BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumAsc-Pos-Lung-Long

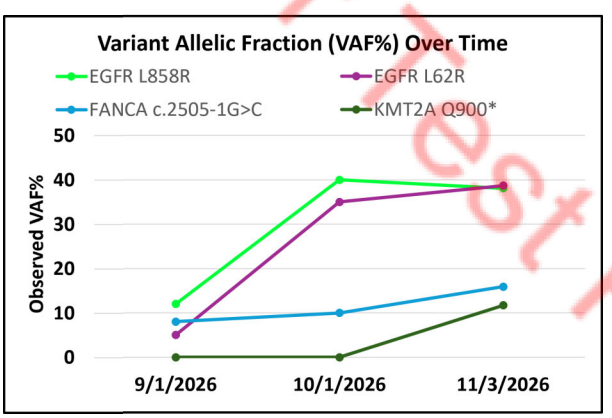
1375 W. Fulton Street, Suite 530
Chicago, IL 60607
Email: contact@belaydiagnostics.com
Phone: (331) 320-0155 | Fax: (800) 501-9246

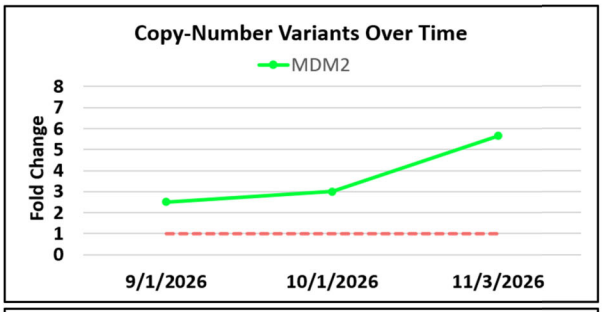
Summit™ 2.0 + Ascent™ Report

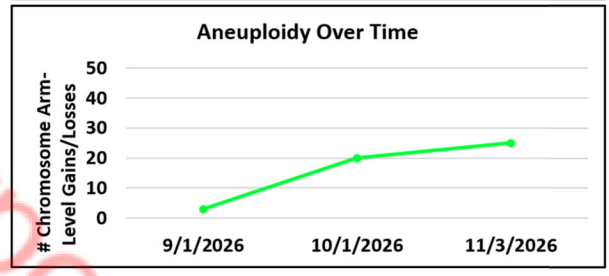
Patient Information	Provisional Diagnosis	Specimen	Physician Information
Name: John Smith **DOB:**01/01/1990 **Sex Assigned at Birth:**Male **MRN:**11xx22xx33	**Diagnosis:**Metastatic Lung Adenocarcinoma **CSF Volume Received:**6 mL	**Type:**CSF **Collected:**11/03/2026 **Received:**11/04/2026 **Specimen ID:**SumAsc-Pos-Lung-Long	**Institution:**Belay Diagnostics **Referring Physician:**Provider Test

RESULT SUMMARY

CLINICALLY SIGNIFICANT VARIANTS - DETECTED







Comments

The clinically significant variants reported in previously submitted specimens from this individual were detected along with a similarly high level of aneuploidy and an additional variant in *KMT2A*.

KMT2A alterations have been reported in non-small cell lung carcinoma with high tumor mutational burden (TMB) as observed in this specimen (PMID: 33298164, 33655698). A high level of chromosomal loss and gain as observed in this specimen indicates chromosomal instability, a key driver of metastasis across cancer types (PMID: 38924459). Clinical correlation is required.

CLINICALLY SIGNIFICANT ALTERATION DETAILS (Tier 1 or 2 per AMP/ASCO/CAP)

Summit™ 2.0 - SNV, MNV, Indel Variants

Alteration	VAF	Actionability Summary		
		FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
EGFR p.L858R c.2573T>G	38.1%	Yes	No	Yes
EGFR p.L62R c.185T>G	38.7%	No	No	Yes
FANCA c.2505-1G>C	15.9%	No	No	Yes

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Summit™ 2.0 - SNV, MNV, Indel Variants

Alteration	VAF	Actionability Summary		
		FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
KMT2A p.Q900* c.2698C>T	11.7%	No	No	No

Summit™ 2.0 - Copy Number Variants

Alteration	Location	Fold Change	Actionability Summary		
			FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
MDM2 Amplification	chr12	5.65	No	No	No

Summit™ 2.0 - Fusion Variants

None

Summit™ 2.0 - Biomarkers

Tumor Mutation Burden (TMB)			Microsatellite Instability (MSI)	
Not Detected	Low	High	Stable	High

Ascent™ - Chromosome Arm Level Loss or Gain

None

VARIANTS OF UNKNOWN SIGNIFICANCE (Tier 3)

Summit™ 2.0 - SNV/MNVs/Indels

ABL2 S936L	*CHD4* R1757H	*CSF1R* E461Q	*FGF14* N19S	*PDGFRB* M234T
ABL2 Y495C	*CHD4* W488*	*EMSY* T316A	*ICOSLG* P294L	*PRDM1* P467L
ARID2 L425P	*CHD4* E444D	*ERBB2* V129fs	*IGF2* P154L	*RAB35* V155I
ARID5B H998R	*CHD4* A247T	*ERBB2* R340Q	*KDM5A* E1139K	*SOX9* K173R
BCL2 A43T	*CHD4* A224P	*EZH2* D664V	*KMT2A* I578M	*SPTA1* E1514K
BCORL1 S878G	*CHD4* E147Q	*FAT1* V4392I	*LRP1B* D868N	*STK40* E387fs
CBL C404Y	*CREBBP* P582S	*FAT1* A3913T	*MYB* P355S	*TET2* D1242Y

Summit™ 2.0 - Gene Level CNVs

None

Summit™ 2.0 - Fusions

None

Ascent™ - Aneuploidy Variants of Unknown Significance

chr1p Loss	chr5q Gain	chr11p Loss	chr16p Gain	chr19q Loss
chr1q Gain	chr6p Loss	chr12p Gain	chr17q Gain	chr20p Loss

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chr3p Loss	chr8q Gain	chr13q Loss	chr18p Loss	chr20q Gain
chr4q Gain	chr9p Loss	chr14q Loss	chr18q Loss	chr21q Gain
chr5p Gain	chr9q Loss	chr15q Loss	chr19p Loss	chr22q Loss

ACTIONABILITY SUMMARY

FDA / NCCN Therapies for the Patient's Tumor Type (Tier 1A)

Biomarker	Therapies	Setting	Source(s)
EGFR L858R	afatinib; amivantamab + lazertinib; dacomitinib; gefitinib; osimertinib	First line	FDA (Approved), NCCN
EGFR L858R	erlotinib	Metastatic	FDA (Approved), NCCN
EGFR L858R	amivantamab + carboplatin + pemetrexed; datopotamab deruxtecan	Subsequent line	FDA (Approved), NCCN
EGFR L858R	osimertinib	Consolidation	FDA (Approved)
EGFR L858R	amivantamab + lazertinib	Subsequent line	NCCN
TMB-High	pembrolizumab	Subsequent line, and no satisfactory alternative therapy	FDA (Approved)

FDA / NCCN Therapies with Resistance / Decreased Response (Tier 1A)

None

Prognostic Implications per NCCN

None

Diagnostic Implications per WHO

None

CLINICAL TRIALS / INVESTIGATIONAL THERAPIES

***EGFR* L62R + *EGFR* L858R**

Therapy	Clinical Trial	Location/Sponsor	Quick Access
SX-682 + atezolizumab	NCT07322341 (Phase 2) SX-682 and Atezolizumab for the Treatment of Advanced or Metastatic, Recurrent Non-small Cell Lung Cancer	Seattle, Washington University of Washington Rwood1@fredhutch.org	https://genomoncology.wetrials.com/v1/NCT07322341
WSD0922-FU	NCT06868485 (Phase 2) A Study to Assess the Efficacy of WSD0922-FU in Patients With C797S+ Advanced Non-small Cell Lung Cancer	Oxnard, California Wayshine Biopharm, Inc. ling.yu@wayshinebiopharm.com	https://genomoncology.wetrials.com/v1/NCT06868485

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furmonertinib; (afatinib or osimertinib)	NCT07185997 (Phase 3) Study to Evaluate Efficacy and Safety of Firmonertinib Compared With Investigator's Choice of EGFR Inhibitor as First-Line Treatment in Participants Who Have Locally Advanced or Metastatic NSCLC With EGFR P-Loop and Alpha C-Helix Compressing (PACC) Uncommon Mutations	Fullerton, California ArriVent BioPharma, Inc. FURMO006CT@arrivent.com	https://genomoncology.wetrials.com/v1/NCT07185997
osimertinib + stereotactic radiosurgery	NCT06741085 (Phase 2) A Study of Stereotactic Radiosurgery (SRS) and Standard Treatment in People With Lung Cancer That Has Spread to the Brain	Miami, Florida Memorial Sloan Kettering Cancer Center pikel@mskcc.org	https://genomoncology.wetrials.com/v1/NCT06741085
zipalertinib	NCT05967689 (Phase 2) A Study of Zipalertinib in Patients With Advanced Non-Small Cell Lung Cancer With Epidermal Growth Factor Receptor (EGFR) Exon 20 Insertions or Other Uncommon Mutation.	Duarte, California Taiho Oncology, Inc. medicalinformation@taihooncology.com	https://genomoncology.wetrials.com/v1/NCT05967689

***EGFR* L858R**

Therapy	Clinical Trial	Location/Sponsor	Quick Access
bevacizumab + osimertinib	NCT04181060 (Phase 3) Osimertinib With or Without Bevacizumab as Initial Treatment for Patients With EGFR-Mutant Lung Cancer	Basking Ridge, New Jersey National Cancer Institute (NCI)	https://genomoncology.wetrials.com/v1/NCT04181060
datopotamab deruxtecan + osimertinib	NCT06350097 (Phase 3) Phase III, Open-label Study of First-line Osimertinib With or Without Datopotamab Deruxtecan for EGFRm Locally Advanced or Metastatic Non-small Cell Lung Cancer	Los Alamitos, California AstraZeneca information.center@astrazeneca.com	https://genomoncology.wetrials.com/v1/NCT06350097
datopotamab deruxtecan + osimertinib; datopotamab deruxtecan	NCT06417814 (Phase 3) A Study to Investigate the Efficacy and Safety of Dato-DXd With or Without Osimertinib Compared With Platinum Based Doublet Chemotherapy in Participants With EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer	Fayetteville, Arkansas AstraZeneca information.center@astrazeneca.com	https://genomoncology.wetrials.com/v1/NCT06417814
izalontamab brengitecan + osimertinib	NCT07680790 (Phase 3) Study of Izalontamab Brengitecan (BMS-986507) in Combination With Osimertinib Versus Osimertinib Monotherapy or Osimertinib in Combination With Platinum-based Chemotherapy for EGFRmt Non-small Cell Lung Cancer (IZABRIGHT-Lung02)	Palm Bay, Florida Bristol-Myers Squibb Clinical.Trials@bms.com	https://genomoncology.wetrials.com/v1/NCT07680790

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FANCA c.2505-1G>C			
Therapy	**Clinical Trial**	**Location/Sponsor**	**Quick Access**
dostarlimab + niraparib	NCT05700721 (Phase 2) Phase II Trial of the PARP Inhibitor Niraparib and PD-1 Inhibitor Dostarlimab in Patients With Advanced Cancers With Active Progressing Brain Metastases (STARLET)	Houston, Texas M.D. Anderson Cancer Center tyap@mdanderson.org	https://genomoncology.wetrials.com/v1/NCT05700721
talazoparib	NCT04692662 (Phase 2) Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	Bethesda, Maryland National Cancer Institute (NCI) zlottjh@mail.nih.gov	https://genomoncology.wetrials.com/v1/NCT04692662

TMB-High			
Therapy	**Clinical Trial**	**Location/Sponsor**	**Quick Access**
pembrolizumab; immune checkpoint inhibitor + pembrolizumab; pembrolizumab + chemotherapy	NCT07223424 (Phase 2) Patient Preference for Subcutaneous vs. Intravenous Immune Therapy	Pittsburgh, Pennsylvania Diwakar Davar bednarzdl@upmc.edu	https://genomoncology.wetrials.com/v1/NCT07223424

TIER 1A THERAPY DETAILS

EGFR L858R		
Therapy	**Approval / Guideline Summary**	**Underlying Evidence**
afatinib	FDA approved for first-line treatment of metastatic NSCLC with non-resistant EGFR mutations. NCCN recommended as Category 1/Useful in certain circumstances (for L858R/exon 19 del) or Category 2A/Preferred intervention (for other sensitizing mutations).	The FDA approval for afatinib was supported by data from the open-label, randomized, phase-III trial LUX-Lung 3 (NCT00949650). LUX-Lung 3 demonstrated that first-line afatinib (n = 138), compared with pemetrexed and cisplatin (n = 115), improved median PFS (HR = 0.73; 10.8 mo. vs. 8.1 mo.), but not median OS (HR = 1.30; 27.6 mo. vs. 40.3 mo.) in patients with metastatic NSCLC with EGFR L858R.
amivantamab + carboplatin + pemetrexed	FDA approved for adults with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or L858R mutations, whose disease has progressed on or after treatment with an EGFR TKI. NCCN recommended as Category 1 /Preferred intervention.	The FDA approval for amivantamab + carboplatin + pemetrexed was supported by data from the randomised, open-label, phase-III trial MARIPOSA-2 (NCT04988295). MARIPOSA-2 demonstrated that subsequent line amivantamab + carboplatin + pemetrexed (n = 131), compared to carboplatin + pemetrexed (n = 263), improved PFS (6.3 mo. vs. 4.2 mo., HR = 0.48; p < 0.0001) in patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R substitution mutations. Additional endpoints include ORR (53% vs. 29%), and median OS (17.7 mo.).
amivantamab + lazertinib	FDA approved for the first-line treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations. NCCN recommended as Category 1/Preferred intervention. Single agent lazertinib is also NCCN-recommended as Category 2A/Useful in certain circumstances.	The FDA approval for lazertinib + amivantamab was supported by data from the randomised, active-controlled, phase-III trial MARIPOSA (NCT04487080). MARIPOSA demonstrated that first line lazertinib + amivantamab (n = 429), compared to osimertinib (n = 429), improved progression-free survival (HR=0.70; p=0.0002) in patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R substitution mutations. Additional endpoints include an ORR of 78% (CR = 5%, PR = 73%) vs. 73% (CR = 3.5%, PR = 70%), median DoR (25.8 mo.), and OS (NR vs. 36.7 mo.).

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amivantamab + lazertinib	NCCN recommended as subsequent line treatment for advanced or metastatic NSCLC with EGFR exon 19 deletions or L858R mutations (Category 2A/Useful in certain circumstances).	
dacomitinib	FDA approved for the first-line treatment of metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations. NCCN recommended as Category 1/Useful in certain circumstances.	In a Phase III trial (ARCHER 1050) that supported FDA approval, treatment with Vizimpro (dacomitinib) as first-line therapy in patients with non-small cell lung cancer harboring an EGFR exon 19 deletion or EGFR L858R resulted in an improved median progression-free survival (mPFS) of 14.7 months compared to 9.2 months with Iressa (gefitinib), with a mPFS of 16.5 months with dacomitnib vs. 9.2 months with Iressa (gefitinib) among patients with EGFR L858R (PMID: 28958502; NCT01777421).
datopotamab deruxtecan	FDA approved for adults with locally advanced or metastatic EGFR-mutated NSCLC who have received prior EGFR-directed therapy and platinum-based chemotherapy. NCCN recommended for non-squamous disease as Category 2A/Preferred intervention.	The FDA approval for datopotamab deruxtecan was supported by data from the pooled analysis of two trials: TROPION-Lung05 (NCT04484142) and TROPION-Lung01 (NCT04656652). Data from the pooled analysis (n = 114) demonstrated that subsequent line datopotamab deruxtecan conferred an ORR of 45% (CR = 4.4%, PR = 40%) in patients with locally advanced or metastatic EGFR-mutated NSCLC who have received prior EGFR-directed therapy and platinum-based chemotherapy. Additional endpoint includes median DoR (6.5 mo.).
erlotinib	FDA approved for metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. NCCN recommended as first line therapy (Category 1 /Useful in certain circumstances).	The FDA approval for erlotinib was supported by data from the open-label, phase-III trial EURTAC (ML20650; PMID: 22285168). EURTAC demonstrated that first-line erlotinib, compared with (carboplatin or cisplatin) + (docetaxel or gemcitabine), improved median PFS (HR = 0.34; p < 0.001; 10.4 mo. vs. 5.2 mo.; no. of events, 83% (71/86) vs. 72% (63/88)) in patients with metastatic NSCLC with EGFR Exon 19 Deletion or EGFR L858R. Secondary endpoints were OS (HR = 0.93) and ORR (65% vs. 16%).
gefitinib	FDA approved for the first-line treatment of metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. NCCN recommended as Category 1/Useful in certain circumstances.	The FDA approval for gefitinib was supported by two trials: IPASS Study 1 and IPASS Study 2 (NCT00322452; PMID: 19692680). Data from the single-arm, open-label phase-III trial IPASS Study 1 demonstrated that first-line gefitinib had an ORR of 50% (n = 106; CR, 0.9%; PR, 49%) in patients with metastatic NSCLC with EGFR Exon 19 Deletion or EGFR L858R. The secondary endpoint was median DOR (6.0 mo.). Data from the open-label, randomized, phase-III trial IPASS Study 2 demonstrated that first-line gefitinib, compared with carboplatin + paclitaxel, improved median PFS (HR = 0.54; 10.9 mo. vs. 7.4 mo.) and had a better ORR (67% (n = 88) vs. 41% (n = 98)) in patients with metastatic Lung Adenocarcinoma with EGFR Exon 19 Deletion or EGFR L858R.
osimertinib	FDA approved for the first-line treatment of metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R mutations. NCCN recommended as Category 1 /Preferred intervention.	In a Phase III (FLAURA) trial that supported FDA approval, treatment with Tagrisso (osimertinib) resulted in a longer median progression-free survival compared to treatment with either Tarceva (erlotinib) or Iressa (gefitinib) (18.9 mo vs 10.2 mo) in previously untreated non-small cell lung cancer patients harboring either EGFR L858R or EGFR exon 19 deletion (PMID: 29151359; NCT02296125).
osimertinib	FDA approved for adults with locally advanced, unresectable (stage III) NSCLC with EGFR exon 19 deletions or L858R mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy.	The FDA approval for osimertinib was supported by data from the double blind, randomized, placebo-controlled, phase-III trial LAURA (NCT03521154). LAURA demonstrated that osimertinib (n = 143), compared to placebo (n = 73), improved PFS (39.1 mo. vs. 5.6 mo., HR = 0.16; p < 0.001) in patients with locally advanced, unresectable stage III NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations whose disease had not progressed during or following definitive platinum-based chemoradiation therapy. Additional endpoint includes OS (immature with 36% of pre-specified deaths).

TMB-High		
Therapy	**Approval / Guideline Summary**	**Underlying Evidence**
pembrolizumab	FDA approved for unresectable or metastatic tumor mutational burden-high (TMB-H, >=10 muts/Mb) solid tumors with progression following prior treatment and with no satisfactory alternative treatment options.	In a retrospective analysis of a Phase II trial (KEYNOTE-158) that supported FDA approval, Keytruda (pembrolizumab) treatment resulted in superior objective response rate (28.3% vs 6.5%) in adult and pediatric patients with TMB high (TMB >= 10 mut/Mb, n=120) advanced solid tumors compared to patients with TMB low (TMB < 10 mut/Mb, n=635) tumors (Ann Oncol, 30 (Suppl 5), Oct 2019, v477-v478; NCT02628067).

TEST DETAILS

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PANEL CONTENT AND REPORTING TRANSCRIPTS				

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ABL1 NM_005157.4^
ABL2 NM_007314.3
ACVR1 NM_001105.4
ACVR1B NM_020328.3
AKT1 NM_001014432.1+
AKT2 NM_001626.4+
AKT3 NM_005465.4
ALK NM_004304.4^+
ANKRD11 NM_001256182.1
ANKRD26 NM_014915.2
APC NM_000038.5+
AR NM_000044.3+
ARAF NM_001654.4
ARFRP1 NM_003224.4
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ARID1B NM_020732.3
ARID2 NM_152641.2
ARID5B NM_032199.2
ASXL1 NM_015338.5
ASXL2 NM_018263.4
ATM NM_000051.3+
ATR NM_001184.3
ATRX NM_000489.3+
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AURKB NM_004217.3
AXIN1 NM_003502.3
AXIN2 NM_004655.3
AXL NM_021913.4
B2M NM_004048.2
BAP1 NM_004656.3
BARD1 NM_000465.2
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BCL2 NM_000633.2
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BCL2L2 NM_001199839.1
BCL6 NM_001706.4
BCOR NM_001123385.1
BCORL1 NM_021946.4
BCR NM_004327.3^
BIRC3 NM_001165.4
BLM NM_000057.2
BMPR1A NM_004329.2
BRAF NM_004333.4^+
BRCA1 NM_007294.3+
BRCA2 NM_000059.3+
BRD4 NM_058243.2
BRIP1 NM_032043.2
BTG1 NM_001731.2
BTK NM_000061.2
EMSY NM_020193.3
CALR NM_004343.3
CARD11 NM_032415.4
CASP8 NM_001228.4
CBFB NM_001755.2
CBL NM_005188.3
CCND1 NM_053056.2+
CCND2 NM_001759.3
CCND3 NM_001760.3+
CCNE1 NM_001238.2+
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ERCC2 NM_000400.3+
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ERRFI1 NM_018948.3
ESR1 NM_001122742.1+
ETS1 NM_001143820.1
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ETV4 NM_001079675.2^
ETV5 NM_004454.2
ETV6 NM_001987.4^
EWSR1 NM_013986.3^
EZH2 NM_004456.4
AMER1 NM_152424.3
ABRAXAS1 NM_139076.2
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FANCD2 NM_033084.3
FANCE NM_021922.2
FANCF NM_022725.3
FANCG NM_004629.1
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FAT1 NM_005245.3
FBXW7 NM_033632.3+
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HLA-A NM_002116.7
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HNRNPK NM_002140.3
HOXB13 NM_006361.5
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IDH1 NM_005896.2+
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KDR NM_002253.2
KEAP1 NM_012289.3
KEL NM_000420.2
KIF5B NM_004521.2
KIT NM_000222.2+
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TCF3 NM_003200.3
TCF7L2 NM_030756.4
TERC

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Date: 11/10/2026
Order ID: SumAsc-Pos-Lung-Long

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CD274 NM_014143.3
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CD74 NM_001025159.2^
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ZFHX3 NM_006885.3
ZNF217 NM_006526.2
ZNF703 NM_025069.1
ZRSR2 NM_005089.3
MTAP NM_002451.3+*

^Summit™ also reports fusion events for this gene
+Summit™ also reports copy number alterations for this gene
*Summit™ only reports copy number alterations for this gene

Aneuploidy (chromosome arm level loss and gain)									
chr1p	chr3p	chr5p	chr7p	chr9p	chr11p	chr13q	chr16q	chr18q	chr20q
chr1q	chr3q	chr5q	chr7q	chr9q	chr11q	chr14q	chr17p	chr19p	chr21q
chr2p	chr4p	chr6p	chr8p	chr10p	chr12p	chr15q	chr17q	chr19q	chr22q
chr2q	chr4q	chr6q	chr8q	chr10q	chr12q	chr16p	chr18p	chr20p	

Methods and Limitations

The Summit™ 2.0 comprehensive genomic profiling (CGP) next-generation sequencing (NGS) test investigates tumor derived nucleic acid extracted from cerebrospinal fluid (CSF) for clinically relevant single/multi nucleotide variants (SNVs, MNVs), insertions and deletions (indels), gene level copy

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Summit™ 2.0 + Ascent™ Report

number variants (CNVs), and other biomarkers such as tumor mutation burden (TMB) and microsatellite instability (MSI). Methodology involves evaluation of 520 genes for SNVs, MNVs, Indels, 62 genes for CNVs, 28 genes for fusions, as well as TMB and MSI (PMID: 41595175). The LOD (limit of detection) for SNVs, MNVs and Indels was determined to be 0.3% variant allelic frequency (VAF), for CNVs was determined to be >=2-fold change for amplifications and <=0.5-fold change for deletions, and for fusions was determined to be >=2 supporting reads. Reporting thresholds for TMB and MSI are: <10 Mut/Mb (TMB low), >=10 Mut/Mb (TMB high), and when total unstable sites are <30% (MSS) and >=30% (MSI-High). Ascent™ evaluates chromosomal arm level loss/gain (aneuploidy), and focal alterations (gene level amplification/deletion) using >0.1x low pass whole genome sequencing (LP-WGS) (PMID: 37014860). The LOD (limit of detection) for aneuploidy was determined to be log2(*r*) of abs (0.09), and for focal alteration was determined to be seq.mean cutoff of 0.1 for amplification and -0.2 for deletions. Variants are called against the human genome build reference hg19 using Summit™Omics pipeline version 1.5.0, developed at Belay Diagnostics.

Tertiary analysis is performed using the precision oncology workbench (GenomOncology) based on the joint AMP/ASCO/CAP consensus guidelines for interpretation of sequence variants in cancer (PMID: 27993330). Please reach out to contact@belaydiagnostics.com for additional information or queries.

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Disclaimers

This test was developed, and its performance characteristics determined by Belay Diagnostics Laboratory (CLIA# 14D2302605), which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). This test may be used for clinical purposes. However, the results of this test do not establish a diagnosis and should not be used alone for diagnosis or patient care decisions or otherwise replace the judgment of a treating physician and must always be interpreted in the context of all relevant clinical and pathological data.

This test is performed only to evaluate for somatic (i.e., tumor-specific) variants within the genes listed and cannot distinguish between germline and somatic alterations with absolute certainty. This test therefore does not report on incidental findings as defined by the American College for Medical Genetics and Genomics (ACMG) (PMID: 37347242). If a germline variant is suspected, follow-up germline testing using non-neoplastic (normal) tissue should be performed by a laboratory permitted to perform germline genetic testing along with genetic counseling. It is possible for a genomic variant to be present yet go undetected by our assay either due to the heterogeneous nature of the specimen or the limits of detection of our assay. Therefore, to the extent a particular genomic variant is not reported, Belay Diagnostics LLC does not guarantee that the variant does not exist in the specimen provided. Likely benign, and benign variants are not reported. For any reported variant of uncertain significance (VUS), if the classification changes, there is no obligation to send out a new report updating this information.

The information presented in the clinical trials and therapeutic sections of this report is compiled from public sources which are continuously updated. While we strive to ensure this information is accurate and complete, we cannot guarantee the accuracy or completeness of this information. This public sourced information is not ranked in order of potential or predicted efficacy and may not be complete. Specific eligibility criteria should be reviewed as applicable. This information may include associations between a genomic variant (or lack of a variant) and one or more therapeutic agents with potential clinical benefit (or lack of clinical benefit), including agents that are being studied in clinical research. The finding of a genomic variant does not necessarily indicate or demonstrate pharmacologic effectiveness (or lack thereof) of any agent or treatment regimen found in public source information. Similarly, the finding of "no clinically significant variant" does not necessarily indicate or demonstrate lack of pharmacologic effectiveness (or lack of effectiveness) of any agent or treatment regimen found in public source information. Belay Diagnostics expressly disclaims, and makes no representation of or warranty of, the accuracy or completeness with respect to the publicly available information included herein or reviewed or collected during creation of this report.

ACTIONABILITY REFERENCES

FDA: U.S. Food & Drug Administration (fda.gov)

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WHO: World Health Organization Classification of Tumours online (tumourclassification.iarc.who.int)

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