Belay Vantage™

MGMT promoter methylation in CSF

ASSAY SPECIFICATIONS

ABOUT BELAY VANTAGE

Vantage test evaluates *MGMT* (O-6-methylguanine-DNA methyltransferase) promoter methylation status in tumor derived DNA (tDNA) extracted from cerebrospinal fluid of known or suspected central nervous system tumors.

METHODOLOGY

Methodology utilizes a quantitative PCR (qPCR) followed by high-resolution melt analysis using the MethylDetect® kit after enzymatic conversion (NEBNext Enzymatic Methyl-seq, New England Biolabs®) on a portion of the library generated in the Summit™ workflow. Methylated and unmethylated melting temperature peaks are evaluated using the LightCycler® 480 Software v.1.5.1 (Roche® LifeScience). Qualitative results are reported as "Negative - Unmethylated", "Positive - Methylated" (for specimens with results above the validated 25% methylated control), or "Indeterminate Results were equivocal" (for specimens with results between unmethylated and methylated control).

INTENDED USE

Vantage uses tDNA to provide prognosis for newly diagnosed high grade glioma patients.[1] This corresponds to better therapeutic response to alkylating agents (e.g. temozolomide).

TEST SPECIFICATIONS

Sample Requirement	Collect minimum 6mL of CSF in standard CSF tube.
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.
Belay 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

Limit of Detection at > 95% Sensitivity[2]	Analytical Specificity	Threshold for Positivity[3]
> 25% Methylation	> 99.9%	≥ 20ng (via Summit™ workflow) ≥ 5ng (directly from CSF derived tumor DNA)

[1]Horbinski C, Ligon KL, Brastianos P, et al. The medical necessity of advanced molecular testing in the diagnosis and treatment of brain tumor patients. Neuro Oncol. 2019 Dec 17;21(12):1498-1508. doi: 10.1093/neuonc/noz119. PMID: 31276167; PMCID: PMC6917404

[2]Limit of Detection (LoD) is defined as the percent of methylation at which the test has a 95% probability of detecting methylation status.

[3]Lowest input of DNA for detection of methylation.

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