Table of Contents

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 2024. The CDLT Panel may also provide input on any other CY 2024 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 April 14, 2023 (CMS-1797-N; 88 FR 23084).

Meeting Format

- The CDLT Panel interim Co-Chairs 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 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 discussed in each session are provided in Appendix 3.

Meeting Connection Instructions and Details

- **<u>Listen-in via audio and watch via Zoom connection only</u>** 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
Wednesday July 19 and Thursday July 20, 2023

Time	Topic	Supporting Resource
8:30 a.m.	**Check-In and Audio/Video Connection Test Check**	
9:00 a.m.	**Welcome and Panel Introductions:** Glenn McGuirk, Interim Designated Federal Officer (DFO) and Meeting Facilitator from the Division of Ambulatory Services; Dr. Chris Chong and Dr. Jochen Lennerz, Interim CDLT Panel Co-Chairs	
9:15 -12:00 p.m.	**Day 1 and 2 Morning Session:** Please view Appendix 3 for exact order of codes.	Appendix 3
12:00- 1:00pm	**Lunch Break** **Please Note:** All speakers please reconnect by 12:45pm	
1:00-4:30 p.m.	**Day 1 and 2 Afternoon Session:** Please view Appendix 3 for exact order of codes.	Appendix 3
4:30 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_ZEd__nZSR2eKNBQKkTEYAA

Note: This link provides attendees 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 2024 New and Reconsidered Codes and Other Information

1. For a list of <u>CY 2024 new and reconsidered codes</u> 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 2024 new and reconsidered code list.

2. For <u>CLFS Annual Laboratory Public meeting agenda</u> from June 22, 2023 please see: https://www.cms.gov/files/document/june-22-2023-agenda-clfs-annual-laboratory-public-meeting.pdf

3. For a recording of the CFLS Annual Laboratory Public Meeting from June 22, 2023, please see links below:
   a. Recording: https://cms.zoomgov.com/rec/share/2Ej35Ey66ORt_cPflE7xE1VisvqGm9f0pYACAoUGDlsi3oQa3emcubUeQNJ0LBHG.O6Br-JePWXFyL2hh
   b. Passcode: #2ENL^#v

4. For a copy of <u>CY 2023 - Clinical Laboratory Fee Schedule Test Codes Final Payment Determinations</u> 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: https://www.cms.gov/files/zip/cy-2023-final-payment-determinations.zip

Appendix 3: Summary of codes

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

Corrections to order of codes:

a. None at this time

FACA Panel Item #	ALM Item #	Subcommittee*	Code #	Code Type	Slide category	Long Code Descriptor
1	26	CHIM	0377U	PLA	Chemistry	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)
2	30	CHIM	0381U	PLA	Chemistry	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of alloisoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LCMS/MS)
3	31	CHIM	0382U	PLA	Chemistry	Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
4	32	CHIM	0383U	PLA	Chemistry	Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
5	47	CHIM	0394U	PLA	Chemistry	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
6	54	CHIM	8X016	NEW	Chemistry	Anti-mullerian hormone (AMH)
7	70	CHIM	X074U	NEW	Multianalyte Assays with Algorithmic Analyses	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression
8	25	MoG	0376U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer specific mortality, includes predictive algorithm to androgen deprivation therapy response, if appropriate
9	80	MoG	X084U	NEW	Multianalyte Assays with Algorithmic Analyses	X084U: Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker [**REVISED by CPT 6-12-2023]
10	84	MoG	X088U	NEW	Multianalyte Assays with Algorithmic Analyses: Immunology	X088U: Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score [**REVISED by CPT 6-12-2023]

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11	72	MoG	X076U	NEW	Multianalyte Assays with Algorithmic Analyses	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer
12	8	CHIM	0359U	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer
13**	9	CHIM	0360U**	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy **Note: Test will not be discussed during meeting as it was recently approved as an existing Advanced Diagnostic Laboratory Test (ADLT)
14	14	CHIM	0365U	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer
15	15	CHIM	0366U	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer
16	16	CHIM	0367U	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection
17	24	CHIM	0375U	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score
18	33	CHIM	0384U	PLA	Multianalyte Assays with Algorithmic Analyses	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease
19	34	CHIM	0385U	PLA	Multianalyte Assays with	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked

FACA Panel Item #	ALM Item #	Subcommittee*	Code #	Code Type	Slide category	Long Code Descriptor
					Algorithmic Analyses; Immunoassay	immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease
20	36	CHIM	0095U	Substantially Revised (PLA)	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Eosinophilic esophagitis), ELISA analysis of (Eotaxin-3 ([CCL26 [{C-C motif chemokine ligand 26}]) and major basic protein ([PRG2 [{proteoglycan 2, pro eosinophil major basic protein}]), enzyme-linked immunosorbent assays (ELISA), specimen obtained by esophageal string test device, algorithm reported as probability of active or inactive eosinophilic esophagitis
21	43	CHIM	0390U	PLA	Multianalyte Assays with Algorithmic Analyses; Immunoassay	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
22	61	CHIM	8X025	NEW	Immunology	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
23	67	CHIM	00X6M	NEW	Multianalyte Assays with Algorithmic Analyses	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations
24	73	CHIM	X077U	NEW	Multianalyte Assays with Algorithmic Analyses	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function
25	81	CHIM	X085U	NEW	Multianalyte Assays with Algorithmic Analyses: Immunology	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS
26	40	CHIM	0387U	PLA	Immunology	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalin fixed paraffin-embedded (FFPE) tissue, report for risk of progression (Do not report 0387U in conjunction with 88341, 88342)
27	42	MoG	0389U	PLA	Genome Sequencing Procedures; RT-PCR	Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD

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28	50	MoG	0398U	PLA	Genomic Sequencing Procedures; methylation analysis	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer
29	3	MoG	0348U	Reconsideration (PLA)	Genomic Sequencing Procedures	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes
30	4	MoG	0350U	Reconsideration (PLA)	Genomic Sequencing Procedures	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes
31	5	MoG	0355U	PLA	Molecular Pathology	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)
32	6	MoG	0356U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (oropharyngeal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence
33	27	MoG	0378U	PLA	Molecular Pathology	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab
34	69	MoG	X073U	NEW	Multianalyte Assays with Algorithmic Analyses	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed first-catch urine), algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer
35	79	MoG	X083U	NEW	Genomic Sequencing Procedures; optical genome mapping	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations
36	2	CHIM	0324U	Reconsideration (PLA)	Microbiology	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug
37	18	CHIM	0369U	PLA	Microbiology; Infectious Disease	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique
38	19	CHIM	0370U	PLA	Microbiology; Infectious Disease	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibiotic resistance genes, multiplex amplified probe technique, wound swab
39	20	CHIM	0371U	PLA	Microbiology; Infectious Disease	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine

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40	21	CHIM	0372U	PLA	Microbiology	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score
41	22	CHIM	0373U	PLA	Microbiology; Infectious Disease	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen
42	23	CHIM	0374U	PLA	Microbiology; Infectious Disease	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
43	38	CHIM	87467	Reconsideration	Microbiology	Hepatitis B surface antigen (HBsAg), quantitative
44	66	CHIM	8X041	NEW	Microbiology	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis D (delta), quantification, including reverse transcription, when performed
45	68	CHIM	X072U	NEW	Immunology	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected
46	74	CHIM	X078U	NEW	Immunology	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
47	82	CHIM	X086U	NEW	Microbiology	Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine
48	29	MoG	0380U	PLA	Genomic Sequencing Procedures; targeted sequence analysis	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype
49	35	MoG	0022U	Substantially Revised (PLA)	Genomic Sequencing Procedures	Targeted genomic sequence analysis panel, non- small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/ or absence of variants and associated therapy(ies) to consider
50	41	MoG	0388U	PLA	Genomic Sequencing Procedures	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
51	45	MoG	0392U	PLA	Genome Sequencing Procedures; dup/del analysis	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug

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52	48	MoG	0395U	PLA	Immunology	Oncology (lung), multi-omics (microbial DNA by shotgun next generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease
53	53	MoG	0401U	PLA	Genomic Sequencing Procedures; targeted variant analysis	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event
54	77	MoG	X081U	NEW	Genomic Sequencing Procedures	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
55	85	MoG	X089U	NEW	Genomic Sequencing Procedures	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype
56	28	MoG	0379U	PLA	Genomic Sequencing Procedures	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
57	37	MoG	0329U	Reconsideration (PLA)	Genomic Sequencing Procedures; exome	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
58	39	MoG	0334U	Reconsideration (PLA)	Genomic Sequencing Procedures; targeted sequence analysis	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
59	52	MoG	0400U	PLA	Genomic Sequencing Procedures	Obstetrics (expanded carrier screening), 145 genes by next generation sequencing, fragment analysis and multiplex ligation dependent probe amplification, DNA, reported as carrier positive or negative
60	55	MoG	8X017	NEW	Genomic Sequencing Procedures	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability
61	56	MoG	8X018	NEW	Genomic Sequencing Procedures	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability
62	57	MoG	8X019	NEW	Genomic Sequencing Procedures	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements

FACA Panel Item #	ALM Item #	Subcommittee*	Code #	Code Type	Slide category	Long Code Descriptor
63	75	MoG	X079U	NEW	Genomic Sequencing Procedures	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
64	83	MoG	X087U	NEW	Genomic Sequencing Procedures; mitochondrial	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder–associated genetic variants
65	7	CHIM	0358U	PLA	Chemistry	Neurology (mild cognitive impairment), analysis of β-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative
66	10	CHIM	0361U	PLA	Immunology	Neurofilament light chain, digital immunoassay, plasma, quantitative
67	46	CHIM	0393U	PLA	Chemistry	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative
68	51	CHIM	0399U	PLA	Immunology	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgG binding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected
69	62	CHIM	8X036	NEW	Immunology	Acetylcholine receptor (AChR); binding antibody
70	63	CHIM	8X037	NEW	Immunology	Acetylcholine receptor (AChR); blocking antibody
71	64	CHIM	8X038	NEW	Immunology	Acetylcholine receptor (AChR); modulating antibody
72	65	CHIM	8X039	NEW	Immunology	Muscle-specific kinase (MuSK) antibody
73	78	CHIM	X082U	NEW	Immunology	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology
74	49	MoG	0396U	PLA	Multianalyte Assays with Algorithmic Analyses; Microarray	Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions
75	76	MoG	X080U	NEW	Multianalyte Assays with	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected

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					Algorithmic Analyses	
76	1	MoG	0326U	Reconsideration (PLA)	Multianalyte Assays with Algorithmic Analyses	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
77	11	MoG	0362U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture–enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes
78	12	MoG	0363U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma
79	13	MoG	0364U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
80	17	MoG	0368U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
81	71	MoG	X075U	NEW	Multianalyte Assays with Algorithmic Analyses	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected
82	44	MoG	0391U	PLA	Multianalyte Assays with Algorithmic Analyses	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score
83	58	MoG	8X020	NEW	Genomic Sequencing Procedures; cell free DNA	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements
84	59	MoG	8X021	NEW	Genomic Sequencing Procedures; cell free DNA	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability

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85	60	MoG	8X022	NEW	Genomic Sequencing Procedures; cell free DNA	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements