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Meeting Background and Purpose

This meeting provides an opportunity for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the CDLT Panel) to publicly convene and make recommendations to the Secretary of the Department of Health and Services and the Administrator of CMS regarding crosswalking and gapfilling for new and reconsidered laboratory tests discussed during the CLFS Annual Public Meeting for CY 2027. The CDLT Panel may also provide input on any other CY 2027 CLFS issues that are designated in the Panel's charter and specified in this agenda. Notice of this meeting and additional supplemental information regarding the CDLT Panel were published in the Federal Register on May 1, 2026 (CMS-1854-N).

Meeting Format

- The CDLT Panel Chair will direct the presentation and discussion of each laboratory test code on the agenda.
- Each laboratory test code under consideration will be introduced and discussed by the CDLT Panel. The focus of discussion is payment of the laboratory test code either through crosswalking the laboratory test code to another existing laboratory test code on the CLFS, or to use the gapfill methodology to determine payment. During the discussion the CDLT Panel and CMS staff may ask questions of the representative of the laboratory that owns the test. Once CDLT Panel discussions are concluded, the suggestions from the Panel are summarized and the Panel votes on their recommendation for payment.
- The meeting is divided into two sessions, one session on each date of the meeting. Session times are approximate and subject to change. The codes and order of discussion in each session are provided in Appendix 3.

Meeting Address and Building Entry

- CMS Central Building Address: 7500 Security Boulevard, Baltimore, MD 21244
- The hybrid meeting will be held in a Federal government building; therefore, Federal security measures are applicable.
- In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 9:00 a.m. and 9:50 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 10:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building earlier than 9:15 a.m. E.D.T. (45 minutes before the convening of the meeting).
- Security measures include the following:
    - Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building. An additional review process is required for all foreign national visitors and must be completed prior to entering the building.

- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set- up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Lunch & Refreshments Notice

- Please note that the cafeteria is currently closed. We appreciate your understanding and flexibility.
- CMS has a limited selection of pre-packaged salads and sandwiches available, along with a coffee machine and light snacks in the lower lobby or you're welcome to bring your own.
- Thank you in advance for your understanding and cooperation.

Virtual Connection Instructions and Details

- **Listen-in via audio and watch via Zoom connection only** details are provided using instructions described in Appendix 1.
- Please note that the video or audio recordings of the meeting will not be immediately available after the conclusion of the meeting.

AGENDA

Tuesday July 14 and Wednesday July 15, 2026

Time	Topic	Supporting Resource
9:30 a.m.	**Check-In and Audio/Video Connection Test Check** CMS Central Building Address: 7500 Security Boulevard, Baltimore, MD 21244	
10:00 a.m.	**Welcome and Panel Introductions:** Rasheeda Arthur, PhD., Designated Federal Officer (DFO) and Meeting Facilitator from the Division of Ambulatory Services. Megan Landsverk, PhD., CDLT Panel Chair	
10:15 -12:30 p.m.	**Day 1 and 2 Morning Session:** Please view Appendix 3 for exact order of codes.	Appendix 3
12:30- 1:30pm	**Lunch Break** **Please Note:** All speakers please reconnect by 1:20pm	
1:30-4:00 p.m.	**Day 1 and 2 Afternoon Session:** Please view Appendix 3 for exact order of codes.	Appendix 3
4:00 p.m.	**Meeting Adjourns**	

*****Please note that the order of the agenda and content of the appendices are subject to change.*****

Appendix 1: Audio and/or Video Access
Join the meeting by Zoom.

Step 1: Please click the link below to register for the webinar:

https://cms.zoomgov.com/webinar/register/WN_5eqGmr2mQTSqS-Mx3fK_rw

Passcode: 772752
Note: This link provides attendees with the ability to view and listen to the meeting. Only confirmed stand-by speakers will have the ability to speak during the meeting.

Step 2: All attendees and participants will be requested to provide their name and email address before joining the meeting.

Step 3: Click "Register."

Appendix 2: Access to CLFS CY 2027 New and Reconsidered Codes and Other Information.

1. For a list of CY 2027 new and reconsidered codes that will be discussed during the CDLT Panel meeting, please go to the CLFS Annual Laboratory Meeting website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings

   Scroll down to "Test Code Updates" for access to the CY 2027 new and reconsidered code list.

2. For the CLFS Annual Laboratory Public meeting agenda from June 10, 2026, please see: https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings#

3. For a copy of CY 2026 - Clinical Laboratory Fee Schedule Test Codes Final Payment Determinations that were discussed during last year's CLFS Annual Laboratory Meeting and the Medicare Advisory Panel for Clinical Diagnostic Laboratory Tests (CDLT Panel) Meeting, please see link above.

Appendix 3: Summary of codes

*Subcommittees: Chemistry, Hematology, Immunology, Microbiology (CHIM); Molecular Pathology, Genomic Sequencing (MoG)

Corrections to order of codes:

a. None currently.

FACA Panel Item #	ALM Code #	Current Code #	Final Code #	Code Type	Code Category	Subcategory	Subcommittee	Long Code Descriptor
1	69	8XX30	TBD	New	Chemistry	Chemistry	CHIM	Glial fibrillary acidic protein (GFAP)
2	108	X300U	TBD	New PLA	Chemistry	immunoassay	CHIM	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxy-l terminal hydrolase L1 (UCH-L1), immunoassay, serum or plasma, individual components reported with the overall result of positive or negative based on threshold comparison
3	13	0609U	TBD	New PLA	MAAA; Chemistry	tumor marker, immunoassay	CHIM	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
4	54	0650U	TBD	New PLA	Genomic Sequencing Procedures; targeted panel	Pharmaco	MoG	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLCO1B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function
5	56	0652U	TBD	New PLA	Genomic Sequencing Procedures; targeted panel	Pharmaco	MoG	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status
6	71	87638	87638	New	Microbiology; Infectious Disease	ID	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); rubeola (measles) virus
7	1	87183	TBD	Reconsidered	Microbiology; Infectious Disease	ID AMP	CHIM	Susceptibility studies, antimicrobial agent; carbapenem resistance genes (eg, blakpc, blandm, blavim, blaoxa-48, blaimp), amplified probe technique, per isolate
8	70	8XX32	TBD	New	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Candida species (eg, C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), pooled result, Candida glabrata and Trichomonas vaginalis, amplified probe technique (Do not report 8XX32 in conjunction with 87481, 87661)
9	68	87XX2	TBD	New	Microbiology; Infectious Disease	ID AMP	CHIM	Infectious agent detection by nucleic acid (DNA or RNA); Macrolide resistance, 23S rDNA gene mutation(s) (eg, Mycoplasma species), amplified probe technique
10	39	0635U	TBD	New PLA	MAAA; Gene Expression Profile	autoimmune, NGS	MoG	Autoimmune (atopic dermatitis), mRNA, next-generation sequencing (NGS), gene expression profiling of 487 genes, noninvasive skin-surface scraping, algorithm reported as likelihood of response to therapy
11	9	0605U	TBD	New PLA	Molecular Pathology	CNV analysis, dPCR	MoG	Allergy and immunology (hereditary alpha tryptasemia), DNA, analysis of TPSAB1 gene copy number variation using digital

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								PCR, whole blood, results reported with genotype-specific interpretation of alpha-tryptase copy number and algorithmic classification as normal or abnormal
12	64	0580U	0580U	Reconsidered	Microbiology; Infectious Disease	ID immunoassay	CHIM	Borrelia burgdorferi, antibody detection of 24 recombinant protein groups, by immunoassay, IgG
13	19	0615U	TBD	New PLA	Microbiology; Infectious Disease panel	ID, immunoassay	CHIM	Borrelia burgdorferi (Lyme disease), antibody detection of 26 recombinant protein groups, by immunoassay, IgM
14	40	0636U	TBD	New PLA	Microbiology; Infectious Disease panel	ID, immunoassay	CHIM	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG
15	41	0637U	TBD	New PLA	Microbiology; Infectious Disease panel	ID, immunoassay	CHIM	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM
16	42	0638U	TBD	New PLA	Microbiology; Infectious Disease panel	ID, immunoassay	CHIM	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG
17	43	0639U	TBD	New PLA	Microbiology; Infectious Disease panel	ID, immunoassay	CHIM	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM
18	80	X258U	TBD	New PLA	Molecular Pathology	STR analysis	MoG	Comparative analysis using short tandem repeat (STR) markers, patient and comparative specimen, DNA, buccal swab and tissue, reported match or mismatch
19	93	X274U	TBD	New PLA	Molecular Pathology	CNV analysis, LPGS, CSF	MoG	Oncology (central nervous system), low-pass whole genome sequence analysis of cerebrospinal fluid, interrogation for chromosome arm-level and focal losses and gains
20	3	0575U	TBD	Reconsidered	Genomic Sequencing Procedures; RT-PCR; ddPCR	MicroRNA	MoG	Transplantation medicine (liver allograft rejection), mirna gene expression profiling by rt-pcr of 4 genes (mir-122, mir-885, mir-23a housekeeping, spike-in control), serum, algorithm reported as risk of liver allograft rejection
21	74	X252U	TBD	New PLA	MAAA; Gene Expression Profile	allograft, RT-PCR	MoG	Transplantation medicine (kidney allograft rejection), mRNA, gene-expression profiling by real-time quantitative PCR of 12 genes (11 content and 1 housekeeping), urine, algorithm reported as a rejection risk score
22	79	X257U	TBD	New PLA	MAAA; Gene Expression Profile	allograft, NGS	MoG	Transplantation medicine (kidney allograft failure), RNA expression transcriptome by next-generation sequencing (NGS), profiling of 13 genes, post-transplant peripheral blood, algorithm reported as a risk score for predicting progressive fibrosis in the kidney allograft
23	34	0630U	TBD	New PLA	MAAA; Gene Expression Profile	FFPE, solid, microarray	MoG	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2)
24	97	X282U	TBD	New PLA	MAAA; Mixed	tumor markers, mixed	MoG	Oncology (pancreas), DNA, genome sequence with 5-hydroxymethylcytosine (5hmC) enrichment and glycan biomarker analysis, whole blood or plasma, algorithm reported as cancer detected or not detected

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25	38	0634U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	ctDNA, targeted, solid tumor	MoG	Oncology (breast cancer), cell-free DNA (cfDNA), evaluation of 11 ESR1 variants (E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D) using droplet digital PCR (ddPCR), plasma, reported as positive or negative
26	73	X251U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	ctDNA, ddPCR	MoG	Human papillomavirus (HPV), genotypes 18, 31, 33, and 35, cell-free DNA (cfDNA), whole blood, multiplex digital droplet PCR (ddPCR), quantitative
27	98	X283U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	ctDNA, ddPCR	MoG	Human papillomavirus (HPV), genotype 16, cell-free DNA (cfDNA), whole blood, digital droplet PCR (ddPCR), quantitative
28	8	0604U	TBD	New PLA	Chemistry	LC-MS/MS, peptide	CHIM	Allergy and immunology (chronic recurrent angioedema), 4 bradykinin peptides, liquid chromatography and tandem mass spectrometry (LC-MS/ MS), whole blood, quantitative
29	18	0614U	TBD	New PLA	Chemistry	PAGE, tissue	CHIM	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 4 enzyme complexes by stained blue native polyacrylamide gel electrophoresis (PAGE), frozen tissue (muscle, liver, heart, cultured skin fibroblasts), diagnostic qualitative result
30	58	0654U	TBD	New PLA	Chemistry	Western Blot, fibro	CHIM	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result
31	59	0655U	TBD	New PLA	Chemistry	Spectrophoto metric, fibro	CHIM	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result
32	60	0656U	TBD	New PLA	Chemistry	Radioactive activity, fibro	CHIM	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result
33	87	X266U	TBD	New PLA	Chemistry	ELISA	CHIM	Inborn error of metabolism (primary mitochondrial disease), determination of fibroblast growth factor 21 (FGF21) concentration by enzyme-linked immunosorbent assay (ELISA), serum or plasma, diagnostic quantitative result
34	51	0647U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, single	MoG	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patient-specific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)
35	46	0642U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, single	MoG	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level
36	105	X294U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, single	MoG	Oncology (colorectal cancer), analysis of minimal residual disease (MRD) using patient-specific assays, reported as

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								amount of circulating tumor DNA (ctDNA) detection and trend over time
37	49	0645U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD heme, single	MoG	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance
38	45	0641U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, baseline	MoG	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment
39	50	0646U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, baseline	MoG	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffin-embedded (FFPE) tumor tissue DNA, baseline assessment
40	94	X278U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, baseline	MoG	Oncology (colorectal cancer), analysis of minimal residual disease (MRD), next-generation sequencing (NGS), circulating tumor DNA (ctDNA) analysis in whole blood and tumor for baseline assessment to evaluate current MRD status and for comparisons to subsequent MRD assessments
41	48	0644U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD heme, baseline	MoG	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification
42	83	X262U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	MRD solid tumor, lymphatic	MoG	Oncology (head and neck), circulating tumor DNA (ctDNA), tumor-informed next-generation sequencing (NGS) analysis for 699 genes of patient-specific somatic variants identified from primary tumor tissue, postoperative lymphatic exudate specimen, algorithm reported as presence or absence of ctDNA
43	15	0611U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	Methylation Profile	MoG	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result (For additional PLA code with identical clinical descriptor, see 0612U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)
44	16	0612U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	Methylation Profile	MoG	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result (For additional PLA code with identical clinical descriptor, see 0611U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)
45	103	X292U	TBD	New PLA	MAAA; Chemistry	cardio, immunoassay	CHIM	Cardiology (peripheral artery disease [PAD]), analysis of 3 proteins (midkine, angiopoietin-1, and kidney injury molecule-1 [KIM-1]), immunoassay, plasma, algorithm reported as a risk score for obstructive PAD
46	44	0640U	TBD	New PLA	Immunology	CTC enumeration, CSF	CHIM	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2),

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								HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells
47	82	X261U	TBD	New PLA	MAAA; Molecular	Methylation, dPCR	MoG	Tobacco use, DNA analysis of 2 methylation markers (1 content: cg05575921 [AHRR] and 1 normalizing: cg08141395), methylation-sensitive digital PCR, saliva, algorithm reported as quantitative percent methylation and estimated average cigarette use per day
48	84	X263U	TBD	New PLA	MAAA; Molecular	Methylation, dPCR	MoG	Tobacco use, DNA analysis of 1 methylation marker (cg05575921 [AHRR]), methylation-sensitive digital PCR, whole blood, algorithm reported as quantitative percentage methylation and estimated average cigarette use per day
49	86	X265U	TBD	New PLA	MAAA; Molecular	Methylation, dPCR	MoG	Alcohol use disorder, DNA analysis of 4 methylation markers (cg02583484, cg04987734, cg09935388, cg04583842), methylation-sensitive digital PCR, whole blood, algorithm reported as a summed T-score
50	92	X273U	TBD	New PLA	MAAA; Molecular	Methylation, dPCR	MoG	Oncology (lung cancer), DNA analysis of 1 methylation marker (cg05575921), methylation-sensitive digital PCR, whole blood, algorithm results reported as the 20-year-hazard ratio for lung cancer
51	100	X286U	TBD	New PLA	MAAA; Molecular	Methylation, dPCR	MoG	Oncology (lung cancer), DNA analysis of 2 methylation markers (1 content: cg05575921 and 1 normalizing: cg08141395), methylation-sensitive digital PCR, saliva, algorithm results reported as the 20-year-hazard ratio for lung cancer
52	104	X293U	TBD	New PLA	MAAA; Molecular	Methylation, dPCR	MoG	Alcohol use disorder, DNA analysis of 5 methylation markers (4 content: cg02583484, cg04987734, cg09935388, cg04583842, and 1 normalizing: cg08141395), methylation-sensitive digital PCR, whole blood or saliva, algorithm reported as a summed T-score
53	10	0606U	TBD	New PLA	Hematology	Hematology	CHIM	Hematology (red cell membrane disorders), RBCs, osmotic gradient ektacytometry, whole blood, quantitative
54	81	X259U	TBD	New PLA	MAAA; Mixed	Hepatic, biomarkers	CHIM	Hepatology (metabolic dysfunction-associated steatohepatitis [MASH]), enzyme-linked immunosorbent assay (ELISA) for YKL40 and quantitative reverse transcription polymerase chain reaction (RT-qPCR) for miR-34a-5p, serum, algorithm reported as a single score for MASH activity and fibrosis
55	20	0616U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk
56	21	0617U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk

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57	22	0618U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
58	23	0619U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk
59	24	0620U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
60	26	0622U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
61	27	0623U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
62	28	0624U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk
63	29	0625U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
64	30	0626U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
65	25	0621U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
66	31	0627U	TBD	New PLA	MAAA; Molecular	Methylation Profile	MoG	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk
67	4	0600U	TBD	New PLA	Microbiology; Infectious Disease panel	ID MOL	CHIM	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
68	85	X264U	TBD	New PLA	Microbiology; Infectious Disease panel	ID MOL	CHIM	Infectious disease (wound infection), DNA, multiplex real-time PCR, wound swab, detection of 27 microbial targets and 28 antibiotic resistance targets, reported as semiquantitative for bacterial and fungal targets, and qualitative for viral- and antibiotic-resistance target
69	101	X287U	TBD	New PLA	Microbiology; Infectious Disease panel	ID MOL	CHIM	Infectious disease (Bartonella species, Borrelia species, and Babesia species), multiplex digital PCR for detection of DNA at the genus level for each species, blood, qualitative reporting of presence or absence of each pathogen at the genus level
70	77	X255U	TBD	New PLA	Genomic Sequencing Procedures; WES	WES + mito, duo	MoG	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat (STR) gene expansions, and variants in nonuniquely mappable

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								regions, blood or saliva, identification and categorization of genetic variants, proband and comparator (Do not report X255U in conjunction with 81415, 81416, 0214U, 0215U, X303U)
71	110	X303U	TBD	New PLA	Genomic Sequencing Procedures; WES	WES + mito, trio	MoG	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat (STR) gene expansions, and variants in nonuniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband and 2 comparators (Do not report X303U in conjunction with 81415, 81416, 81425, 81426, 0213U, 0214U, 0215U, 0567U, X255U)
72	72	X250U	TBD	New PLA	Genomic Sequencing Procedures; WGS	WGS + mito, duo	MoG	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy number variants, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat (STR) gene expansions, blood, saliva or genomic DNA, identification and categorization of genetic variants, proband and comparator (Do not report X250U in conjunction with 81425, 81426, 0212U, 0213U, 0214U, 0215U, 0567U, X272U)
73	90	X271U	TBD	New PLA	Genomic Sequencing Procedures; WGS	WGS + mito, duo	MoG	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis combination of short and long reads for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat (STR) genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variant, proband and comparator (Do not report X271U in conjunction with 81425, 81426, 0212U, 0213U, X302U)
74	99	X285U	TBD	New PLA	Genomic Sequencing Procedures; WGS	WGS + mito, duo; prenatal	MoG	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions and maternal cell contamination, fetal sample, identification

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								and categorization of genetic variants, proband and maternal comparator
75	91	X272U	TBD	New PLA	Genomic Sequencing Procedures; WGS	WGS + mito, trio	MoG	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat (STR) gene expansions, blood, saliva or genomic DNA, identification and categorization of genetic variants proband and 2 comparators (Do not report X272U in conjunction with 81425, 81426, 0212U, 0213U, 0214U, 0215U, 0567U, X250U)
76	109	X302U	TBD	New PLA	Genomic Sequencing Procedures; WGS	WGS + mito, trio	MoG	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis combination of short and long reads for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat (STR) genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variant, proband and 2 comparators (Do not report X302U in conjunction with 81425, 81426, 0212U, 0213U, X271U)
77	102	X291U	TBD	New PLA	Genomic Sequencing Procedures; WGS	WGS + mito, trio, prenatal	MoG	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions and maternal cell contamination, fetal sample, identification and categorization of genetic variants, proband and 2 comparators
78	61	0657U	TBD	New PLA	Genomic Sequencing Procedures; WGS	Rapid WGS + mito, comparator	MoG	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by next-generation sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results (Use 0657U in conjunction with 0658U)
79	62	0658U	TBD	New PLA	Genomic Sequencing Procedures; WGS	Rapid WGS + mito, proband	MoG	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide

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								variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants (Use 0658U in conjunction with 0657U)
80	63	0659U	TBD	New PLA	Genomic Sequencing Procedures; WGS	Ultra Rapid WGS + mito, proband	MoG	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
81	11	0607U	TBD	New PLA	Microbiology; targeted panel	Reproductive, tissue, RT-PCR	MoG/ CHIM	Reproductive medicine (endometrial microbiome assessment), real-time PCR analysis for 31 bacterial DNA targets from endometrial biopsy, reported with quantified levels of bacterial presence and targeted treatment recommendations
82	12	0608U	TBD	New PLA	Microbiology; targeted panel	Reproductive, tissue, RT-PCR	MoG/ CHIM	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 (Do not report 0608U in conjunction with 0607U)
83	2	0562U	TBD	Reconsidered	Genomic Sequencing Procedures; cfDNA	ctDNA, targeted, solid tumor	MoG	Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (snvs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free dna, plasma, reported as presence of actionable variants
84	52	0648U	TBD	New PLA	Genomic Sequencing Procedures; targeted panel	FFPE, Solid tumor	MoG	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from formalin-fixed paraffin-embedded (FFPE) tissue
85	106	X295U	TBD	New PLA	Genomic Sequencing Procedures; targeted panel	FFPE, Solid tumor, RNA	MoG	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, RNA analysis, 350 or more genes for RNA alterations (eg, gene rearrangements and splice isoforms)
86	5	0601U	TBD	New PLA	MAAA; Mixed	ID, biomarkers	CHIM	Infectious disease (periprosthetic joint infection), analysis of 11 biomarkers (alpha defensins 1–3, C-reactive protein, microbial antigens for Staphylococcus [SPA, SPB], Enterococcus, Candida, and C. acnes, total nucleated cell count, percent neutrophils, RBC count, and absorbance at 280 nm) using immunoassays, hematology, clinical chemistry, synovial fluid, and diagnostic algorithm reported as a probability score
87	14	0610U	TBD	New PLA	Microbiology; Infectious Disease	ID culture susep	CHIM	Infectious disease (antimicrobial susceptibility), phenotypic antimicrobial susceptibility testing of positive blood culture using microfluidic sensor technology to quantify bacterial growth response to multiple antibiotic types, reporting

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								categorical susceptibility (susceptible, susceptible dose dependent, intermediate, resistant), minimum inhibitory concentration, and interpretive comments
88	33	0629U	TBD	New PLA	Microbiology; Infectious Disease	ID MOL	CHIM	Infectious disease (tuberculosis), DNA, analysis of 1 target by PCR with clustered regularly interspaced short palindromic repeat (CRISPR)-based probe detection, plasma or serum, qualitative report as detected or not detected
89	89	X269U	TBD	New PLA	Chemistry	Mass Spec	CHIM	Oncology (monoclonal gammopathy), immunoprecipitation and matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, identification of intact monoclonal immunoglobulin isotypes (IgG, IgA, IgM, kappa, lambda), and M-protein concentrations in conjunction with turbidimetry, blood, semiquantitative
90	32	0628U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Nephrology (kidney disease-related genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles
91	55	0651U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Oncology (hereditary cancer), genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing (NGS) and digital multiplex ligation-dependent probe amplification for variants, small indels (<40 base pairs), using saliva, whole blood or nail clipping, interpretive clinical report with variant classification
92	57	0653U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants
93	65	8XX19	TBD	New	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Alport syndrome, genomic sequence analysis panel, must include *COL4A3, COL4A4,* and *COL4A5,*interrogation for sequence variants and copy number variants, when performed
94	76	X254U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Oncology (hereditary hematologic cancer), genomic DNA, whole genome sequence (single-nucleotide variants, deletions/insertions, and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, analysis of over 105 genes, genomic DNA isolated from blood, saliva, cultured skin fibroblasts (skin biopsy), identification and categorization of genetic variants
95	96	X280U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Oncology (hereditary cancer), genome sequence for 117 genes (single-nucleotide variants, deletions/insertions, and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, blood, saliva, cultured skin fibroblasts (skin biopsy) or extracted genomic DNA, diagnostic, identification and categorization of genetic variants

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96	66	8XX17	TBD	New	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Genetic testing for heritable immune conditions (eg, combined immunodeficiency/severe combined immunodeficiency, antibody deficiencies, autoinflammatory disorders, phagocytic disorders, hemophagocytic lymphohistiocytosis, hyper IgE syndromes, complement deficiencies), genomic sequence analysis panel, must include sequencing of at least 15 genes, interrogation for sequence variants and copy number variants
97	67	8XX22	TBD	New	Genomic Sequencing Procedures; gene panel	Hereditary	MoG	Genetic testing for heritable complement-mediated thrombotic microangiopathy (CM-TMA) (eg, atypical hemolytic uremic syndrome [aHUS], C3 glomerulopathy [C3G]), genomic sequence analysis panel, must include sequencing of 8 or more genes, interrogation for sequence variants and copy number variants
98	95	X279U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	Hereditary, Carrier	MoG	Carrier screening (cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia, and Duchenne muscular dystrophy), genomic sequence analysis panel, 6 genes (CFTR, SMN1, HBB, HBA1, HBA2, DMD) (Do not report X279U in conjunction with 81443)
99	75	X253U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	allograft, dPCR	MoG	Transplantation medicine (allograft rejection), quantification of donor-derived cell-free DNA (cfDNA) using digital PCR analysis of 45 single-nucleotide polymorphisms, plasma, reported as quantity of donor-derived cfDNA in plasma to determine the probability of allograft rejection
100	47	0643U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	ctDNA, Comprehensive Profile, urine	MoG	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for single-nucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability
101	6	0602U	TBD	New PLA	MAAA; Mixed	endocrinology, biomarkers	MoG	Endocrinology (diabetes), insulin (INS) gene methylation using digital droplet PCR, insulin, and C-peptide immunoassay, serum, Hemoglobin A1c immunoassay, whole blood, algorithm reported as diabetes-risk score
102	53	0649U	TBD	New PLA	MAAA; Molecular	Alz, targeted	MoG	Neurology (Alzheimer disease), DNA, targeted next-generation sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status
103	88	X268U	TBD	New PLA	MAAA; Gene Expression Profile	FFPE, solid, NGS	MoG	Oncology (prostate), mRNA, next-generation sequencing (NGS) gene expression profiling of 22 genes, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score
104	107	X298U	TBD	New PLA	MAAA; Molecular	genotyping	MoG	Obesity, DNA genotyping, analysis of up to 41 genes, buccal swab or blood specimen, patient biometrics, risk-score

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								algorithm to identify a predisposition to up to 4 phenotypes, reported as likelihood to benefit from therapeutics
105	7	0603U	TBD	New PLA	Therapeutic Drug Assay	Therapeutic	CHIM	Drug assay, presumptive, 77 drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS), results reported as positive or negative
106	17	0613U	TBD	New PLA	MAAA; Mixed	tumor markers, molecular	MoG/ CHIM	Oncology (urothelial carcinoma), DNA methylation and mutation analysis of 6 biomarkers (TWIST1, OTX1, ONECUT2, 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
107	36	0632U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	prenatal, targeted	MoG	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected (Do not report X219U in conjunction with 0488U)
108	37	0633U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	prenatal, targeted	MoG	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), next-generation sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm reported as a fetal risk score
109	78	X256U	TBD	New PLA	Genomic Sequencing Procedures; cfDNA	prenatal, targeted	MoG	Obstetrics (fetal platelet antigen noninvasive prenatal test [NIPT]), cell-free DNA (cfDNA) sequence analysis for detection of fetal presence or absence of 1 human platelet antigen or more (HPA-1a, HPA-1b, HPA-3a, HPA-5b, and others) when performed, reported as maternal/fetal incompatibility detected or not detected per selected antigen
110	35	0631U	TBD	New PLA	Genomic Sequencing Procedures; gene panel	tumor, CHIP	MoG/ CHIM	Oncology (solid tumor), DNA, sequence analysis of 15 genes including BRCA1 and BRCA2 for identification of clonal hematopoiesis, blood, reported as tumor-derived or nontumor-derived