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	<i>РІКЗСА</i>	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.Maintain specimen at room temperature. Do not freeze or refrigerate.Specimen must be shipped within 24 hours of collection and received at Belay Diagnostics within 48 hours of collection.			
Transport Temperature				
Shipping				
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

¹Limit of Detection (LoD) is defined as the variant allelic fraction at which the test has a 95% probability of detecting an oncogenic variant. ²Lowest 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™, Belay Diagnostics™, SUMMIT™, VANTAGE™, any associated logos, and all associated Belay Diagnostics registered or unregistered trademarks are property of Belay Diagnostics. All third-party marks — ® and ™ — are the property of their respective owners. ©2024 Belay Diagnostics. All rights reserved. AS100 10/2024

