BELAY DIAGNOSTICS™

1375 W Fulton St., Suite 530,
Chicago, IL 60607
contact@belaydiagnostics.com
P: 331-320-0155
F: 800-501-9246

Sample Collection	
Date*:	(MM/DD/YY)
Time*:	XX:XX am/pm
Kit #:	_____

Belay Lab Use Only

*Required. If required fields are not provided, testing may be delayed.

PATIENT INFORMATION

Last Name*	Middle Name	**First Name***
Date of Birth* (MM/DD/YY)	Sex at birth: ○ Male ○ Female	MRN
Phone	**Email Address***	
Street Address		
City	State	Zip

Ancestry (select all that apply):

- ○ Ashkenazi Jewish
- ○ Asian
- ○ Black/African American
- ○ Hispanic/Latino
- ○ Middle Eastern
- ○ Native American
- ○ Pacific Islander
- ○ White/Non-Hispanic
- ○ Unknown
- ○ Other: _____

ORDERING CLINICIAN INFORMATION

Clinician Name*	**NPI #***
Account#/Clinic/Institution*	Phone #
Street Address	
City	State / Zip
Additional Recipient	Email or Fax

BILLING INFORMATION

Place of Service*

- ○ inpatient
- ○ ER
- ○ outpatient
- ○ non-hospital

For inpatient, registered outpatient or ER patients, please contact Belay Diagnostics for the correct requisition form to use.

Belay Diagnostics will directly bill non-hospital patients and certain hospital outpatients for testing ordered pursuant to this test requisition based on the billing information provided by the patient in the informed consent on the back of this form.

PROVISIONAL DIAGNOSIS

Example: Glioma

ORDER CHOICE* & SPECIMEN REQUIREMENTS

○ **Summit™ and/or** ○ **Vantage™**

≥6mLs of CSF collected in a sterile tube via:

○ Lumbar Puncture ○ Ommaya reservoir ○ Ventricular Catheter
○ Aspiration of CSF Space: ○ Ventricle ○ Cistern ○ Other

This laboratory does not accept specimens from Creutzfeldt-Jacob Disease (CJD) or other prion-disease patients

SUMMIT™ TEST PANEL

Genes evaluated for select SNVs, MNVs, and Indels

AKT1	*CDH1*	*ERBB2*	*FGFR2*	*GNAS*	*IDH2*	*NRAS*	*SMAD4*
APC	*CDKN2A*	*ERBB3*	*FGFR3*	*H3F3A*	*KRAS*	*PIK3CA*	*TERT*
BRAF	*CTNNB1*	*ERCC2*	*FUS*	*HRAS*	*MYD88*	*PTEN*	*TP53*
CD79B	*EGFR*	*FBXW7*	*GATA3*	*IDH1*	*NFE2L2*	*RAF1*	*VHL*

Additional molecular markers evaluated

Aneuploidy (Chromosome Arm-level loss or gain)

VANTAGE™ TEST

MGMT promoter methylation status

PATIENT HISTORY

Cancer History Questions	Yes	No	Unknown
Does the patient have a history of cancer? (If "Yes", complete "Primary Cancer Data" to the right)	○	○	○
Has the patient undergone biopsy or resection? (If "Yes", attach pathology or cytology report)	○	○	○
If "Yes", has genomic profiling on tumor been completed for the patient? (If "Yes", attach genomic profiling report)	○	○	○
Has the patient received/currently receiving chemotherapy?	○	○	○
Has patient received/currently receiving radiotherapy?	○	○	○

Primary Cancer Data (complete if answered "yes" to history of cancer):

- ○ Brain
- ○ Breast
- ○ Colon
- ○ Kidney
- ○ Lung
- ○ Lymphoma
- ○ Melanoma
- ○ Prostate
- ○ Other (please specify):

CA Stage:

Date of DX: (MM/DD/YY)

○ Pathology Report Attached

○ Genomic Profiling Report Attached

Was CSF cytology testing performed? ○ Yes ○ No ○ Unknown
If yes, the results are: ○ Negative ○ Positive

Clinician Notes/Intraoperative Interpretation

ICD10/Diagnostic Codes: https://www.icd10data.com/ICD10CM/Codes/R00-R99/R90-R94/R94-/R94.02

○ C 71.0 - C 71.9	Malignant neoplasm of the brain
○ C 79.31	Secondary malignant neoplasm of the brain
○ Z 85.841	Personal history of malignant neoplasm of the brain
○ D 32.9	Benign neoplasm of the meninges, unspecified, meningioma, meningioma of brain
○ D 32.0	Benign neoplasm of cerebral meninges, intracranial meningioma, meningioma of brain
○ R 94.02	Abnormal brain scan
○ D 33.2	Benign neoplasm of brain, unspecified
○ G 06.0	Intracranial abscess and granuloma
○ G 93.9	Disorder of brain, unspecified
○ Other:	

MEDICAL NECESSITY AND ORDERING PROVIDER AUTHORIZATION

I am the patient's treating physician and my signature certifies: (1) I am authorized under applicable law to order the tests on this test requisition form; (2) the clinical information entered on this form is accurate and this test is medically necessary; (3) I have prepared documentation demonstrating the medical necessity of the test, included it in the patient's medical record, and will make it available to Belay upon request; (4) I will use the test results to inform my treatment decisions and medical management of the patient; (5) I have explained the nature, purpose, potential benefits, risks, and alternatives to the patient, and the patient has had the opportunity to ask questions regarding the test including the collection, use, and disclosure of their sample and health information; and (6) I have obtained informed consent from the patient to have the test performed using the consent form enclosed with this test requisition form, notified the patient they may receive a copy of this informed consent for their records, and will provide a copy of this informed consent to Belay upon request.

Ordering Clinician/Authorized Signature*: _____ **Date*:** _____

☐ **By checking this box, I confirm that I have discussed Belay's billing options, including if applicable the Assay Evolution Program Protocol, with the patient, and the patient requests that Belay provide the patient with additional information regarding such options**

BELAY DIAGNOSTICS

INFORMED CONSENT FOR SAMPLE RELEASE, TESTING, AND FINANCIAL RESPONSIBILITY

Patient Full Name:_____ Patient DOB: ____ / ____ / _____. MRN: _____

Address:_____ Email: _____. Phone: (_____) _____ - _____

Your healthcare provider intends to order Summit™ and/or Vantage™ (Test(s)) offered by Belay Diagnostics (Belay). By signing below, you acknowledge receipt of information regarding the financial responsibility, potential risks, benefits, and limitations of testing and provide your authorization as to the matters listed in this consent. If you have any questions or need additional information about Test(s), please consult your healthcare provider before signing this consent.

Testing Overview

Summit analyzes cerebrospinal fluid samples on a molecular level to detect aneuploidy, mutations, and methylation signatures that are known to be associated with brain and spinal cord cancers. Vantage analyzes cerebrospinal fluid samples to assess MGMT promotor methylation status. The results of Summit and/or Vantage may assist your healthcare provider in choosing a treatment plan that is best for your medical condition. However, undergoing Test(s) does not guarantee that a successful treatment will be identified or that all relevant aneuploidy, mutations, and methylation signatures will be found. Test(s) may not provide information about susceptibility to developing disease in the future, and a negative result does not rule out the presence of aneuploidy, mutations, and methylation.

Financial Responsibility

Coverage for Test(s) is not available through public or private third-party health insurance payers. Belay will directly bill you for the full cost of Test(s), which is Four Thousand Dollars ($4,000) for Summit and Two Hundred and Seventy Five Dollars ($275) for Vantage. A 5% discount may be applied to the Summit test for payments made within 30 days of invoicing (Prompt Pay Discount). You are solely responsible for this cost. Belay will generally invoice you at the time the Test(s)are released to your healthcare provider. [However, Belay offers a limited patient assistance program through which financial assistance may be available on the basis of need. Belay cannot determine if you would qualify for financial assistance unless you submit a complete program application. If you submit an application, Belay will not charge you until it makes a determination on your application (except you may be charged sooner if you fail to submit a complete program application within 15 days of receipt).] You may contact Belay at contact@belaydiagnostics.com or by calling +1 (331) 320-0155 at any time with questions relating to your financial responsibility for Test(s).

Sample Collection and Release

Belay will perform Test(s) using genomic material extracted from your cerebrospinal fluid sample. By signing below you authorize Belay to work with your healthcare provider to obtain your sample and any information related to you or your medical condition that is relevant for Test(s). Performing the requested Test(s) may exhaust the sample that is sent to Belay, and additional Test(s) may not be possible unless you provide additional samples.

Disclosure of Results

Belay will report the results of Test(s) to your healthcare provider, who will discuss your results and next steps with you. Based on your results, your healthcare provider will determine if any follow-up testing is appropriate. The results and other data and information generated during the performance of Test(s) may be used and disclosed in a manner consistent with our Notice of Privacy Practices, which can be found at belaydiagnostics.com/privacy-practices/. Belay is under no ongoing obligation to update, revisit, or later re-evaluate Test(s) results after those results have been made available to your healthcare provider through Test(s) reports described above.

Retention of Samples and Secondary Data

☐ **New York Residents Only: I authorize BD to retain my specimen for potential future testing, for research ordered by my healthcare provider and/or for quality control purposes. (If this box is not checked, unused specimen will be destroyed 60 days after testing is completed.)Opting in or out will not impact the quality of care or testing you receive.**

By signing this consent below, you nevertheless authorize the use of your sample, results, and other data and information generated during the performance of Test(s) for the purposes described in this consent. At the end of the testing process, Belay may choose to destroy or return your sample, maintain it for a future Test(s) ordered by your healthcare provider, or convert it into "Residual Information and Materials" (as defined below) and retain it indefinitely.

Belay may redact information that directly identifies you from your sample, the results of Test(s), other data and information generated during performance of Test(s), and other health or demographic information that Belay receives about you to create "Residual Information and Materials." Belay may maintain and use the Residual Information and Materials for any purpose permitted by federal and state law, including but not limited to:

- Ongoing development of testing methodologies to aid in improved diagnosis of primary and metastatic brain cancers.
- Performing quality assurance, test validation, and other operations purposes.
- Conducting commercial development and research, including performing additional analyses using the Residual Information and Materials for scientific and/or research purposes.
- Aggregating the Residual Information and Materials with similar residual information from other individuals, which may be used to create, or be disclosed to, databases or datasets that are solely or jointly owned by Belay or may be submitted to public databases to advance medical research.

The Residual Information and Materials may also be shared with third-parties, including, but not limited to, pharmaceutical and medical device companies, hospitals and universities, and other entities. You are not entitled to compensation for the use of the Residual Information and Materials or rights to any products or discoveries resulting from use of the Residual Information and Materials. Notwithstanding the foregoing, Belay will retain any of your identifiable or de-identified data as required by applicable federal or state laws or regulations.

By signing below, I confirm that I have read this consent in its entirety, understand it, and have had the opportunity to speak with my healthcare provider about Test(s) including the cost and financial responsibility, purpose, risks, benefits, and testing alternatives. I understand that I may raise any future questions or concerns related to Test(s) or this consent with my healthcare provider at any time. I request that my Test(s) proceed and authorize my sample to be taken and released for the performance of Test(s). I further authorize Belay to maintain, use, and disclose my sample and any information related to my Test(s) as described in this consent.

I agree that I will be solely responsible for the full cost of Test(s). I understand that Belay may charge me in this amount at the time my Test(s) results are released to my healthcare provider unless I request an application for the BelayAccess™ program. I understand that if I complete an application, Belay will not charge me until it makes a determination on my application (except that Belay may charge me sooner if I fail to submit a complete program application within 15 days of receipt). If my application is not accepted, I agree that Belay may charge me for the Test(s).

I agree that Belay may contact me at the email address or telephone number listed above for any additional information relating to my medical history that may be required for Test(s). I also understand that this consent is voluntary, treatment from my healthcare provider is not conditioned upon it, and I may opt out of it at any time by contacting Belay at contact@belaydiagnostics.com or by calling +1 (331) 320-0155.

_____ _____

Patient or Representative/Guardian Signature

Representative/Guardian Printed Name and Relationship to Patient (If Applicable)

Date: _____ / _____ / _____
MM DD YY

☐ **By checking the following box, I am requesting an application for the BelayAccess™ program through which financial assistance may be available to certain patients on the basis of need.**