Belay Vantage™

MGMT promoter methylation in CSF

BELAY DIAGNOSTICS

Vantage uses quantitative polymerase chain reaction to evaluate *MGMT* promoter methylation in cerebrospinal fluid of individuals with known or suspected central nervous system tumors.

An advanced approach to determining *MGMT* promoter methylation status

WHY CHOOSE BELAY VANTAGE?

1. Analysis in CSF sample is less invasive than brain biopsy
2. Assay uses a highly effective enzymatic conversion method, minimizing DNA damage[1]
3. Vantage™ can be ordered concomitantly with Summit™ testing, using same patient specimen
4. Collection of CSF is well tolerated and included in the standard of care for many patients with suspicion of CNS tumors
5. Turnaround time is average 7-10 business days from receipt of specimen

MGMT promoter methylation testing is recommended in all high-grade gliomas.[2]

CLINICAL SIGNIFICANCE

- *MGMT*, a DNA suicide repair enzyme, encodes O-6-methylguanine-DNA methyltransferase[2]
- Gene suppression or methylation of the *MGMT* gene promoter decreases its DNA-repair function
- Epigenetic modification of the CpG island at specific sites within the *MGMT* promoter silences the gene[3] and reduces expression, making tumors more sensitive to alkylating chemotherapies

Scaling new heights in neurologic insights

MGMT promoter methylation informs treatment decisions

- Serves as a predictive biomarker for temozolomide (TMZ) response in patients with *IDH1*-wild-type malignant gliomas.[4]
- Prognostic in gliomas with *IDH1* mutation treated with combined TMZ chemo-irradiation and associated with extended progression-free survival.[4]
- Median survival increases 50% in glioblastoma patients when treated with TMZ if *MGMT* promoter is methylated.[5]
- TMZ has little effect in GBM patients when *MGMT* is unmethylated.[5]

Additional information about Belay Vantage

BELAY VANTAGE ASSAY SPECIFICATIONS

Clinical Performance	Positive - Methylated / Negative - Unmethylated / Indeterminate
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 specimen shipping kit.
Transport Temperature	Maintain specimen at room temperature. Do not freeze or refrigerate.
Methodology	Quantitative PCR (qPCR) followed by high-resolution melt analysis
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. New England Biolabs, Inc. NEBNext® Enzymatic Methyl-seq (EM-seq™). Updated April 2019. Accessed May 20, 2024. https://www.neb.com/-/media/nebus/files/application-notes/technote_nebnext_enzymatic_methyl-seq.pdf?rev=015e017f782a4bc9b50b61f1b0f3c807 **2.** 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. **3.** Mansouri A, Hachem LD, Mansouri S, et al. MGMT promoter methylation status testing to guide therapy for glioblastoma: refining the approach based on emerging evidence and current challenges. Neuro Oncol. 2019;21(2):167-178. doi:10.1093/neuonc/noy132 **4.** Wick W, Meisner C, Hentschel B, et al. Prognostic or predictive value of *MGMT* promoter methylation in gliomas depends on IDH1 mutation. *Neurology*. 2013;81(17):1515-1522. doi:10.1212/WNL.0b013e3182a95680 **5.** 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

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.

 TB101-v4 11/2024

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