BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumPos-AscNeg-DMG-H3 K27M

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

# Summit™ 2.0 + Ascent™ Report

| Patient Information | Provisional Diagnosis | Specimen | Physician Information |
|---|---|---|---|
| **Name:**Jane Doe<br>**DOB:**01/01/1990<br>**Sex Assigned at Birth:**Female<br>**MRN:**11xx22xx33 | **Diagnosis:**Glioma<br>**CSF Volume Received:**6 mL | **Type:**CSF<br>**Collected:**11/03/2026<br>**Received:**11/04/2026<br>**Specimen ID:**SumPos-AscNeg-DMG-H3 K27M | **Institution:**Belay Diagnostics<br>**Referring Physician:**Provider Test |

## RESULT SUMMARY

## CLINICALLY SIGNIFICANT VARIANTS - DETECTED

**Comments**

H3-3A K28M (K27M) and *TP53* variants are characteristic findings in diffuse midline glioma, H3 K27-altered (see Actionability Summary). 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 |
| *H3-3A* p.K28M c.83A>T | 1.4% | Yes | Yes | Yes |
| *TP53* p.R248W c.742C>T | 0.4% | No | Yes | Yes |

**Summit™ 2.0 - Copy Number Variants**

*None*

**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**

| | | | | |
|---|---|---|---|---|
| *ALK* R806C | *LRP1B* G1166S | *PTPRS* V580E | *SETD2* T767A | *SPEN* A3054T |
| *BIRC3* K260R | *PAK5* G118D | *RAD52* G59R | *SH2B3* Q54P | |

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| Summit™ 2.0 - Gene Level CNVs |
|---|
| None |

| Summit™ 2.0 - Fusions |
|---|
| None |

| Ascent™ - Aneuploidy Variants of Unknown Significance |
|---|
| *None* |

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## ACTIONABILITY SUMMARY

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

| Biomarker | Therapies | Setting | Source(s) |
|---|---|---|---|
| *H3-3A* K28M | dordaviprone | Subsequent line | FDA (Approved), NCCN |

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

*None*

**Prognostic Implications per NCCN**

| Biomarker | Prognostic Association | Diseases | Note |
|---|---|---|---|
| *H3-3A* K28M | Unfavorable | Glioma | K27M/K28M gliomas typically do not have MGMT promoter methylation, and the mutation is an adverse prognostic marker in children and adults. |

**Diagnostic Implications per WHO**

| Biomarker | Diseases | Note |
|---|---|---|
| *H3-3A* K28M | Central Nervous System Neoplasm | The H3 p.K28M (also known as K27M) mutation plays a crucial role in diffuse midline glioma, H3 K27-altered. This mutation, despite affecting only 3-17% of the total cellular H3 pool, creates a dominant negative effect that results in widespread loss of H3 K28 trimethylation on the wildtype histone H3 (PMID: 23539183; PMID: 24183680; PMID: 23603901; PMID: 25200322). While K28M is the most common variant, K28I mutations can occasionally occur with similar effects. Presence of an H3 p.K28M/I mutation is an essential diagnostic criterion for the H3 K27-mutant subtype. Various midline circumscribed glial or glioneuronal tumours, including pilocytic astrocytomas (PMID: 29302777), subependymomas (PMID: 30389438), and gangliogliomas (PMID: 27984673) have been described as also have this mutation. Exceedingly rare, non-midline, cortical or hemispheric diffuse gliomas with H3 p.K28M have also been described (PMID: 28966033; PMID: 29763623; PMID: 28506301), though their biology is less well understood. |
| *TP53* R248W | Central Nervous System Neoplasm | TP53 mutations are present in a wide variety of CNS neoplasms. In medulloblastoma, TP53 mutation is observed in 14% of the WNT-activated subtype (somatic), and in 10-15% of the SSH-activated subtype (about half germline), where it defines an SHH-activated and TP53-mutant category. TP53 mutations are also observed in gliomas, including IDH-mutant astrocytoma (desirable diagnostic criterion), IDH-wildtype glioblastoma (20-25%) (PMID: 26919320; PMID: 24120142), H3 G34-mutant diffuse hemispheric glioma (~90%), H3-wildtype and IDH-wildtype diffuse pediatric-type high-grade glioma (30-50%), and H3 K27-altered diffuse midline glioma, but are rare or absent in IDH-mutant and 1p/19q-codeleted oligodendroglioma, pleomorphic xanthoastrocytoma, angiocentric glioma, and chordoid glioma. TP53 mutations have also been observed in choroid plexus carcinoma (~50%), choroid plexus papilloma (<10%; PMID: 20308654), embryonal tumour with multilayered rosettes (7%), cerebellar liponeurocytoma (4 of 20 cases; PMID: 15446583), and malignant transformation of DIG/DIA. Germline mutations of TP53 are associated with Li-Fraumeni syndrome, which is characterized by multiple primary neoplasms in children and adults, including brain tumors such as SHH-activated medulloblastoma, IDH-mutant astrocytoma, and choroid plexus carcinoma. |

## CLINICAL TRIALS / INVESTIGATIONAL THERAPIES

| *H3-3A* K28M | | | |
|---|---|---|---|
| **Therapy** | **Clinical Trial** | **Location/Sponsor** | **Quick Access** |

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|---|---|---|---|
| ACT001 | **NCT06838676** (Phase 2)<br>ACT001 for the Treatment of Diffuse Intrinsic Pontine Gliomas and H3K27-altered High Grade Gliomas | Aurora, Colorado<br>Nationwide Children's Hospital<br>kelsey.troyer@nationwidechildrens.org | https://genomoncology.wetrials.com/v1/NCT06838676 |
| M032 | **NCT07076498** (Phase 1)<br>Engineered HSV-1 M032 for the Treatment of Children and Adults With Newly Diagnosed Diffuse Midline Glioma After Standard of Care Radiation | Houston, Texas<br>M.D. Anderson Cancer Center<br>gkfriedman@mdanderson.org | https://genomoncology.wetrials.com/v1/NCT07076498 |
| dordaviprone | **NCT05009992** (Phase 2)<br>Combination Therapy for the Treatment of Diffuse Midline Gliomas | Birmingham, Alabama<br>University of California, San Francisco<br>PNOC022@ucsf.edu | https://genomoncology.wetrials.com/v1/NCT05009992 |
| pegargiminase + temozolomide + radiation therapy | **NCT07389278** (Phase 1/Phase 2)<br>Combination ADI-PEG 20, TMZ, and RT for Treatment of Newly Diagnosed High-grade Glioma (HGG) | San Francisco, California<br>Sabine Mueller, MD, PhD<br>PNOC034@ucsf.edu | https://genomoncology.wetrials.com/v1/NCT07389278 |
| triapine + intensity-modulated radiation therapy | **NCT06860594** (Phase 1)<br>Testing the Addition of an Anti-Cancer Drug, Triapine, to the Usual Radiation Therapy for Recurrent Glioblastoma or Astrocytoma | Duarte, California<br>National Cancer Institute (NCI) | https://genomoncology.wetrials.com/v1/NCT06860594 |

***TP53* R248W**

| Therapy | Clinical Trial | Location/Sponsor | Quick Access |
|---|---|---|---|
| AO-252 | **NCT06136884** (Phase 1)<br>A First-In-Human, Phase 1 Study Evaluating Oral TACC3 PPI Inhibitor, AO-252, in Advanced Solid Tumors With or Without Brain Metastases | Detroit, Michigan<br>A2A Pharmaceuticals Inc.<br>rfrnka@coiledtx.com | https://genomoncology.wetrials.com/v1/NCT06136884 |
| BTP-114 | **NCT02950064** (Phase 1)<br>A Study to Determine the Safety of BTP-114 for Treatment in Patients With Advanced Solid Tumors With BRCA Mutations | Sarasota, Florida<br>Placon Therapeutics | https://genomoncology.wetrials.com/v1/NCT02950064 |

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|---|---|---|---|
| anti-KRAS and anti-TP53 peripheral blood lymphocytes + aldesleukin + cyclophosphamide + fludarabine; anti-KRAS and anti-TP53 peripheral blood lymphocytes + pembrolizumab + aldesleukin + cyclophosphamide + fludarabine | NCT03412877 (Phase 2) Administration of Autologous T-Cells Genetically Engineered to Express T-Cell Receptors Reactive Against Neoantigens in People With Metastatic Cancer | Bethesda, Maryland National Cancer Institute (NCI) IRC@nih.gov | https://genomoncology.wetrials.com/v1/NCT03412877 |
| crizotinib + talazoparib; axitinib + talazoparib; palbociclib + talazoparib | NCT04693468 (Phase 1) Talazoparib and Palbociclib, Axitinib, or Crizotinib for the Treatment of Advanced or Metastatic Solid Tumors, TalaCom Trial | Houston, Texas M.D. Anderson Cancer Center tyap@mdanderson.org | https://genomoncology.wetrials.com/v1/NCT04693468 |

## TIER 1A THERAPY DETAILS

**H3-3A K28M**

| Therapy | Approval / Guideline Summary | Underlying Evidence |
|---|---|---|
| dordaviprone | FDA approved for patients >=1 year of age with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy. NCCN recommended as Category 2A, Useful in certain circumstances (adult) / Other recommended intervention (pediatric). | The FDA approval for dordaviprone was supported by data across five open-label, non-randomized trials: ONC006 (NCT02525692), ONC013 (NCT03295396), ONC014 (NCT03416530), ONC016 (NCT05392374), and ONC018 (NCT03134131). Data from the analysis (n = 50) demonstrated that subsequent line dordaviprone conferred an ORR of 22% (PR = 16%, MR = 6%) in patients with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy. Additional endpoint includes median DoR (10.3 mo.). |

## TEST DETAILS

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**PANEL CONTENT AND REPORTING TRANSCRIPTS**

*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
*ARID1A* NM_006015.4
*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+
*DNAJB1* NM_006145.1
*DNMT1* NM_001130823.1
*DNMT3A* NM_022552.4
*DNMT3B* NM_006892.3
*DOT1L* NM_032482.2
*E2F3* NM_001949.4
*EED* NM_003797.3
*EGFL7* NM_016215.4
*EGFR* NM_005228.3^+
*EIF1AX* NM_001412.3
*EIF4A2* NM_001967.3
*EIF4E* NM_001130679.1
*EML4* NM_019063.3
*EP300* NM_001429.3
*EPCAM* NM_002354.2
*EPHA3* NM_005233.5
*EPHA5* NM_004439.5
*EPHA7* NM_004440.3
*EPHB1* NM_004441.4
*ERBB2* NM_004448.2+
*ERBB3* NM_001982.3+
*ERBB4* NM_005235.2
*ERCC1* NM_001983.3+
*ERCC2* NM_000400.3+
*ERCC3* NM_000122.1
*H2BC5* NM_021063.3
*H3C1* NM_003529.2
*H3C2* NM_003537.3
*H3C3* NM_003531.2+
*H3C4* NM_003530.4
*H3C6* NM_003532.2
*H3C7* NM_021018.2
*H3C8* NM_003534.2
*H3C10* NM_003536.2
*H3C11* NM_003533.2
*H3C12* NM_003535.2
*H3C15* NM_001005464.2
*H3C14* NM_021059.2
*H3C13* NM_001123375.2
*H3-4* NM_003493.2
*HLA-A* NM_002116.7
*HLA-B* NM_005514.6
*HLA-C* NM_002117.5
*HNF1A* NM_000545.5
*HNRNPK* NM_002140.3
*HOXB13* NM_006361.5
*HRAS* NM_005343.2+
*HSD3B1* NM_000862.2
*HSP90AA1* NM_001017963.2
*ICOSLG* NM_015259.4
*ID3* NM_002167.4
*MYC* NM_002467.4+
*MYCL* NM_001033082.2+
*MYCN* NM_005378.4+
*MYD88* NM_002468.4+
*MYOD1* NM_002478.4
*NAB2* NM_005967.3^
*NBN* NM_002485.4
*NCOA3* NM_181659.2
*NCOR1* NM_006311.3
*NEGR1* NM_173808.2
*NF1* NM_001042492.2+
*NF2* NM_000268.3+
*NFE2L2* NM_006164.4+
*NFKBIA* NM_020529.2
*NKX2-1* NM_001079668.2
*NKX3-1* NM_006167.3
*NOTCH1* NM_017617.3
*NOTCH2* NM_024408.3
*NOTCH3* NM_000435.2
*NOTCH4* NM_004557.3
*NPM1* NM_002520.6
*NRAS* NM_002524.4+
*NRG1* NM_013964.3+
*COP1* NM_022457.5
*RHEB* NM_005614.3
*RHOA* NM_001664.2
*RICTOR* NM_152756.3+
*RIT1* NM_006912.5
*RNF43* NM_017763.4
*ROS1* NM_002944.2^
*RPS6KA4* NM_003942.2
*RPS6KB1* NM_003161.3+
*RPS6KB2* NM_003952.2
*RPTOR* NM_020761.2
*RUNX1* NM_001754.4
*RUNX1T1* NM_175635.2
*RYBP* NM_012234.5
*SDHA* NM_004168.2
*SDHAF2* NM_017841.2
*SDHB* NM_003000.2
*SDHC* NM_003001.3
*SDHD* NM_003002.3
*SETBP1* NM_015559.2
*SETD2* NM_014159.6+
*SF3B1* NM_012433.2
*SH2B3* NM_005475.2
*SH2D1A* NM_002351.4
*SHQ1* NM_018130.2

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*AURKA* NM_198433.1
*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
*BBC3* NM_001127240.2
*BCL10* NM_003921.4
*BCL2* NM_000633.2
*BCL2L1* NM_138578.1
*BCL2L11* NM_001204108.1
*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 +
*CD274* NM_014143.3
*CD276* NM_001024736.1
*CD74* NM_001025159.2 ^
*CD79A* NM_001783.3
*CD79B* NM_000626.2 +
*CDC73* NM_024529.4
*CDH1* NM_004360.3 +
*CDK12* NM_016507.2
*CDK4* NM_000075.3 +
*CDK6* NM_001259.6 +
*CDK8* NM_001260.1
*CDKN1A* NM_000389.4
*CDKN1B* NM_004064.3
*CDKN2A* NM_000077.4 +
*CDKN2B* NM_004936.3 +
*CDKN2C* NM_001262.2
*CEBPA* NM_004364.3
*CENPA* NM_001809.3
*CHD2* NM_001271.3
*CHD4* NM_001273.2
*CHEK1* NM_001114122.2 +
*CHEK2* NM_007194.3 +
*ERCC4* NM_005236.2
*ERCC5* NM_000123.3
*ERG* NM_001136154.1
*ERRFI1* NM_018948.3
*ESR1* NM_001122742.1 +
*ETS1* NM_001143820.1
*ETV1* NM_004956.4 ^
*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
*TENT5C* NM_017709.3
*FANCA* NM_000135.2
*FANCC* NM_000136.2
*FANCD2* NM_033084.3
*FANCE* NM_021922.2
*FANCF* NM_022725.3
*FANCG* NM_004629.1
*FANCI* NM_001113378.1
*FANCL* NM_001114636.1
*FAS* NM_000043.4
*FAT1* NM_005245.3
*FBXW7* NM_033632.3 +
*FGF1* NM_001144934.1 +
*FGF10* NM_004465.1 +
*FGF14* NM_175929.2 +
*FGF19* NM_005117.2 +
*FGF2* NM_002006.4 +
*FGF23* NM_020638.2 +
*FGF3* NM_005247.2 +
*FGF4* NM_002007.2 +
*FGF5* NM_004464.3 +
*FGF6* NM_020996.1 +
*FGF7* NM_002009.3 +
*FGF8* NM_033163.3 +
*FGF9* NM_002010.2 +
*FGFR1* NM_023110.2 +
*FGFR2* NM_000141.4 ^+
*FGFR3* NM_000142.4 ^+
*FGFR4* NM_213647.1 +
*FH* NM_000143.3
*FLCN* NM_144997.5
*FLI1* NM_002017.4
*FLT1* NM_002019.4
*FLT3* NM_004119.2
*FLT4* NM_182925.4
*FOXA1* NM_004496.3
*FOXL2* NM_023067.3
*FOXO1* NM_002015.3
*FOXP1* NM_032682.5
*FRS2* NM_001278351.1
*FUBP1* NM_003902.3 +
*FYN* NM_002037.5
*GABRA6* NM_000811.2
*GATA1* NM_002049.3
*IDH1* NM_005896.2 +
*IDH2* NM_002168.2 +
*IGF1* NM_001111283.1
*IGF1R* NM_000875.3
*IGF2* NM_001127598.1
*IKBKE* NM_014002.3
*IKZF1* NM_006060.4
*IL10* NM_000572.2
*IL7R* NM_002185.3
*INHA* NM_002191.3
*INHBA* NM_002192.2
*INPP4A* NM_001134224.1
*INPP4B* NM_003866.2
*INSR* NM_000208.2
*IRF2* NM_002199.3
*IRF4* NM_002460.3
*IRS1* NM_005544.2
*IRS2* NM_003749.2
*JAK1* NM_002227.2
*JAK2* NM_004972.3 +
*JAK3* NM_000215.3
*JUN* NM_002228.3
*KAT6A* NM_006766.3
*KDM5A* NM_001042603.1
*KDM5C* NM_004187.3
*KDM6A* NM_021140.2
*KDR* NM_002253.2
*KEAP1* NM_012289.3
*KEL* NM_000420.2
*KIF5B* NM_004521.2
*KIT* NM_000222.2 +
*KLF4* NM_004235.4
*KLHL6* NM_130446.2
*KMT2B* NM_014727.1
*KMT2C* NM_170606.2
*KMT2D* NM_003482.3
*KRAS* NM_004985.3 +
*LAMP1* NM_005561.3 +
*LATS1* NM_004690.3
*LATS2* NM_014572.2
*LMO1* NM_002315.2
*LRP1B* NM_018557.2
*LYN* NM_002350.3
*LZTR1* NM_006767.3
*MAGI2* NM_012301.3
*MALT1* NM_006785.3
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*MAP2K4* NM_003010.3
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*MAP3K13* NM_004721.4
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*MAP3K4* NM_005922.2
*MAPK1* NM_002745.4
*MAPK3* NM_002746.2
*MAX* NM_002382.4
*MCL1* NM_021960.4
*MDC1* NM_014641.2
*MDM2* NM_002392.5 +
*MDM4* NM_002393.4 +
*MED12* NM_005120.2
*MEF2B* NM_001145785.1
*MEN1* NM_130799.2
*MET* NM_000245.2 +
*NSD1* NM_022455.4
*NTRK1* NM_002529.3 ^
*NTRK2* NM_006180.3 ^
*NTRK3* NM_001012338.2
*NUP93* NM_014669.4
*NUTM1* NM_175741.1 ^
*PAK1* NM_001128620.1
*PAK3* NM_002578.3
*PAK5* NM_020341.3
*PALB2* NM_024675.3
*PRKN* NM_004562.2
*PARP1* NM_001618.3
*PAX3* NM_181457.3 ^
*PAX5* NM_016734.2
*PAX7* NM_001135254.1
*PAX8* NM_013953.3 ^
*PBRM1* NM_018313.4
*PDCD1* NM_005018.2
*PDCD1LG2* NM_025239.3
*PDGFRA* NM_006206.4 +
*PDGFRB* NM_002609.3 +
*PDK1* NM_001278549.1
*PDPK1* NM_002613.4
*PGR* NM_000926.4
*PHF6* NM_032458.2
*PHOX2B* NM_003924.3
*PIK3C2B* NM_002646.3
*PIK3C2G* NM_004570.4
*PIK3C3* NM_002647.2
*PIK3CA* NM_006218.2 +
*PIK3CB* NM_006219.2 +
*PIK3CD* NM_005026.3
*PIK3CG* NM_002649.2
*PIK3R1* NM_181523.2
*PIK3R2* NM_005027.3
*PIK3R3* NM_003629.3
*PIM1* NM_002648.3
*PLCG2* NM_002661.3
*PLK2* NM_006622.3
*PMAIP1* NM_021127.2
*PMS1* NM_000534.4
*PMS2* NM_000535.5
*PNRC1* NM_006813.2
*POLD1* NM_001256849.1
*POLE* NM_006231.2
*PPARG* NM_138712.3 ^
*PPM1D* NM_003620.3
*PPP2R1A* NM_014225.5
*PPP2R2A* NM_001177591.1
*PPP6C* NM_001123355.1
*PRDM1* NM_001198.3
*PREX2* NM_024870.2
*PRKAR1A* NM_212472.2
*PRKCI* NM_002740.5
*PRKDC* NM_006904.6
*PRSS8* NM_002773.3
*PTCH1* NM_000264.3 +
*PTEN* NM_000314.4 +
*PTPN11* NM_002834.3
*PTPRD* NM_002839.3
*PTPRS* NM_002850.3
*PTPRT* NM_133170.3
*SLIT2* NM_004787.1
*SLX4* NM_032444.2
*SMAD2* NM_005901.5
*SMAD3* NM_005902.3
*SMAD4* NM_005359.5 +
*SMARCA4* NM_001128849.1 +
*SMARCB1* NM_003073.3 +
*SMARCD1* NM_003076.4
*SMC1A* NM_006306.3
*SMC3* NM_005445.3
*SMO* NM_005631.4 +
*SNCAIP* NM_005460.2
*SOCS1* NM_003745.1
*SOX10* NM_006941.3
*SOX17* NM_022454.3
*SOX2* NM_003106.3
*SOX9* NM_000346.3
*SPEN* NM_015001.2
*SPOP* NM_001007228.1
*SPTA1* NM_003126.2
*SRC* NM_198291.2
*SRSF2* NM_003016.4
*STAG1* NM_005862.2
*STAG2* NM_001042749.1
*STAT3* NM_139276.2
*STAT4* NM_003151.3
*STAT5A* NM_003152.3
*STAT5B* NM_012448.3
*STK11* NM_000455.4
*STK40* NM_032017.1
*SUFU* NM_016169.3 +
*SUZ12* NM_015355.2
*SYK* NM_003177.5
*TBX3* NM_016569.3
*ELOC* NM_005648.3
*TCF3* NM_003200.3
*TCF7L2* NM_030756.4
*TERC*
*TERT* NM_198253.2 +
*TET1* NM_030625.2
*TET2* NM_001127208.2
*TFE3* NM_006521.4 ^
*TFRC* NM_003234.2 +
*TGFBR1* NM_004612.2
*TGFBR2* NM_001024847.2
*TMEM127* NM_017849.3
*TMPRSS2* NM_001135099.1 ^
*TNFAIP3* NM_006290.3
*TNFRSF14* NM_003820.2
*TOP1* NM_003286.2
*TOP2A* NM_001067.3
*TP53* NM_000546.5 +
*TP63* NM_003722.4
*TRAF2* NM_021138.3
*TRAF7* NM_032271.2 +
*TSC1* NM_000368.4
*TSC2* NM_000548.3
*TSHR* NM_000369.2
*U2AF1* NM_006758.2
*VEGFA* NM_001025366.2
*VHL* NM_000551.3 +
*VTCN1* NM_024626.3

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BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumPos-AscNeg-DMG-H3 K27M

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# Summit™ 2.0 + Ascent™ Report

| | | | | |
|---|---|---|---|---|
| *CIC* NM_015125.3+ | *GATA2* NM_032638.4 | *MGA* NM_001164273.1 | *QKI* NM_006775.2 | *CCN6* NM_003880.3 |
| *CREBBP* NM_004380.2 | *GATA3* NM_001002295.1+ | *MITF* NM_000248.3 | *RAB35* NM_006861.6 | *WT1* NM_024426.4 |
| *CRKL* NM_005207.3 | *GATA4* NM_002052.3 | *MLH1* NM_000249.3 | *RAC1* NM_018890.3 | *XIAP* NM_001167.3 |
| *CRLF2* NM_022148.2 | *GATA6* NM_005257.4 | *KMT2A* NM_001197104.1 | *RAD21* NM_006265.2 | *XPO1* NM_003400.3 |
| *CSF1R* NM_005211.3 | *GEN1* NM_182625.3 | *MLLT3* NM_004529.2 | *RAD50* NM_005732.3 | *XRCC2* NM_005431.1 |
| *CSF3R* NM_156039.3 | *GID4* NM_024052.4 | *MPL* NM_005373.2 | *RAD51* NM_002875.4 | *YAP1* NM_001130145.2 |
| *CSNK1A1* NM_001025105.2 | *GLI1* NM_005269.2 | *MRE11* NM_005591.3 | *RAD51B* NM_133509.3 | *YES1* NM_005433.3 |
| *CTCF* NM_006565.3 | *GNA11* NM_002067.2 | *MSH2* NM_000251.2 | *RAD51C* NM_058216.2 | *ZBTB2* NM_020861.1 |
| *CTLA4* NM_005214.4 | *GNA13* NM_006572.4 | *MSH3* NM_002439.4 | *RAD51D* NM_002878.3 | *ZBTB7A* NM_015898.2 |
| *CTNNA1* NM_001903.2 | *GNAQ* NM_002072.3 | *MSH6* NM_000179.2 | *RAD52* NM_134424.2 | *ZFHX3* NM_006885.3 |
| *CTNNB1* NM_001904.3+ | *GNAS* NM_000516.4+ | *MST1* NM_020998.3 | *RAD54L* NM_001142548.1 | *ZNF217* NM_006526.2 |
| *CUL3* NM_003590.4 | *ADGRA2* NM_032777.9 | *MST1R* NM_002447.2 | *RAF1* NM_002880.3+ | *ZNF703* NM_025069.1 |
| *CUX1* NM_181552.3 | *GPS2* NM_004489.4 | *MTOR* NM_004958.3 | *RANBP2* NM_006267.4 | *ZRSR2* NM_005089.3 |
| *CXCR4* NM_003467.2 | *GREM1* NM_013372.6 | *MUTYH* NM_001128425.1 | *RARA* NM_000964.3 | *MTAP* NM_002451.3+* |
| *CYLD* NM_015247.2 | *GRIN2A* NM_000833.3 | *MYB* NM_001130173.1 | *RASA1* NM_002890.2 | |
| *DAXX* NM_001141970.1 | *GRM3* NM_000840.2 | | *RB1* NM_000321.2+ | |
| *DCUN1D1* NM_020640.2 | *GSK3B* NM_002093.3 | | *RBM10* NM_005676.4 | |
| *DDR2* NM_001014796.1 | *H3-3A* NM_002107.4+ | | *RECQL4* NM_004260.3 | |
| *DDX41* NM_016222.2 | *H3-3B* NM_005324.3 | | *REL* NM_002908.2 | |
| *DHX15* NM_001358.2 | *H3-5* NM_001013699.2 | | *RET* NM_020975.4^+ | |
| *DICER1* NM_177438.2 | *HGF* NM_000601.4 | | | |
| *DIS3* NM_014953.3 | *H1-2* NM_005319.3 | | | |

^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 | |

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**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 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.

**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

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# Summit™ 2.0 + Ascent™ Report

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)

**NCCN**: National Comprehensive Cancer Network® (NCCN®). Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. The NCCN Guidelines® and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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

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