BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumAsc-Pos-Med-Ped

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<br>**DOB:**01/01/2015<br>**Sex Assigned at Birth:**Male<br>**MRN:**11xx22xx33 | **Diagnosis:**Medulloblastoma<br>**CSF Volume Received:**6 mL | **Type:**CSF<br>**Collected:**11/03/2026<br>**Received:**11/04/2026<br>**Specimen ID:**SumAsc-Pos-Med-Ped | **Institution:**Belay Diagnostics<br>**Referring Physician:**Provider Test |

## RESULT SUMMARY

## CLINICALLY SIGNIFICANT VARIANTS - DETECTED

**Comments**

Chr17q gain was observed alongside chr17p loss and is indicative of isochromosome 17q [i(17q)], a characteristic finding in non-WNT/non-SHH medulloblastoma (PMID: 22090452, 22358457). Clinical correlation is required.

***Gene variants with limited actionability*** - Variants in epigenetic regulator *ARID1A* have been reported in non-WNT/non-SHH Group 3 medulloblastoma (PMID: 29269116). 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 |
| *ARID1A* p.Q1416* c.4246C>T | 41.3% | No | No | No |

**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**

| Alteration | Type of Relevant Genes | Actionability Summary | | |
|---|---|---|---|---|
| | | FDA/NCCN Therapies Associated | Prognostic /Diagnostic Guidelines | Clinical Trial Options |
| chr17p whole arm Loss | Fully Contained: *TP53* | No | No | Yes |

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| Ascent™ - Chromosome Arm Level Loss or Gain | | | | |
|---|---|---|---|---|
| | | Actionability Summary | | |
| **Alteration** | **Type of Relevant Genes** | **FDA/NCCN Therapies Associated** | **Prognostic /Diagnostic Guidelines** | **Clinical Trial Options** |
| chr17q whole arm Gain | Fully Contained: *BRCA1*, *CD79B*, *ERBB2*, *NF1*, *RPS6KB1* | No | No | No |

## VARIANTS OF UNKNOWN SIGNIFICANCE (Tier 3)

| Summit™ 2.0 - SNV/MNVs/Indels | | | |
|---|---|---|---|
| *ERBB3* P30L | *MDM4* I175T | *PAK5* G118D | *TFE3* I436fs |
| *MDC1* A1734T | *NOTCH1* R703C | *RARA* T43S | |

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

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

| Ascent™ - Aneuploidy Variants of Unknown Significance | |
|---|---|
| chr12p Gain | chr13q Loss |

## ACTIONABILITY SUMMARY

*None*

## CLINICAL TRIALS / INVESTIGATIONAL THERAPIES

| *TP53* Loss | | | |
|---|---|---|---|
| **Therapy** | **Clinical Trial** | **Location/Sponsor** | **Quick Access** |
| eflornithine | NCT04696029 (Phase 2)<br>DFMO as Maintenance Therapy for Molecular High/Very High Risk and Relapsed Medulloblastoma | Little Rock, Arkansas<br>Giselle Sholler<br>BCCEnroll@pennstatehealth.psu.edu | https://genomoncology.wetrials.com/v1/NCT04696029 |
| filgrastim + pegfilgrastim + carboplatin + cisplatin + cyclophosphamide + methotrexate + topotecan + vincristine | NCT05535166 (Phase 2)<br>Molecular and Clinical Risk-Directed Therapy for Infants and Young Children With Newly Diagnosed Medulloblastoma | Palo Alto, California<br>St. Jude Children's Research Hospital<br>tabatha.doyle@stjude.org | https://genomoncology.wetrials.com/v1/NCT05535166 |

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## TIER 1A THERAPY DETAILS

*None*

## TEST DETAILS

*Summit™ 2.0 + Ascent™ Report*

**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+
*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
*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
*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+
*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
*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
*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+
*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
*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
*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

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*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+
*CIC* NM_015125.3+
*CREBBP* NM_004380.2
*CRKL* NM_005207.3
*CRLF2* NM_022148.2
*CSF1R* NM_005211.3
*CSF3R* NM_156039.3
*CSNK1A1* NM_001025105.2
*CTCF* NM_006565.3
*CTLA4* NM_005214.4
*CTNNA1* NM_001903.2
*CTNNB1* NM_001904.3+
*CUL3* NM_003590.4
*CUX1* NM_181552.3
*CXCR4* NM_003467.2
*CYLD* NM_015247.2
*DAXX* NM_001141970.1
*DCUN1D1* NM_020640.2
*DDR2* NM_001014796.1
*DDX41* NM_016222.2
*DHX15* NM_001358.2
*DICER1* NM_177438.2
*DIS3* NM_014953.3
*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
*GATA2* NM_032638.4
*GATA3* NM_001002295.1+
*GATA4* NM_002052.3
*GATA6* NM_005257.4
*GEN1* NM_182625.3
*GID4* NM_024052.4
*GLI1* NM_005269.2
*GNA11* NM_002067.2
*GNA13* NM_006572.4
*GNAQ* NM_002072.3
*GNAS* NM_000516.4+
*ADGRA2* NM_032777.9
*GPS2* NM_004489.4
*GREM1* NM_013372.6
*GRIN2A* NM_000833.3
*GRM3* NM_000840.2
*GSK3B* NM_002093.3
*H3-3A* NM_002107.4+
*H3-3B* NM_005324.3
*H3-5* NM_001013699.2
*HGF* NM_000601.4
*H1-2* NM_005319.3
*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
*MAP2K1* NM_002755.3
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*MAP3K13* NM_004721.4
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*MAPK1* NM_002745.4
*MAPK3* NM_002746.2
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*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+
*MGA* NM_001164273.1
*MITF* NM_000248.3
*MLH1* NM_000249.3
*KMT2A* NM_001197104.1
*MLLT3* NM_004529.2
*MPL* NM_005373.2
*MRE11* NM_005591.3
*MSH2* NM_000251.2
*MSH3* NM_002439.4
*MSH6* NM_000179.2
*MST1* NM_020998.3
*MST1R* NM_002447.2
*MTOR* NM_004958.3
*MUTYH* NM_001128425.1
*MYB* NM_001130173.1
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*PIK3C3* NM_002647.2
*PIK3CA* NM_006218.2+
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*PIK3CD* NM_005026.3
*PIK3CG* NM_002649.2
*PIK3R1* NM_181523.2
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*PLCG2* NM_002661.3
*PLK2* NM_006622.3
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*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
*QKI* NM_006775.2
*RAB35* NM_006861.6
*RAC1* NM_018890.3
*RAD21* NM_006265.2
*RAD50* NM_005732.3
*RAD51* NM_002875.4
*RAD51B* NM_133509.3
*RAD51C* NM_058216.2
*RAD51D* NM_002878.3
*RAD52* NM_134424.2
*RAD54L* NM_001142548.1
*RAF1* NM_002880.3+
*RANBP2* NM_006267.4
*RARA* NM_000964.3
*RASA1* NM_002890.2
*RB1* NM_000321.2+
*RBM10* NM_005676.4
*RECQL4* NM_004260.3
*REL* NM_002908.2
*RET* NM_020975.4^+
*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
*CCN6* NM_003880.3
*WT1* NM_024426.4
*XIAP* NM_001167.3
*XPO1* NM_003400.3
*XRCC2* NM_005431.1
*YAP1* NM_001130145.2
*YES1* NM_005433.3
*ZBTB2* NM_020861.1
*ZBTB7A* NM_015898.2
*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)** |
|---|

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BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumAsc-Pos-Med-Ped

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# Summit™ 2.0 + Ascent™ Report

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 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 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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# Summit™ 2.0 + Ascent™ Report

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