BELAY DIAGNOSTICS

Date: 05/26/2026
Order ID: Van-Neg-CNS

1375 W. Fulton Street, Suite 530
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Vantage™ Report

Patient Information	Provisional Diagnosis	Specimen	Provider Information
Name: Jane Doe **DOB**: 01/01/1990 **Sex Assigned at Birth:** Female **MRN**: 11xx22xx33	**Diagnosis:** Central Nervous System Neoplasm **ICD10:** C71.9	**Type:** CSF **Collected Date:** 05/14/2026 **Received Date:** 05/15/2026 **Specimen ID:** Van-Neg-CNS	**Ordering Provider:** Provider Test **Institution:** Belay Diagnostics

RESULT SUMMARY

NEGATIVE - Methylation of the *MGMT* promoter was NOT detected.

ACTIONABILITY SUMMARY

Therapies with Resistance/Decreased Response	
Therapy	**Setting**
temozolomide	Patients with glioblastoma that is not *MGMT* promoter methylated derive less benefit from treatment with TMZ compared to those whose tumors are methylated (PMID: 15758010).

Honey V Reddi, Ph.D., FACMG, Laboratory Director

TEST DETAILS

Methods and Limitations

The Vantage™ *MGMT* Promoter Methylation Assay utilizes a quantitative PCR (qPCR) followed by high-resolution melt analysis (HRM) using the EpiMelt MGMT kit (MethylDetect) 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”, or “Indeterminate – Results were equivocal”. Specimens with results above the validated 25% methylated control are interpreted as “Positive”. Specimens with results between unmethylated and methylated control are interpreted as “Indeterminate”.

Disclaimers

This test was developed, and its performance characteristics determined by Belay Diagnostics Laboratory (CLIA# 14D2302605), which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). This test may be used for clinical purposes. However, the results of this test do not establish a diagnosis and should not be used alone for diagnosis or patient care decisions or otherwise replace the judgment of a treating physician and must always be interpreted in the context of all relevant clinical and pathological data.

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Actionability References