MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: June 16, 2026
Effective Date: June 18, 2026

LiquidHALLMARK CSF

Test ID: LUCSF

Useful for:
Genomic profiling of suspected primary brain tumors or brain or leptomeningeal metastases for predicting prognosis and identifying matched targeted therapies or emerging resistance mechanisms

This test is **not useful for** prenatal screening.

Clinical Information:
LiquidHALLMARK CSF enables genomic profiling of cerebrospinal fluid (CSF) cell-free DNA to detect clinically relevant and actionable alterations associated with FDA-approved and emerging therapies, including key biomarkers such as *EGFR, BRAF, KRAS, ERBB2,* and *H3 (histone) gene mutations*, as well as other guideline-recommended targets.

In patients with suspected or confirmed CNS or leptomeningeal metastases, CSF-based analysis can complement tissue and plasma testing by improving detection of tumor-derived alterations within the central nervous system. Results may support therapy selection and provide insight into molecular evolution and treatment response over time.

This test is intended as an adjunct to standard diagnostic approaches and is not a substitute for primary diagnosis.

Genetics Information:
This test uses amplicon-based next-generation sequencing (NGS) to determine single nucleotide variants (SNVs, including cis-trans), deletions and insertions (delins), copy number variations (CNVs), and microsatellite instability (MSI). Circulating tumor DNA (ctDNA) is used to detect somatic (ie, tumor specific) mutations in 81 genes.

Note: This test is performed to evaluate for somatic (ie, tumor-specific) mutations. Although germline (ie, inherited) alterations may be detected, this test cannot distinguish between germline variants and somatic mutations with absolute certainty.

Methods:
Amplicon-Based Next-Generation Sequencing

Reference Values:
An interpretive report will be provided

Specimen Requirements:

Specimen Type:	Cerebral Spinal Fluid
Container/Tube:	Sterile Specimen Tube, 6 mL (T485)
Specimen Volume:	5 mL
Collection Instructions:	1. Perform lumbar puncture and discard the first 1 mL to 2 mL of cerebrospinal fluid (CSF). 2. Collect CSF directly into a sterile tube. 3. Inspect specimen for visible discoloration. **Specimen must be clear and colorless to perform testing.** 4. Freeze sample upright prior to placing in transport container. 5. Send frozen.
Minimum Volume:	1 mL

Necessary Information:

1. Order questions are required for testing to proceed.
If not ordering electronically, submit LiquidHALLMARK Patient Information with the specimen.
2. A pathology report is recommended. Testing may proceed without this information; however, it aids in providing a more thorough and accurate interpretation of results. Ordering healthcare professionals are strongly encouraged to provide the information and send it with the specimen.

Specimen Stability Information:

Specimen Type	Temperature	Time
CSF	Frozen	30 days

Cautions:

This report reflects the analysis of DNA from an extracted nucleic acid sample, and in very rare cases (for example, bone marrow transplant or recent blood transfusion) the analyzed DNA may not reflect the patient's genome, leading possibly to false negative and/or false positive results. Nucleic acid studies do not constitute a definitive test for the selected conditions in all individuals.

This circulating tumor (ct) DNA test is clinically validated for CSF specimens only.

It should be realized that there are possible sources of error. Errors can result from trace contamination, rare technical errors, rare genetic variants that interfere with analysis, recent scientific developments, and alternative classification systems.

Test sensitivity may be altered based on factors such as excessive cell lysis before processing, sampling during treatment, tissue heterogeneity, and the relative yield of circulating nucleic acids from sample.

Sensitivity of this test has been determined for the test methodology for a set of variants that do not necessarily include those identified in the report. Sensitivity and specificity data for all variants reported are not available. Where reported allele frequencies fall below 0.1% (single nucleotide variations/deletions-insertions), absolute number of variant reads supporting the call are considered, but specificity data is not available on this. Deletions or insertions involving more than 30 base pairs may not be reliably detected by the sequencing

methodology. Although most of the intended targeted regions are sequenced in their entirety, some regions may be incompletely covered due to technical limitations. Therefore, absence of a detected variant in these regions and in regions not covered by this test does not exclude the presence of a disease-causing variant. Intronic variants and synonymous substitutions are not reported unless previously documented as clinically significant. Variants classified as benign or likely benign in ClinVar and/or variants with population allele frequency (in external or internal databases) of greater than 1% (non-founder mutations) are not reported.

This test is not intended for and cannot confirm germline status in any manner. Variants detected may be of tumor-derived somatic, germline, or non-tumor somatic origins, including mosaicism, clonal hematopoiesis of indeterminate potential (CHIP). Genes with alterations that may be derived from CHIP include, but are not limited to, *ASXL1, ATM, CBL, DNMT3A, JAK2, MPL, MYD88, SF3B1, TET2, TP53,* and *U2AF1*. Clinical correlation is recommended. Genetic counseling may be considered if deemed appropriate clinically.

The absence of ctDNA findings may correlate with low systemic disease volume or disease that is being effectively treated. It is also possible that there are genomic alterations in targets not included in the panel or others not detectable by this analysis due to inherent analytical limitations.

This test should be one of many aspects used by the treating healthcare professional to help with a diagnosis and treatment plan, but it is not a diagnosis itself. Clinical diagnosis provided by the treating healthcare professional is used to determine the relevant indication for determining appropriate clinical actionability/evidence and matching clinical trials, presentation of which may be adversely affected in cases of incomplete or incorrect diagnosis information provided. Any mention of pharmacologic agents or their on-label or off-label use should not be considered as a recommendation or endorsement for therapeutic use. Approved indications for the listed therapies may have additional criteria of medical and treatment history and combination chemotherapy. Percentage map is for visualization purposes only and is not drawn to scale. Clinical correlation is advised. Past treatment or mutation history is not being considered for selection of clinical trials presented. Clinical correlation and suitability with specific trial's inclusion and exclusion criteria are advised. Drug and clinical trial information are obtained from curated databases including NCI thesaurus and ClinicalTrials.gov. Clinical trial curated database is updated with trials verified within the last month. Tiering of clinical actionability/evidence associated with a drug recommendation may be updated in source data but not reflected as at the time of the report. For latest information, refer to the US Food and Drug Administration website and the respective source data websites for professional guidelines.
Lucence does not warrant that the data from such third-party databases, websites, or guidelines are accurate, complete, or up to date and excludes all liability for any loss or damage howsoever arising as a result of any reliance on the accuracy of the data.

CPT Code:
81455

Day(s) Performed: Monday through Friday **Report Available:** 8 to 12 days

Questions
Contact Sarah Wittwer, Laboratory Resource Coordinator at 800-533-1710.