

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
Collection and Sample Requirements	Collect ≥ 6 mL of CSF in your institution's standard CSF tubes. Samples < 6 mL will be processed and results reported if established reporting thresholds are met. Wrap tubes in Parafilm, if available, to prevent leakage. Label each tube with the collection date and two unique patient identifiers matching those on Test Requisition Form (TRF).
Temperature Control	Shipping within 24 hours of collection: Maintain specimens at room temperature. Specimens must be received at Belay within 4 calendar days of collection. Shipping 1-3 days after collection: Refrigerate within 4-6 hours of collection. Ship at ambient temperature. Specimens must be received at Belay within 2 calendar days of shipment. Shipping after more than 3 days: Freeze at -80°C within 4-6 hours of collection. Ship on dry ice. Note, frozen samples cannot be shipped in Belay shipping kits and require alternate shipping containers provided by the client.
Packing and Shipping	Open Belay shipping kit and remove contents. Activate temperature tracker and attach to biohazard bag. Insert labeled tubes into absorbent sleeve, place in biohazard bag, and seal. Wrap the gel blanket around the biohazard bag, place inside Styrofoam container, and close lid. Place the TRF, signed informed consent, and any clinical reports on top of Styrofoam container and close outer lid. Place kit inside provided FedEx bag, seal, add FedEx label, and schedule pickup or include in your standard pickup procedures.
Methodology	Quantitative PCR followed by high-resolution melt analysis
Orders and Results	Include TRF in shipping kit or fax form to 800-501-9246. Test results available via fax, encrypted email, or Belay portal.
Turnaround Time	Average 10-14 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.cancer.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.

