



FINAL REPORT

PATIENT

MRN:

DOB:

Age: | Sex:

PHYSICIAN	SAMPLE	CLINICAL BACKGROUND
DOCTOR	LUCENCE ID: CS-26-XXXXXX	Indication: Lung Adenocarcinoma
CLINIC	Date of Report: May 04 2026	Diagnosis: Metastatic Stage IV Lung
Account ID:	Date Collected: Apr 28 2026	Adenocarcinoma
	Date Received: Apr 29 2026	Biomarker: NA
	Type: Cerebrospinal fluid in Sterile	
	Container (6.5 mL)	

ctDNA - SUMMARY OF FINDINGS

No genomic alterations were identified in this patient's sample. The absence of CSF ctDNA alterations may correlate with low leptomeningeal disease involvement, or disease which is being effectively treated. It is also possible that there are genomic alterations in targets not included in the panel or others not detectable by this analysis due to inherent analytical limitations. Further clinical correlation is advised, with consideration of follow-up tissue or CSF testing.

- Microsatellite Status: MS Stable
- No ctDNA alterations were found in the following treatment-relevant genes: *ALK, BRAF, EGFR, ERBB2, KRAS, MET, NTRK1, NTRK2, NTRK3, RET, ROS1*
- No FDA-approved therapies are available in Lung Adenocarcinoma associated with Genomic Findings (ctDNA).

NOTE

- This test is not intended for, and cannot confirm germline status in any manner. Variants detected may be of tumor-derived somatic, germline, or non-tumor somatic origins, including mosaicism and clonal hematopoiesis of indeterminate potential (CHIP).
- It is possible that there are alterations in targets not included in the panel or others not detectable by this analysis due to inherent analytical limitations. Clinical correlation is recommended.

ctDNA SEQUENCING PERFORMANCE SPECIFICATIONS

	SNVs/Indels
Raw on-target reads	15,316,629
Unique on-target reads (non-duplicates)	2,541,272
Mean depth of coverage	8,410.53
Uniformity: Pct reads > 0.2*Mean	99.38%
Coverage	99.76% (50x), 99.76% (100x), 98.76% (1000x)

DEFINITIONS

LEVELS OF CLINICAL ACTIONABILITY OF GENOMIC FINDINGS

Categorization of Clinical actionability is guided by AMP/ASCO/CAP consensus recommendation for the interpretation and reporting of sequence variants in cancer (PMID: 27993330, PMID: 32246132). Clinical actionability corresponds to Tier 1 evidence level (FDA, guidelines, well-powered studies with expert consensus), of the AMP/ASCO/CAP consensus recommendations.

Description	Therapy association with Finding	Criteria
CLINICAL ACTIONABILITY	Sensitive	Therapies with FDA Approval, FDA Breakthrough Designation, from Professional Guidelines, or with results from Phase III trials in Relevant Indication or in Other Indications available for Genomic findings.
	Resistance	Therapies with FDA Approval, FDA Breakthrough Designation, from Professional Guidelines, or with results from Phase III trials or Compelling Clinical Evidence from Clinical Studies and/or Case Reports in Relevant Indication or in Other Indications available for Genomic findings.
UNCERTAIN CLINICAL ACTIONABILITY	-	No therapies meeting criteria for Clinical Actionability / Evidence are available, although such Genomic findings may have prognostic impact in Relevant Indication. A subset of findings may have Evidence from Clinical Trials, Studies or Reports, which are provided.



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TEST DETAILS

The LiquidHALLMARK® CSF assay is a next-generation sequencing (NGS) based test that identifies targeted somatic genomic alterations including single nucleotide variations, copy number variations, and microsatellite instability (MSI) in circulating tumor DNA (ctDNA) ([PMID: 35486650](#)).

This clinical test was developed and its performance characteristics determined by Lucence Health Inc. It has not been cleared or approved by the US Food and Drug Administration. The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes, and should not be regarded as investigational or for research, unless otherwise stated above. Lucence Health Inc. is a Clinical Laboratory Improvement Amendments (CLIA)-certified clinical diagnostic laboratory (CLIA ID Number: 05D2200843) and is accredited to College of American Pathologists (CAP) laboratory quality standards.

VALIDATED GENOMIC ALTERATIONS TESTED (ctDNA)_(v1)

SINGLE NUCLEOTIDE VARIANTS, INDELS AND GENE COPY NUMBER ALTERATIONS*

ABL1	CDKN2A #	GNA11	KEAP1 ¹	NRAS #	RIT1
AKT1 ¹	CREBBP	GNAQ	KIT #	NTRK1	ROS1
ALK #	CTNNB1	GNAS	KRAS #	NTRK3	SF3B1
APC	EGFR #†	H3-3A	MAP2K1 (MEK1)	PDGFRA #	SMAD4 #1
AR #	ERBB2 (HER2) #	H3-3B	MAP2K2 (MEK2)	PIK3CA #1	SMO
ARAF	ERCC2	H3C2	MAPK1 (ERK2)	PIK3R1	SPOP
ATM #	ESR1 #	H3C3	MED12	PPP2R1A	STK11
BRAF #	EZH2	HNF1A	MET #	PTEN #^	TERT
BRCA1 #1	FBXW7 #	HRAS	MLH1	PTPN11	TP53 #1
BRCA2 #1	FGFR1 #	IDH1	MTOR	RAF1	U2AF1
CCND1 #	FGFR2 #	IDH2	MYC #	RB1 #	VHL
CCND2 #1	FGFR3 #	JAK1	NF1	RET	
CDH1	FLT3	JAK2	NFE2L2	RHEB	
CDK6 #1	GATA3	JAK3	NOTCH1	RHOA	

*Targeted regions selected to maximize detection of known hotspot mutations, in all clinically relevant exons of tested genes.

†Includes sequencing of EGFR kinase and extracellular domain mutations.

Includes detection of gene copy number alterations.

^Full coverage, ¹>97% coverage of coding exons.

MICROSATELLITE INSTABILITY (MSI)

BAT25 BAT26 NR21 NR24 NR27 MONO27

TARGETED GENES REFERENCE TRANSCRIPTS

ABL1	NM_005157.6	EZH2	NM_004456.5	JAK3	NM_000215.4	PIK3R1	NM_181523.3
AKT1	NM_001014432.2	FBXW7	NM_033632.3	KEAP1	NM_203500.2	PPP2R1A	NM_014225.6
ALK	NM_004304.5	FGFR1	NM_023110.3	KIT	NM_000222.3	PTEN	NM_000314.8
APC	NM_000038.6	FGFR2	NM_000141.5	KRAS	NM_033360.4	PTPN11	NM_002834.5
AR	NM_000044.6	FGFR3	NM_000142.5	MAP2K1	NM_002755.4	RAF1	NM_002880.4
ARAF	NM_001654.5	FLT3	NM_004119.3	MAP2K2	NM_030662.4	RB1	NM_000321.3
ATM	NM_000051.4	GATA3	NM_001002295.2	MAPK1	NM_002745.5	RET	NM_020975.6
BRAF	NM_004333.6	GNA11	NM_002067.5	MED12	NM_005120.3	RHEB	NM_005614.4
BRCA1	NM_007294.4	GNAQ	NM_002072.5	MET	NM_000245.4	RHOA	NM_001664.4
BRCA2	NM_000059.4	GNAS	NM_000516.7	MLH1	NM_000249.4	RIT1	NM_006912.6
CCND1	NM_053056.3	H3-3A	NM_002107.7	MTOR	NM_004958.4	ROS1	NM_002944.3
CCND2	NM_001759.4	H3-3B	NM_005324.5	MYC	NM_002467.6	SF3B1	NM_012433.4
CDH1	NM_004360.5	H3C2	NM_003537.4	NF1	NM_001042492.3	SMAD4	NM_005359.6
CDK6	NM_001145306.2	H3C3	NM_003531.3	NFE2L2	NM_006164.5	SMO	NM_005631.5

Laboratory Director Joseph Michael Anderson, MD, FCAP
CLIA ID Number: 05D2200843 D TBC-LHI V 1.0

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CDKN2A	NM_000077.5	HNF1A	NM_000545.8	NOTCH1	NM_017617.5	SPOP	NM_001007228.2
CREBBP	NM_004380.3	HRAS	NM_005343.4	NRAS	NM_002524.5	STK11	NM_000455.5
CTNNB1	NM_001904.4	IDH1	NM_005896.4	NTRK1	NM_002529.4	TERT	NM_198253.3
EGFR	NM_005228.5	IDH2	NM_002168.4	NTRK3	NM_001012338.3	TP53	NM_000546.6
ERBB2	NM_004448.4	JAK1	NM_002227.4	PDGFRA	NM_006206.6	U2AF1	NM_006758.3
ERCC2	NM_000400.4	JAK2	NM_004972.4	PIK3CA	NM_006218.4	VHL	NM_000551.4
ESR1	NM_000125.4						

METHODS

Amplicon-based sequencing analysis is carried out by proprietary technology owned by Lucence. Nucleic acid (cfDNA) is extracted from the cerebrospinal fluid (CSF) sample. The extracted DNA undergoes sequencing library construction for genes targeted in the LiquidHALLMARK® CSF assay. Quality and concentration of constructed libraries are determined and then sequenced on an Illumina NextSeq/Novaseq instrument with 2x150 paired-end reads. Targeted regions listed in the Tested Genomic Alterations (ctDNA) section or a relevant subset of the list, selected to maximize detection of known hotspot mutations, are analyzed for sequence variants. List available on physician request. Six microsatellite loci (BAT25, BAT26, NR21, NR24, NR27, MONO27) are analyzed for insertions/deletions in homopolymeric regions. Samples with microsatellite instability (MSI) detected in two or more of six sites are considered MSI-High (MSI-H) and those with MSI detected in one of six sites are considered MSI-Low (MSI-L). Sequences are aligned to reference sequences based on human genome build GRCh37/UCSC hg19. Data is analyzed using in-house bioinformatics pipelines, and proprietary sequencing error-correction methodology is applied on raw sequencing data. Copy number changes are calculated based on adjusted read count, and its variation from normalized baseline read count determined across control samples. All sequence alterations are described according to the Human Genome Variation Society (HGVS) nomenclature guidelines as published in [PMID: 26931183](#) (HGVS nomenclature v15.11, 2016). Clinical actionability of genomic findings is determined based on curated databases from publicly available data sources, including peer-reviewed publications of genomic alterations and biomarkers and associated drugs. Tiering of clinical actionability is based on AMP/ASCO/CAP consensus recommendation ([PMID: 27993330](#), [PMID: 32246132](#)) where clinical actionability are based on Tier 1 evidence level (FDA, guidelines, Phase III trials, well-powered studies with expert consensus). Drug and clinical trial information are obtained from curated databases including NCI thesaurus and ClinicalTrials.gov. Clinical trial curated database is updated with trials verified within the last month.

ANALYTICAL AND CLINICAL PERFORMANCE SPECIFICATIONS

Test performance specifications are determined using commercial ctDNA standards, contrived samples including cell line DNA, and CSF clinical samples for specific variants at varying allele frequencies described below. Specificity has been determined for the entirety of bases targeted in the assay and it is not variant- or hotspot-specific. The limit of detection for SNVs/indels is determined to be 0.1% and 0.75% based on 25ng and 5ng input, respectively. For copy number alterations, the limit of detection has been determined to be an excess of 2 copies for a copy number gain of 2-fold (2 vs. 4), and a deficiency of 1 copy for a copy number loss of 2-fold (2 vs. 1). The limit of detection for microsatellite instability is determined to be 5% DNA with insertions/deletions in the microsatellite loci in the background of normal DNA.

Input DNA (ng)	Mutation Class	Sensitivity By Mutant Allele Frequency					Specificity
		0.1%	0.5%	0.75%	2.5%	5%	
25	SNVs	>90%	>99%	-	-	>99%	>95%
	Indels	>93%	>99%	-	-	>99%	>91%
5	SNVs	-	-	>99%	>99%	-	>95%
	Indels	-	-	>98%	>99%	-	>91%

The clinical performance characteristics of this test are based on known associations with genomic alterations and response to or selection for therapy in the clinical literature, professional society guidelines and clinical trials databases ([PMID: 26378224](#), [PMID: 28365644](#), [PMID: 27601506](#), [PMID: 35426374](#), [PMID: 27993330](#), [clinicaltrials.gov](#)).

This report has been reviewed and approved by	Date and Time
 Joseph Michael Anderson, MD, FCAP Laboratory Director	May 04 2026, 1830 hrs (PDT)



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APPENDIX



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TARGETED THERAPIES RECOMMENDED INDEPENDENT OF GENOMIC FINDINGS IN RELEVANT INDICATION exists#}}

The following targeted therapies are approved in the relevant indication independent of specific genomic findings. Approved indications for the listed therapies may have additional criteria of medical and treatment history and combination chemotherapy.

Cancer Type	Drugs	Status
Lung Non-Small Cell Carcinoma	Durvalumab	FDA Approval
Lung Non-Small Cell Carcinoma	Nivolumab	FDA Approval
Lung Non-Small Cell Carcinoma	Ipilimumab + Nivolumab	FDA Approval

GLOSSARY OF TERMS AND ABBREVIATIONS

AACR	American Association for Cancer Research
Actionability	Actionability of a genomic finding is determined by the evidence of effective targeted therapy demonstrated in clinical trials and clinical/pre-clinical studies.
AMP	Association for Molecular Pathology
ASCO	American Society of Clinical Oncology
Biomarkers	Genomic findings that are not categorized as variants (SNVs, indels), fusions or copy number changes.
BTD	Breakthrough Therapy Designation
CAP	College of American Pathologists
ctDNA	Circulating tumor DNA
Chemotherapy	Cytotoxic drugs that stop the growth of fast-growing cells, both normal and tumor cells.
CI	Confidence Interval
Compelling Clinical Evidence	Evidence from multiple Clinical Studies and/or Case Reports predicting resistance to targeted therapies due to presence of Genomic Findings.
Copy Number Gain	Increased gene copy number present in the ctDNA. The copy number gain is reported as a relative fold-change in copy number, calculated as the detected copy number relative to a normal diploid copy number (2 copies). Relative copy number detected in circulation depends on the fraction of ctDNA that is of tumor origin (tumor fraction) and the degree of copy number gain in the tumor.
Copy Number Loss	Reduced gene copy number present in the ctDNA. The copy number loss is reported as a relative fold-change in copy number, calculated as the detected copy number relative to a normal diploid copy number (2 copies). Relative copy number detected in circulation depends on the fraction of ctDNA that is of tumor origin (tumor fraction).
COSMIC	Catalogue of Somatic Mutations In Cancer
CTC	Circulating tumor cells
dMMR	Deficient Mismatch Repair
ESMO	European Society for Medical Oncology
FDA	U.S. Food and Drug Administration
FDA Breakthrough Designation	FDA Breakthrough Designation is given to drugs with preliminary clinical evidence demonstrating substantial positive outcomes in the treatment of serious or life-threatening conditions over other available therapies.
Genomic Findings	Genomic Findings include mutations, copy number variations, fusions, genomic rearrangements and microsatellite instability detected by analyzing ctDNA.
GOF	Gain-of-Function
IASLC	International Association for the Study of Lung Cancer
LOF	Loss-of-Function

Microsatellite status	Microsatellite instability (MSI) is a condition of genetic instability in short nucleotide repeats (microsatellites) due to a deficiency in DNA mismatch repair (MMR) in the tumor. MSI is characterized by an excessive amount of short insertion or deletion mutations in the tumor genome.
MMR	Mismatch Repair
NCIt	National Cancer Institute thesaurus
NSCLC	Non-Small Cell Lung Cancer
OS	Overall Survival
PFS	Progression Free Survival
PMID	PubMed Identifier
Relevant Indication or Related	Relevant Indication is based on clinical diagnosis provided and is a disease term from the controlled vocabulary of disease terms from the National Cancer Institute thesaurus (NCIt), determined based on the most relevant match from clinical diagnosis provided. Related indication refers to a hierarchical subtype or supertype of the relevant indication defined by the controlled disease vocabulary defined at the National Cancer Institute thesaurus (NCIt). In cases where the specific disease is unknown or unclear, the NCIt disease term defaulted to for actionability determination is "Malignant Neoplasm".
SNV	Single Nucleotide Variant
Somatic status	Somatic (not inherited) status of genomic findings is inferred primarily from the individual variant allele frequencies (VAF) and VAFs of genomic findings relative to one another, effect of variant on protein function and variant information from public databases such as Clinvar supporting an uncertain clinical significance in a germline context.
Targeted clinical trials	Clinical trials with specific genomic findings required as inclusion criteria.
Targeted therapy	Drugs targeting specific proteins/molecules in or on cancer cells.
Treatment-relevant genes	Genes that harbor clinically actionable alterations with FDA-approved targeted therapies, or genes that are included in the recommendations by professional oncology guidelines for molecular testing in the context of the relevant indication.
VAF	Variant Allele Frequency



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LIMITATIONS AND DISCLAIMERS

This report reflects the analysis of DNA from an extracted nucleic acid sample, and in very rare cases (for example, bone marrow transplant or recent blood transfusion) the analyzed DNA may not reflect the patient's genome, leading possibly to false negative and/or false positive results. Nucleic acid studies do not constitute a definitive test for the selected condition(s) in all individuals. This test is clinically validated for cerebrospinal fluid samples only. It should be realized that there are possible sources of error. Errors can result from trace contamination, rare technical errors, rare genetic variants that interfere with analysis, recent scientific developments, and alternative classification systems. Test sensitivity may be altered based on factors such as excessive cell lysis before processing, sampling during treatment, tissue heterogeneity, and the relative yield of circulating nucleic acids from the sample. CSF specimens with elevated albumin and immunoglobulin G may also result in reduced assay sensitivity or assay failure. Sensitivity of this test has been determined for the test methodology for a set of variants which do not necessarily include those identified in this report. Sensitivity and specificity data for all variants reported are not available. Where reported allele frequencies fall below 0.1% or 0.75% depending on input for SNV or Indel, absolute number of variant reads supporting the call are considered, but specificity data is not available on this. Deletions or insertions involving more than 30 bp may not be reliably detected by the sequencing methodology. Although most of the intended targeted regions are sequenced in their entirety, some regions may be incompletely covered due to technical limitations. Therefore, absence of a detected variant in these regions and in regions not covered by this test does not exclude the presence of a pathogenic variant. Intronic variants and synonymous substitutions are not reported unless previously documented as clinically significant. Variants classified as benign or likely benign in ClinVar and/or variants with population allele frequency (in external or internal databases) of greater than 1% (non-founder mutations) are not reported but are available on request.

This test is not intended for, and cannot confirm germline status in any manner. Variants detected may be of tumor-derived somatic, germline, or non-tumor somatic origins, including mosaicism and clonal hematopoiesis of indeterminate potential (CHIP). Genes with alterations may be derived from CHIP include, but are not limited to: *ATM*, *JAK2*, *SF3B1*, *TP53*, and *U2AF1*. Clinical correlation is recommended. Genetic counseling may be considered if deemed appropriate clinically.

For cases where no genomic alterations are identified, the absence of CSF ctDNA alterations may correlate with low leptomeningeal disease involvement, or disease which is being effectively treated. It is also possible that there are genomic alterations in targets not included in the panel or others not detectable by this analysis due to inherent analytical limitations. Further clinical correlation is advised, with consideration of follow-up tissue and CSF testing.

This test should be one of many aspects used by the treating healthcare provider to help with a diagnosis and treatment plan, but it is not a diagnosis itself. Clinical diagnosis provided by the treating healthcare provider is used to determine Relevant Indication for determining appropriate clinical actionability / evidence and matching clinical trials, presentation of which may be adversely affected in cases of incomplete or incorrect diagnosis information provided. Any mention of pharmacologic agents, or their on-label or off-label use should not be considered as a recommendation or endorsement for therapeutic use. Approved indications for the listed therapies may have additional criteria of medical and treatment history and combination chemotherapy. Percentage map is for visualization purposes only and is not drawn to scale. Clinical correlation is advised. Past treatment or mutation history is not being considered for selection of clinical trials presented. Clinical correlation and suitability with specific trial's inclusion and exclusion criteria is advised. Drug and clinical trial information are obtained from curated databases including NCI thesaurus and ClinicalTrials.gov. Clinical trial curated database is updated with trials verified within the last month. Tiering of clinical actionability / evidence associated with a drug recommendation may be updated in source data, but not reflected as at the time of the report. For latest information, please refer to the FDA website and the respective source data websites for professional guidelines.

Lucence does not warrant that the data from such third party databases, websites, or guidelines are accurate, complete, or up to date and excludes all liability for any loss or damage howsoever arising as a result of any reliance on the accuracy of the data.

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