

## Advanced Diagnostic Laboratory Tests Under the Medicare CLFS

Test Code	Lab Name	Test Name	Test Descriptor	Approval Date	New ADLT Initial Period	Payment Amount for Dates of Service Before Initial Period	Payment Amount for Dates of Service During New ADLT Initial Period
0356U	Naveris, Inc.	NavDx	Oncology (oropharyngeal) evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence	03/18/2024	4/1/2024 – 12/31/2024	Contractor Priced	\$1,800.00
0315U	Castle Biosciences, Inc.	DecisionDx®-SCC	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B)	06/30/2023	7/1/23 - 3/31/24	Contractor Priced	\$8,500.00
0360U*	Biodesix, Inc.	Nodify CDT®	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy	06/30/2023	N/A	N/A	N/A
0295U	Prelude Corporation	DCISionRT®	Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score	03/23/2023	4/1/23-12/31/23	Contractor Priced	\$5,435.00
0108U	Castle Biosciences, Inc. / Cernostics, Inc.	TissueCypher® Barrett's Esophagus Assay	Gastroenterology (Barrett's esophagus), whole slide-digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer	03/24/2022	4/1/22-12/31/22	Contractor Priced	\$2,350.00
0340U	Natera, Inc.	Signatera	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate	06/17/2021	7/1/21 - 3/31/22	Contractor Priced	\$3,500.00
0242U	Guardant Health, Inc.	Guardant360 CDx	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	03/18/2021	4/1/21-12/31/21	Contractor Priced	\$5,000.00
0239U	Foundation Medicine, Inc.	FoundationOne Liquid CDx	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations	01/25/2021	4/1/21-12/31/21	Contractor Priced	\$3,500.00
81554 (Eff. 1/1/2021)	Veracyte	Envisia Genomic Classifier	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])	09/17/2020	10/1/20-6/30/21	Contractor Priced	\$5,500.00
0172U (Eff. 7/1/2020)	Myriad	myChoice CDx	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 homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	12/11/2019	1/1/20-9/30/20	Contractor Priced	\$4,040.00
0090U	Myriad	myPath Melanoma	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant)	9/6/2019	10/1/19-6/30/20	Contractor Priced	\$1,950.00
0080U	Biodesix, Inc.	BDX-XL2	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy	5/17/2019	7/1/19-3/31/20	Contractor Priced	\$3,520.00
81529 (Eff. 1/1/2021)	Castle Biosciences, Inc.	DecisionDx-Melanoma	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis	5/17/2019	7/1/19-3/31/20	Contractor Priced	\$7,193.00
81552* (Eff. 1/1/2020) (Previously	Castle Biosciences, Inc.	DecisionDx-UM	Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	5/17/2019	N/A	N/A	N/A
81538*	Biodesix, Inc.	VeriStrat	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival (VeriStrat, Biodesix, Inc.)	12/21/2018	N/A	N/A	N/A
0037U	Foundation Medicine, Inc.	FoundationOne CDx	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	05/18/2018	7/1/18 - 3/31/19	Contractor Priced	\$3,500.00

\*Existing ADLT. An existing ADLT is a laboratory test for which ADLT status has been granted by CMS and payment for the test has been made under the Medicare CLFS prior to January 1, 2018. See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Guidance-for-Laboratories-on-ADLTs.pdf> for more information.

