Personalis®

Please place collection kit barcode here.

NeXT Dx® & NeXT Personal Dx®
TEST REQUISITION FORM

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

A. Test Order *(Tests are not currently available in New York State)*

☐ NeXT Dx only Comprehensive genomic profiling for therapy selection	☐ NeXT Personal Dx only Liquid biopsy for molecular residual disease detection ○ Initial test order ○ Subsequent test order	☐ NeXT Dx and NeXT Personal Dx Check box if ordering both tests

B. Patient Information *(or attach patient demographic sheet that includes information in the table below; * fields remain required even with attachment)*

FIRST NAME*	LAST NAME*	MI	BIRTH SEX
			M ○ F ○ I ○

DATE OF BIRTH*	MRN	PHONE NUMBER

STREET ADDRESS (Street, Unit #)	CITY	STATE	ZIP

C. Ordering Clinician

INSTITUTION NAME	SITE ID

INSTITUTION ADDRESS (Street, Unit #)	CITY	STATE	ZIP

ORDERING CLINICIAN (full legal name)	NPI	EMAIL / FAX (required for report delivery)

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

RECIPIENT NAME	INSTITUTION NAME	EMAIL / FAX (required for report delivery)

D. Specimen Retrieval

1. **TUMOR SPECIMEN** *(skip tumor specimen information for subsequent NeXT Personal Dx tests)*

SELECT ONE:	SPECIMEN ID:	TUMOR SPECIMEN COLLECTION DATE (mm/dd/yyyy)	○ I do NOT want Personalis to exhaust the material to perform Test(s)
○ Specific tumor specimen requested ○ Pathologist chooses specimen			
SELECT ONE: ○ Contact path lab to obtain specimen ○ I will arrange specimen shipment	SPECIMEN BIOPSY SITE: ○ Primary ○ Other ○ Metastasis _____	PATHOLOGIST (full legal name):	
2. **BLOOD SPECIMEN**	☐ Indicate if submitting a pre-surgical or pre-biopsy blood sample	INSTITUTION (Name, City):	
SELECT ONE: ○ I will collect sample in the clinic ○ I request mobile phlebotomy	SAMPLE COLLECTION DATE (mm/dd/yyyy)	EMAIL, FAX or PHONE	

E. Patient Diagnosis

PRIMARY CANCER DIAGNOSIS (select one)
○ Breast cancer ○ Colorectal cancer ○ Lung cancer
○ Melanoma ○ Prostate cancer ○ Other: _____

ICD-10 DIAGNOSIS CODE(S)

STAGE ○ I ○ II ○ III ○ IV ○ Other: _____

○ Receiving or planning to receive immunotherapy
Drug name: _____

ATTACHMENTS
☐ Tumor specimen pathology report
☐ Medical records

DISEASE STATUS (select all that apply) ☐ Active disease ☐ Recurrent ☐ Relapsed ☐ Refractory ☐ Metastatic ☐ NED

F. Billing Information *(If patient primary or secondary insurance cards are available, please attach. If not, complete the following table)*

○ Commercial Insurance
○ Medicare (Attach ABN) ○ Bill Facility ○ Other
○ Medicaid
○ Self-pay
In-Patient Disharge date: _____

Insurance provider	Policy #	Insured name	Insured DOB (mm/dd/yyyy)	Relationship to patient	Prior authorization #

G. Authorized Signature and Consent

By my signature I acknowledge that I have read and agreed to the Certificate of Medical Necessity on the back of this page

SIGN HERE: (required to process test(s)) Signature _____ Date (mm/dd/yyyy) _____

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Test Descriptions

NeXT Dx

Personalis' NeXT Dx test identifies 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.

NeXT Personal Dx

Personalis' NeXT Personal Dx test is a personalized tumor-informed liquid biopsy designed to detect molecular residual disease (MRD) using circulating tumor DNA (ctDNA) from patients previously diagnosed with a solid tumor cancer. Individualized molecular profiles are established by upfront tissue and matched normal whole genome sequencing (WGS). The assay delivers high ctDNA sensitivity down to the 1-3 parts per million (PPM) range by tracking up to 1800 somatic variants in a personalized patient panel.

Patient ineligibility: NeXT Dx and NeXT Personal Dx should be used for testing solid tumor cancers only and should not be used for testing hematologic cancers. Patients are ineligible to use NeXT Dx or NeXT Personal Dx if the patient has had a blood transfusion within the last three (3) months or has ever had an allogeneic bone marrow transplant. Patients are ineligible to use NeXT Personal Dx if the patient has a solid tumor cancer with a concurrent hematologic malignancy.

Commonly Used ICD-10 Codes

Melanoma

C43.59	Malignant melanoma of other parts of trunk
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.4	Malignant melanoma of scalp and neck

Breast Cancer (F)

Right

C50.411	Malignant neoplasm of upper-outer quadrant, right female breast
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.911	Malignant neoplasm of unspecified site, right female breast
C50.311	Malignant neoplasm of lower-inner quadrant, right female breast
C50.811	Malignant neoplasm of overlapping sites, right female breast
D05.11	Intraductal carcinoma in situ, right breast
C50.111	Malignant neoplasm of central portion, right female breast
C50.211	Malignant neoplasm upper-inner quadrant, right female breast
C50.511	Malignant neoplasm upper-outer quadrant, right female breast

Left

C50.412	Malignant neoplasm of upper-outer quadrant, left female breast
C50.912	Malignant neoplasm of unspecified site, left female breast
C50.812	Malignant neoplasm of overlapping sites, left female breast
C50.212	Malignant neoplasm of upper-inner quadrant, left female breast
C50.512	Malignant neoplasm of lower-outer quadrant, left female breast
C50.112	Malignant neoplasm of central portion, left female breast

Lung Cancer

C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung

Colorectal Cancer

C18.7	Malignant neoplasm of sigmoid colon
C18.2	Malignant neoplasm of ascending colon
C18.0	Malignant neoplasm of cecum
C18.6	Malignant neoplasm of descending colon
C18.1	Malignant neoplasm of appendix
C18.4	Malignant neoplasm of transverse colon
C18.3	Malignant neoplasm of hepatic flexure
C18.8	Malignant neoplasm of overlapping sites of colon
C21.8	Malignant neoplasm of overlapping sites of rectum, anus, and anal canal
C17.0	Malignant neoplasm of duodenum

Please see www.personalis.com/icd-10-codes for more information

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

My signature, on the front page of this form, constitutes a Certificate of Medical Necessity, certifies that I am the patient's health care provider and confirms that the patient is eligible for testing. An authorized health care provider has explained to the patient or the patient's authorized representative (either hereafter called "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. At a minimum, the patient has been provided with the consent information available at www.personalis.com. Informed consent has been obtained from the patient that is signed, dated, and in writing to the extent legally required, in accordance with applicable law, to permit Personalis, Inc. to (a) perform the testing specified herein, no other tests; (b) release the test results to me or my organization as the ordering provider; (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-genome, whole-exome and/or transcriptome analysis data) and any materials extracted or derived from the patient's sample(s), 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-genome, whole-exome and transcriptome analysis data) and any materials extracted or derived from the patient's sample(s), 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, a copy of the written consent will be maintained and made available to Personalis, Inc. upon reasonable request.