Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - August 2025 Meeting

The proposed agenda for the August 2025 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
102023	Molecular Wound Infection Test	Infectious disease (wound infection), identification of 65 organisms and 30 antibiotic resistance genes, wound swab, real-time PCR, reported as positive or negative for each organism
102024	Synovasure Comprehensive PJI Panel with	Periprosthetic joint infection (PJI), analysis of 11 biomarkers using immunoassays, hematology,

	SynTuition	and clinical chemistry, utilizing synovial fluid, diagnostic algorithm reported as a probability score
102025	The Diabetes Risk Test	Endocrinology (diabetes), INS gene methylation using digital droplet PCR, hemoglobin A1c, insulin, and C-peptide using immunoassay, serum, algorithm reported as diabetes risk score
102027	SLL Comprehensive Drug Analysis	Drug assay, presumptive, 30 or more drugs or metabolites, urine liquid chromatography with tandem mass spectrometry (LC-MS / MS), single or tandem method or drug-specific calibration and matrix-matched quality control material, qualitative or quantitative
102042	~~LucentAD p-Tau 217~~ **DELETE 0551U**	~~*0551U Tau, phosphorylated, pTau217, by single molecule array (SIMOA), using plasma*~~
102043	~~Serotonin Receptor Genotype (*HTR2A* and *HTR2C)*~~ **DELETE 0033U**	~~*0033U HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])*~~
102044	~~Neurofilament Light Chain (NfL)~~ **DELETE 0361U**	~~*0551U Neurofilament light chain, digital immunoassay, plasma, quantitative*~~
102045	alpha tryptasemia TPSAB1 gene CNV test by digital PCR	Allergy and Immunology (Hereditary Alpha Tryptasemia), DNA, analysis of TPSAB1 gene copy number variation (CNV) using digital PCR, whole blood, results reported with genotype-specific interpretation of alpha-tryptase copy number and algorithmic classification as Normal or Abnormal
102046	Bradykinin, Total quantitative, by liquid chromatography and tandem mass spectrometry	Allergy and Immunology (chronic recurrent angioedema), 4 bradykinin (BK) peptides, liquid chromatography and tandem mass spectrometry, whole blood, quantitative
102049	~~VitaGraft Kidney - Baseline + 1st Plasma Test~~ **DELETE 0508U**	~~0508U Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single-nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell-free DNA with risk for active rejection~~
102050	~~VitaGraft Kidney – Subsequent~~ **DELETE 0509U**	~~0509U Transplantation medicine, quantification of donor-derived cell-free DNA using up to 12 single-nucleotide polymorphisms (SNPs) previously identified, plasma, reported as percentage of donor-derived cell-free DNA with risk for active rejection~~

102051	~~VitaGraft Kidney~~ **DELETE 0544U**	~~0544U Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA percentage reported as risk for rejection~~
102052	Osmotic Gradient Ektacytometry (OGE)	Hematology (red cell membrane disorders), red blood cells, osmotic gradient ektacytometry, whole blood, diagnostic, quantitative
102053	Eurofins TRAC™ ID	Transplantation medicine, donor-derived cell-free DNA and 8 infectious disease targets (BKV, HSV1, HSV2, VZV, EBV, CMV, HHV-6, and TTV) using whole genome next- generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA and detection of one or more infectious agents
102054	~~+RNAinsight for GYNPlus, Ambry Genetics~~ **DELETE 0135U**	~~0135U Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure) (Use in conjunction with 81162)~~
102055	~~+RNAinsight for BreastNext, Ambry Genetics~~ **DELETE 0131U**	~~0131U Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure) (Use in conjunction with 81162, 81432, 0102U)~~
102056	~~+RNAinsight for OvaNext, Ambry Genetics~~ **DELETE 0132U**	~~0132U Hereditary ovarian cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure) (Use in conjunction with 81432, 81162, 0103U)~~
102058	PersonaCRC	Oncology (colorectal cancer liver metastases), RNA, gene expression profiling by next-generation sequencing of 150 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as prognostic risk classification

102059	~~Proofer 7 HPV mRNA E6 and E7 Biomarker Test~~ **DELETE 0463U**	~~0463U Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker~~
102060	EMMA / ALICE	Reproductive medicine (endometrial microbiome assessment), real time PCR analysis for 30 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations
102061	Alice (Analysis of Infectious Chronic Endometritis)	Reproductive medicine (endometrial microbiome assessment), real time PCR analysis for 10 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations
102062	BluePrint 80 Genes Molecular Subtyping Profile	Oncology (breast), mRNA, gene expression profiling by micro-array of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as index which is diagnostic of a molecular subtype (luminal, basal, Her2)
102063	PredicineCARE Assay **REVISE 0539U**	0539U Oncology (solid tumor), cell-free circulating tumor DNA (ctDNA), ~~152~~ <u>200</u> genes, next-generation sequencing, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, <u>tumor mutational burden (TMB)</u> and microsatellite instability, using whole-blood samples, mutations with clinical actionability reported as actionable variant
102064	ClarityDX Prostate	Oncology (prostate), immunoassay for total prostate-specific antigen (PSA) and free PSA, serum or plasma, combined with clinical features, algorithm reported as a probability score for clinically significant prostate cancer
102066	~~ClarityDx Prostate~~ **DELETE 0550U**	~~0550U Oncology (prostate), enzyme-linked immunoassay (ELISA) for total prostate specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal exam findings, prostate volume, and PI-RADS, algorithm reported as a risk score for the presence of high-grade prostate cancer~~

102068	PreClara Ratio (sFlt-1/PlGF) **REVISE TEST NAME ONLY 0524U**	0524U Obstetrics (preeclampsia), sFlt-1/PlGF ratio, immunoassay, utilizing serum or plasma, reported as a value
102069	LifeScale Gram Negative Kit LSGN with the LifeScale AST System	Infectious disease (antimicrobial resistance), blood culture isolate, utilizing microfluidic sensor technology to assess bacterial growth and cell mass in response to varying antibiotic types and concentrations, diagnostic, reported as categorical susceptibility, minimum inhibitory concentration and interpretive comments
102070	HelioHCC Strat	Oncology (liver), prognosis for patients newly diagnosed with hepatocellular carcinoma (HCC) through analysis of methylation patterns on circulating cell-free DNA (cfDNA), algorithm reported as a quantitative result
102071	HelioHCC Trace	Oncology (liver), minimal residual disease (MRD) monitoring for patients previously diagnosed with hepatocellular carcinoma (HCC) through analysis of methylation patterns on circulating cell-free DNA (cfDNA), algorithm reported as a quantitative result
102072	AssureMDx	Oncology (urothelial carcinoma), DNA methylation (TWIST1, OTX1, ONECUT2) and mutation analysis of FGFR3, HRAS, TERT promoter region, methylation-specific PCR and targeted next-generation sequencing, urine, algorithm reported as a probability index for bladder cancer and upper tract urothelial carcinoma