BELAY DIAGNOSTICS

Date: 10/17/2025
Order ID: SumPos-CNS-Peds-1

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

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Patient Information	Provisional Diagnosis	Specimen	Physician Information
Name: John Smith **DOB:**01/01/2015 **Sex Assigned at Birth:**Male **MRN:**11xx22xx33	**Diagnosis:**Glioma **ICD10:**C71.0-C.71.9	**Type:**CSF **Collected:**01/01/2025 **Received:**01/02/2025 **Specimen ID:**SumPos-CNS-Peds-1	**Institution:**Belay Diagnostics **Referring Physician:**Provider Test

RESULT SUMMARY

POSITIVE

Comments
A high level of chromosomal loss and gain was observed in this specimen and indicates chromosomal instability, a key driver of metastasis across cancer types (PMID: 38924459).

ALTERATION DETAILS

Clinically Significant Genomic Variants (Tier 1 or 2 per AMP/ASCO/CAP)

Alteration	VAF	Actionability Summary		
		FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
H3-3A p.K28M c.83A>T	46.9%	Yes	Yes	Yes
ATRX p.E95fs c.284_288delinsGAAAAT	78.1%	No	No	No
FH p.A393V c.1178C>T	50.4%	No	No	No
TP53 c.375+1_375+8del	80.5%	No	Yes	No

Copy Number Variants

Alteration	Location	Fold Change	Actionability Summary		
			FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
MET Amplification	chr7	3.39	No	Yes	No
MYC Amplification	chr8	2.04	No	Yes	No

Fusion Variants

Alteration	Breakpoint	Actionability Summary		
		FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options

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Fusion Variants

Alteration	Breakpoint	Actionability Summary		
		FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
CCDC6-RET Fusion	CCDC6 intron 1 NM_005436.4 chr10:61618457 RET intron 11 NM_020975.4 chr10:43611228	Yes	No	No

Biomarkers

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

Aneuploidy Variants (Chromosome Arm Level Loss or Gain): *None*

Aneuploidy Variants of Unknown Significance

chr10q Loss	chr16p Loss	chr19q Loss	chr3p Gain	chr7p Gain
chr12p Gain	chr16q Loss	chr1p Gain	chr3q Gain	chr7q Gain
chr12q Gain	chr17p Loss	chr1q Gain	chr4q Loss	chr8p Gain
chr13q Loss	chr18p Loss	chr21q Loss	chr5p Loss	chr8q Gain
chr14q Loss	chr18q Loss	chr2p Gain	chr5q Loss	
chr15q Loss	chr19p Loss	chr2q Gain	chr6q Loss	

Variants of Unknown Significance (Tier 3)

SNV/MNVs/Indels		Gene Level CNVs	Fusions
ASXL2 S276C	*MGA* I1959V	*RICTOR* Loss	None
AXIN2 K580E	*NUTM1* P355L		
BCOR D1712N	*PIK3CD* M441L		
CHD4 P491H	*RPS6KB2* P267L		
EP300 K1140*	*SLIT2* H245R		
EPHA3 R447Q	*SLX4* N1834S		
EPHA5 I540F	*SPTA1* Q2146R		
IDH2 T435M	*SPTA1* Y653C		
KDM5A N1657S			

ACTIONABILITY SUMMARY

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

Biomarker	Therapies	Setting	Source(s)
CCDC6-RET Fusion	selpercatinib	Subsequent line, or no satisfactory alternative therapy	FDA (Approved)
H3-3A K28M	dordaviprone	Subsequent line	FDA (Approved), NCCN
TMB-High	pembrolizumab	Subsequent line, and no satisfactory alternative therapy	FDA (Approved), NCCN
TMB-High	nivolumab	Recurrent or progressive	NCCN

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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.
MET Amplification	Central Nervous System Neoplasm	MET amplifications or fusions occur in several central nervous system neoplasms. They are common in high-grade IDH-mutant astrocytomas (PMID: 30343896) and diffuse, pediatric-type high-grade glioma, H3-wildtype and IDH-wildtype (PMID: 27748748), but they may also occur in adult-type IDH-wildtype glioblastomas (PMID: 29718398; PMID: 30343896; PMID: 25135958). MET fusions are a diagnostic criterion for infant-type hemispheric glioma, where structural genomic variants, often driven by focal intragenic DNA copy-number changes, result in the acquisition of fusion genes involving numerous 5 partners and MET or other RTK genes.
MYC Amplification	Central Nervous System Neoplasm	MYC amplification has been observed in multiple central nervous system neoplasms. MYC amplification is observed in IDH-wildtype glioblastoma, particularly linked to primitive neuronal components along with MYCN amplifications in ~40% of these cases (PMID: 18452568). Overexpression of MYC is a common feature of non-WNT /non-SHH medulloblastomas, and MYC amplification, often accompanied by PVT1; MYC fusion (PMID: 22832581), occurs in 17% of group 3 tumors (PMID: 20921458; PMID: 28726821). Recurrent focal gains or amplifications affecting the MYC region are also associated with the MYC/FOXR2-activated subtype of pineoblastoma (PMID: 31820118; PMID: 31768671). MYC amplification has also been observed in IDH-mutant astrocytoma, H3 G34-mutant diffuse hemispheric glioma (PMID: 23539269), and oligodendroglioma, IDH-mutant and 1p/19q-codeleted.
TP53 c. 375+1_375+8del	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
PEP-CMV vaccine + nivolumab + tetanus toxoid vaccine + temozolomide	**NCT06639607** (Phase 1/Phase 2) PEP-CMV + Nivolumab for Newly Diagnosed Diffuse Midline Glioma/High-grade Glioma and Recurrent Diffuse Midline Glioma/High-grade Glioma, Medulloblastoma, and Ependymoma	Saint Louis, Missouri Washington University School of Medicine pedshemonctrialreferral@wustl.edu
abemaciclib + temozolomide; temozolomide	**NCT06413706** (Phase 2) A Study Comparing Abemaciclib Plus Temozolomide to Temozolomide Monotherapy in Children and Young Adults With High-grade Glioma Following Radiotherapy	Phoenix, Arizona Eli Lilly and Company clinical_inquiry_hub@lilly.com
atovaquone + radiation therapy	**NCT06624371** (Phase 1) Atovaquone Combined With Radiation in Children With Malignant Brain Tumors	Atlanta, Georgia Emory University aflacdevtreferral@choa.org
dordaviprone + panobinostat + radiation therapy; dordaviprone + paxalisib + radiation therapy	**NCT05009992** (Phase 2) Combination Therapy for the Treatment of Diffuse Midline Gliomas	Birmingham, Alabama University of California, San Francisco PNOC022@ucsf.edu

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retroviral vector transduced B7-H3 CAR T cells	NCT05835687 (Phase 1) Loc3CAR: Locoregional Delivery of B7-H3-CAR T Cells for Pediatric Patients With Primary CNS Tumors	Memphis, Tennessee St. Jude Children's Research Hospital tabatha.doyle@stjude.org

TMB-High		
Therapy	**Clinical Trial**	**Location/Sponsor**
pembrolizumab	NCT02332668 (Phase 1/Phase 2) A Study of Pembrolizumab (MK-3475) in Pediatric Participants With an Advanced Solid Tumor or Lymphoma (MK-3475-051/KEYNOTE-051)	Aurora, Colorado Merck Sharp & Dohme LLC 1-888-577-8839

TIER 1A THERAPY DETAILS

***CCDC6-RET* Fusion**		
Therapy	**Approval / Guideline Summary**	**Underlying Evidence**
selpercatinib	FDA approved for patients 2 years of age and older with locally advanced or metastatic solid tumors with a RET fusion, who had progression on prior systemic treatment or have no satisfactory alternative options.	The FDA approval for selpercatinib was supported by data from two clinical trials: LIBRETTO-001 (NCT03157128) and LIBRETTO-121 (NCT03899792). Data from the multicenter, open-label, phase-I/II trial LIBRETTO-001 demonstrated that selpercatinib (n = 41) conferred an ORR of 44% (CR, 4.9%; PR, 39%) and a median DOR of 24.5 mo. in locally advanced or metastatic, RET-fusion-positive solid neoplasms, other than NSCLC and thyroid carcinoma, that have received prior systemic treatment or lack treatment options. Data from the multicenter, open-label, phase-I/II trial LIBRETTO-121 demonstrated that selpercatinib did not elicit a response in one patient with locally advanced refractory RET-fusion positive malignant peripheral nerve sheath tumor.

***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.).

TMB-High		
Therapy	**Approval / Guideline Summary**	**Underlying Evidence**
nivolumab	NCCN recommended for recurrent or progressive pediatric high-grade diffuse glioma that is TMB-High (Category 2A/Preferred intervention).	The NCCN guideline recommendation for subsequent line nivolumab was supported by data from two case studies (PMIDs: 27001570, 30160041). The case studies demonstrated both clinically significant responses and profound radiologic responses in two siblings with recurrent, hypermutated glioblastoma.
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				
ABL1 NM_005157.4^	*DNAJB1* NM_006145.1	*H2BC5* NM_021063.3	*MYC* NM_002467.4+	*COP1* NM_022457.5

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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
CALR NM_004343.3
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CASP8 NM_001228.4
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CCND3 NM_001760.3+
CCNE1 NM_001238.2+
CD274 NM_014143.3
CD276 NM_001024736.1
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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+
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+
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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
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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
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MYCN NM_005378.4+
MYD88 NM_002468.4
MYOD1 NM_002478.4
NAB2 NM_005967.3^
NBN NM_002485.4
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NEGR1 NM_173808.2
NF1 NM_001042492.2
NF2 NM_000268.3
NFE2L2 NM_006164.4
NFKBIA NM_020529.2
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NKX3-1 NM_006167.3
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NOTCH4 NM_004557.3
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NRG1 NM_013964.3+
NSD1 NM_022455.4
NTRK1 NM_002529.3^
NTRK2 NM_006180.3^
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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
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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+
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PDPK1 NM_002613.4
PGR NM_000926.4
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PIK3C2G NM_004570.4
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PIK3CA NM_006218.2+
PIK3CB NM_006219.2+
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PIK3CG NM_002649.2
PIK3R1 NM_181523.2
PIK3R2 NM_005027.3
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PLK2 NM_006622.3
PMAIP1 NM_021127.2
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
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^

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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+
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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

BELAY DIAGNOSTICS

Date: 10/17/2025
Order ID: SumPos-CNS-Peds-1

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Summit ™ 2.0 Report

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

Methods and Limitations

The Summit™ 2.0 comprehensive genomic profiling 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), chromosomal arm level loss/gain (aneuploidy), and other biomarkers such as tumor mutational burden (TMB) and microsatellite instability (MSI). Methodology involves evaluation of 520 genes for SNVs, MNVs, Indels, 62 genes for CNVs, 27 genes for fusions, as well as TMB, MSI and low pass whole genome sequencing (>0.1x) for the detection of chromosomal aneuploidy (PMID: 37014860). Libraries are sequenced on the Illumina NovaSeq XPlus. 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, for fusions was determined to be >=2 supporting reads, and for aneuploidy was determined to be log2(*r*) of 0.09. Reporting on TMB and MSI requires >=15ng total nucleic acid yield, for TMB low <10 Mut/Mb, >=10 Mut/Mb for TMB high and MSI high when total unstable sites is >=5%. Variants (mutations and aneuploidy) are called against the human genome build reference hg19 using Summit™Omics pipeline version 1.0.0, 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 Report

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