay detects the presence of gyrA S91F point mutations in Neisseria gonorrhoeae infections, vaginal swab, a rectal swab, gyrA S91 wild type strains are predicted to be ciprofloxacin sensitive, gyrA S91F mutant strains are predicted to be ciprofloxacin resistant
101620	Collagenofibrotic Glomerulopathy Confirmation, Mass Spectrometry (MSCG)	Collagenofibrotic glomerulopathy via laser microdissection of paraffin sections, sample processing (digestion), liquid chromatography tandem mass spectrometry (LC MS/MS) using shotgun proteomics (bioinformatic database analysis), semi-quantitative detection of collagen type III and periostin and internal control proteins, interpretation of proteome in conjunction with morphology and clinical history (when available)
101621	IDH1, IDH2, and TERT Mutation Analysis, Next-Generation Sequencing, Tumor	IDH1 (isocitrate dehydrogenase 1), IDH2 (isocitrate dehydrogenase 2) and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (SNV, deletions and insertions)
101622	ProsTAV PSA test	Oncology (prostate), blood (PBls), predictive model utilizing telomere analysis through telomere analysis variables (TAV) of the lymphocytes, isolate the peripheral blood mononucleated cells (PBMCs) according to PBL isolation protocol, results (positive or negative) used to determine patient care
101623	OptiSeq Colorectal Cancer NGS Panel	Oncology (Colorectal Cancer); cfDNA and gDNA; 43 mutated genes, 45 methylated genes Next-generation sequencing (NGS); Blood and Formalin-Fixed Paraffin Embedded tissue Algorithm result type Screening; Variant allele fraction (%) and methylation level (%)
101624	Amyloid Protein Identification, Fat Aspirate, Mass Spectrometry (AMPIF)	Amyloid typing, Congo red staining, sample processing (digestion), liquid chromatography tandem mass spectrometry (LC MS/MS) using shotgun proteomics (bioinformatic database analysis), semi-quantitative detection of amyloid proteins (minimum 42 amyloid and 3 signature), interpretation of proteome in conjunction with morphology and clinical history (when available). Additional mutation search on known hereditary types (when detected)
101626	~~Viracor~~ Eurofins TRAC™ dd-cfDNA, ~~Viracor Eurofins, Viracor Eurofins~~ Transplant Genomics Inc, Transplant Genomics Inc **REVISE 0118U Test Name, Laboratory Name and**	0118U Transplantation medicine, quantification of donorderived cell-free DNA using whole genome next- generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA

	Manufacturer Name only	
101627	Fibrillary Glomerulonephritis Confirmation, Mass Spectrometry, Paraffin (MSFGN)	Fibrillary glomerulonephritis via laser microdissection of paraffin sections, sample processing (digestion), liquid chromatography tandem mass spectrometry (LC MS/MS) using shotgun proteomics (bioinformatic database analysis), semi-quantitative detection of fibrillary glomerulonephritis-related proteins (DNAJB9 protein and internal control proteins), interpretation of proteome in conjunction with morphology and clinical history (when available)
101628	3D Predict(TM) Brain **REVISE 0248U**	▲0248U Oncology (brain or brain metastasis), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor response prediction for each drug
101629	Caris Assure™ liquid biopsy test	Oncology (solid tumor), cell-free DNA & RNA by next generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability and tumor mutational burden
101632	UNITY Fetal Antigen™ NIPT	Obstetrics (fetal antigen non-invasive prenatal test), cell-free DNA sequence analysis for the detection of the fetal presence or absence of one or more of the Rh, C, c, D, E, Duffy (Fya) or Kell (K) antigen in alloimmunized pregnancies, reported as detected or not detected.
101633	Northstar Select™	Oncology (solid tumor), cell-free circulating DNA genomic sequence analysis panel of 80 genes or more, interrogation for sequence variants, aneuploidy-corrected gene copy number amplifications and losses, gene rearrangements and microsatellite instability
101634	Mycoplasma genitalium 23S rRNA	PCR, 23S rRNA point mutations in Mycoplasma genitalium infections, fresh specimen such as a vaginal swab, a rectal swab, 23S rRNA wild type strains are predicted to be macrolide sensitive, if mutations at 23S rRNA loci 2058 and 2059 are detected strains are predicted to be macrolide resistant
101636	CellSearch® Circulating Melanoma Cell (CMC) Test	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization, and enumeration based on differential CD146, high-molecular weight melanoma-associated antigen, CD34 and CD45 protein biomarkers, peripheral blood
101637	CellSearch® PD-L1 Circulating Tumor Cell (CTC-PDL1) Test	Oncology (solid tumor), circulating tumor cell selection, morphological characterization, and enumeration based on differential EpCAM, cytokeratins 8, 18 and 19, and CD45 protein biomarkers, and quantification of PD-L1 protein biomarker expressing cells, peripheral blood
101638	CellSearch® ER Circulating Tumor Cell (CTC-ER) Test	Oncology (solid tumor), circulating tumor cell selection, morphological characterization, and enumeration based on differential EpCAM, cytokeratins 8, 18 and 19, and CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker expressing cells, peripheral blood
101639	~~Spectrum PGT-M, Natera, Inc, Natera, Inc~~ **DELETE 0396U**	~~0396U Obstetrics (pre-implantation genetic testing), evaluation of 300,000 DNA single nucleotide polymorphisms by microarray, embryonic tissue, algorithm reported as a probability for single gene germline conditions~~
101641	UNITY Fetal Risk Screen™	Obstetrics (single-gene non-invasive prenatal test), cell-free DNA sequence analysis of one or more targets (e.g., CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants, and

		relative mutation dosage analysis based on molecular counts to determine the fetal inheritance of the maternal mutation, algorithm reported as a fetal risk score (e.g., 9 in 10) for the condition (e.g., cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia)
101642	Northstar Response™	Oncology (pan-solid tumor), next-generation sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of tumor burden, and if for a subsequent time-point, any change thereof
101643	Prospera	Transplantation medicine, quantification of donor-derived cell-free dna using next-generation sequencing, plasma, reported as percentage of donor derived cell-free dna in the total cell-free dna
101644	Stockholm3	Oncology (prostate), analysis of five circulating proteins (plasma), germline polygenic risk score (60 SNPs), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer
101645	CancerVision	Next Generation Sequencing (NGS), target-enhanced whole genome sequencing, detection of genomic alterations in solid tumor tissues, single nucleotide variants (SNVs), multi-nucleotide variants (MNVs), insertions and deletions (indels), copy number alterations (CNAs), and structural variants (SVs), insights into mutational signatures, tumor mutational burden (TMB), microsatellite instability (MSI), and homologous recombination deficiency (HRD) are provided, aiding in the identification of actionable mutations and immuno-oncology markers for personalized cancer therapy
101646	QuantiDNA™ Colorectal Cancer Triage Test	Oncology, DNA, 1, isobDNA technology with branched DNA, blood, diagnostic, high or low risk
101647	OncoAssure Prostate	Oncology (Prostate), mRNA gene expression profiling by real-time RT-PCR of 6 genes (4 content and 2 housekeeping), utilizing formalin-fixed paraffin-embedded tissue. Algorithm reported as a risk score.
101648	Rh Test	Fetal RhD gene analysis, next generation sequencing of circulating cell free DNA of maternal fetal blood, analysis of 13 amplicons in exons 1, 4, 6, 7, 9 and introns 1 (3), 3, 5 (2), 7, 8
101649	QClamp Plex VEXAS UBA1 Mutation TEST	Autoimmune Disease (VEXAS syndrome), DNA, 8 mutations from UBA1 gene, xenonucleic acid (XNA) mediated PCR clamping PCR and allele specific ligation technology, blood, diagnostic, positive or negative
101650	QuantiVirus™ HPV E6/E7 mRNA Test for Cervical Cancer	Oncology (Cervical Cancer), RNA, (14 types), isobDNA technology (branched DNA) Pap-smear, diagnostic, high or low risk
101651	PrecivityAD2™ blood test	Neurology (Alzheimer's disease), blood beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (p-tau217, np-tau217, p-tau217 / np-tau217 ratio), immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) combined into an algorithm
101652	OptiSeq Dual Cancer Panel Kit	Oncology, gDNA, 8 genes; Xeno-nucleic acid (XNA) based next-generation sequencing (NGS) methodology, Blood, Formalin-Fixed Paraffin Embedded tissue, Screening, Variant allele fraction (%)
101653	~~INFINITI® Neural Response Panel, PersonalizeDx Labs, AutoGenomics Inc~~	~~0078U Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder~~

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101654	ColoScape PLUS	Oncology, (CRC) cell-free DNA and protein, 8 genes for mutations, 7 genes for methylation, 4 for proteins, real-time [RT]-PCR and enzyme linked immunosorbent assays [ELISA], blood, diagnostic positive or negative
101655	~~ADEXUSDx hCG Test, NOWDiagnostics, NOWDiagnostics~~ **DELETE 0167U**	~~0167U Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood~~
101657	Urinary Tract Infection Testing	DNA is isolated from the urine sample and array-based qPCR assays to simultaneously detect Acinetobacter baumannii, Candida Albicans, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia Coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Providencia stuarttii, Pseudomonas aeruginosa, Staphylococcus saprophyticus, and Streotococcus agalactiae (Group B Strep), interpreted using algorithm and the detected presence and/or absence of microbia is report
101658	Vaginal Infection Testing	DNA is isolated from the sample and array-based qPCR assays simultaneously detect Atopobium vaginae, Bacteroides fragilis, Bacterial Vaginosis-Associated Bacteria (BVABl, BVAB2, and BVAB3), Mycoplasma hominis, Gardnerella vagina/is (trivalent pool), Haemophilus ducreyi, Megasphaera Type 1, Megasphaera Type 2, Mobiluncus spp. (M. curtisii and M. mulieris), Ureaplasma urealyticum, Prevotella bivia, Enterococcus faecalis, Treponema pallidum (Syphilis), Candida albicans, Candida Group (C. dubliniensis, C. lusitaniae, and C. tropicalis), Candida glabrata, Candida krusei, Candida parapsilosis, Mycoplasma genitalium, Chlamydia trachomatis, Trichomonas vaginalis, Herpes Simplex Virus 1, Herpes Simplex Virus 2, Neisseria gonorrhoeae, Staphylococcus aureus, Streptococcus agalactiae (Group B Strep), and Escherichia coli, presence or absence of normal vaginal flora (Lactobacillus crispatus, Lactobacillus gasseri, Lactobacillus iners, or Lactobacillus jenseniz) is detected using array-based qPCR, data is interpreted using an algorithm presence and/or absence of microbiota
101659	EndoSign® Barrett's Esophagus Test	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus.
101660	Avantect Ovarian Cancer Test	Oncology (ovarian), DNA, whole genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as a cancer detected or not detected.
101661	Allelica Breast Cancer Multi-Ancestry Polygenic Risk Score (PRS) Test	Polygenic risk score (breast cancer), Genome-wide analysis to determine ancestry followed by analysis of 530,000 - 690,000 ancestry-specific single nucleotide polymorphisms (SNPs), algorithm personalized to genetic ancestry and reported as lifetime, 5- and 10- year risk of breast cancer, utilizes saliva or blood samples
101662	Allelica Coronary Artery Disease	Polygenic risk score (CAD), Genome-wide analysis to determine ancestry followed by DNA sequence

	(CAD) Multi-Ancestry Polygenic Risk Score (PRS) Test	analysis of 648 - 6.6 million ancestry-specific single nucleotide polymorphisms (SNPs), algorithm personalized to genetic ancestry and reported as relative risk of CAD, utilizes saliva or blood samples
101663	Tempus xE	Oncology (solid organ neoplasm), whole exome sequencing, DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), interrogation for sequence variants, insertion and deletion alterations, copy number variants, microsatellite instability, and tumor mutational burden
101664	PurIST(SM)	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole transcriptome data, reported as probability of predicted molecular subtype (basal-like, classical)
101665	VitaGraft Kidney – Baseline + 1st Plasma Test	Plasma, urine, dd-cfDNA is quantified based on SNPs (single nucleotide polymorphisms), heterologous alleles for the recipient and the graft, homozygous genotype in the genomic DNA, evidence of the heterologous allele in the plasma or urine, informative SNPs identified once per patient are utilized measuring the dd-cfDNA percentage in the sample
101667	VitaGraft Kidney - Subsequent	Plasma, dd-cfDNA is quantified based on SNPs (single nucleotide polymorphisms), heterologous alleles for the recipient and the graft, blood and urine, homozygous genotype in the genomic DNA, evidence of the heterologous allele, the total concentration of dd-cfDNA from the patient's plasma using ddPCR
101668	MindX Blood Test - Psychosis	Psychiatry (psychotic disorders), blood, RNA sequencing, algorithm reported as current and future psychosis risk and recommended treatment
101669	Tempus p-MSI	Oncology (prostate), augmentative algorithmic analysis of digitized whole slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of MSI-High
101670	Tempus p-Prostate	Oncology (prostate), augmentative algorithmic analysis of digitized whole slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin-fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker
101671	P.A.R.I.S® Test	Oncology (solid tumors), cell culture of patient derived tumor organoids in 3D microenvironment, 36 or more drug panel, tumor-response prediction for each drug
101672	Procise ADL	Chemistry, FDA-cleared test for adalimumab
101673	Procise IFX	Chemistry, FDA-cleared test for infliximab
101674	MyGenVar Pharmacogenomics Test	Hematology/oncology, Diabetes, Cardiology, Pain management, Genetic disorders, Neurology, Psychiatry, DNA, panel of genes (>10 genes) including but not limited to ABCG2, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP3A5, DYPD, SLCO1B1, TPMT, UGT1A1, VKORC1, Time Polymerase Chain Reaction (RT-PCR) or Next-generation sequencing depending on the drug indications when appropriate, blood, aid in predictive of drug dosage, response or help identify patients who are more likely to experience adverse events from to a particular medication, clinical interpretation and correlation between genotype and medication responses
101675	PrecisView(R)CNS	Prescription and OTC therapeutic drug monitoring (TDM), any number of drug classes, definitive LC-

		MS/MS, plasma, electronic medical record (EMR) reconciliation, algorithm results of drug-drug interaction of prescribed and detected non-prescribed medications, patient compliance assessment by presence of prescribed drug analytes in circulation, 80 or more drugs or substances, qualitative and quantitative report with therapeutic minimally and maximum effective dose of prescribed and non-prescribed medications in circulation
101676	SyncView®Rx	Prescription and OTC therapeutic drug monitoring (TDM), any number of drug classes, definitive LC-MS/MS, plasma, electronic medical record (EMR) reconciliation, algorithm results of drug-drug interaction of prescribed and detected non-prescribed medications, patient compliance assessment by presence of prescribed drug analytes in circulation, 200 or more drug analytes, analytic determination of drug minimum range of detection, qualitative report of prescribed and non-prescribed medications in circulation
101677	SyncView®Pain	Prescription and OTC therapeutic drug monitoring (TDM), any number of drug classes, definitive LC-MS/MS, plasma, electronic medical record (EMR) reconciliation, algorithm results of drug-drug interaction of prescribed and detected non-prescribed medications, patient compliance assessment by presence of prescribed drug analytes in circulation, 90 or more drugs or substances, specific to pain, depression, and anxiety, qualitative report of prescribed and non-prescribed medications in circulation
101678	SyncView®PainPlus	Prescription and OTC therapeutic drug monitoring (TDM), any number of drug classes, definitive LC-MS/MS, plasma, electronic medical record (EMR) reconciliation, algorithm results of drug-drug interaction of prescribed and detected non-prescribed medications, patient compliance assessment by presence of prescribed drug analytes in circulation, 110 or more drugs or substances, specific to pain, depression, and anxiety with illicit drug detection, qualitative report of prescribed and non-prescribed medications in circulation