NEOVARE™ PERSONALIZED DIAGNOSTICS by siParadigm

PR 888-782-5430 / 866-369-4114
USA 888-599-5227 / 201-599-9044 / 201-599-9066 / 888-890-4774 (Toll-free fax)

Patient Information — Clinical Information — Billing Information — Informed Consent

Requisition # _____
Specimen # _____
Pick-up Confirmation# _____

Patient Information (REQUIRED)

Name Last _____ First _____

Date of Birth ___ / ___ / ___ (mm / dd / yyyy) Street _____

City _____ State _____ ZIP _____

Phone# _____ MRN / Patient ID# _____

Gender Identity: ☐ Male ☐ Female
☐ Female-to-Male (FTM)/Transgender Male/Trans Man
☐ Male-to-Female (MTF)/Transgender Female/Trans Woman
☐ Genderqueer, neither exclusively male nor female
☐ Additional gender category or other, please specify _____
☐ Choose not to disclose

Ethnicity
☐ African-American ☐ Jewish-Ashkenazi ☐ Asian ☐ Adopted ☐ Native American
☐ Middle Eastern ☐ Caucasian/NW European ☐ Jewish-Sephardic
☐ Hispanic ☐ Non-Hispanic or Non-Latino ☐ Other;_____
☐ Unknown ☐ Asked but Unknown ☐ Choose not to disclose

Sexual Orientation:
☐ Lesbian, gay, or homosexual ☐ Straight or heterosexual ☐ Bisexual ☐ Don't know
☐ Something else, please describe _____ ☐ Choose not to disclose

Race:
☐ American Indian or Alaska Native; ☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Other _____
☐ Unknown ☐ Asked but Unknown ☐ Choose not to disclose

Specimen Information (REQUIRED)

Collection DATE ___ / ___ / ___ (mm / dd / yyyy) Time _____

Sent DATE ___ / ___ / ___ (mm / dd / yyyy) Time _____

Specimen TYPE _____

☐ Blood ☐ Saliva ☐ Buccal swab ☐ Other _____

Ordering Physician/Sending Facility (REQUIRED)

Billing Information (REQUIRED)

☐ Insurance Billing **(Attach a copy of both sides of insurance card)**
☐ Facility/Hospital billing
☐ Self pay - No insurance, does not qualify, not Medicare or Medicaid Must include check $250.00

(For our legally compliant & patient-friendly billing policy visit www.neovare.com)

Clinical Information (REQUIRED)

Diagnosis Code/ICD-10 Code **(REQUIRED)*** _____

*** Use page 2 for details.**

Panel(s) Requested

☐ **Neovare Portfolio**
Pathologists to select optimal panels/tests based on personal/family history and insurance coverage up to 45 genes

☐ **Hereditary Breast and Ovarian Cancer Risk Assessment Panel**
(16-Gene panel plus full genes BRCA1, BRCA2, ATM, BARD1, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD51D, RAD51C, RAD50, STK11, TP53)

☐ **Lynch Syndrome & Hereditary Colon Cancer Risk Assessment Panel**
(18-Gene panel including APC, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH3, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53)

☐ **Hereditary Prostate Cancer Risk Assessment Panel**
(15-Gene panel including ATM, BRCA1, BRCA2, BRIP1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, RAD51C, RAD51D, TP53)

☐ **Hereditary Pancreatic Cancer Risk Assessment Panel**
(19-Gene panel including BRCA1, BRCA2, APC, ATM, BMPR1A, CDK4, CDKN2A, EPCAM, MEN1, MLH1, MSH2, MSH6, NF1, PALB2, PMS2, SMAD4, STK11, TP53, VHL)

☐ **BRCA1/BRCA2**
Full gene sequencing and deletion/duplication analysis

☐ **Individual Genes**

☐ *AKT1	☐ BRCA1	☐ CHEK2	☐ FANCC	☐ *GATA2	☐ MSH2	☐ *PIK3CA	☐ RAD51	☐ SDHA	☐ SUFU
☐ *ALK	☐ BRCA2	☐ DICER1	☐ FANCD2	☐ *HRAS	☐ MSH3	☐ PMS2	☐ RAD51B	☐ SDHB	☐ *TERT
☐ APC	☐ BRIP1	☐ DPYD	☐ FANCE	☐ *KIT	☐ MSH6	☐ POLD1	☐ RAD51C	☐ SDHC	☐ TP53
☐ ASXL1	☐ *CASR	☐ *EGFR	☐ FANCF	☐ *MAX	☐ MUTYH	☐ POLE	☐ RAD51D	☐ SDHD	☐ TSC1
☐ ATM	☐ CDC73	☐ EPCAM	☐ FANCG	☐ MEN1	☐ NBN	☐ POT 1	☐ RB1	☐ SLX4	☐ TSC2
☐ AXIN2	☐ CDH1	☐ ERCC2	☐ FANCI	☐ *MET	☐ NF1	☐ PRKAR1A	☐ RECQL4	☐ SMAD4	☐ VHL
☐ BAP1	☐ *CDK4	☐ ERCC4	☐ FANCL	☐ *MITF	☐ NF2	☐ PTCH1	☐ *RET	☐ SMARCA4	☐ WT1
☐ BARD1	☐ CDKN1B	☐ ERCC5	☐ FANCM	☐ MLH1	☐ PALB2	☐ PTEN	☐ RNF43	☐ SMARCB1	☐ XRCC2
☐ BLM	☐ CDKN2A	☐ FANCA	☐ FBXW7	☐ MRE11(A)	☐ *PDGFRA	☐ RAD50	☐ RUNX1	☐ STK11	

* Genes with partial coverage of the coding regions and mutation hotspots.

Physician (REQUIRED)

Confirmation of Informed Consent & Statement of Medical Necessity:
I affirm each of the following: 1) I have provided genetic testing information to the patient and the patient has consented to such testing. 2) Testing is medically necessary for the diagnosis of a disease or syndrome. 3) The results will be used in the patient's medical management and treatment decisions. 4) The person listed as the ordering physician is authorized by law to order the test(s) requested herein.

Signature *(**MANDATORY FOR TESTING** – Results will be delayed if consent signature is missing) _____ **Date** _____

Patient/Legal Guardian (REQUIRED)

Consent: I give permission to Neovare by siParadigm to perform genetic testing as requested by my physician. In the event that one of the following apply.

1) I do not have health insurance -**Attach Check**
2) I do not qualify for testing based on nationally recognized clinical criteria for medical necessity for hereditary cancer testing - **Attach Check**
3) I do not qualify for testing based on my insurance company's medical necessity policy for hereditary cancer testing and will be responsible to make payment of $250.00 upon receipt of bill as noted in red below
***This self pay rate is NOT available to those patients with Medicare/Medicaid due to governmental guidelines. A signed ABN is required for these patients.**

I authorize Neovare by siParadigm to perform testing to determine my risk for hereditary cancer AND I understand that I will personally pay $250.00 out of pocket for testing (to include extra shipping and handling) for these services.

Signature *(**MANDATORY FOR TESTING** – Results will be delayed if consent signature is missing) _____ **Date** _____

Additional patient signature is REQUIRED - Page 4

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Testing Indications (REQUIRED)

Hereditary breast cancer

- ☐ Early onset breast cancer <= 45, male breast cancer, or Ashkenazi Jewish ancestry
- ☐ Breast cancer <= 50 with limited family history, multiple primary breast cancers, or a close blood relative with breast, ovarian, pancreatic or prostate cancer
- ☐ Breast cancer > 50 with close blood relative with breast, ovarian, pancreatic, metastatic or high grade prostate cancer
- ☐ Breast cancer > 50 with 3 total diagnosis of breast cancers in patient and/or relatives
- ☐ Close blood relative with any of the 1st three criteria

Hereditary gynecological cancer (breast/ovarian/endometrial)

- ☐ Ovarian, fallopian tube, or primary peritoneal cancer at any age
- ☐ Close blood relative with ovarian, fallopian tube, or primary peritoneal cancer at any age
- ☐ Uterine cancer ≤50 y.o. or with abnormal MSI/IHC
- ☐ Multiple primary cancers in one person (e.g. uterine, breast, or colorectal)

Hereditary pancreatic cancer

- ☐ Pancreatic cancer at any age
- ☐ Multiple primary cancers in one person (e.g. pancreatic and melanoma)
- ☐ Multiple close family members with pancreatic and/or other cancers

Hereditary prostate cancer

- ☐ Multiple affected first-degree relatives with prostate cancer
- ☐ Metastatic or intraductal prostate cancer or Gleason score > 7
- ☐ Prostate cancer with a family history of other cancers (e.g. breast, ovarian, pancreatic)

Hereditary colorectal cancer

- ☐ ≥10 colorectal polyps in an individual
- ☐ Colorectal cancer <50 y.o. or with evidence of MMR deficiency
- ☐ Patient has primary colorectal/uterine cancers with one of Lynch syndrome assosciated tumors* or being <50 yrs.
- ☐ Patient has primary colorectal/uterine cancers and has a one or more close relatives with Lynch syndrome assosciated tumors*
- ☐ 2 close relatives or more having primary colorectal/uterine cancers with one of Lynch syndrome assosciated tumors*

* Lynch syndrome associated tumors: colorectal, endometrial, gastric, ovarian, pancreatic, urothelial, brain, liver (biliary tract), small intestine and sebaceous glands

☐ Other _____

ICD-10 Diagnosis Codes (REQUIRED)

Breast		
☐	Z85.3	Personal history of malignant neoplasm of breast
☐	Z80.3	Family history of malignant neoplasm of breast
☐	C50.911	Malignant neoplasm of unspecified site, female - right breast
☐	C50.912	Malignant neoplasm of unspecified site, female - left breast
☐	C50.919	Malignant neoplasm of unspecified site of female breast
☐	C50.921	Malignant neoplasm of unspecified site of right male breast
☐	C50.922	Malignant neoplasm of unspecified site of left male breast
☐	C50.921	Malignant neoplasm of unspecified site of unspecified male
☐	D05.10	Intraductal carcinoma in situ of unspecified breast
☐	Z15.01	Genetic susceptibility of breast
Ovary		
☐	Z85.43	Personal history of malignant neoplasm of ovary
☐	Z80.41	Family history of malignant neoplasm of ovary
☐	C56.1	Malignant neoplasm of right ovary
☐	C56.2	Malignant neoplasm of left ovary
☐	C56.9	Malignant neoplasm of unspecified ovary
☐	Z15.02	Genetic susceptibility of ovary
Pancreas		
☐	Z85.07	Personal history of malignant neoplasm of pancreas
☐	C25.9	Malignant neoplasm of pancreas, unspecified
Prostate		
☐	Z85.46	Personal history of malignant neoplasm of prostate
☐	Z80.42	Family history of malignant neoplasm of prostate
☐	C61	Malignant neoplasm of prostate
☐	Z15.03	Genetic susceptibility of prostate
Digestive Organs		
☐	Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
☐	Z80.0	Family history of malignant neoplasm of digestive organs
Other Organs		
☐	Z80.8	Family history of malignant neoplasm of other organ
☐	Z15.019	Genetic susceptibility to other malignant neoplasm

☐ Other _____

Specimen Requirements

Specimen	Whole blood	Saliva
Volume	6-10 cc in purple top (EDTA) tube (For Chromosomal microarray : SNP Array requires 1 cc minimum)	1 cc of freshly collected saliva in Oragene container per kit's specific instructions. (Fill up to black line with 1 cc of saliva and close lid. Once lid is closed, it automatically adds 1 cc of buffer for a total volume of 2 cc.)
Storage	Room temperature at 15-30 °C (short-term) Refrigerated at 2-8 °C (long-term) **DO NOT FREEZE**	In sterile bag, room temperature at 15-30 °C
Stability	When stored refrigerated per above, stable for 7 days	When stored per above, stable up to 1 year

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Name: _____ **Provider:** _____ **DOB:** ____ / ____ / ____
mm / dd / yyyy

Personal History:

Have you ever been diagnosed with **Breast, Ovarian, Colon, Pancreatic, or Uterine** (Endometrial) cancer? If so, which one and at what age?

_____

_____

_____

Family History:

The following questions apply to **your family** and should include your **mother's side (maternal)** and your **father's side (paternal).** The following family members should be considered:
1st degree Mother, Father, Brothers, Sisters, Children, **2nd degree** Aunts, Uncles, Nieces, Nephews, Grandmothers, Grandfathers, **3rd degree** Greats and Cousins

Please note: Testing criteria differs for Medicare/Medicaid and commercial insurances

	Breast, Ovarian, Colon, Pancreatic, & Uterine Cancers	Family Member(s) (including Maternal or Paternal)	Age at Diagnosis
☐ ☐	1 Colon or Uterine (Endometrial) cancer **under age 50** (1st or 2nd degree relative)		
☐ ☐	1 Breast cancer **under age 50** (1st or 2nd degree relative)		
☐ ☐	1 Ovarian cancer **at any age** (1st or 2nd degree relative)		
☐ ☐	1 Male Breast cancer **at any age** (1st or 2nd degree relative)		
☐ ☐	1 Pancreatic cancer **at any age** (1st degree relative)		
☐ ☐	1 Metastatic Prostate cancer **at any age** (1st degree relative)		
☐ ☐	2 Different Breast cancers **at any age** in the same relative		
☐ ☐ ☐ ☐	3 Breast cancers **at any age** in any relatives on same side of family 3+ Uterine, Colorectal, Stomach/Gastric (or other Lynch syndrome cancers) **at any age** on same side of family (1st or 2nd degree)		

☐ I have already been tested for hereditary cancers

Patient's Signature _____ Date _____

For Office Use Only:

Patient meets NCCN guidelines ☐ Yes ☐ No

Patient meets Medicare / Medicaid criteria ☐ Yes ☐ No

☐ Patient offered genetic testing
☐ Accepted
☐ Declined

By signing below, I certify that the patient's personal and family history is accurate and should be used as an addendum to the patient's chart and clinical notes

_____ _____
Provider's Signature Date

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Informed Consent

As the patient/patient's authorized representative, I understand the following and freely give my consent to this genetic testing:

General description and purpose of the test. My healthcare provider has recommended that I receive (a) hereditary genetic test(s). My healthcare provider has explained that the purpose of this test is to look for mutations or genetic alterations known to be associated with (a) genetic disease(s), condition(s), or pharmaceutical therapy, and has discussed this disease, condition or therapy with me. I have reviewed the information about this specific test and the relevant disease(s) or condition(s) tested for with my healthcare provider, and my healthcare provider has explained the test's risks and benefits.

Limitations of the test. This test analyzes specific gene regions and does not rule out the possibility of an issue in other gene regions. Donor DNA from transplants and recent transfusions can cause inaccurate results. As in any lab test, there is a possibility of false positive and/or false negative errors.

Availability of genetic counseling before and after testing. I have been provided with information about obtaining genetic counseling prior to giving my consent for this testing. I further understand that my healthcare provider may recommend consultation with a medical geneticist, genetic counselor, and/or a physician after the testing is completed.

Meaning of a positive test result. A positive test result is indication that I (or my close blood relatives) may be predisposed to (a) specific disease(s) or have the specific condition(s) tested for. I may wish to consider further independent testing and/or to consult a physician or genetic counselor. I further understand that the ability of genetic testing to provide information as to risk and the level of certainty if a test result is positive varies with the type of test. I will ask my doctor about the level of certainty of a positive result.

Meaning of a negative test result. A negative test result indicates that the clinically significant variant tested for was not detected. Negative results may also be due to (1) technical reasons (i.e. poor sample quality) and/or (2) the need to test other family members. I have discussed information about the detection rate for the disease(s)/condition(s) with my health care provider and understand that a negative result does not guarantee that I will not develop the disease/condition for which testing was performed. In other words, a negative test result means that I have the same risk for the disease(s)/condition(s) as the general population.

Meaning of a variant of uncertain significance test result. Variant of uncertain significance (VUS) is a genetic change that has no currently known pathogenic or likely pathogenic effect linked with increased risk of developing hereditary cancer. We continuously monitor future updates as more information becomes available on the clinical significance of these variants.

Disclosure of test results. Test results will be released only to the ordering healthcare provider(s) listed on the test requisition form, or to others with my written consent. My test results will be available to me after they have been released by my healthcare professional.

I authorize my insurance benefits to be paid directly to Neovare by siParadigm and authorize Neovare to release personal information regarding my testing to my insurer for billing purposes. I also authorize Neovare to bill my insurance company for testing. I know that I am financially responsible for any amounts not paid by my insurer and that I will send Neovare any money received from my insurer. I also authorize Neovare to be my designated representative to appeal any denial of benefits.

I have read (or have had read to me) all of the above and have had the opportunity to ask questions I might have about the procedure, risks, and alternatives before consenting. My signature below acknowledges my consent to having this testing performed.

Patient signature _____ **Date** _____ **Relationship to patient** _____
(REQUIRED) **(if representative)**

Specimen Retention Consent

No tests other than those authorized by my healthcare provider will be performed on my sample. The sample will be destroyed at the end of the testing process or not more than 60 days after the sample was taken, unless I expressly authorize a longer period of retention in writing.

I agree to the use of my de-identified biospecimen for research to improve genetic testing and contribute to scientific research in strict compliance with Health Insurance Portability and Accountability Act (HIPAA), an Institutional Review Board (IRB) and all applicable regulatory and ethical guidelines.

☐ **YES** ☐ **NO**

Patient signature _____ **Date** _____ **Relationship to patient** _____
(REQUIRED) **(if representative)**