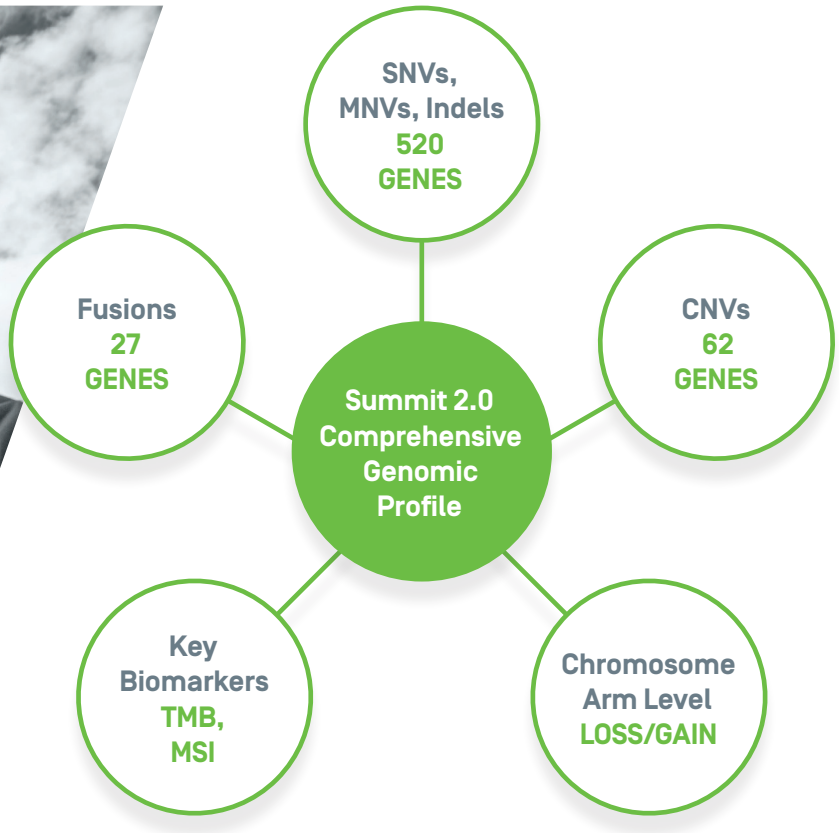
Belay Summit™ 2.0

Comprehensive Genomic Profile in CSF

BELAY DIAGNOSTICS

Summit interrogates tumor-derived nucleic acid in CSF to help inform the diagnosis and management of primary and secondary CNS malignancies.



Proprietary next-generation sequencing of nucleic acid in CSF

WHY CHOOSE BELAY SUMMIT?

1. Molecular characterization can markedly enhance diagnostic accuracy, tumor classification, predictive prognosis,and treatment selection[1]
2. CNS metastasis can have different molecular profiles than the primary tumors with distinct targetable mutations, due to clonal evolution during neoplasm migration[2]
3. Genomic abnormalities associated with CNS cancers can be detected prior to performing resections or biopsies that impose clinical risk

Summit 2.0 Analytical Performance Characteristics (n=71)

PARAMETER	METRICS
Limit of detection	≥0.3% VAF (SNVs, MNVs, Indels)
	log2(r) of 0.09 (Chromosome arm level aneuploidy)

VARIANT TYPE	SENSITIVITY (PPA)	SPECIFICITY (NPA)
SNVs, MNVs, Indels	97%	97%
CNVs	100%	100%
Chromosome Arm Loss/Gain[3]	91%	99%
Fusions	100%	100%
TMB and MSI	100%	N/A

PPA = Positive percent agreement NPA = Negative percent agreement

Large-scale gene profile addresses clinical needs

SNVS, MNVS, INDELS	CNVS (62 GENES)	CHROMOSOME ARM LEVEL LOSS/GAIN	FUSIONS (27 GENES)	KEY BIOMARKERS
520 Genes (see detailed table)	*AKT2, ALK, AR, ATM, BRAF, BRCA1, BRCA2, CCND1, CCND3, CCNE1, CDK4, CDK6, CDKN2A, CDKN2B, CHEK1, CHEK2, EGFR, FGFR2, FGFR3, ERBB2, ERBB3, ERCC1, ERCC2, ESR1, FGF1, FGF10, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF7, FGF8, FGF9, FGFR1, FGFR4, JAK2, KIT, KRAS, LAMP1, MDM2, MDM4, MET, MTAP, MYC, MYCL, MYCN, NRAS, NRG1, PDGFRA, PDGFRB, PIK3CA, PIK3CB, PTEN, RAF1, RICTOR, RPS6KB1, TFRC, RET*	All chromosome arms (only q arms for acrocentric chromosomes 13, 14, 15, 21, and 22)	*ABL1, ALK, BCR, BCOR, BRAF, CD74, EGFR, ETV1, ETV4, ETV6, EWSR1, FGFR2, FGFR3, MET, MYB, NAB2, NTRK1, NTRK2, NTRK3, NUTM1, PAX3, PAX8, PPARG, ROS1, TFE3, TMPRSS2, YAP1*	Tumor Mutational Burden (TMB) Microsatellite Instability (MSI)

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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	

SNVs, MNVs, Indels, CNVs, Fusions, TMB, MSI

*ABL1 **	*CARD11*	*DNMT1*	***FGF4***	*HIST1H3B*	*KIF5B*	***MYCN***	*PIK3CG*	***RICTOR***	*SUZ12*
ABL2	*CASP8*	*DNMT3A*	***FGF5***	*HIST1H3C*	***KIT***	*MYD88*	*PIK3R1*	*RIT1*	*SYK*
ACVR1	*CBFB*	*DNMT3B*	***FGF6***	*HIST1H3D*	*KLF4*	*MYOD1*	*PIK3R2*	*RNF43*	*TBX3*
ACVR1B	*CBL*	*DOT1L*	***FGF7***	*HIST1H3E*	*KLHL6*	*NAB2 **	*PIK3R3*	*ROS1 **	*TCEB1*
AKT1	***CCND1***	*E2F3*	***FGF8***	*HIST1H3F*	*KMT2B*	*NBN*	*PIM1*	*RPS6KA4*	*TCF3*
AKT2	*CCND2*	*EED*	***FGF9***	*HIST1H3G*	*KMT2C*	*NCOA3*	*PLCG2*	***RPS6KB1***	*TCF7L2*
AKT3	***CCND3***	*EGFL7*	***FGF10***	*HIST1H3H*	*KMT2D*	*NCOR1*	*PLK2*	*RPS6KB2*	*TERC*
***ALK **	***CCNE1***	***EGFR **	***FGF14***	*HIST1H3I*	***KRAS***	*NEGR1*	*PMAIP1*	*RPTOR*	*TERT*
ANKRD11	*CD274*	*EIF1AX*	***FGF19***	*HIST1H3J*	***LAMP1***	*NF1*	*PMS1*	*RUNX1*	*TET1*
ANKRD26	*CD276*	*EIF4A2*	***FGF23***	*HIST2H3A*	*LATS1*	*NF2*	*PMS2*	*RUNX1T1*	*TET2*
APC	*CD74 **	*EIF4E*	***FGFR1***	*HIST2H3C*	*LATS2*	*NFE2L2*	*PNRC1*	*RYBP*	*TFE3 **
AR	*CD79A*	*EML4*	***FGFR2 **	*HIST2H3D*	*LMO1*	*NFKBIA*	*POLD1*	*SDHA*	***TFRC***
ARAF	*CD79B*	*EP300*	***FGFR3 **	*HIST3H3*	*LRP1B*	*NKX2-1*	*POLE*	*SDHAF2*	*TGFBR1*
ARFRP1	*CDC73*	*EPCAM*	***FGFR4***	*HLA-A*	*LYN*	*NKX3-1*	*PPARG **	*SDHB*	*TGFBR2*
ARID1A	*CDH1*	*EPHA3*	*FH*	*HLA-B*	*LZTR1*	*NOTCH1*	*PPM1D*	*SDHC*	*TMEM127*
ARID1B	*CDK12*	*EPHA5*	*FLCN*	*HLA-C*	*MAGI2*	*NOTCH2*	*PPP2R1A*	*SDHD*	*TMPRSS2 **
ARID2	***CDK4***	*EPHA7*	*FLI1*	*HNF1A*	*MALT1*	*NOTCH3*	*PPP2R2A*	*SETBP1*	*TNFAIP3*
ARID5B	***CDK6***	*EPHB1*	*FLT1*	*HNRNPK*	*MAP2K1*	*NOTCH4*	*PPP6C*	*SETD2*	*TNFRSF14*
ASXL1	*CDK8*	***ERBB2***	*FLT3*	*HOXB13*	*MAP2K2*	*NPM1*	*PRDM1*	*SF3B1*	*TOP1*
ASXL2	*CDKN1A*	***ERBB3***	*FLT4*	*HRAS*	*MAP2K4*	***NRAS***	*PREX2*	*SH2B3*	*TOP2A*
ATM	*CDKN1B*	*ERBB4*	*FOXA1*	*HSD3B1*	*MAP3K1*	***NRG1***	*PRKAR1A*	*SH2D1A*	*TP53*
ATR	***CDKN2A***	***ERCC1***	*FOXL2*	*HSP90AA1*	*MAP3K4*	*NSD1*	*PRKCI*	*SHQ1*	*TP63*
ATRX	***CDKN2B***	***ERCC2***	*FOXO1*	*ICOSLG*	*MAP3K13*	*NTRK1 **	*PRKDC*	*SLIT2*	*TRAF2*
AURKA	*CDKN2C*	*ERCC3*	*FOXP1*	*ID3*	*MAP3K14*	*NTRK2 **	*PRSS8*	*SLX4*	*TRAF7*
AURKB	*CEBPA*	*ERCC4*	*FRS2*	*IDH1*	*MAPK1*	*NTRK3 **	*PTCH1*	*SMAD2*	*TSC1*
AXIN1	*CENPA*	*ERCC5*	*FUBP1*	*IDH2*	*MAPK3*	*NUP93*	***PTEN***	*SMAD3*	*TSC2*
AXIN2	*CHD2*	*ERG*	*FYN*	*IGF1*	*MAX*	*NUTM1 **	*PTPN11*	*SMAD4*	*TSHR*
AXL	*CHD4*	*ERRFI1*	*GABRA6*	*IGF1R*	*MCL1*	*PAK1*	*PTPRD*	*SMARCA4*	*U2AF1*
B2M	***CHEK1***	***ESR1***	*GATA1*	*IGF2*	*MDC1*	*PAK3*	*PTPRS*	*SMARCB1*	*VEGFA*
BAP1	***CHEK2***	*ETS1*	*GATA2*	*IKBKE*	***MDM2***	*PAK7*	*PTPRT*	*SMARCD1*	*VHL*
BARD1	*CIC*	*ETV1 **	*GATA3*	*IKZF1*	***MDM4***	*PALB2*	*QKI*	*SMC1A*	*VTCN1*
BBC3	*CREBBP*	*ETV4 **	*GATA4*	*IL10*	*MED12*	*PARK2*	*RAB35*	*SMC3*	*WISP3*
BCL10	*CRKL*	*ETV5*	*GATA6*	*IL7R*	*MEF2B*	*PARP1*	*RAC1*	*SMO*	*WT1*
BCL2	*CRLF2*	*ETV6 **	*GEN1*	*INHA*	*MEN1*	*PAX3 **	*RAD21*	*SNCAIP*	*XIAP*
BCL2L1	*CSF1R*	*EWSR1 **	*GID4*	*INHBA*	***MET **	*PAX5*	*RAD50*	*SOCS1*	*XPO1*
BCL2L2	*CSF3R*	*EZH2*	*GLI1*	*INPP4A*	*MGA*	*PAX7*	*RAD51*	*SOX2*	*XRCC2*
BCL2L11	*CSNK1A1*	*FAM123B*	*GNA11*	*INPP4B*	*MITF*	*PAX8 **	*RAD51B*	*SOX9*	*YAP1 **
BCL6	*CTCF*	*FAM175A*	*GNA13*	*INSR*	*MLH1*	*PBRM1*	*RAD51C*	*SOX10*	*YES1*
*BCOR **	*CTLA4*	*FAM46C*	*GNAQ*	*IRF2*	*MLL*	*PDCD1*	*RAD51D*	*SOX17*	*ZBTB2*
BCORL1	*CTNNA1*	*FANCA*	*GNAS*	*IRF4*	*MLLT3*	*PDCD1LG2*	*RAD52*	*SPEN*	*ZBTB7A*
*BCR **	*CTNNB1*	*FANCC*	*GPR124*	*IRS1*	*MPL*	***PDGFRA***	*RAD54L*	*SPOP*	*ZFHX3*
BIRC3	*CUL3*	*FANCD2*	*GPS2*	*IRS2*	*MRE11A*	***PDGFRB***	***RAF1***	*SPTA1*	*ZNF217*
BLM	*CUX1*	*FANCE*	*GREM1*	*JAK1*	*MSH2*	*PDK1*	*RANBP2*	*SRC*	*ZNF703*
BMPR1A	*CXCR4*	*FANCF*	*GRIN2A*	***JAK2***	*MSH3*	*PDPK1*	*RARA*	*SRSF2*	*ZRSR2*
***BRAF **	*CYLD*	*FANCG*	*GRM3*	*JAK3*	*MSH6*	*PGR*	*RASA1*	*STAG1*	
BRCA1	*DAXX*	*FANCI*	*GSK3B*	*JUN*	*MST1*	*PHF6*	*RB1*	*STAG2*	
BRCA2	*DCUN1D1*	*FANCL*	*H3F3A*	*KAT6A*	*MST1R*	*PHOX2B*	*RBM10*	*STAT3*	
BRD4	*DDR2*	*FAS*	*H3F3B*	*KDM5A*	*MTOR*	*PIK3C2B*	*RECQL4*	*STAT4*	
BRIP1	*DDX41*	*FAT1*	*H3F3C*	*KDM5C*	***MTAP***	*PIK3C2G*	*REL*	*STAT5A*	
BTG1	*DHX15*	*FBXW7*	*HGF*	*KDM6A*	*MUTYH*	*PIK3C3*	***RET***	*STAT5B*	**Qualitative** TMB MSI
BTK	*DICER1*	***FGF1***	*HIST1H1C*	*KDR*	*MYB **	***PIK3CA***	*RFWD2*	*STK11*	
C11orf30	*DIS3*	***FGF2***	*HIST1H2BD*	*KEAP1*	***MYC***	***PIK3CB***	*RHEB*	*STK40*	
CALR	*DNAJB1*	***FGF3***	*HIST1H3A*	*KEL*	***MYCL***	*PIK3CD*	*RHOA*	*SUFU*	

Bold Gene Name = CNV * = Fusion

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Traditional CNS tumor detection methods have limitations

CSF CYTOLOGY

- Low sensitivity
- Excludes genomic data

CNS IMAGING

- Lacks specificity in differentiating cancer from inflammatory or non-neoplastic conditions
- Lacks personalized molecular data

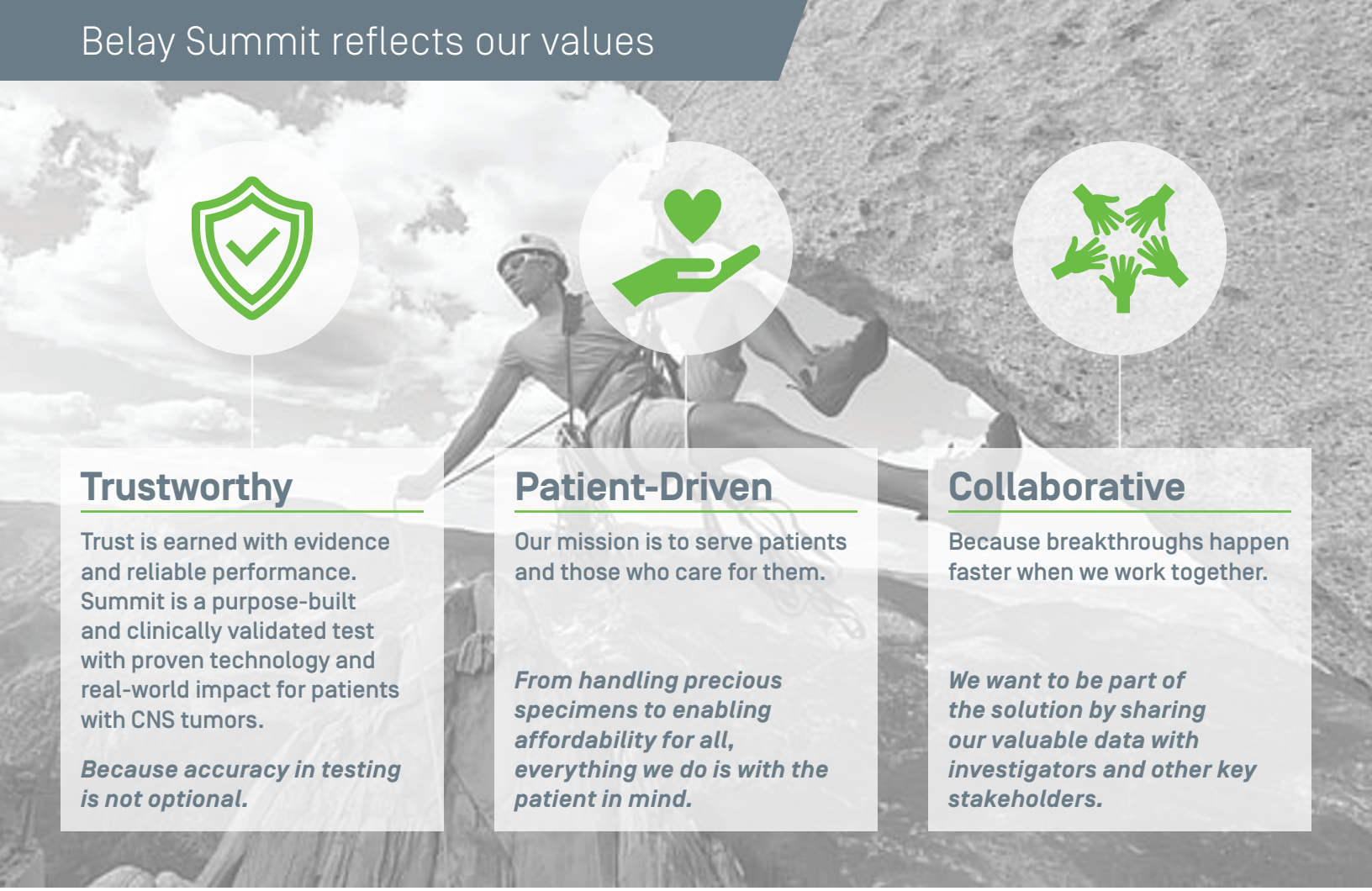
BRAIN BIOPSY

- Highly invasive, risk of hemorrhage, neurological injury, stroke, death
- Nondiagnostic in 10-17% of cases[4,5]
- Significant inter and intra-tumoral heterogeneity
- Biopsy infeasible: brain stem, spinal cord, optic pathway, diffuse midline gliomas, comorbidities

Per NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®):

1. NGS is the preferred method for pathologic workup of CNS tumors[6]
2. Histologically similar CNS neoplasms can be differentiated more accurately in terms of prognosis and in response to different therapies with molecular testing[6]
3. Assessment of circulating tumor DNA or circulating tumor cells increases sensitivity of tumor cell detection and assessment of treatment response specifically in leptomeningeal disease[6]
4. CSF analysis should include flow cytometry, CSF cytology, and cell count, and may consider gene rearrangements, and CSF-tDNA in primary CNS lymphoma[6]
5. When available, CSF-tDNA testing can be considered with CSF cytology to increase sensitivity of tumor cell detection and assessment of residual disease after surgery in adult medulloblastoma. Additionally, molecular profiling to identify clinically relevant subtypes is recommended to encourage opportunities for clinical trial.[6]

Belay Summit reflects our values



Trustworthy

Trust is earned with evidence and reliable performance. Summit is a purpose-built and clinically validated test with proven technology and real-world impact for patients with CNS tumors.

Because accuracy in testing is not optional.

Patient-Driven

Our mission is to serve patients and those who care for them.

From handling precious specimens to enabling affordability for all, everything we do is with the patient in mind.

Collaborative

Because breakthroughs happen faster when we work together.

We want to be part of the solution by sharing our valuable data with investigators and other key stakeholders.

Assay specifications

Sample Requirements	Minimum 6 mLs of CSF
Transport Container	Standard CSF collection tube used at point of collection
Shipping and Transport Temperature	Sample should be collected and placed in shipping box: 1. Ship at room temperature within 24 hours of collection and send priority overnight **OR** 2. Collect and store refrigerated at 4°C for up to 3 days post collection and ship at room temperature priority overnight **OR** 3. Store frozen at -80°C (no time limit) within 2-4 hours of collection and ship on dry ice priority overnight
Methodology	Next-generation sequencing
Orders and Results	Include test requisition in shipping kit or fax form to 800-501-9246. Test results available via fax, encrypted email, or Belay portal.
Turnaround Time	Average 10-14 days from receipt of specimen

References: 1. Park SH, Won J, Kim SI, Lee Y, Park CK, Kim SK, Choi SH. Molecular Testing of Brain Tumor. J Pathol Transl Med. 2017 May;51(3):205-223. doi: 10.4132/jptm.2017.03.08. Epub 2017 May 12. PMID: 28535583; PMCID: PMC5445205. **2.** Shen E, Van Swearingen AED, Price MJ, Bulsara K, Verhaak RGW, Baëta C, Painter BD, Reitman ZJ, Salama AKS, Clarke JM, Anders CK, Fecci PE, Goodwin CR, Walsh KM. A Need for More Molecular Profiling in Brain Metastases. Front Oncol. 2022 Jan 25;11:785064. doi: 10.3389/fonc.2021.785064. PMID: 35145903; PMCID: PMC8821807. **3.** DOI: 10.1016/j.jmoldx.2025.03.010 **4.** Bander, E.D., Jones, S.H., Pisapia, D. et al. Tubular brain tumor biopsy improves diagnostic yield for subcortical lesions. J Neurooncol 141, 121–129 (2019). https://doi.org/10.1007/s11060-018-03014-w **5.** Malone H, Yang J, Hershman DL, Wright JD, Bruce JN, Neugut AI. Complications Following Stereotactic Needle Biopsy of Intracranial Tumors. World Neurosurg. 2015;84(4):1084-1089. doi:10.1016/j.wneu.2015.05.025 **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed June 23, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.

This test was developed, and its performance characteristics determined by Belay Diagnostics, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). This test may be used for clinical purposes.

 TB200 10/10/25

BELAY DIAGNOSTICS