

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
Wednesday, July 29, 2020 and Thursday, July 30, 2020

---

**Table of Contents**

**Meeting Background and Purpose** ..... 2

**Meeting Format**..... 3

**Meeting Connection Instructions and Details** ..... 3

**AGENDA** ..... 4

**Appendix A: Audio and/or Video Access: Join the meeting by WebEx or telephone** ..... 5

**July 29, 2020** ..... 5

**July 30, 2020** ..... 6

**Appendix B: Access to CLFS CY 2021 New and Reconsidered Codes and Other Related Information**..... 7

**Appendix 1 Session 1 – July 29, 2020 Summary of codes**..... 8

**Appendix 2 Session 2 - July 30, 2020 Summary of codes** ..... 17

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

Wednesday, July 29, 2020 and Thursday, July 30, 2020

---

## Meeting Background and Purpose

This meeting provides an opportunity for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the CDLT Panel) to publically 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 2021. The CDLT Panel may also provide input on any other CY 2021 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 4, 2020 (CMS- 1743-N; <https://www.govinfo.gov/content/pkg/FR-2020-05-04/pdf/2020-09391.pdf>).

# Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

## CMS Public Meeting

Wednesday, July 29, 2020 and Thursday, July 30, 2020

---

### 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 sessions 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 WebEx connection only** details are provided using instructions described in Appendix A.
- Please note that the video or audio recordings of the meeting will not be immediately available after the conclusion of the meeting.

# Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

## CMS Public Meeting

Wednesday, July 29, 2020 and Thursday, July 30, 2020

### AGENDA

#### Wednesday July 29, 2020

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

#### Thursday July 30, 2020

Time	Topic	Supporting Resource
8:30 a.m.	<b>Check-In and Audio/Video Connection Test Check</b>	
9:00 a.m.	<b>Reconvene Meeting:</b> Karen Nakano, M.D., Panel Chair, CMS Physician	
9:15 -12:00 p.m.	<b>Session 2:</b> VI. Chromosomal Related Tests VII. Other Methods of sequencing VIII. Immunology IX. Genomic Sequencing Related Tests X. Chemistry and Other Tests	Appendix 2
12:00- 1:00pm	<b>Lunch Break</b> <b>Please Note:</b> All speakers please reconnect by 12:45pm	
1:00-4:30 p.m.	<b>Session 2: (continued):</b> VI. Chromosomal Related Tests VII. Other Methods of sequencing VIII. Immunology IX. Genomic Sequencing Related Tests X. Chemistry and Other Tests	Appendix 2
4:30 p.m.	<b>Meeting Adjourns</b>	

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

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

Wednesday, July 29, 2020 and Thursday, July 30, 2020

---

## Appendix A: Audio and/or Video Access: Join the meeting by WebEx or telephone

July 29, 2020

---

To start the session via WebEx

---

1. Go to: <https://letsmeet.webex.com/letsmeet/onstage/g.php?MTID=e62eaf11cebb23317e6af67de881e017>
  2. Enter your name and email address (or registration ID).
  3. Enter the session password: dgG3jei8Si8
  4. Click "Join Now".
  5. Follow the instructions that appear on your screen
- 

Audio conference information

---

To receive a call back, provide your phone number when you join the training session, or call the number below and enter the access code.

US Toll: +1-855-829-8848

Having trouble dialing in? Try these backup numbers:

US Toll: +1-415-655-0001

Click here to search for global call-in numbers:

<https://letsmeet.webex.com/letsmeet/globalcallin.php?MTID=tb206acc17b45e43937127a8f937f0893>

Access code: 160 271 6736

---

To join Toll Free

---

1. Dial: 1-855-829-8848
2. Follow the instructions you hear on the phone.

Your WebEx Meeting Number: 160 271 6736

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

Wednesday, July 29, 2020 and Thursday, July 30, 2020

---

**July 30, 2020**

---

To start the session via WebEx

---

1. Go to: <https://letsmeet.webex.com/letsmeet/onstage/g.php?MTID=e22483ec9743e03e90663ed8835853261>
  2. Enter your name and email address (or registration ID).
  3. Enter the session password: mSkR5ynrj35
  4. Click "Join Now".
  5. Follow the instructions that appear on your screen
- 

Audio conference information

---

To receive a call back, provide your phone number when you join the training session, or call the number below and enter the access code.

US Toll: +1-855-829-8848

Having trouble dialing in? Try these backup numbers:

US Toll: +1-415-655-0001

Click here to search for global call-in numbers:

<https://letsmeet.webex.com/letsmeet/globalcallin.php?MTID=tb206acc17b45e43937127a8f937f0893>

Event Number/ Access code: 160 463 4493

---

To join Toll Free

---

1. Dial: 1-855-829-8848
2. Follow the instructions you hear on the phone.

Your WebEx Meeting Number: 160 463 4493

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

Wednesday, July 29, 2020 and Thursday, July 30, 2020

---

## Appendix B: Access to CLFS CY 2021 New and Reconsidered Codes and Other Related Information

1. For a list of CY 2021 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.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html)

Scroll down to “Test Code Updates” for access to the CY 2021 new and reconsidered code list.

2. For CLFS Annual Laboratory Public meeting agenda from June 22, 2020 please see:  
<https://www.cms.gov/files/document/agenda-clfs-annual-laboratory-meeting-june-22-2020.pdf>
3. For a copy of the presentations form the CFLS Annual Laboratory Public Meeting from June 22, 2020, please see: <https://www.cms.gov/presentations-medicare-clinical-laboratory-fee-schedule-annual-laboratory-public-meeting-june-22>

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

**Appendix 1 Session 1 – July 29, 2020 Summary of codes**

FACA List #	ALM Item #	Sub-committee	Code #	Code Type	FACA Mtg. Category / ALM Category	Long Code Descriptor
1	14	A	0141U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology Bacterial and Fungal	Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected
2	15	A	0142U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology Bacterial and Fungal	Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected
3	24	A	0151U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology: Bacterial and Viral Pulmonary Pathogens	Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative results
4	99	A	0202U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology: Bacterial and Viral	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
5	13	A	0140U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology Fungal	Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected
6	25	A	0152U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology: Multiple Pulmonary Pathogens	Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens
7	107	B	0210U	New--Proprietary Laboratory Analyses	I. Microbiology / Microbiology	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)
8	95	D	U0001	NEW	I. Microbiology / Microbiology: Viral	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
9	96	D	U0002	NEW	I. Microbiology / Microbiology: Viral	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
10	131	D	U0003	NEW	I. Microbiology / Microbiology: Viral	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique,



**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

FACA List #	ALM Item #	Sub-committee	Code #	Code Type	FACA Mtg. Category / ALM Category	Long Code Descriptor
						making use of high throughput technologies as described by CMS-2020-01-R
11	132	D	U0004	NEW	I. Microbiology / Microbiology: Viral	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R
12	2	A	87635	NEW	I. Microbiology / Microbiology: Viral	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
13	97	D	86328	NEW	I. Microbiology / Microbiology: Viral	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
14	98	D	86769	NEW	I. Microbiology / Microbiology: Viral	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
15	53	C	0181U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1
16	54	C	0182U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10
17	55	C	0183U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19
18	56	C	0184U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2
19	57	C	0185U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4
20	58	C	0186U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2
21	59	C	0187U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2
22	60	C	0188U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
23	61	C	0189U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2
24	62	C	0190U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3
25	63	C	0191U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6
26	64	C	0192U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9
27	65	C	0193U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26
28	66	C	0194U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8
29	68	C	0196U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3
30	69	C	0197U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1
31	70	C	0198U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5
32	71	C	0199U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12
33	72	C	0200U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3
34	73	C	0201U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2
35	118	C	0221U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
36	119	C	0222U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3
37	52	C	0180U	New--Proprietary Laboratory Analyses	II. Hematopoetic Related Tests / MolPath: Blood Typing	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons
38	16	A	0143U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(For additional PLA code with identical clinical descriptor, see 0150U. See Appendix O to determine appropriate code assignment)
39	17	A	0144U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
40	18	A	0145U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
41	19	A	0146U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
42	20	A	0147U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
43	21	A	0148U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
44	22	A	0149U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
45	23	A	0150U	New--Proprietary Laboratory Analyses	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(For additional PLA code with identical clinical descriptor, see 0143U. See Appendix O to determine appropriate code assignment
46	3	A	80XX1	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Salicylate
47	74	C	80XX2	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Amiodarone
48	75	C	80XXX	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Acetaminophen
49	77	D	81XX3	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)
50	120	C	80XX3	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Carbamazepine; 10,11-epoxide
51	121	C	80XX4	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Felbamate
52	122	C	80XX5	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring /	Flecainide

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

FACA List #	ALM Item #	Sub-committee	Code #	Code Type	FACA Mtg. Category / ALM Category	Long Code Descriptor
					Chemistry: Drug Testing, Monitoring	
53	123	C	80XX6	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Itraconazole
54	124	C	80XX7	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Leflunomide
55	125	D	80XX8	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Methotrexate
56	126	D	802XX	NEW	III. Drug Testing, Metabolism and Therapeutic monitoring / Chemistry: Drug Testing, Monitoring	Rufinamide
57	116	C	0219U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MolPath: Other than GSP, MAAA microbiology	Infectious agent (human immunodeficiency virus), targeted viral next generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility
58	78	D	81XX4	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Microbiology	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis
59	127	D	815X3	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Microbiology	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera Type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
60	4	A	81XX2	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / Other Methods of Sequencing: Thyroid Cancer Gene expression	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)
61	105	A	0208U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MolPath: mRNA gene expression thyroid	Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma
62	6	A	002XM/0014M	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Protein Liver fibrosis	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
63	39	B	0166U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Protein	Liver disease, 10 biochemical assays ( $\alpha$ 2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation
64	12	A	0139U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Chemistry	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, $\alpha$ -ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)
65	43	B	0170U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / Other Methods of Sequencing: Gene sequencing Autism Spectrum Disorder	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis
66	76	D	81XX1	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Gene expression idiopathic pulmonary fibrosis	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
67	37	B	0164U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Protein	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
68	41	B	0168U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / Other Methods of Sequencing: Aneuploidy DNA sequencing	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy
69	46	B	0174U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Mass spec, Proteins Solid tumors	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents
70	129	D	003XM	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy
71	130	D	004XM	NEW	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA	Oncology (bladder), mRNA, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)
72	36	B	0163U	New--Proprietary Laboratory Analyses	IV. Tests with algorithm in code descriptor to report risk/likelihood/predictive score / MAAA: Protein colorectal SCREENING	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas
73	1	A	81307	Reconsideration	V. Reconsidered codes / Oncology: Breast FGS procedure	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence
74	7	A	0071U	Reconsideration	V. Reconsidered codes / Drug Metabolism	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, full gene sequence
75	8	A	0101U	Reconsideration	V. Reconsidered codes / Genomic Sequencing Related tests: Duplication/Deletion Colon Cancer	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

FACA List #	ALM Item #	Sub-committee	Code #	Code Type	FACA Mtg. Category / ALM Category	Long Code Descriptor
						resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])
76	9	A	0102U	Reconsideration	V. Reconsidered codes / Genomic Sequencing Related tests: Duplication/Deletion Colon Cancer	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])
77	10	A	0103U	Reconsideration	V. Reconsidered codes / Genomic Sequencing Related tests: Duplication/Deletion Ovarian Cancer	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])
78	11	A	0129U	Reconsideration	V. Reconsidered codes / Genomic Sequencing Related tests: Duplication/Deletion Breast Cancer related	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)



**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

**Appendix 2 Session 2 - July 30, 2020 Summary of codes**

FACA List #	ALM Item #	Sub-committee	Code #	Code Type	FACA Mtg. Category / ALM Category	Long Code Descriptor
79	79	D	8X010	NEW	VI. Chromosomal Related Tests / Chromosomal Related Tests	CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed
80	80	D	8X009	NEW	VI. Chromosomal Related Tests / Chromosomal Related Tests	IGH@/BCL2(t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative
81	85	D	8X000	NEW	VI. Chromosomal Related Tests / Chromosomal Related Tests	NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis
82	86	D	8X001	NEW	VI. Chromosomal Related Tests / Chromosomal Related Tests	NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis
83	87	D	8X002	NEW	VI. Chromosomal Related Tests / Chromosomal Related Tests	NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis
84	106	A	0209U	New--Proprietary Laboratory Analyses	VI. Chromosomal Related Tests / MolPath: Chromosome analysis	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities
85	84	D	8X020	NEW	VI. Chromosomal Related Tests / Chromosomal Related Tests	NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis
86	26	B	0153U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Gene expression breast	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
87	28	B	0155U	New--Proprietary Laboratory Analyses (chemotherapy sensitivity analyses)	VII. Other Methods of Sequencing / Other Methods of Sequencing: Gene analysis breast	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin-embedded breast tumor tissue, reported as PIK3CA gene mutation status
88	49	B	0177U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Gene analysis	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
89	30	B	0157U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	APC (APC regulator of WNT signaling pathway) (eg, familial adenomatosis polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0157U in conjunction with 81201)
90	31	B	0158U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0158U in conjunction with 81292)
91	32	B	0159U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0159U in conjunction with 81295)
92	33	B	0160U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0160U in conjunction with 81298)
93	34	B	0161U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) *(Use 0161U in conjunction with 81317)
94	35	B	0162U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure) *(Use 0162U in conjunction with 81292, 81295, 81298, 81317, 81435)
95	81	D	8X008	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Targeted sequence analysis	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)
96	82	D	8X006	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Common variants	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)
97	83	D	8X007	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10
98	88	D	8XX00	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Common variants	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
99	89	D	8XX01	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Common variants	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)
100	93	D	8XX02	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Common variants	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)
101	94	D	8XX03	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Common variants	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)
102	44	B	0171U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Common variants	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence
103	90	D	8X003	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: FGS	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence
104	91	D	8X005	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Known Familial variant	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant
105	92	D	8X004	NEW	VII. Other Methods of Sequencing / Other Methods of Sequencing: Targeted sequence analysis	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)
106	27	B	0154U	New--Proprietary Laboratory Analyses (chemotherapy sensitivity analyses)	VII. Other Methods of Sequencing / Other Methods of Sequencing: Gene analysis	Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status
107	29	B	0156U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / MolPath: Copy number sequence analysis	Copy number (eg, intellectual disability, dysmorphism), sequence analysis
108	51	C	0179U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Targeted sequence analysis	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
109	67	C	0195U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Targeted sequencing	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)
110	42	B	0169U	New--Proprietary Laboratory Analyses	VII. Other Methods of Sequencing / Other Methods of Sequencing: Sequence analysis	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
111	38	B	0165U	New--Proprietary Laboratory Analyses	VIII. Immunology / Immunology	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
112	40	B	0167U	New--Proprietary Laboratory Analyses	VIII. Immunology / Immunology	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood
113	50	B	0178U	New--Proprietary Laboratory Analyses	VIII. Immunology / Immunology	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction
114	5	A	81XX6	NEW	IX. Genomic Sequencing Related tests / Genomic Sequencing Related tests	Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2
115	45	B	0173U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / Genomic Sequencing Related tests	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
116	47	B	0175U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / Genomic Sequencing Related tests	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes
117	100	A	0203U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / Molpath: mRNA gene expression	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness
118	101	A	0204U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / Molpath: mRNA gene expression	Oncology (thyroid), mRNA, gene expression analysis of 593 genes for sequence variants and rearrangements, including BRAF, RAS, RET, PAX8 and NTRK, utilizing fine needle aspirate, reported as detected/not detected
119	102	A	0205U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: Gene analysis	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

<b>FACA List #</b>	<b>ALM Item #</b>	<b>Sub-committee</b>	<b>Code #</b>	<b>Code Type</b>	<b>FACA Mtg. Category / ALM Category</b>	<b>Long Code Descriptor</b>
						neovascular age-related macular degeneration risk associated with zinc supplements
120	108	B	0211U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: NGS	Oncology (pan-tumor), DNA and RNA by next generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association
121	109	B	0212U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
122	110	B	0213U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling)
123	111	B	0214U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
124	112	B	0215U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (eg, parent, sibling)
125	113	B	0216U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
126	114	B	0217U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely

**Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests**  
**CMS Public Meeting**  
**Wednesday, July 29, 2020 and Thursday, July 30, 2020**

FACA List #	ALM Item #	Sub-committee	Code #	Code Type	FACA Mtg. Category / ALM Category	Long Code Descriptor
						mappable regions, blood or saliva, identification and categorization of genetic variants
127	115	B	0218U	New--Proprietary Laboratory Analyses	IX. Genomic Sequencing Related tests / MolPath: GSP	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
128	48	B	0176U	New--Proprietary Laboratory Analyses	X. Chemistry and Other Tests / Immunoassay: ELISA GI IBS	Cytotoxic distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
129	103	A	0206U	New--Proprietary Laboratory Analyses	X. Chemistry and Other Tests / Other: ELISA, cell morphology Alzheimer	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCε) concentration in response to amylopheroïd treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease
130	104	A	0207U	New--Proprietary Laboratory Analyses	X. Chemistry and Other Tests / Other: ELISA, cell morphology Alzheimer	Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)
131	117	C	0220U	New--Proprietary Laboratory Analyses	X. Chemistry and Other Tests / Other: Oncology: Breast, Light microscopy	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
132	128	D	82XX1	NEW	X. Chemistry and Other Tests / Chemistry	Estradiol; free, direct measurement (eg, equilibrium dialysis)