Belay Summit™
multi-analyte tDNA in CSF

ASSAY SPECIFICATIONS

ABOUT BELAY SUMMIT
Summit next-generation sequencing test investigates tumor derived DNA (tDNA) extracted from cerebrospinal fluid (CSF) for clinically relevant variants including single nucleotide, multi nucleotide, and insertion/deletion variants, along with chromosomal aneuploidies associated with primary and metastatic central nervous system cancers.

METHODOLOGY
Methodology involves targeted duplex sequencing of 32 key genes (SNVs, MNVs and Indels) and low pass whole genome sequencing (>0.1x) for the detection of chromosomal arm level loss or gain and aneuploidy. Post target enrichment libraries, generated from 20-40ng of tDNA, are sequenced on the Illumina® NovaSeq XPlus, generating 100 bp paired-end sequence reads. The LOD (limit of detection) for SNVs, MNVs and Indels was determined as 0.3% variant allelic fraction (VAF). Variants (mutations and aneuploidy) are called against the human genome build reference hg19 using the Summit™ Genome Analytics (SGA) pipeline, developed at Belay Diagnostics.

INTENDED USE
Summit uses tDNA to aid in the detection and molecular characterization of primary and secondary CNS tumors to help inform diagnosis and treatment in patients with suspicion of brain tumors.

GENE PANEL

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*

TEST SPECIFICATIONS

Specimen Requirement	Collect >= 6 mL of CSF in standard CSF tubes.
Transport Temperature	Maintain specimen at room temperature. Do not freeze or refrigerate.
Shipping	Specimen must be shipped within 24 hours of collection and received at Belay Diagnostics within 48 hours of collection.
Shipping Kit	Send specimen to Belay Diagnostics in Belay shipping kit. Request kits from Customer Service at 331-320-0155 or contact@belaydiagnostics.com.
Orders and Results	Fax Belay Test Requisition Form to 800-501-9246. Test results available via fax or encrypted email.
Turnaround Time	Average 7-10 business days.

PERFORMANCE SPECIFICATIONS

Alteration Type	Limit of Detection at > 95% Sensitivity[1]	Analytical Specificity	Threshold for Positivity[2]
SNVs, MNVs, INDELs	0.3% VAF	> 99.9%	≤ 20ng – 0.12% 21-40ng – 0.03%
Aneuploidy	Chromosome arm level	> 99.9%	N/A

[1] Limit of Detection (LoD) is defined as the variant allelic fraction at which the test has a 95% probability of detecting an oncogenic variant.
[2] Lowest mutant allelic fraction detected for SNVs, MNVs and Indels @20ng DNA input.
SNV - Single nucleotide variant; MNV - Multi-nucleotide variant; INDEL - Insertions and deletions.

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Belay Diagnostics in a manner consistent with CLIA requirements.

BELAY DIAGNOSTICS