Personalis®

NeXT Dx Test
REQUISITION FORM

FAX: 1 (650) 752-1350
EMAIL: clientservices@personalis.com

Patient Information

FIRST NAME		LAST NAME		MI
STREET ADDRESS		CITY	STATE	ZIP
RACE	ETHNICITY	DATE OF BIRTH (mm/dd/yyyy)	PRIMARY PHONE NUMBER	BIRTH SEX M ○ F ○ I ○
EMAIL				
MEDICAL RECORD NUMBER (MRN)		STUDY ID		

OFFICE USE ONLY

Ordering Provider

HOSPITAL/INSTITUTION		ACCOUNT NO
ORDERING PROVIDER (full legal name)		
STREET ADDRESS		
CITY	STATE	ZIP
NPI#		PHONE
EMAIL		FAX

☐ Send Copy (please check box for additional copy of report)

NAME	INSTITUTION
PHONE	EMAIL

Please Attach the Following

- ☐ Copy of recent pathology and/or cytology reports
- ☐ Test results from all other Molecular Diagnostic Tests
- ☐ Clinical notes and/or progress notes

Test Selection

☐ Personalis NeXT Dx™ Test

(NeXT Dx test requires tumor and matched normal).

Pathology Information ☐ (Please check box to send additional copy of report to the Pathologist listed below)

HOSPITAL / INSTITUTION NAME	SUBMITTING PATHOLOGIST NAME	
EMAIL	PHONE	FAX

Specimen Information (Please note that samples collected in New York State are ineligible for NeXT Dx testing at this time)

Choose one: ○ SPECIFIC SPECIMEN REQUESTED ○ PATHOLOGIST CHOOSES SPECIMEN	SPECIMEN ID SPECIMEN PROCUREMENT ○ I will arrange specimen shipment ○ Contact pathology lab to obtain specimen		SPECIMEN TYPE **Tumor Specimen** Collection date (mm/dd/yyyy): _____ ○ FFPE* Tumor content (%) _____ (*Minimum 20% tumor content required)
DIAGNOSIS (e.g. Adenocarcinoma)	STAGE	PRIMARY TUMOR SITE (original cancer site if metastasis, e.g. lung)	
DATE OF DIAGNOSIS (mm/dd/yyyy)	ICD-10 Primary Diagnosis Codes _____		
SPECIMEN BIOPSY SITE ☐ Primary ☐ Metastasis ☐ Recurrence ☐ Refractory ☐ Relapse	HISTOLOGY		
CURRENT THERAPIES			**Normal Specimen** Collection date (mm/dd/yyyy): _____ ○ Blood ○ Saliva
PRIOR THERAPIES			

Patient Status (Required for Medicare patients)

○ OFFICE (Non-hospital) ○ OUTPATIENT ○ INPATIENT (Not yet discharged) ○ INPATIENT (discharge date required - mm/dd/yyyy) ☐ ABN attached

Billing Information (Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.)

○ Insurance
○ Medicare
○ Medicaid
○ Self Pay
○ Bill Facility
○ Other _____

	INSURANCE PROVIDER	POLICY #	GROUP #	INSURED NAME	INSURED DOB (mm/dd/yyyy)	RELATIONSHIP TO PATIENT	PRIOR AUTHORIZATION #
PRIMARY							
SECONDARY							

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NeXT Dx™ Test Consent

Please review this information carefully and discuss it with your patient or patient's legal guardian. Please note that samples collected in New York State are ineligible for NeXT Dx testing at this time. The NeXT Dx test is performed by the Personalis Clinical Laboratory, Personalis, Inc. ("Personalis").

Benefits and Purpose of the Personalis NeXT Dx Test

The purpose of the Personalis NeXT Dx test is to identify genetic changes in a patient's tumor that may help guide the treatment of their cancer. For example, some changes in the tumor may indicate whether a patient's tumor is likely or not likely to respond to specific treatments. These treatments might be approved for treatment of the patient's type of cancer, or other types of cancers, or through participation in a clinical trial. After testing is complete, a detailed written report in English, discussing each detected genetic change that may help guide the patient's treatment, will be sent to the ordering healthcare provider(s) for their review.

Risks and Limitations of the Personalis NeXT Dx Test

No test is 100% accurate. Personalis takes steps to reduce the risk of errors, but there are technical and biological limitations to the test. Thus, there is always a small chance of an inaccurate result that could potentially affect the decisions made by the patient, patient's family, or ordering healthcare provider(s). It is possible that the Personalis NeXT Dx test may not identify all or any genetic changes that can help guide the treatment of a patient's cancer. Even if a genetic change is identified, it is possible that it may not help guide treatment of the patient's cancer. Because FDA-approved drugs, clinical trials, and our knowledge of how certain genes affect cancer are constantly changing, we may not understand the significance of some changes identified in a patient's tumor. It is also possible that a patient's tumor has a change in a gene not tested or reported by the Personalis NeXT Dx test. The accuracy of NeXT Dx test results may be affected by the quality of samples provided. If, for example, samples are contaminated, mislabeled, or have other problems when they are sent to Personalis, the samples may not be usable for the Personalis NeXT Dx test or the results of the test may not be accurate. The results of the Personalis NeXT Dx test become part of a patient's medical record. Patients or their legal guardians must understand and agree to assign all applicable health insurance benefits and/or insurance reimbursement they have under their health plan(s) to Personalis for services performed by Personalis. They must also agree to appoint Personalis as their authorized representative and convey to Personalis, to the full extent permissible under the law, the power to: (1) file medical claims with the health plan(s); (2) file appeals and grievances with the health plan(s) and/or any agency or governmental body with applicable authority; (3) obtain and release medical records and insurance information as necessary to process a claim, appeal or grievance; and (4) collect payment of any and all medical benefits and insurance proceeds (including Medicare and Medicaid). Such appointment and conveyance must include all the patient's rights in connection with any claim, right, or cause of action including litigation against the health plan(s) that they may have, including the right to claim on patient's behalf all such benefits, claims, or reimbursement, and to seek any other applicable remedy, including fines.

If the patient or the patient's legal guardian chooses or is required to share the patient's genetic information with other entities (e.g., life insurance companies), it may affect the decisions that they make about the patient's coverage. Although federal and certain state laws including the Genetic Information Nondiscrimination Act (GINA) and the California Genetic Information Nondiscrimination Act, respectively, provide protection against discrimination in certain instances, they may not protect the patient in all cases. For example, while GINA makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against patients based on a patient's genetic information, subject to certain exceptions, there are limitations. GINA does not protect the patient against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or other products and services. GINA may also not apply to patients who are covered by specific forms of federal and military insurance.

In addition, performing the NeXT Dx test on a patient's normal (non-tumor) tissue may reveal health information unrelated to the patient's cancer diagnosis ("incidental findings"). This test is not a replacement for hereditary (germline) cancer genetic testing. While it is possible that the Personalis NeXT Dx test may identify changes in the tumor that may also be inherited, additional testing to determine if a particular genetic change is hereditary should be discussed with the patient and should consider the patient's personal and family health history. Referral to genetic counseling should be considered if clinically indicated. Learning about the genetic information obtained from this test and the implications for the patient and the patient's cancer treatment may cause emotional or psychological stress.

Alternatives to the Personalis NeXT Dx Test

Patients or their legal guardians have the right to refuse this test. If they decide not to take this test, they should discuss other testing and/or treatment options with their healthcare provider.

Privacy and Confidentiality

The patient's individually identifiable health information obtained in connection with the Personalis NeXT Dx test will be maintained, used and disclosed by Personalis in accordance with applicable law. In addition, Personalis may remove personal identifiers in accordance with applicable law (such as the patient's name, address, or birth date) from the test information so that the patient cannot be identified based on standards set forth in applicable law. This is called de-identified information. This de-identified information may be retained by Personalis indefinitely and can be used for research and development work that may help Personalis improve its tests to the benefit of patients and others, and may be published in scientific and medical journals and conferences. Personalis may also work with outside third parties, providing them access to this de-identified information. If researchers discover something from a patient's de-identified information (for example, a genetic change that increases the patient's risk for developing other types of cancers) the patient will not be re-contacted by Personalis or other researchers with access to the database.

Revocation of Consent

Patients or their legal guardians may decide to revoke or withdraw their consent at any time. If a patient or the patient's legal guardian decides to withdraw consent, any further testing and processing of the patient's sample(s) will not proceed. However, withdrawal of consent will not have any effect on any testing, processing, or other use or sharing of the patient's sample(s) that has already occurred, on any anonymized or de-identified test results or associated data (including whole-exome and transcriptome analysis data), or any anonymized or de-identified materials extracted or derived from the patient's sample, such as DNA and RNA, for which the patient provided consent for Personalis to retain. To revoke a patient's consent, the patient or legal guardian, or the ordering healthcare provider(s), must submit a written request to 1330 O'Brien Drive, Menlo Park, CA 94025, attention: Privacy Officer.

Certificate of Medical Necessity/Consent/Test Authorization and Provider Signature

My signature constitutes a Certificate of Medical Necessity and certifies that I am the patient's health care provider. I have explained to the patient the nature and purpose of the testing to be performed, discussed the risks and benefits of the testing, and offered alternatives to such testing. I have obtained informed consent, that is signed, dated, and in writing to the extent legally required, from the patient or the patient's authorized representative, in accordance with applicable law, to permit Personalis, Inc. to (a) perform the testing specified herein, (b) release the test results to me or my organization as the ordering provider and patient's treating clinician; (c) release the test results to the patient's third-party payer as needed for reimbursement purposes, (d) retain test results and associated data (including genetic data such as whole-exome and transcriptome analysis data) and any materials extracted or derived from the patient's sample, such as DNA and RNA, for an indefinite period for internal quality assurance and/or other operations purposes (including after any revocation of the patient's consent to the extent permitted under applicable law), and (e) anonymize or de-identify the test results and associated data (including genetic data such as whole-exome and transcriptome analysis data) and any materials extracted or derived from the patient's sample, such as DNA and RNA, and use and disclose such anonymized or de-identified test results, associated data, and material for future unspecified research or other purposes (including after any revocation of the patient's consent to the extent permitted under applicable law).

If written consent is legally required, I will maintain a copy of the written consent and make it available to Personalis, Inc. upon reasonable request.

PROVIDER SIGNATURE DATE (mm/dd/yyyy)