CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10265	**Date: August 7, 2020**
	Change Request 11937

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: October 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 5, 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: 10265	Date: August 7, 2020	Change Request: 11937

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

EFFECTIVE DATE: October 1, 2020
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IMPLEMENTATION DATE: October 5, 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)

- Payment Amount for Specific Advanced Diagnostic Laboratory Tests (ADLTs)
    - For dates of service beginning on or after April 1, 2020 through December 31, 2021, the payment amount for the ADLT *DecisionDx-Melanoma*™ is equal to $7,193.00. The fee schedule amount for *DecisionDx-Melanoma*™ reflects the weighted median of private payor rates for the test, as determined from applicable information collected and reported to CMS during the new ADLT initial period. Once this ADLT is assigned its own unique Healthcare Common Procedure Coding System (HCPCS) code, meaning one that describes only a single test, the HCPCS code and payment amount will be included on the CLFS file.
- 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.

Codes Effective June 25, 2020

Please note that since the issuing of Transmittal R10217CP, CR 11815, *Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment*, the following codes were added to the national HCPCS file with an effective date of June 25, 2020. The codes are contractor-priced 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).

- 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

- 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 October 1, 2020

Proprietary Laboratory Analysis (PLAs)

Please see table attached to the Transmittal entitled "**CY2020 CLFS Quarterly Updates**", Tab "**New Codes Effective 10-1-2020**". The listed new codes have been added to the national HCPCS file with an effective date of October 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.

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	
11937.1	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
11937.1.1	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
11937.2	Contractors shall retrieve and load for testing and claims processing purposes the October 2020 quarterly CLFS data file from the CMS mainframe approximately six weeks prior to the beginning of the quarter.	X	X							VDC
11937.2.1	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 October release or the 4th quarter release of 2020, the data file name is the following: MU00.@BF12394.CLAB.V2020Q4	X	X							VDC
11937.2.2	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
11937.2.3	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
11937.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis (**NOTE** - This		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	requirement is applicable to the January quarterly release CR only).									
11937.4	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 to the January quarterly release CR only).	X								
11937.5	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	
11937.5.1	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							
11937.6	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		
11937.7	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	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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 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 October 1, 2020

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 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.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
PredictSURE IBDTM Test, KSL Diagnostics, PredictImmune Ltd	0203U	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	AI IBD MRNA XPRSN PRFL 17	5	October 1, 2020
Afirma Xpression Atlas, Veracyte, Inc, Veracyte, Inc	0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected	ONC THYR MRNA XPRSN ALYS 593	5	October 1, 2020
Vita Risk®, Arctic Medical Laboratories, Arctic Medical Laboratories	0205U	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 neovascular age-related macular-degeneration risk associated with zinc supplements	OPH AMD ALYS 3 GENE VARIANTS	5	October 1, 2020
DISCERN™, NeuroDiagnostics, NeuroDiagnostics	0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease	NEURO ALZHEIMER CELL AGGREGJ	5	October 1, 2020
DISCERN™, NeuroDiagnostics, NeuroDiagnostics	0207U	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)	NEURO ALZHEIMER QUAN IMAGING	5	October 1, 2020
Afirma Medullary Thyroid Carcinoma (MTC) Classifier, Veracyte, Inc, Veracyte, Inc	0208U	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	ONC MTC MRNA XPRSN ALYS 108	5	October 1, 2020
CNGnome™, PerkinElmer Genomics, PerkinElmer Genomics	0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities	CYTOG CONST ALYS INTERROG	5	October 1, 2020
BioPlex 2200 RPR Assay - Quantitative, Bio-Rad Laboratories, Bio-Rad Laboratories	0210U	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)	SYPHILIS TST ANTB IA QUAN	5	October 1, 2020
MI Cancer Seek™ - NGS Analysis, Caris MPI d/b/a Caris Life Sciences, Caris MPI d/b/a Caris Life Sciences	0211U	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	ONC PAN-TUM DNA&RNA GNRJ SEQ	5	October 1, 2020
Genomic Unity® Whole Genome Analysis – Proband, Variantyx Inc, Variantyx Inc	0212U	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	RARE DS GEN DNA ALYS PROBAND	5	October 1, 2020
Genomic Unity® Whole Genome Analysis - Comparator, Variantyx Inc, Variantyx Inc	0213U	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)	RARE DS GEN DNA ALYS EA COMP	5	October 1, 2020
Genomic Unity® Exome Plus Analysis - Proband, Variantyx Inc, Variantyx Inc	0214U	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	RARE DS XOM DNA ALYS PROBAND	5	October 1, 2020
Genomic Unity® Exome Plus Analysis - Comparator, Variantyx Inc, Variantyx Inc	0215U	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)	RARE DS XOM DNA ALYS EA COMP	5	October 1, 2020
Genomic Unity® Ataxia Repeat Expansion and Sequence Analysis, Variantyx Inc, Variantyx Inc	0216U	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	NEURO INH ATAXIA DNA 12 COM	5	October 1, 2020
Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis, Variantyx Inc, Variantyx Inc	0217U	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 mappable regions, blood or saliva, identification and categorization of genetic variants	NEURO INH ATAXIA DNA 51 GENE	5	October 1, 2020
Genomic Unity® DMD Analysis, Variantyx Inc, Variantyx Inc	0218U	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	NEURO MUSC DYS DMD SEQ ALYS	5	October 1, 2020
Sentosa® SQ HIV-1 Genotyping Assay, Vela Diagnostics USA, Inc, Vela Operations Singapore Pte Ltd	0219U	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	NFCT AGT HIV GNRJ SEQ ALYS	5	October 1, 2020
PreciseDx™ Breast Cancer Test, PreciseDx, PreciseDx	0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	ONC BRST CA AI ASSMT 12 FEAT	5	October 1, 2020

Navigator ABO Blood Group NGS, Grifols Immunohematology Center, Grifols Immunohematology Center	0221U	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	ABO GNOTYP NEXT GNRJ SEQ ABO	5	October 1, 2020
Navigator Rh Blood Group NGS, Grifols Immunohematology Center, Grifols Immunohematology Center	0222U	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	RHD&RHCE GNTYP NEXT GNRJ SEQ	5	October 1, 2020