NEOVARE™
PERSONALIZED DIAGNOSTICS
by siParadigm

Patient Information — Clinical Information — Billing Information — Informed Consent

Requisition # _____
Your specimen # _____
Pick up confirmation # _____

Patient Information

Name Last _____ First _____

DOB (mm/dd/yy) _____ Biologic sex ☐ F ☐ M

Street _____

City _____ Zip Code _____ State _____

Phone# _____

Medical Record Number (MRN) _____

Ethnicity (Check all that apply) ☐ African-American ☐ Asian ☐ Caucasian/NW European ☐ Hispanic ☐ Jewish-Ashkenazi ☐ Jewish-Sephardic ☐ Middle Eastern ☐ Native American ☐ Adopted ☐ Other _____

Specimen Information

Collection date _____ Time _____

Sent date _____ Time _____

Specimen type _____

☐ Blood ☐ Saliva ☐ Buccal swab ☐ Other _____

Ordering Physician/Sending Facility

Billing Information

☐ Insurance Billing (Attach a copy of both sides of insurance card)

☐ Institutional Billing

Patient Payment ☐ Check ☐ Credit Card ☐ Bill Me

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

Clinical Information

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

☐ **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 analyses)

☐ **Hereditary Breast and Ovarian Cancer Risk 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 Panel**
(19-Gene panel including APC, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH3, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53)

For patients who don't meet current clinical practice and insurance policy coverage guidelines, we provide array platform options (Neovare Screen) upon request.

☐ **Germline Homologous Recombinant Deficiency (HRD) pathway mutations (full length BRCA 1/2 mutations plus 40 genes)**
For PARP inhibitors treatment (non-FDA approved for ovarian, breast, pancreatic and castration-resistant metastatic prostate).
In addition to the lavender tube for germline testing, please send FFPE tumor tissue and mark test on the solid tumor requisition.

Physician

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) _____

Date _____

Patient/Legal Guardian

Consent: I give permission to Neovare by siParadigm to perform genetic testing as requested. In order to avoid coverage denial by my insurance for 1) not meeting clinical practice guidelines, or 2) policy coverage guidelines, I authorize Neovare pathologists to select appropriate test(s) to perform based on my personal and family histories of cancer. If the pathologist determines that my insurance will not pay for testing, I authorize Neovare to perform testing using the array platform technology to determine my risk for hereditary cancer. I understand that I will personally pay $100 out of pocket for testing ($150 for Puerto Rico to include extra shipping & handling).

Signature *(mandatory for testing) _____

Date _____

USA: Call: 201-599-9044, Call: 888-599-5227, Fax: 201-599-9066, PR: Call: 888-782-5430, Fax: 866-369-4114
25 Riverside Dr. Suite 2, Pine Brook, NJ 07058 **www.neovare.com**

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Patient History (Required)

Previous molecular and/or genetic testing? ☐ Yes ☐ No

If yes, please attach the reports.

Previous genetic counseling? ☐ Yes ☐ No

Name of counselor _____

Phone number _____

Known variant identified in the family? ☐ Yes ☐ No

If yes, what gene? _____

Currently diagnosed with hematological cancer? ☐ Yes ☐ No

Currently taking radiation therapy/chemotherapy? ☐ Yes ☐ No

Bone marrow transplant recipient? ☐ Yes ☐ No

Testing Indications (Required)

Hereditary breast cancer

- ☐ Early onset breast cancer <= 45, male breast cancer, or Ashkenazi Jewish ancestry
- ☐ Breast cacner <= 50 with limitied 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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Medical History (Please be as thorough and accurate as possible when answering)

Personal and/or family history of any one of the following:

- ☐ Two or more cancers on the same side of the family
- ☐ A personal or family history of cancer at age 60 or younger
- ☐ Any one or more of the following rare conditions:
  - ☐ Male breast cancer ☐ 10 or more colorectal polyps
  - ☐ Triple negative breast cancer ☐ Sarcoma
- ☐ Concerned about personal and/or family history of cancer
- ☐ Ashkenazi Jewish descent
- ☐ A family member that has had genetic testing for hereditary cancer risk

	Personal History of Cancer	Family History of Cancer				
Type of Cancer	**Age at Diagnosis**	**Relationship**	**Maternal**	**Paternal**	**Age at Diagnosis**	**Pathology and other relevant information**
Breast ☐ Male ☐ Female			☐	☐		**TYPE** ER ☐+ ☐- ☐? PR ☐+ ☐- ☐? HER2/neu ☐+ ☐- ☐? Metastatic ☐Y ☐N **PRESENTATION** ☐left breast ☐right breast ☐both
Ovarian			☐	☐		☐ Fallopian tube ☐ Primary peritoneal
Colon/rectal			☐	☐		**LYNCH SCREENING** ☐MSI ☐IHC **NO. OF POLYPS** ☐1 ☐2-5 ☐6-9 ☐10-19 ☐20-99 ☐100 and above
Endometrial			☐	☐		**LYNCH SCREENING** ☐MSI ☐IHC(MMR)
Prostate			☐	☐		**METASTATIC** ☐Yes ☐No **GLEASON SCORE** _____
Uterine			☐	☐		☐ Clear cell ☐ Endometroid ☐ Mucinous ☐ Sarcoma ☐ Serous
Pancreatic			☐	☐		☐ Adenocarcinoma ☐ Neuroendocrine ☐ Intraductal papillary mucinous neoplasm ☐ Other
Kidney (renal)			☐	☐		☐ Clear cell ☐ Papillary Type I or II ☐ Transitional Cell
Melanoma			☐	☐		☐ In-situ ☐ Invasive

If there are other conditions not covered on above list, please indicate them below.

	Personal History of Cancer	Family History of Cancer				
Type of Cancer	**Age at Diagnosis**	**Relationship**	**Maternal**	**Paternal**	**Age at Diagnosis**	**Pathology and other relevant information**
			☐	☐		
			☐	☐		
			☐	☐		
			☐	☐		

Degrees of Blood Relatives	
First Degree	Parent, Sibling, Child
Second Degree	Grandparent, Aunt, Uncle, Niece, Nephew, Grandchild, Half-Sibling
Third Degree	Great-Grandparent, Great-Aunt, Great-Uncle, Great-Grandchild, First Cousin, Half-Aunt, Half-Uncle

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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.

Retention of specimens. 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.

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.

Signature _____ Date _____ Relationship to patient (if representative) _____