

Belay Vantage™

MGMT promoter methylation in CSF

BELAY
DIAGNOSTICS

Vantage uses quantitative polymerase chain reaction to evaluate *MGMT* promoter methylation in CSF of individuals with known or suspected CNS tumors.

An advanced approach for ascertaining methylation status

WHY CHOOSE BELAY VANTAGE?

- 1 Analysis in CSF sample is less invasive than brain biopsy
- 2 *MGMT* promoter methylation testing is recommended in all high-grade gliomas.¹
- 3 Serves as a predictive biomarker for temozolomide (TMZ) response in patients with *IDH1*-wild-type malignant gliomas.²
- 4 Prognostic in gliomas with *IDH1* mutation treated with combined TMZ chemo-irradiation and associated with extended progression-free survival.²
- 5 Median survival increases 50% in glioblastoma patients when treated with TMZ if *MGMT* promoter is methylated.³

As published in *Cancer Genetics*,⁴ Vantage demonstrates accuracy and precision in measuring *MGMT* status:

Sensitivity **96%**

Specificity **100%**



Epigenetic regulation

- / *MGMT*, a DNA suicide repair enzyme, encodes O-6-methylguanine-DNA methyltransferase¹
- / Gene suppression or methylation of the *MGMT* gene promoter decreases its DNA-repair function and reduces expression, making tumors more sensitive to alkylating chemotherapies

Assay specifications

Clinical Performance	Positive - Methylated / Negative - Unmethylated / Indeterminate
Sample Requirements	≥ 6 mL of CSF. A sample <6 mL of CSF will be processed and results reported provided the sample meets established reporting thresholds
Transport Container	Standard CSF collection tube used at point of collection
Shipping and Transport Temperature	Sample should be collected and placed in shipping box: Ship at room temperature within 24 hours of collection and send priority overnight OR Collect and store refrigerated at 4°C for up to 3 days post collection and ship at room temperature priority overnight OR Store frozen at -80°C (no time limit) within 2-4 hours of collection and ship on dry ice priority overnight
Methodology	Quantitative PCR 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, encrypted email, or Belay portal.
Turnaround Time	Average 7-10 days from receipt of specimen

References: **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.** 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 **3.** 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 **4.** <https://doi.org/10.1016/j.cancergen.2025.04.001>

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.

