2021 Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests
CMS Public Meeting

Table of Contents

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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 2022. The CDLT Panel may also provide input on any other CY 2022 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 3, 2021 (CMS- 1741-N; 2021-09260.pdf (govinfo.gov)).

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 laboratory that owns the test. Once CDLT Panel discussions are concluded, the suggestions from the Panel are summarized and the Panel votes on the suggestions 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.

Meeting 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.

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AGENDA

Wednesday July 28, 2021

Time	Topic	Supporting Resource
8:30 a.m.	**Check-In and Audio/Video Connection Test Check**	
9:00 a.m.	**Welcome and Panel Introductions:** Karen Nakano, M.D., Panel Chair, CMS Physician and Glenn McGuirk, Panel Designated Federal Officer	
9:15 -12:00 p.m.	**Session 1:** I. Immunology II. Microbiology III. Drug Testing, Metabolism and Therapeutic monitoring IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Appendix 1
12:00-1:00pm	**Lunch Break** **Please Note:** All speakers please reconnect by 12:45pm	
1:00-4:30 p.m.	**Session 1: (continued):** I. Immunology II. Microbiology III. Drug Testing, Metabolism and Therapeutic monitoring IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Appendix 1
4:30 p.m.	**Meeting Adjourns**	

Thursday July 29, 2021

Time	Topic	Supporting Resource
8:30 a.m.	**Check-In and Audio/Video Connection Test Check**	
9:00 a.m.	**Reconvene Meeting:** Karen Nakano, M.D., Panel Chair, CMS Physician	
9:15 -12:00 p.m.	**Session 2:** IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score (con't) V. Chemistry VI. Genomic Sequencing Related Tests Other Methods of sequencing VII. Other Genomic Sequencing Related Tests	Appendix 2
12:00-1:00pm	**Lunch Break** **Please Note:** All speakers please reconnect by 12:45pm	
1:00-4:30 p.m.	**Session 2: (continued):** IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score (con't) V. Chemistry VI. Genomic Sequencing Related Tests Other Methods of sequencing VII. Other Genomic Sequencing Related Tests	Appendix 2
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

Please click the link below to join the webinar:

https://cms.zoomgov.com/j/1614064381?pwd=L0w5Q3pNcEwxWDEyS1h0elVxeEozdz09

Webinar ID: 161 406 4381

Password: 546633

US: +1 669 254 5252 or +1 646 828 7666

Appendix 2: Access to CLFS CY 2022 New and Reconsidered Codes and Other Information

1. For a list of CY 2022 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 2022 new and reconsidered code list.

2. For CLFS Annual Laboratory Public meeting agenda from June 24, 2021 please see: https://www.cms.gov/files/document/agenda-clfs-annual-laboratory-meeting-june-24-2021.pdf

3. For a copy of the presentations form the CFLS Annual Laboratory Public Meeting from June 24, 2021, please see: https://www.cms.gov/files/document/cms-clfs-alm-6-24-21-slide-set.pdf

Appendix 3: Session 1 – July 28, 2021 Summary of codes

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
1	7	A	0226U	NEW	Immunology	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum
2	8	A	86413	NEW	Immunology	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) antibody,quantitative
3	63	A	863X4	NEW	Immunology	Mitochondrial antibody (eg, M2), each
4	64	A	865X0	NEW	Immunology	Voltage-gated calcium channel antibody, each
5	65	B	86XX0	NEW	Immunology	Actin (smooth muscle) antibody (ASMA), each
6	66	B	86X00	NEW	Immunology	Antineutrophil cytoplasmic antibody (ANCA); screen, each antibody
7	67	B	86X01	NEW	Immunology	Antineutrophil cytoplasmic antibody (ANCA); titer, each antibody
8	79	C	0X65U	NEW	Immunology	Hematology (heparin-induced thrombocytopenia) platelet antibody reactivity by flow cytometry, serum
9	80	C	0X66U	NEW	Immunology	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen IV binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen IV binding
10	81	C	0X67U	NEW	Immunology	Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level
11	82	C	0X68U	NEW	Immunology	von Willebrand factor (VWF), type 2B, platelet-binding evaluation, radioimmunoassay, plasma
12	83	C	0X69U	NEW	Immunology	von Willebrand factor (VWD), type 2N, factor VIII and VWF binding evaluation, enzyme-linked immunosorbent assays (ELISA), plasma
13	40	D	860XX	NEW	Immunology	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)
14	41	D	860X1	NEW	Immunology	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each
15	42	D	860X2	NEW	Immunology	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
16	43	D	863X2	NEW	Immunology	Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; cell-based immunofluorescence assay (CBA), each

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
17	44	D	863X3	NEW	Immunology	Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
18	45	D	862X0	NEW	Immunology	Endomysial antibody (EMA), each immunoglobulin (Ig) class
19	46	D	862XX	NEW	Immunology	Gliadin (deamidated) (DGP) antibody, each immunoglobulin (Ig) class
20	47	D	862X1	NEW	Immunology	Tissue transglutaminase, each immunoglobulin (Ig) class
21	98	D	0X85U	NEW	Immunology	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen III binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen III binding
22	4	A	86408	NEW	Immunology	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen
23	5	A	86409	NEW	Immunology	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
24	1	A	87426	NEW	Microbiology	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
25	2	A	0223U	NEW	Microbiology	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
26	3	A	0224U	NEW	Microbiology	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed
27	9	A	0240U	NEW	Microbiology	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
28	10	A	0241U	NEW	Microbiology	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
29	57	A	87636	NEW	Microbiology	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
30	58	A	87637	NEW	Microbiology	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]),

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
						influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
31	60	A	87811	NEW	Microbiology	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; ~~Streptococcus, group B~~ severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]
32	68	B	8715X	NEW	Microbiology	Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets
33	59	A	87428	NEW	Microbiology	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARSCoV-2 [COVID-19]) and influenza virus types A and B
34	11	A	0227U	NEW	Drug Testing, Metabolism and Therapeutic monitoring	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation
35	53	A	81338	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)
36	54	A	81339	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10
37	61	A	801XX	NEW	Drug Testing, Metabolism and Therapeutic monitoring	Hydroxychloroquine
38	32	C	0248U	NEW	Drug Testing, Metabolism and Therapeutic monitoring	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug
39	48	D	80151	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	Amiodarone
40	49	D	80161	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	Carbamazepine; 10,11-epoxide
41	50	D	80167	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	Felbamate

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
42	51	D	80181	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	Flecainide
43	52	D	81279	Reconsidered	Drug Testing, Metabolism and Therapeutic monitoring	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)
44	6	A	0225U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
45	12	A	0228U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
46	55	A	815X0	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
47	56	A	815X1	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis
48	25	B	0017M	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue, algorithm reported as cell of origin
49	26	B	0243U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia
50	69	B	002XM	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
51	70	B	0X56U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score

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52	73	B	0X59U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin- surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics
53	28	C	0245U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage
54	30	C	0247U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone– binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth
55	31	C	0252U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy
56	33	C	0249U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report
57	36	C	0253U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)
58	37	C	0254U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested
59	84	C	0X71U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score
60	100	D	0X70U	NEW	Tests with algorithm in code descriptor to report risk/likelihood/predictive score	Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score

Appendix 4: Session 2 – July 29, 2021 Summary of codes

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
61	62	A	826X0	NEW	Chemistry	Elastase, pancreatic (EL-1), fecal; quantitative
62	71	B	0X57U	NEW	Chemistry	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report
63	72	B	0X58U	NEW	Chemistry	Very long chain acyl- coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood
64	74	B	0X60U	NEW	Chemistry	Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative
65	35	C	0251U	NEW	Chemistry	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma
66	38	C	835X1	NEW	Chemistry	Interleukin-6 (IL-6)
67	39	C	8352X	NEW	Chemistry	Immunoglobulin light chains (ie, kappa, lambda), free, each
68	90	D	0X77U	NEW	Chemistry	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)
69	13	A	0229U	NEW	Genomic Sequencing Related Tests	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
70	14	B	0230U	NEW	Genomic Sequencing Related Tests	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
71	15	B	0231U	NEW	Genomic Sequencing Related Tests	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions

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72	16	B	0232U	NEW	Genomic Sequencing Related Tests	CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
73	17	B	0233U	NEW	Genomic Sequencing Related Tests	FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
74	18	B	0234U	NEW	Genomic Sequencing Related Tests	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
75	19	B	0235U	NEW	Genomic Sequencing Related Tests	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
76	20	B	0236U	NEW	Genomic Sequencing Related Tests	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions
77	21	B	0237U	NEW	Genomic Sequencing Related Tests	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
78	22	B	0238U	NEW	Genomic Sequencing Related Tests	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
79	23	B	0239U	NEW	Genomic Sequencing Related Tests	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations
80	76	B	0X62U	NEW	Genomic Sequencing Related Tests	Rare constitutional and other heritable disorders, whole- genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
81	34	C	0250U	NEW	Genomic Sequencing Related Tests	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden
82	77	C	0X63U	NEW	Genomic Sequencing Related Tests	Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and next-generation sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes
83	78	C	0X64U	NEW	Genomic Sequencing Related Tests	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole-genome sequencing
84	86	C	0X73U	NEW	Genomic Sequencing Related Tests	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid
85	87	C	0X74U	NEW	Genomic Sequencing Related Tests	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid
86	88	C	0X75U	NEW	Genomic Sequencing Related Tests	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid
87	89	D	0X76U	NEW	Genomic Sequencing Related Tests	Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood, buccal swab, or amniotic fluid, comprehensive
88	91	D	0X78U	NEW	Genomic Sequencing Related Tests	Hematology (genetic platelet disorders), genomic sequence analysis of 43 genes, blood, buccal swab, or amniotic fluid
89	92	D	0X79U	NEW	Genomic Sequencing Related Tests	Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid
90	93	D	0X80U	NEW	Genomic Sequencing Related Tests	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU) blood, buccal swab, or amniotic fluid
91	94	D	0X81U	NEW	Genomic Sequencing Related Tests	Hematology (inherited thrombocytopenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid
92	95	D	0X82U	NEW	Genomic Sequencing Related Tests	Hematology (genetic platelet function disorder), genomic sequence analysis of 31 genes, blood, buccal swab, or amniotic fluid
93	96	D	0X83U	NEW	Genomic Sequencing Related Tests	Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid
94	97	D	0X84U	NEW	Genomic Sequencing Related Tests	Red blood cell antigen typing, DNA, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes

FACA Panel Item #	ALM Item #	Subcommittee	Code #	Code Type	Slide category	Long Code Descriptor
95	75	B	0X61U	NEW	Other Genomic Sequencing Related Tests	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
96	27	C	0244U	NEW	Other Genomic Sequencing Related Tests	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffinembedded tumor tissue
97	29	C	0246U	NEW	Other Genomic Sequencing Related Tests	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens
98	85	C	0X72U	NEW	Other Genomic Sequencing Related Tests	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
99	99	D	812X0	NEW	Other Genomic Sequencing Related Tests	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis
100	24	NA	~~0152U~~	REMOVED FROM LIST (under gapfill)	-	~~Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, PCR and plasma, untargeted next-generation sequencing, plasma, detection of >1,000 potential microbial organisms report for significant positive pathogens~~
101	101	D	G0327	NEW		Colorectal cancer screening; blood-based biomarker