CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10217	**Date: July 8, 2020**
	Change Request 11815

Transmittal 10174, dated June 12, 2020, is being rescinded and replaced by Transmittal 10217, dated, July 8, 2020 to revise the policy section to include additional COVID-19 codes 87426, 0223U and 0224U. All other information remains the same.

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: July 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2020

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 10217	Date: July 8, 2020	Change Request: 11815

Transmittal 10174, dated June 12, 2020, is being rescinded and replaced by Transmittal 10217, dated, July 8, 2020 to revise the policy section to include additional COVID-19 codes 87426, 0223U and 0224U. All other information remains the same.

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: July 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2020

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

B. Policy: Clinical Laboratory Fee Schedule

Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following CMS website for additional information regarding these tests: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests —DELAYED

- Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule "Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule" (CMS-1621-F) was published in the Federal Register on June 23, 2016. The CLFS final rule implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019 through June 30, 2019.
- Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. In summary, revisions are as follows:
    - The next data reporting period of January 1, 2022 through March 31, 2022, will be based on the original data collection period of January 1, 2019 through June 30, 2019.
    - After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2025, 2028, etc.).

- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2024. There is a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024.

Coronavirus-19 (COVID-19) Policy Updates

- **Payment for Specimen Collection for Purposes of COVID-19 Testing**

For the duration of the Public Health Emergency (PHE) for the COVID-19 pandemic and in an effort to be as expansive as possible within the current authorities to have diagnostic testing available to Medicare beneficiaries who need it, in the interim final rule with comment period (IFC), CMS-1744-IFC, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, CMS changed the Medicare payment rules to provide payment to independent laboratories for specimen collection from beneficiaries who are homebound or inpatients not in a hospital for COVID-19 testing under certain circumstances. For more information on this policy update, please refer to https://www.cms.gov/files/document/covid-final-ifc.pdf.

- **Revisions to Ordering Requirements for Clinical Laboratory Diagnostic Testing**

In the interim final rule with comment period, CMS-5531-IFC, Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, on an interim basis for the duration of the PHE for the COVID-19 pandemic, CMS removed the requirement that certain clinical diagnostic laboratory tests must be ordered by a treating physician or non-physician practitioner (NPP). This will allow any healthcare professional authorized to do so under State law to order COVID-19 diagnostic laboratory tests (including serological and antibody tests). Because the symptoms for coronavirus, influenza and respiratory syncytial virus (RSV) are often the same, such that concurrent testing for all three viruses is warranted, this interim policy also applies to influenza and RSV tests, but only when they are furnished in conjunction with a medically necessary COVID-19 diagnostic laboratory test to establish or rule out a COVID-19 diagnosis or identify an adaptive immune response to SARS-COV-2. For more information on this policy update, please refer to https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.

- **Coverage of COVID-19 Serology Testing**

In the interim final rule with comment period, CMS-5531-IFC, Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, CMS finalized on an interim basis, that during the PHE for the COVID-19 pandemic, Medicare will cover FDA-authorized COVID-19 serology tests as they are reasonable necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. CMS amended § 410.32(a)(3) to reflect this determination of coverage. For more information on this policy update, please refer to https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.

- **High Throughput Technologies**

CMS issued CMS Ruling CMS-2020-01-R concerning payment under Medicare Supplementary Medical Insurance (Part B) of certain clinical diagnostic laboratory tests for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 making use of high throughput technologies. As described in CMS Ruling CMS 2020-01-R, a high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day. For more information on this policy update, please refer to https://www.cms.gov/files/document/cms-2020-01-r.pdf.

Clinical Laboratory Fee Schedule Beginning January 1, 2018

- Effective January 1, 2018, CLFS rates are based on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014.
- The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.
- For more details, visit PAMA Regulations, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.
- **Access to Data File:** The quarterly clinical laboratory fee schedule data file shall be retrieved electronically through CMS' mainframe telecommunications system. Under normal circumstances, CMS will make the updated CLFS data file available to A/B MAC contractors approximately 6 weeks prior to the beginning of each quarter. For example, the updated file will typically be made available for download and testing on or before approximately February 15th for the April 1st release. Internet access to the quarterly clinical laboratory fee schedule data file shall be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, shall use the Internet to retrieve the quarterly clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

- **Pricing Information:** The clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees are established in accordance with section 1833(h)(4)(B) of the Act. Also note additional specimen collection codes below during the PHE.

New Codes Effective April 1, 2020

Please note: MACs shall establish payment for CPT code 0014M, effective April 1, 2020. This code was inadvertently left off the April 2020 CLFS CR. This code was added to the national HCPCS file with an effective date of April 1, 2020 and therefore does not need to be manually added to the HCPCS files by the MACs. This code will be included on the CLFS for the July 2020 (quarter 3) release. This new code is contractor-priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- CPT Code 0014M

Long Descriptor: 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

Short Descriptor: LIVER DS ALYS 3 BMRK SRM ALG

Laboratory: Enhanced Liver Fibrosis™ (ELFTM) Test, Siemens Healthcare Diagnostics Inc/Siemens Healthcare Laboratory LLC

TOS: 5

New Codes Effective April 10, 2020

As described above in the COVID-19 Policy Updates section, Coverage of COVID-19 Serology Testing, the below listed new codes have been added to the national HCPCS file with an effective date of April 10, 2020 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- CPT Code: 86328

Long Descriptor: 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])

Short Descriptor: Ia nfct ab sarscov2 covid19

TOS: 5

- CPT Code: 86769

Long Descriptor: Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

Short Descriptor: Sars-cov-2 covid-19 antibody

TOS: 5

New Codes Effective April 14, 2020

Per the above discussion in the COVID-19 Policy Updates section, High Throughput Technologies, two new HCPCS codes have been created for laboratories to bill under the Medicare Clinical Laboratory Fee Schedule for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 making use of these high throughput technologies. The listed new codes have been added to the national HCPCS file with an effective date of April 14, 2020 and do not need to be manually added to the HCPCS files by the MACs. Such tests, as identified by U0003 and U0004, in accordance with CMS Ruling CMS-2020-01-R, shall be paid at the rate of $100. These new codes are:

- Code: U0003

Long Descriptor: 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, making use of high throughput technologies as described by CMS-2020-01-R

Short Descriptor: Cov-19 amp prb hgh thruput

TOS: 5

- Code: U0004

Long Descriptor: 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

Short Descriptor: Cov-19 test non-cdc hgh thru

TOS: 5

New Codes Effective May 20, 2020

The listed new code will be added to the national HCPCS file with an effective date of May 20, 2020; however until such time MAC's may need to manually add it to the HCPCS files. Additionally, this new code is contractor-priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction.

- Code: 0202U

Short Descriptor: Nfct ds 22 trgt sars-cov-2

TOS: 5

Long Descriptor: 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

New Codes Effective June 25, 2020

The listed new code will need to be manually added to the national HCPCS file by the MACs with an effective date of June 25, 2020. Additionally, this new code is contractor-priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Social Security

Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code:87426

Long Descriptor: 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])

Short Descriptor: CORONAVIRUS AG IA

TOS: 5

Proprietary Laboratory Analysis (PLAs)

The listed new codes will need to be manually added to the national HCPCS files by the MACs with an effective date of June 25, 2020. Additionally, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction.

- Code: 0223U

Laboratory Name: QIAstat-Dx Respiratory SARS CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH

Long Descriptor: 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

Short Descriptor: NFCT DS 22 TRGT SARS-COV-2

TOS: 5

- Code: 0224 U

Laboratory Name: COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory

Long Descriptor: Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed

Short Descriptor: ANTIBODY SARS-COV-2 TITER(S

TOS: 5

New Codes Effective July 1, 2020

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2020 CLFS Quarterly Updates**", Tab "**New Codes Effective 7-1-2020**". The listed new codes have been added to the national HCPCS file with an effective date of July 1, 2020 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction. MACs shall only price PLA codes for laboratories within their jurisdiction.

The table includes the laboratory, long descriptor, short descriptor, and TOS of each new code.

Revised Codes Effective July 1, 2020

Proprietary Laboratory Analysis (PLAs)

The laboratory name of the following existing code was changed effective July 1, 2020:
Existing code 0068U
Laboratory Name: MYCODART-PCR™ DualAmplification Real Time PCR Panel for 6 Candida species, RealTime Laboratories, Inc/MycoDART, Inc, RealTime Laboratories, Inc

Deleted Codes Effective July 1, 2020
Existing code 0124U is being deleted.
Existing code 0125U is being deleted.
Existing code 0126U is being deleted.
Existing code 0127U is being deleted.
Existing code 0128U is being deleted.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11815.1	Contractors shall be aware that the CLFS will be released quarterly, as needed, and establish hours to accommodate retrieval and implementation of the quarterly CLFS data file.	X	X							VDC
11815.1.1	CMS shall notify contractors by email approximately six weeks prior to the beginning of the quarter when the Clinical Laboratory Fee Schedule (CLFS) data file is ready for download. CMS shall provide the file name.									CMS

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11815.2	Contractors shall retrieve and load for testing and claims processing purposes the July 2020 quarterly CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.	X	X							VDC
11815.2.1	Contractors shall note that the CLFS data file name will be in the following format: MU00.@BF12394.CLAB.VyyyyQr Note: The naming convention of the file is such that "yyyy" equals the calendar year (for example, V2020) and "r" equals the release number (for example, Q3 reflects Quarter 3 or July release) with January = 1, April = 2, July = 3, and October = 4 For example, for the July release or the 3rd quarter release of 2020, the data file name is the following: MU00.@BF12394.CLAB.V2020Q3	X	X							VDC
11815.2.2	Contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., SSM or A/B MAC Part B name and number).	X	X							VDC
11815.2.3	Contractors shall address any questions/concerns regarding the content of the files and/or specific HCPCS codes contained within by emailing CLFS_Inquiries@cms.hhs.gov.	X	X							VDC
11815.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis (**NOTE** - This requirement is applicable to the January quarterly release CR only).		X							
11815.4	A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients (**NOTE** - This requirement is applicable	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	to the January quarterly release CR only).									
11815.5	Contractors shall be aware of any new Advanced Diagnostic Laboratory Test (ADLT) codes, and/or CPT/HCPCS codes (including their TOS designation(s) and Effective date), and/or any deleted/terminated codes as applicable listed in this Change Request and shall update their systems as necessary to accept/delete/terminate them.	X	X						X	
11815.5.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (IOCE) update, contractors shall locally price the codes until they appear on the CLFS file and/or, for Part A claims, the IOCE.	X	X							
11815.6	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11815.7	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	article release notifications, or review them in the MLN Connects weekly newsletter.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Rasheeda Arthur, 410-786-3434 or rasheeda.johnson1@cms.hhs.gov , Laura Ashbaugh, 410-786-1113 or laura.ashbaugh2@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

New Codes Effective July 1, 2020

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of July 1, 2020 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2020 as they were received after the 2019 public meeting.

MACs shall only price PLA codes for laboratories within their jurisdiction.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
myChoice® CDx, Myriad Genetics	0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of	ONC SLD TUM ALYS BRCA1 BRCA2	5	July 1, 2020
Psych HealthPGx Panel, RPRD Diagnostics, RPRD Diagnostics	0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	PSYC GEN ALYS PANEL 14 GENES	5	July 1, 2020
LC-MS/MS Targeted Proteomic Assay, OncoOmicDx Laboratory, LDT	0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin- fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or	ONC SOLID TUMOR 30 PRTN TRGT	5	July 1, 2020
Genomind® Professional PGx Express™ CORE, Genomind, Inc, Genomind, Inc	0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	PSYC GEN ALYS PANEL 15 GENES	5	July 1, 2020
IBS*chek*®, Commonwealth Diagnostics International, Inc, Commonwealth	0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	CDTB&VINCULIN IGG ANTB IA	5	July 1, 2020
therascreen® *PIK3CA* RGQ PCR Kit, QIAGEN, QIAGEN	0177U	Oncology (breast cancer), DNA, *PIK3CA (phosphatidylinositol-4,5-bisphosphate 3- kinase catalytic subunit alpha)* gene analysis of 11 gene variants utilizing plasma, reported as	ONC BRST CA DNA PIK3CA 11	5	July 1, 2020
VeriMAP™ Peanut Sensitivity - Bead Based Epitope Assay, AllerGenis™	0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical	PEANUT ALLG ASMT EPI CLIN RX	5	July 1, 2020
Resolution ctDx Lung™, Resolution Bioscience, Resolution Bioscience, Inc	0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior	ONC NONSM CLL LNG CA ALYS 23	5	July 1, 2020
Navigator ABO Sequencing, Grifols Immunohematology Center, Grifols	0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, *ABO (ABO, alpha 1-3-N-*	ABO GNOTYP ABO 7 EXONS	5	July 1, 2020
Navigator CO Sequencing, Grifols Immunohematology Center, Grifols	0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, *AQP1 (aquaporin 1 [Colton blood group])* exon 1	CO GNOTYP AQP1 EXON 1	5	July 1, 2020
Navigator CROM Sequencing, Grifols Immunohematology Center, Grifols	0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, *CD55 (CD55 molecule [Cromer blood group])* exons 1-10	CROM GNOTYP CD55 EXONS 1-10	5	July 1, 2020
Navigator DI Sequencing, Grifols Immunohematology Center, Grifols	0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, *SLC4A1 (solute carrier family 4 member 1 [Diego blood group])* exon 19	DI GNOTYP SLC4A1 EXON 19	5	July 1, 2020
Navigator DO Sequencing, Grifols Immunohematology Center, Grifols	0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, *ART4 (ADP-ribosyltransferase 4 [Dombrock blood group])* exon 2	DO GNOTYP ART4 EXON 2	5	July 1, 2020
Navigator FUT1 Sequencing, Grifols Immunohematology Center, Grifols	0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, *FUT1 (fucosyltransferase 1 [H blood group])* exon 4	FUT1 GNOTYP FUT1 EXON 4	5	July 1, 2020
Navigator FUT2 Sequencing, Grifols Immunohematology Center, Grifols	0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, *FUT2 (fucosyltransferase 2)* exon 2	FUT2 GNOTYP FUT2 EXON 2	5	July 1, 2020
Navigator FY Sequencing, Grifols Immunohematology Center, Grifols	0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, *ACKR1 (atypical chemokine receptor 1 [Duffy blood group])* exons 1-2	FY GNOTYP ACKR1 EXONS 1-2	5	July 1, 2020
Navigator GE Sequencing, Grifols Immunohematology Center, Grifols	0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, *GYPC (glycophorin C [Gerbich blood group])* exons 1-4	GE GNOTYP GYPC EXONS 1-4	5	July 1, 2020
Navigator GYPA Sequencing, Grifols Immunohematology Center, Grifols	0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, *GYPA (glycophorin A [MNS blood group])* introns 1, 5, exon 2	GYPA GNOTYP NTRNS 1 5 EXON 2	5	July 1, 2020
Navigator GYPB Sequencing, Grifols Immunohematology Center, Grifols	0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, *GYPB (glycophorin B [MNS blood group])* introns 1, 5, pseudoexon 3	GYPB GNOTYP NTRNS 1 5 SEUX 3	5	July 1, 2020
Navigator IN Sequencing, Grifols Immunohematology Center, Grifols	0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, *CD44 (CD44 molecule [Indian blood group])* exons 2, 3, 6	IN GNOTYP CD44 EXONS 2 3 6	5	July 1, 2020
Navigator JK Sequencing, Grifols Immunohematology Center, Grifols	0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, *SLC14A1 (solute carrier family 14 member 1 [Kidd blood group])* gene promoter, exon 9	JK GNOTYP SLC14A1 EXON 9	5	July 1, 2020
Navigator JR Sequencing, Grifols Immunohematology Center, Grifols	0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, *ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group])* exons 2- 26	JR GNOTYP ABCG2 EXONS 2-26	5	July 1, 2020
Navigator KEL Sequencing, Grifols Immunohematology Center, Grifols	0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, *KEL (Kell metallo-endopeptidase [Kell blood group])* exon 8	KEL GNOTYP KEL EXON 8	5	July 1, 2020
Navigator *KLF1* Sequencing, Grifols Immunohematology Center, Grifols	0195U	*KLF1 (Kruppel-like factor 1),* targeted sequencing (ie, exon 13)	KLF1 TARGETED SEQUENCING	5	July 1, 2020
Navigator LU Sequencing, Grifols Immunohematology Center, Grifols	0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, *BCAM (basal cell adhesion molecule [Lutheran blood group])* exon 3	LU GNOTYP BCAM EXON 3	5	July 1, 2020
Navigator LW Sequencing, Grifols Immunohematology Center, Grifols	0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, *ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group])* exon 1	LW GNOTYP ICAM4 EXON 1	5	July 1, 2020
Navigator RHD/CE Sequencing, Grifols Immunohematology Center, Grifols	0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, *RHD (Rh blood group D antigen)* exons	RHD&RHCE GNTYP RHD1-10&RHCE5	5	July 1, 2020
Navigator SC Sequencing, Grifols Immunohematology Center, Grifols	0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, *ERMAP (erythroblast membrane associated protein [Scianna blood group])* exons 4, 12	SC GNOTYP ERMAP EXONS 4 12	5	July 1, 2020
Navigator XK Sequencing, Grifols Immunohematology Center, Grifols	0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, *XK (X- linked Kx blood group)* exons 1-3	XK GNOTYP XK EXONS 1-3	5	July 1, 2020
Navigator YT Sequencing, Grifols Immunohematology Center, Grifols	0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, *ACHE (acetylcholinesterase [Cartwright blood group])* exon 2	YT GNOTYP ACHE EXON 2	5	July 1, 2020