CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13884	**Date: August 24, 2026**
	Change Request 14569

SUBJECT: October 2026 Quarterly Update to the Clinical Laboratory Fee Schedule (CLFS) and Clinical Laboratory Improvement Amendments (CLIA): Healthcare Common Procedure Coding System (HCPCS) Codes, Waived Tests, and Reasonable Charge Payments

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of quarterly updates to the CLFS.

EFFECTIVE DATE: October 1, 2026
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 5, 2026

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: 13884	Date: August 24, 2026	Change Request: 14569

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EFFECTIVE DATE: October 1, 2026
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I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of quarterly updates to the CLFS.

II. GENERAL INFORMATION

A. Background: This CR combines three formerly individual recurring CRs into one recurring quarterly CR:

- Quarterly CLFS updates
- Annual CLIA edits and new waived test updates
- Quarterly CLIA edits and new waived test updates

Clinical Laboratory Fee Schedule (CLFS):

- The CLFS, codified under Section 1833(h) of the Social Security Act, establishes Medicare Part B payment rates for Clinical Diagnostic Laboratory Tests (CDLTs) based on statutory methodologies and regulatory requirements at 42 CFR Part 414, Subpart G. Under the Protecting Access to Medicare Act (PAMA) of 2014, applicable laboratories must report private payer rates and associated volumes for each HCPCS code, which CMS uses to calculate a weighted median payment rate for each CDLT.
- This applies to Chapter 16, Section 20.

Clinical Laboratory Improvement Amendments (CLIA):

- The CLIA regulations require facilities to be appropriately certified for each test they perform. To ensure that Medicare and Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that qualifies as a CLIA laboratory test is currently edited at the CLIA certificate level. Each year, the HCPCS codes considered as laboratory tests under CLIA may change. Contractors need to be updated on the new HCPCS codes subject to and excluded from CLIA edits, as well as discontinued HCPCS codes.

- **B. Policy: Clinical Laboratory Fee Schedule (CLFS)**
    - Protecting Access to Medicare Act of 2014 (PAMA)
        - Section 1834A of the Act, as established by Section 216(a) of the PAMA, required significant changes to how Medicare pays for 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 is the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the collection period.

- Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests
- On February 3, 2026, Section 6226 of the Consolidated Appropriations Act of 2026 specified an updated data reporting for CDLTs that aren't Advanced Diagnostic Laboratory Tests (ADLTs). It also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation:
  - The data reporting period is May 1, 2026 – July 31, 2026, and is based on the data collection period of January 1, 2025, through June 30, 2025.
  - There is no phased-in reduction in Calendar Year (CY) 2026. Beginning January 1, 2027, payment may not be reduced by more than 15% (15 percent) compared to the payment amount established for a test the preceding year.
  - Information on data collection and reporting can be found at https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-pama-reporting-resources
- Advanced Diagnostic Laboratory Tests (ADLTs)
- Please refer to the following CMS website for additional information regarding these tests: https://www.cms.gov/medicare/clinical-laboratory-fee-schedule/adlt-information
- New Codes Effective October 1, 2026
  - *Proprietary Laboratory Analysis (PLAs) and Additional New Codes*
  - Please see the table attached to the Transmittal entitled **"Quarter 4 of 2026_Update_CLFS_CLIA,"** Tab "**Q4 New Codes".**
  - The listed new codes were added to the national HCPCS file with an effective date of October 1, 2026, 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 Subsection (§) 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction.
  - The table includes the laboratory, long and short descriptors, effective date, Type of Service (TOS) of each new code and CLIA status (Waived 'Y' or non-Waived 'N').
- Deleted Codes Effective October 1, 2026
- Please see the table attached to the Transmittal entitled "**Quarter 4 of 2026_Update_CLFS_CLIA,"** Tab "**Q4 Deleted Codes.**" The listed codes are being deleted with a delete date of October 1, 2026.
- The table includes the code, short descriptor and the delete date of the code.

- **Clinical Laboratory Improvement Amendments**
  - All HCPCS codes listed in **"Quarter 4 of 2026_Update_CLFS_CLIA,**" Tab **"Q4 New Codes"** with an indicator of 'N' in Column G are subject to CLIA edits. These HCPCS codes require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). Facilities without a valid, current CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2), or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4), must not be paid for these tests unless they bill the appropriate HCPCS service code with a QW modifier.
  - ***NOTE*** This instruction is NOT intended to replace any previous instructions indicating that laboratories with a valid CLIA certificate of waiver or CLIA certificate for provider-performed microscopy procedures can bill the above codes with a QW modifier. This applies to Chapter 16, Section 70.9.

- Tests marked with an indicator of 'Y' in column G listed on "**Quarter 4 of 2026_Update_CLFS_CLIA,**" indicate the test(s) are approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The HCPCS codes for these new tests must include the QW modifier to be recognized as waived tests.
- This applies to Chapter 16, Section 70.8 of the Internet Only Manual. Note: FDA approval information about these tests and their uses can be found by using the search feature at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm and referring to the FDA Review Decision Summary documentation about the tests.

III. 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	
14569.1	Contractors shall review the CY 2026 CLFS Quarter 4 Updates; and • Add new ADLT, CPT, and HCPCS codes (with TOS designations and effective dates) on the "Q4 New Codes" tab; **and/or** • Terminate HCPCS codes on the "Q4 Deleted Codes" tab	X	X						X	CVM
14569.2	Contractors shall, as needed, update their systems/files with HCPCS codes subject to and excluded from CLIA editing, as identified in table "Quarter 4 of 2026_Update_CLFS_CLIA. "		X						X	
14569.2.1	Contractors shall include new waived tests in CLIA covered code files. HCPCS codes must have the modifier QW to be recognized as a waived		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	test(s).									
14569.3	Contractors shall apply CLIA edits to the HCPCS codes identified in table "Quarter 4 of 2026_Update_CLFS_CLIA" as subject to CLIA edits.		X							
14569.4	Contractors shall deny claims submitted with the following criteria: • CLIA certificate of waiver (certificate type code 2), when billed ***without*** the 'QW' modifier, **OR** • CLIA certificate for provider-performed microscopy procedures certificate type code 4) (when billed ***without*** the 'QW' modifier).		X							
14569.5	Contractors shall not reject claims utilizing the FDA website Review Decision Summary (RDS) documentation for HCPCS codes identified in table "Quarter 4 of 2026_Update_CLFS_CLIA. "		X							
14569.6	Contractors shall update any new ADLT codes, and/or Current Procedural Terminology (CPT)/HCPCS	X	X						X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	codes (including their TOS designation(s) and Effective date), and/or any deleted/terminated codes as applicable.									
14569.7	Contractors shall locally price covered CLFS codes not on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (IOCE) until they appear on the CLFS file and/or IOCE.	X	X							
14569.8	Contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X							
14569.9	Contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X								
14569.10	Contractors shall retrieve the CY 2026 Clinical Laboratory Fee Schedule from the CMS cloud.	X								Hybrid Cloud Data Center (HCDC), PCS
14569.11	Contractors shall process claims utilizing the cloud fee schedule for the payment limit of separately payable Medicare Part B laboratory tests.	X	X							PCS
14569.12	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors shall adjust claims if they are brought to their attention.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part B, A/B MAC Part A

V. 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

VI. CONTACTS

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

VII. 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, 2026

The following new codes have been added to the national HCPCS file with an effective date of Ocotber 1, 2026 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	HCPCS Code	Effective Date	Short Descriptor	Long Descriptor	TOS	CLIA waived? "Y" or "N"	CLIA Waived Effective Date
Human Papillomavirus (HPV) Types 18, 31, 33, and 35, Droplet Digital PCR, Blood, Mayo Clinic, Laboratory Developed Test	0660U	10/1/2026	HPV GNOTYP 18/31/33/35 CFDNA	Human papillomavirus (HPV), genotypes 18, 31, 33, and 35, cell-free DNA (cfDNA), whole blood, multiplex digital droplet PCR (ddPCR), quantitative	5	N	
Human Papillomavirus (HPV) Type 16, Droplet Digital PCR, Blood, Mayo Clinic, Laboratory Developed Test	0661U	10/1/2026	HPV GENOTYPE 16 CFDNA DDPCR	Human papillomavirus (HPV), genotype 16, cell-free DNA (cfDNA), whole blood, digital droplet PCR (ddPCR), quantitative	5	N	
Exosome Kidney Transplant Report (EkTRA), One LambdaTM Laboratories, Part of Thermo Fisher Scientific	0662U	10/1/2026	TRNSPLJ MED KAR RTQPCR 12GEN	Transplantation medicine (kidney allograft rejection), mRNA, gene-expression profiling by real-time quantitative PCR of 12 genes (11 content and 1 housekeeping), urine, algorithm reported as a rejection risk score	5	N	
UNITY Platelet Fetal AntigenTM NIPT, BillionToOne Laboratory	0663U	10/1/2026	OB FETAL PLTLT AG NIPT CFDNA	Obstetrics (fetal platelet antigen noninvasive prenatal test [NIPT]), cell-free DNA (cfDNA) sequence analysis for detection of fetal presence or absence of 1 human platelet antigen or more (HPA-1a, HPA-1b, HPA-3a, HPA-5b, and others) when performed, reported as maternal/fetal incompatibility detected or not detected per selected antigen	5	N	
ProtegaTM, Verici Dx	0664U	10/1/2026	TRNSPLJ MED KAF NGS 13 GENES	Transplantation medicine (kidney allograft failure), RNA expression transcriptome by next-generation sequencing (NGS), profiling of 13 genes, post-transplant peripheral blood, algorithm reported as a risk score for predicting progressive fibrosis in the kidney allograft	5	N	
NIS2+®, Labcorp	0665U	10/1/2026	HEP MASH ELISA YKL40 RTQPCR	Hepatology (metabolic dysfunction-associated steatohepatitis [MASH]), enzyme-linked immunosorbent assay (ELISA) for YKL40 and quantitative reverse transcription polymerase chain reaction (RT-qPCR) for miR-34a-5p, serum, algorithm reported as a single score for MASH activity and fibrosis	5	N	
Alturos WoundPrecisionTM qPCR Panel, Alturos Labs, LLC	0666U	10/1/2026	NFCT DS WND DNA MULT RTPCR	Infectious disease (wound infection), DNA, multiplex real-time PCR, wound swab, detection of 27 microbial targets and 28 antibiotic resistance targets, reported as semiquantitative for bacterial and fungal targets, and qualitative for viral- and antibiotic-resistance targets	5	N	
FGF21, Children's Hospital Colorado Laboratory	0667U	10/1/2026	IEM PMD FGF21 CONCTRJ ELISA	Inborn error of metabolism (primary mitochondrial disease), determination of fibroblast growth factor 21 (FGF21) concentration by enzyme-linked immunosorbent assay (ELISA), serum or plasma, diagnostic quantitative result	5	N	
Avantect Pancreatic Cancer Test*, ClearNote® Health *with glycan biomarker analysis	0668U	10/1/2026	ONC PNCRS DNA 5HMC & GLYCAN	Oncology (pancreas), DNA, genome sequence with 5-hydroxymethylcytosine (5hmC) enrichment and glycan biomarker analysis, whole blood or plasma, algorithm reported as cancer detected or not detected	5	N	

BBB Direct Detect Multiplex, Galaxy Diagnostics, Inc	0669U	10/1/2026	NFCT DS BBB SPECIES MULTDPCR	Infectious disease (Bartonella species, Borrelia species, and Babesia species), multiplex digital PCR for detection of DNA at the genus level for each species, blood, qualitative reporting of presence or absence of each pathogen at the genus level	5	N	
Genomic Unity® 2.0 – Duo, Variantyx, Inc	0670U	10/1/2026	RARE DS WGSA S/L READ CMPRTR	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis combination of short and long reads for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat (STR) genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variant, proband and comparator (Do not report 0670U in conjunction with 81425, 81426, 0212U, 0213U, 0671U)	5	N	
Genomic Unity® 2.0 – Trio, Variantyx, Inc	0671U	10/1/2026	RARE DS WGSA S/L RD 2CMPRTRS	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis combination of short and long reads for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat (STR) genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variant, proband and 2 comparators (Do not report 0671U in conjunction with 81425, 81426, 0212U, 0213U, 0670U)	5	N	
Genomic Unity® Exome Plus Analysis – Duo, Variantyx, Inc	0672U	10/1/2026	RARE DS WHOLE EXOME CMPRTR	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat (STR) gene expansions, and variants in nonuniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband and comparator (Do not report 0672U in conjunction with 81415, 81416, 0214U, 0215U, 0673U)	5	N	
Genomic Unity® Exome Plus Analysis – Trio, Variantyx, Inc	0673U	10/1/2026	RARE DS WHOLE EXOME 2CMPRTRS	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat (STR) gene expansions, and variants in nonuniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband and 2 comparators (Do not report 0673U in conjunction with 81415,81416, 81425, 81426, 0213U, 0214U, 0215U, 0567U, 0672U)	5	N	
Genomic Unity® Whole Genome Analysis – Duo, Variantyx, Inc	0674U	10/1/2026	RARE DS MTDNA BLD/SLV/GEND NA	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy number variants, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat (STR) gene expansions, blood, saliva, or genomic DNA, identification and categorization of genetic variants, proband and comparator (Do not report 0674U in conjunction with 81425, 81426, 0212U, 0213U, 0214U, 0215U, 0567U, 0675U)	5	N	
Genomic Unity® Whole Genome Analysis – Trio, Variantyx, Inc	0675U	10/1/2026	RARE DS MTDNA PRBND&2CMPR TRS	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat (STR) gene expansions, blood, saliva, or genomic DNA, identification and categorization of genetic variants proband and 2 comparators (Do not report 0675U in conjunction with 81425, 81426, 0212U, 0213U, 0214U, 0215U, 0567U, 0674U)	5	N	
IriSight® Comprehensive Analysis – Prenatal Duo, Variantyx, Inc	0676U	10/1/2026	RARE DS WGSA MATERNAL CMPRTR	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions and maternal cell contamination, fetal sample, identification and categorization of genetic variants, proband and maternal comparator	5	N	
IriSight® Comprehensive Analysis – Prenatal Trio, Variantyx, Inc	0677U	10/1/2026	RARE DS WGSA FETAL SAMPLE	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions and maternal cell contamination, fetal sample, identification and categorization of genetic variants, proband and 2 comparators	5	N	

OncoAlly® Comprehensive Hereditary Cancer Analysis, Variantyx, Inc	0678U	10/1/2026	ONC HHM GENOME SEQ 117 GENES	Oncology (hereditary cancer), genome sequence for 117 genes (single-nucleotide variants, deletions/insertions, and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, blood, saliva, cultured skin fibroblasts (skin biopsy) or extracted genomic DNA, diagnostic, identification and categorization of genetic variants	5	N	
OncoAlly® Hereditary Hematologic Cancer Analysis, Variantyx, Inc	0679U	10/1/2026	ONC HHM DNA ALYS >105 GENES	Oncology (hereditary hematologic cancer), genomic DNA, whole genome sequence (single-nucleotide variants, deletions/insertions, and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, analysis of over 105 genes, genomic DNA isolated from blood, saliva, cultured skin fibroblasts (skin biopsy), identification and categorization of genetic variants	5	N	
Smoke Signature© (Blood), Quantigen®	0680U	10/1/2026	TOBAC USE DNA ALYS 1MTHYLTN	Tobacco use, DNA analysis of 1 methylation marker (cg05575921 [AHRR]), methylation-sensitive digital PCR, whole blood, algorithm reported as quantitative percentage methylation and estimated average cigarette use per day	5	N	
Smoke Signature© (Saliva), Quantigen®	0681U	10/1/2026	TOBAC USE DNA ALYS 2MTHYLTN	Tobacco use, DNA analysis of 2 methylation markers (1 content: cg05575921 [AHRR] and 1 normalizing: cg08141395), methylation-sensitive digital PCR, saliva, algorithm reported as quantitative percent methylation and estimated average cigarette use per day	5	N	
Smoke Signature© Lung CA™ (Blood), Quantigen®	0682U	10/1/2026	ONC LNG CA DNA ALYS 1MTHYLN	Oncology (lung cancer), DNA analysis of 1 methylation marker (cg05575921), methylation-sensitive digital PCR, whole blood, algorithm results reported as the 20-year-hazard ratio for lung cancer	5	N	
Smoke Signature© Lung CATM (Saliva), Quantigen®	0683U	10/1/2026	ONC LNG CA DNA ALYS 2MTHYLN	Oncology (lung cancer), DNA analysis of 2 methylation markers (1 content: cg05575921 and 1 normalizing: cg08141395), methylation-sensitive digital PCR, saliva, algorithm results reported as the 20-year-hazard ratio for lung cancer	5	N	
Alcohol T-ScoreTM (Blood), Quantigen®	0684U	10/1/2026	AUD 4MTHYLTN MRK PCR WHL BLD	Alcohol use disorder, DNA analysis of 4 methylation markers (cg02583484, cg04987734, cg09935388, cg04583842), methylation-sensitive digital PCR, whole blood, algorithm reported as a summed T-score	5	N	
Alcohol T-ScoreTM (Saliva), Quantigen®	0685U	10/1/2026	AUD 5MTHYLTN MRK PCR BLD/SLV	Alcohol use disorder, DNA analysis of 5 methylation markers (4 content: cg02583484, cg04987734, cg09935388, cg04583842, and 1 normalizing: cg08141395), methylation-sensitive digital PCR, whole blood or saliva, algorithm reported as a summed T-score	5	N	
Decipher Prostate Genomic Classifier, Veracyte Labs SD Corporation	0686U	10/1/2026	ONC PRST8 MRNA GENE XPRSN 22	Oncology (prostate), mRNA, next-generation sequencing (NGS) gene expression profiling of 22 genes, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score	5	N	
Know Error®, Theranostix, Inc	0687U	10/1/2026	CMPRTV ALYS STR MRK DNA BUCC	Comparative analysis using short tandem repeat (STR) markers, patient and comparative specimen, DNA, buccal swab and tissue, reported match or mismatch	5	N	
Oncodetect® Molecular Residual Disease Test – Baseline, Genomic Health Inc	0688U	10/1/2026	ONC CLRCT CA ALYS MRD CTDNA	Oncology (colorectal cancer), analysis of minimal residual disease (MRD), next-generation sequencing (NGS), circulating tumor DNA (ctDNA) analysis in whole blood and tumor for baseline assessment to evaluate current MRD status and for comparisons to subsequent MRD assessments	5	N	
Oncodetect® Molecular Residual Disease Test – Monitoring, Genomic Health Inc	0689U	10/1/2026	ONC CLRT CA ALYS MRD PT-SPEC	Oncology (colorectal cancer), analysis of minimal residual disease (MRD) using patient-specific assays, reported as amount of circulating tumor DNA (ctDNA) detection and trend over time	5	N	
GraftAssureTM, Insight Molecular Diagnostics Inc	0690U	10/1/2026	TRNSPLJ MED AR DPCR ALYS 45	Transplantation medicine (allograft rejection), quantification of donor-derived cell-free DNA (cfDNA) using digital PCR analysis of 45 single-nucleotide polymorphisms, plasma, reported as quantity of donor-derived cfDNA in plasma to determine the probability of allograft rejection	5	N	
HorizonTM 5, NateraTM, Inc	0691U	10/1/2026	CARRIER SCREENING GSAP 6GENS	Carrier screening (cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia, and Duchenne muscular dystrophy), genomic sequence analysis panel, 6 genes (CFTR, SMN1, HBB, HBA1, HBA2, DMD) (Do not report 0691U in conjunction with 81443)	5	N	
HART® PAD, Complete Omics	0692U	10/1/2026	CRD PAD ALYS 3PRTN IA PLASMA	Cardiology (peripheral artery disease [PAD]), analysis of 3 proteins (midkine, angiopoietin-1, and kidney injury molecule-1 [KIM-1]), immunoassay, plasma, algorithm reported as a risk score for obstructive PAD	5	N	
LymphDetectTM Head & Neck, Droplet Biosciences, Droplet Biosciences	0693U	10/1/2026	ONC H&N CTDNA 699 GENES VRNT	Oncology (head and neck), circulating tumor DNA (ctDNA), tumor-informed next-generation sequencing (NGS) analysis for 699 genes of patient-specific somatic variants identified from primary tumor tissue, postoperative lymphatic exudate specimen, algorithm reported as presence or absence of ctDNA	5	N	

Immunoglobulin Isotypes (GAM) for the EXENT® Analyser, The Binding Site, Part of Thermo Fisher Scientific	0694U	10/1/2026	ONC MG MALDI-TOF MS ISOTYPES	Oncology (monoclonal gammopathy), immunoprecipitation and matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, identification of intact monoclonal immunoglobulin isotypes (IgG, IgA, IgM, kappa, lambda), and M-protein concentrations in conjunction with turbidimetry, blood, semiquantitative	5	N	
Belay AscentTM, Belay Diagnostics LLC	0695U	10/1/2026	ONC CNS WGSA CSF INTERROG	Oncology (central nervous system), low-pass whole genome sequence analysis of cerebrospinal fluid, interrogation for chromosome arm-level and focal losses and gains	5	N	
Guardant360® Tissue RNA, Guardant Health, Inc	0696U	10/1/2026	ONC SO TGSA RNA ALYS 350/>	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, RNA analysis, 350 or more genes for RNA alterations (eg, gene rearrangements and splice isoforms)	5	N	
MyPhenomeRxTM, Phenomix Sciences Clinical Laboratory	0697U	10/1/2026	OB DNA GNOTYP ALYS <41 GENES	Obesity, DNA genotyping, analysis of up to 41 genes, buccal swab or blood specimen, patient biometrics, risk-score algorithm to identify a predisposition to up to 4 phenotypes, reported as likelihood to benefit from therapeutics	5	N	
Alinity i TBI, Abbott Laboratories	0698U	10/1/2026	NEURO TBI ALYS GFAP UCHL1	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxy-terminal hydrolase L1 (UCHL1), immunoassay, serum or plasma, individual components reported with the overall result of positive or negative based on threshold comparison	5	N	
FebriDx® Bacterial/Non-Bacterial Point-of-Care Assay, Lumos Diagnostics, LLC, Lumos Diagnostics, LLC	0442U-QW	10/1/2026	Nfct ds respir nfctj mxa&crp	Infectious disease (respiratory infection), myxovirus resistance protein a (mxa) and c-reactive protein (crp), fingerstick whole blood specimen, each biomarker reported as present or absent	n/a because the TOS is the same	Y	3/24/2026

Deleted Codes Effective October 1, 2026		
The following codes are being deleted with a deletion date of October 1, 2026.		
CPT Code	**Short Descriptor**	**Delete Date**
0556U	NFCT DS P-S DNA&RNA 12 TRGTS	10/1/2026
0557U	NFCT DS BV DNA MRK VAG FLUID	10/1/2026
0585U	TGSAP SO NEO CFDNA 521 GENES	10/1/2026