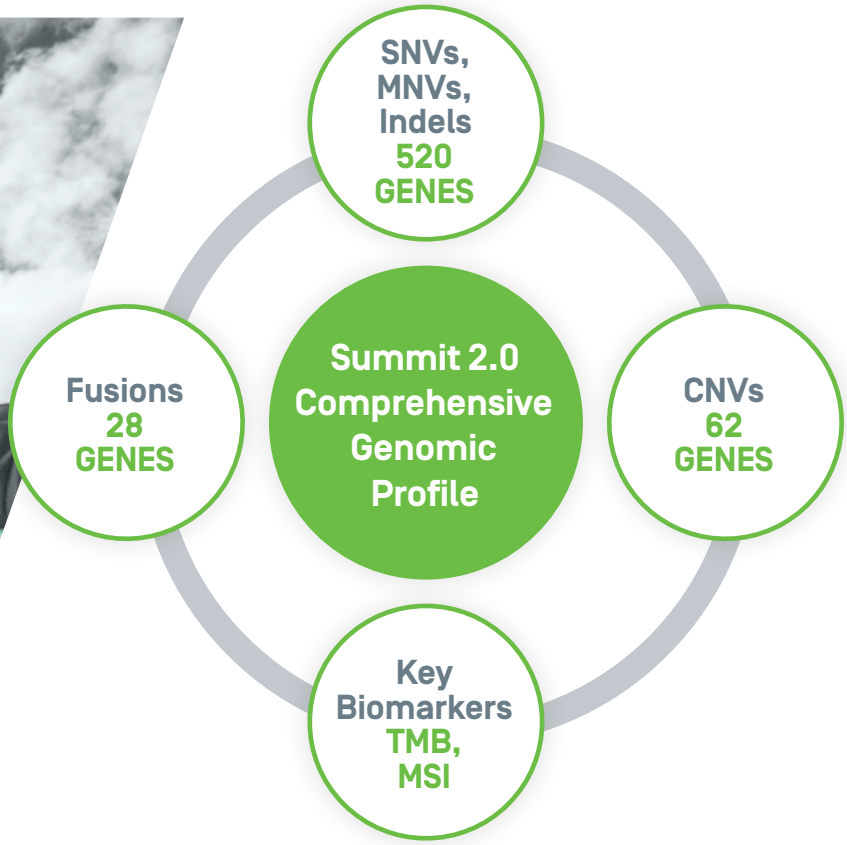
Belay Summit™ 2.0

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] **in adult and pediatric patients**
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

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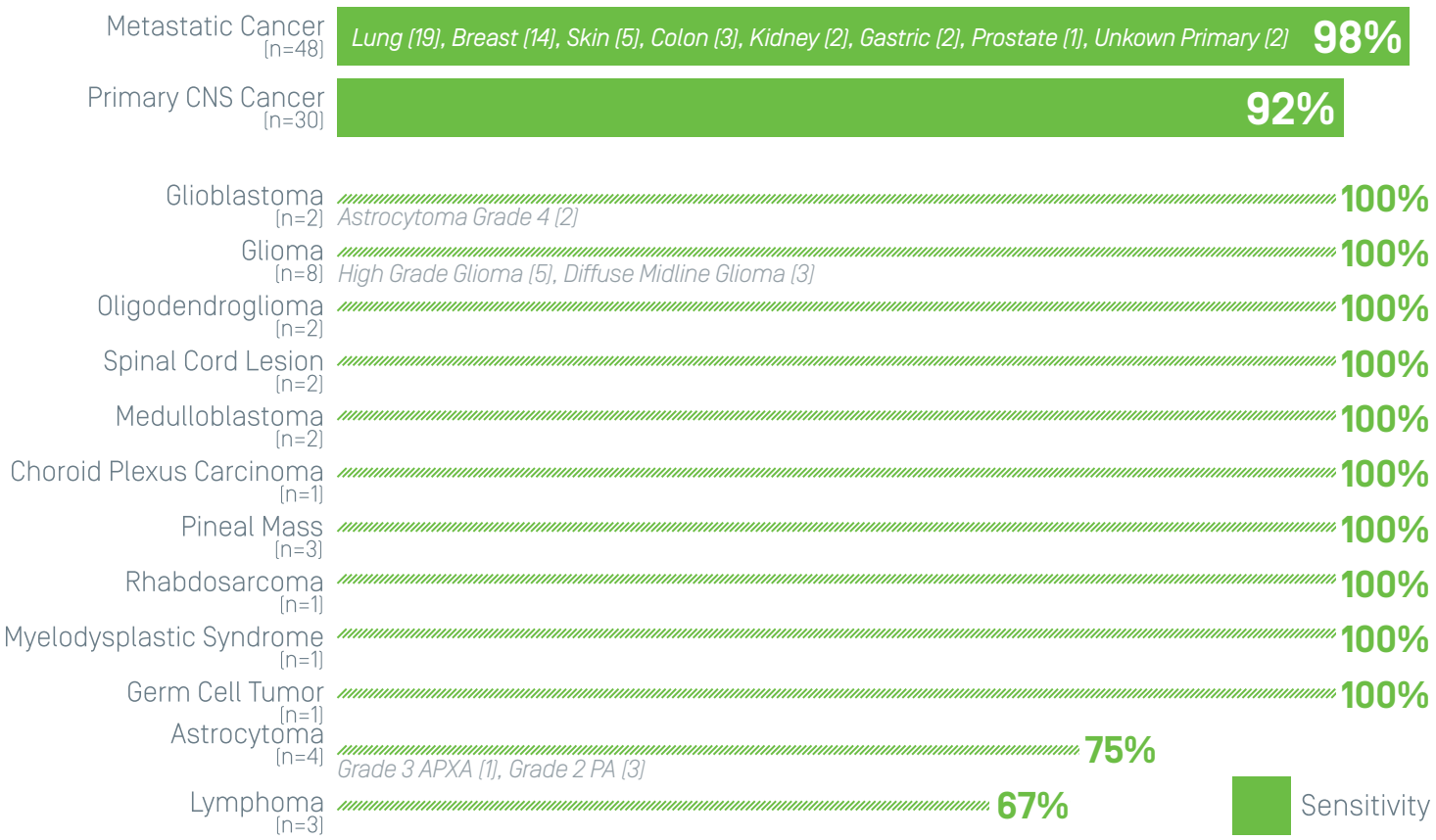
Summit 2.0 Clinical Sensitivity (n=118)

Sensitivity **96%** | Specificity **98%**



Large-scale gene profile addresses clinical needs

SNVS, MNVS, INDELS	CNVS (62 GENES)	FUSIONS (28 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*	*ABL1, ALK, BCR, BRAF, CD74, EGFR, ETV1, ETV4, ETV6, EWSR1, FGFR1, FGFR2, FGFR3, MET, MYB, MYC, NAB2, NTRK1, NTRK2, NTRK3, NUTM1, PAX3, AX8, PPARG, ROS1, TFE3, TMPRSS2, YAP1*	Tumor Mutational Burden (TMB) Microsatellite Instability (MSI)

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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	**Qualitative**
BTG1	DHX15	FBXW7	HGF	KDM6A	MUTYH	PIK3C3	**RET**	STAT5B	TMB
BTK	DICER1	**FGF1**	HIST1H1C	KDR	MYB *	**PIK3CA**	RFWD2	STK11	MSI
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

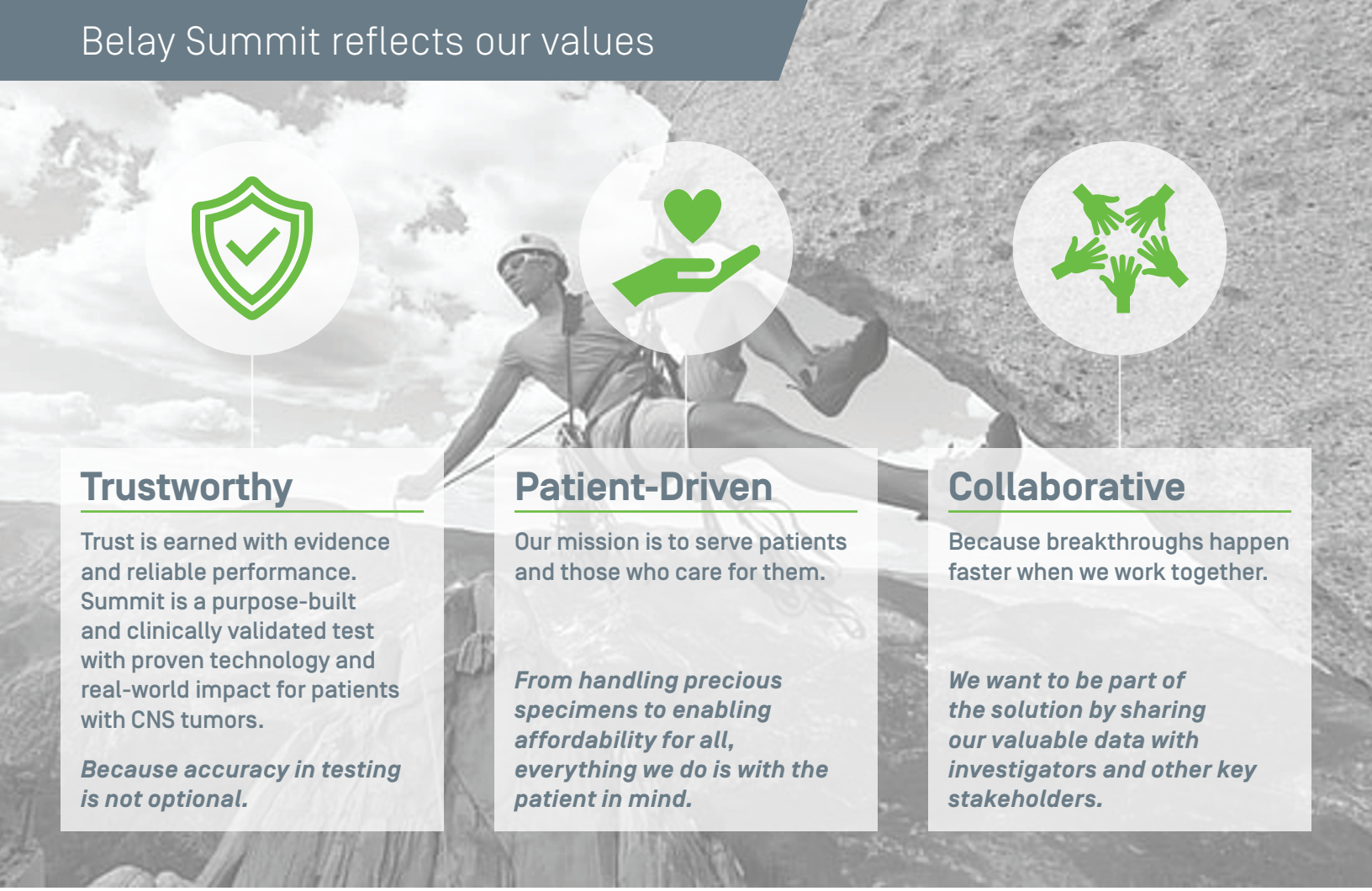
BRAIN BIOPSY

- 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 CSF-tDNA 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 and adult intracranial and spinal ependymoma**. 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.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed December 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 12/31/25

BELAY DIAGNOSTICS