

## 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
TBD	Veracyte	Envisia Genomic Classifier	TBD	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	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
TBD	Castle Biosciences, Inc.	DecisionDx-Melanoma	TBD	5/17/2019	7/1/19-3/31/20	Contractor Priced	\$7,193.00
81552* (Eff. 1/1/2020) (Previously 0081U)	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	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