Belay Summit™

multi-analyte tDNA in CSF

BELAY DIAGNOSTICS

Summit detects mutations and aneuploidy from tumor-derived DNA in CSF to help inform the diagnosis and management of primary and secondary CNS malignancies.

Advanced liquid biopsy in CSF

WHY CHOOSE BELAY SUMMIT?

1. Sequencing of tDNA in CSF can identify genetic alterations commonly associated with CNS cancers, and may ultimately preempt tumor biopsy in certain instances[1]
2. Collection of CSF is well tolerated and currently included in the standard of care for patients with suspicion of CNS tumors
3. Turnaround time is average 7-10 business days from receipt of specimen

Traditional CNS tumor detection options have limitations:

CSF CYTOLOGY	• Low sensitivity • Excludes genomic data • Requires substantial volume of CSF [>10 mL][2]
CNS IMAGING	• Lacks specificity in differentiating cancer from inflammatory or non-neoplastic conditions • Multiple MRIs often necessary to inform diagnosis
BRAIN BIOPSY	• Insufficient volume or integrity of tissue for sampling and molecular testing • Highly invasive, risk of hemorrhage, neurological injury, stroke, death • Nondiagnostic in up to 17% of cases[3] • Significant inter and intra-tumoral heterogeneity • Inoperable cases such as brain stem, spinal cord, optic pathway and diffuse midline gliomas, preexisting conditions, pediatric patients

Scaling new heights in neurologic insights

Genes evaluated for select SNVs, MNVs, and INDELs

AKT1	*CDH1*	*ERBB2*	*FGFR2*	*GNAS*	*IDH2*	*NRAS*	*SMAD4*
APC	*CDKN2A*	*ERBB3*	*FGFR3*	*H3F3A**	*KRAS*	*PIK3CA*	*TERT*
BRAF	*CTNNB1*	*ERCC2*	*FUS*	*HRAS*	*MYD88*	*PTEN*	*TP53*
CD79B	*EGFR*	*FBXW7*	*GATA3*	*IDH1*	*NFE2L2*	*RAF1*	*VHL*

SNV=single nucleotide variant; MNV=multinucleotide variant; INDEL=insertion and deletion
*Also known as H3-3A

Additional information about Belay Summit

BELAY SUMMIT ASSAY SPECIFICATIONS

Sample Requirements	≥ 6 mL of CSF
Transport Container	Standard CSF collection tube
Shipping	Must be shipped within 24 hours of CSF collection and received within 48 hours at Belay Diagnostics. Ship to Belay Diagnostics in Belay shipping kit.
Transport Temperature	Maintain specimen at room temperature. Do not freeze or refrigerate.
Methodology	Next-generation sequencing
Orders & Results	Include test requisition in shipping kit or fax form to 800-501-9246. Test results available via fax or encrypted email.
Turnaround Time	Average 7-10 business days

References: 1. Wen PY, Weller M, Lee EQ, et al. Glioblastoma in adults: a Society for Neuro-Oncology (SNO) and European Society of Neuro-Oncology (EANO) consensus review on current management and future directions. *Neuro Oncol*. 2020;22(8):1073-1113. doi:10.1093/neuonc/noaa106 **2.** Douville C, Curtis S, Summers M, et al. Seq-ing the SINEs of central nervous system tumors in cerebrospinal fluid. *Cell Rep Med*. 2023;4(8):101148. doi:10.1016/j.xcrm.2023.101148 **3.** 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

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.

Belay™, Belay Diagnostics™, SUMMIT™, any associated logos, and all associated Belay Diagnostics registered or unregistered trademarks are property of Belay Diagnostics.

© 2024 Belay Diagnostics. All Rights Reserved. TB100-v4 11/2024

BELAY DIAGNOSTICS