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PLEASE SUBMIT THE FOLLOWING WITH REQUISITION FORM

□ Statement of Medical Necessity (Signed by Physician)

- □ Informed Consent Form (Signed by Pt & Physician)
- □ SOAP & Progress Note (Signed by Physician)

CANCERGENOMICS TESTING REQUISITION FORM										
	PATIE	ENT II	NFORMATION							
Patient First Name	tient First Name Patient				t Last Name					
Date of Birth (MM/DD/YYYY)	Phone Number			ldress						
Address			City		State	Zip				
Ethnicity: 🗌 African Americar	n 🗌 Asian 🗌 Caucasian [🗌 Hisp	panic 🗌 Jewish(As	shkenazi) 🗌	Portuguese]Other				
PATIENT INSU		SPECIMEN INFORMATION								
Insurance 🔲 Self-Pay 🗌 Client Bill			Date Sample Collected (mm/dd/yy) (required)							
Name of the insurance	Secondary Insurance, If a	Secondary Insurance, If any			Medical Record#					
Insurance Policy/ID number	Name of the insured		Buccal Swab							
Insurance Group number	Date of Birth of Insured		— 🗌 Other (specify source)							
ORDERII	NG PHYSICIAN/SENDIN	g faq	CILITY (Each Listed	l person will re	eceive a copy of the	e report)				
Facility Name (Facility Code):			Address: City:							
State/Country :			Zip:		Phone:					
Ordering Licensed Provider Name (Last, First)(Code)			NPI# Pho			Fax				
	STATEMENT	OFN	NEDICAL NECE	SSITY						
By submission of this test requisition as the ordering provider is authoric requisition form are reasonable a disorder; (iv) the test results will de (v) have obtained this patient's and appropriate diagnosis code(s) are i	zed by law to order the test(s) rec nd medically necessary for the o termine my patient's medical ma I relatives', when applicable, writte	quested diagnos nagemen en infor	I; (iii) certify that any is and/or treatmen ent and treatment d med consent to und	<pre>/ custom par t of a diseas lecisions of t</pre>	nel and/or ordere se, illness, impair his patient's conc	d test(s) requested on this test ment, symptom, syndrome or lition on this date of service;				
Signature of Provider (required)		Date:								
INDICATIONS FOR TEST	ING (CHECK ALL THAT APPLY)									
□ Diagnostic □ Family history □ I										
Will Patient management be chang	ed depending on the test results?	? 🗌 Yes	i∏ No							
CLINICAL HISTORY Clinical Presentation						records and clinical notes				
Please indicate any clinical presentations an	d/or Endings that may be relevant to gene	etic testin				a direct association for disease. Please list nedical records and/or pedigree.				

PATIENT VISIT HISTORY

Date of the Previous Patient Visit

Date of the Last Genetic Testing, if any

PATIENT CLI	NICAL HISTO	RY			•			
Cancer /Tumer	Age at DX	Pathology and	Other info					
Breast		Туре:	E	ER (+) (-) unk	PR 🗌 (+) 🗌 (-) 🗖] unk HER2/neu	□ (+) □(-) □ unk	
2nd primary breast		Туре:	E	ER_ (+)_(-)_ unk	PR□(+)□(-)□] unk HER2/neu	□ (+) □(-) □ unk	
Ovarian		Fallopian tube	Primary peritonea	I				
Prostate		Gleason score:						
Hematologic		Type: Allogeneic bone marrow or peripheral stem cell transport						
Other Cancer		Туре:						
Other clinical history	/:	1						
Pre- Genetic C	ounselling:							
	-	ling institution if	Genetic counseling is	required by patients	benefits.			
		-	elect the genes below			g Panel (Test All G	enes)	
MUTYH PTEN BMPR1A ATM POLE	□ CDK4 □ GJB2 □ GJB6 □ BRCA2	□ FBN1 □ GREM □ PALB2 □ CDH1	□ TP53 □ NF1	 BRCA1 SMAD4 STK11 POLD1 	 MSH2 BARD1 MSH6 CHEK2 	□ MITF □ BAP1 □ KIT □ TERT □ APC	□ PMS2 □ NBN □ CDKN2A	
POLE INDICATION (S)		□ RAD5		Codes	□ MLH1			
 C25.0 Malignant neoplasm of head of pancreas C25.1 Malignant neoplasm of tail of pancreas C25.3 Malignant neoplasm of pancreatic duct C25.4 Malignant neoplasm of other parts of pancreas C25.7 Malignant neoplasm of other parts of pancreas C25.7 Malignant neoplasm of other parts of pancreas C25.8 Malignant neoplasm of other parts of pancreas C25.9 Malignant neoplasm of pancreas, unspecified C50.011 Malignant neoplasm of nipple and areola, right female breast C50.021 Malignant neoplasm of nipple and areola, right male breast C50.022 Malignant neoplasm of nipple and areola, left male breast C50.021 Malignant neoplasm of central portion of right female breast C50.111 Malignant neoplasm of central portion of left female breast C50.121 Malignant neoplasm of central portion of left male breast C50.121 Malignant neoplasm of central portion of left female breast C50.121 Malignant neoplasm of upper-inner quadrant of right female breast C50.211 Malignant neoplasm of upper-inner quadrant of right female breast C50.212 Malignant neoplasm of upper-inner quadrant of right male breast C50.212 Malignant neoplasm of upper-inner quadrant of right male breast C50.212 Malignant neoplasm of upper-inner quadrant of right male breast C50.213 Malignant neoplasm of lower-inner quadrant of right male breast C50.312 Malignant neoplasm of lower-inner quadrant of right male breast C50.312 Malignant neoplasm of lower-inner quadrant of right male breast C50.312 Malignant neoplasm of lower-inner quadrant of right male breast C50.312 Malignant neoplasm of upper-outer quadrant of right male breast C50.312 Malignant neoplasm of lower-inner quadrant of right male breast C50.312 Malignant neoplasm of lowe			 C50.522 Malignant neoplasm of lower-outer quadrant of left male breast C50.611 Malignant neoplasm of axillary tail of right female breast C50.622 Malignant neoplasm of axillary tail of left female breast C50.622 Malignant neoplasm of overlapping sites of right female breast C50.812 Malignant neoplasm of overlapping sites of left female breast C50.812 Malignant neoplasm of overlapping sites of left male breast C50.821 Malignant neoplasm of overlapping sites of left male breast C50.821 Malignant neoplasm of overlapping sites of left male breast C50.821 Malignant neoplasm of overlapping sites of left male breast C50.821 Malignant neoplasm of unspecified site of right female breast C50.912 Malignant neoplasm of unspecified site of left male breast C50.922 Malignant neoplasm of unspecified site of left male breast C50.922 Malignant neoplasm of unspecified site of left male breast C50.922 Malignant neoplasm of ginspecified site of left male breast C50.922 Malignant neoplasm of fight ovary C56.2 Malignant neoplasm of right fallopian tube C57.01 Malignant neoplasm of right fallopian tube C57.02 Malignant neoplasm of right fallopian tube C51.1 Lobular carcinoma in situ of right breast D05.02 Lobular carcinoma in situ of right breast D05.12 Intraductal carcinoma in situ of right breast D05.12 Intraductal carcinoma in situ of right breast D05.29 Unspecified type of carcinoma in situ of right breast D05.20 Lobular carcinoma in situ of left breast D05.20 Unspecified type of carcinoma in situ of right breast D05.31 Other specified type of carcinoma in situ of right breast D05.44 Presonal history of malignant neoplasm of pancreas Z85.37 Personal history of malignant ne					
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 C17.0 Malignant neop C17.1 Malignant neop C17.2 Malignant neop C18.0 Malignant neop C20 Malignant neopal C21.1 Malignant neopal C21.1 Malignant neopal C21.1 Intrahepatic bile C22.2 Hepatoblastoma C55 Malignant neopal C62.12 Malignant neopal C62.12 Malignant neopal C62.12 Malignant neopal C62.19 Malignant neopal C22.9 Malignant neopal C24.9 Malignant neopal C63.9 Malignant neopal C15.3 Malignant neopal C15.3 Malignant neopal C15.4 Malignant neopal C17.3 Meckel's divertical C16.8 Malignant neopal C17.8 Malignant neopal<	lasm of jejunum lasm of jejunum lasm of cecum sm of rectum lasm of caral canal ma educt carcinoma a sm of uterus part unspi plasm of descended tei lasm of small intestine lasm of small intestine lasm of liver, not specif lasm of biliary tract uns lasm of nitestinal tract lasm of nale genital or lasm of appendix lasm of overlapping sit lasm of overlapping sit	stis unspecified leed as primary pecified part unspecified gan, unspecified soophagus es of esophagus es of esophagus es of stomach es of small intestine es of colon es of rectum, anus	 C23 Malignant neoplasn C26.1 Malignant neoplasn C51 Malignant neoplasn C52 Malignant neoplasn C52 Malignant neoplasn C53 Malignant neoplasn C54 Malignant neoplasn C56.0 Malignant neoplasn C60.0 Malignant neoplasn C60.1 Malignant neoplasn C60.2 Malignant neoplasn C60.2 Malignant neoplasn C60.3 Malignant neoplasn C62.90 Malignant neoplasn C62.90 Malignant neoplasn C62.90 Malignant neoplasn C62.91 Malignant neoplasn C62.92 Malignant neoplasn C63.20 Malignant neoplasn C62.00 Malignant neoplasn C62.00 Malignant neoplasn C62.01 Malignant neoplasn C63.10 Malignant neoplasn C51 Malignant neoplasn	n of gallbladder sm of spleen n of vulva n of vulva n of cervix uteri n of corpus uteri n of corpus uteri sm of glans penis sm of glans penis sm of scrotum sm of ill-defined sites with sm of overlapping sites of asm of nyspecified testis asm of right testis unspecified sam of other specified male sam of other specified male sam of unspecified undesc asm of unspecified undesc asm of undescended left t asm of unspecified descen asm of unspecified sperma	Image: Control of the second secon	3.11 Malignant neoplasm	of pyloric antrum of body of stomach of ascending colon of hepatic flexure of splenic flexure of transverse colon of descending colon of anus unspecified of cloacogenic zone of ampulla of Vater n of left epididymis of fundus of stomach of colon unspecified of penis unspecified of of right epididymis of stomach unspecified f rectosigmoid junction	
Additional ICD10 c		co or omary tract			I			

INFORMED CONSENT

For the purposes of this consent, "I", "my", and "your" will refer to me or to my child, including my unborn child, if my child is the person for whom the healthcare provider has ordered testing.

PURPOSE OF THIS TEST

The purpose of this test is (a) to see if I may have a genetic variant or chromosome rearrangement causing a genetic disorder; or (b) to evaluate the chance that I will develop or passon a genetic disorder in the future. If I already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I agree to inform the laboratory of this information.

WHAT TYPE OF TEST RESULTS CAN I EXPECT FROM GENETIC TESTING?

1. Positive: A change in your DNA was found, which is very likely the cause of your features/symptoms. This is the most straightforward test result, which can be used as the basis to test other family members to determine their chances of having either the disease or a child with the disease.

2. Negative: No variants were found to explain your symptoms. This does not mean that you do not have a genetic condition. It is still possible that there is a genetic variant not found by the test that was ordered. Your healthcare provider or genetic counselor may discuss more testing either now or in the future.

3. Variant of Uncertain Significance (VUS): A change in a gene was found. However, we are not sure whether this variant is the cause of your symptoms/features. More information is needed. We may suggest testing other family members to help figure out the meaning of the test result.

4. Unexpected Results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may find you are at risk for another genetic condition I am not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. We may disclose this information to the ordering healthcare provider if it likely affects medical care. Because medical and scientific knowledge is constantly changing, new information that becomes available may supplement the information **OmniHealth Diagnostics, LLC** used to interpret my results.

Healthcare providers can contact OmniHealth Diagnostics, LLC at any time to discuss the classification of an identified variant.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?

For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient's sample can help with the interpretation of the test results. These tests are often referred to as "trio tests" since they typically include samples from the patient and both parents. Samples from relatives should be submitted with the patient's sample. Clinical information must be provided for the patient and any relative who submits a sample.

I understand that **OmniHealth Diagnostics, LLC** will use the relative sample(s) when needed for the interpretation of my test results and that my test report may include clinical and genetic information about relative when it is relevant to the interpretation of the test results. I further understand that relatives will not receive an independent analysis of data nor a separate report.

RISKS AND LIMITATIONS OF GENETIC TESTING

1. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.

2. Accurate interpretation of test results may require knowing the true biological relationships in a family. I understand that if I fail to accurately state the biological relationships in my family, it could lead to incorrect interpretation of the test results, incorrect diagnoses, and/or inconclusive test results. If genetic testing reveals that the true biological relationships in a family are not as I reported them, including non-paternity (the reported father is not the biological father) and consanguinity (the parents are related by blood), I agree to have these findings reported to the healthcare provider who ordered the test.

3. Although genetic testing is highly accurate, inaccurate results may occur. These reasons include, but are not limited to mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other reasons.

4. I understand that this test may not detect all of the long-term medical risks that I might experience. The result of this test does not guarantee my health and that additional diagnostic tests may still need to be done.

5. I agree to provide an additional sample if the initial sample is not adequate.

PATIENT CONFIDENTIALITY AND GENETIC COUNSELING

It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area at www.nsgc.org. Further testing or additional consultations with a healthcare provider may be necessary.

To maintain confidentiality, test results will only be released to the referring healthcare provider, the ordering laboratory, to me, to other healthcare providers involved in my care, diagnosis and treatment, or to others with my consent or as permitted or required by law. Federal laws prohibit unauthorized disclosure of this information. More information can be found at: www.genome.gov/10002077

INTERNATIONAL SAMPLES

If I reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my residence.

SAMPLE RETENTION

After testing is complete, my sample may be de-identified and be used for test development and improvement, internal validation, quality assurance, and training purposes. **OmniHealth Diagnostics, LLC** will not return DNA samples to you or to referring healthcare providers, unless specific prior arrangements have been made. I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not retain them for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. **OmniHealth Diagnostics, LLC** will not perform any tests on the biological sample other than those specifically authorized.

DATABASE PARTICIPATION

De-identified health history and genetic information can help healthcare providers and scientists understand how genes affect human health. Sharing this de-identified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. **OmniHealth Diagnostics, LLC** shares this type of information with healthcare providers, scientists, and healthcare databases. **OmniHealth Diagnostics, LLC** will not share any personally identifying information and will replace the identifying information with a unique code not derived from any personally identifying information. Even with a unique code, there is a risk that I could be identified based on the genetic and health information that is shared. **OmniHealth Diagnostics, LLC** believes that this is unlikely, though the risk is greater if I have already shared my genetic or health information with public resources, such as genealogy websites.

INFORMED CONSENT

EXOME/GENOME SEQUENCING SECONDARY FINDINGS

Applicable Only for Full Exome Sequencing and Genome Sequencing Tests. • Does not pertain to Xpanded® or Slice tests

As many different genes and conditions are analyzed in an exome or genome sequencing test, these tests may reveal some findings not directly related to the reason for ordering the test. Such findings are called "incidental" or "secondary" and can provide information that was not anticipated.

Secondary findings are variants, identified by an exome or genome sequencing test, in genes that are unrelated to the individual's reported clinical features.

The American College of Medical Genetics and Genomics (ACMG) has recommended that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for all probands undergoing exome or genome sequencing. Please refer to the latest version of the ACMG recommendations for reporting of secondary findings in clinical exome and genome sequencing for complete details of the genes and associated genetic disorders. Reportable secondary findings will be confirmed by an alternate test method when needed.

WHAT WILL BE REPORTED FOR THE PATIENT? - All pathogenic and likely pathogenic variants associated with specific genotypes identified in the genes (for which a minimum of 10X coverage was achieved by exome sequencing or a minimum of 15X coverage was achieved by genome sequencing), as recommended by the ACMG.

WHAT WILL BE REPORTED FOR RELATIVES? - The presence or absence of any secondary finding(s) reported for the proband will be provided for all relatives analyzed by an exome or genome sequencing test.

LIMITATIONS - Pathogenic and/or likely pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. The absence of reportable secondary findings for any particular gene does not mean there are no pathogenic and/or likely pathogenic variants in that gene. Pathogenic variants and/or likely pathogenic variants that may be present in a relative, but are not present in the proband, will not be identified, or reported. Only changes at the sequence level will be reported in the secondary findings report. Larger deletions/duplications, abnormal methylation, triplet repeat or other expansion variants, or other variants not routinely identified by clinical exome and genome sequencing will not be reported.

FINANCIAL AGREEMENT AND GUARANTEE - For insurance billing, I understand and authorize **OmniHealth Diagnostics, LLC** to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made directly to I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by **OmniHealth Diagnostics, LLC** as part of a benefit investigation. I agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for services performed by **OmniHealth Diagnostics, LLC** on my behalf, I agree to endorse the insurance check and forward it to **OmniHealth Diagnostics, LLC** within 30 days of receipt as payment towards **OmniHealth Diagnostics, LLC** claim for services rendered.

MEDICARE

A completed Advance Beneficiary Notice (ABN) is required for Medicare patients.

DIGITAL PATIENT LETTER CONSENT

Applicable Only for Commercial Insurance

• Estimate is provided by your health insurance company and therefore NO estimate will be sent for any orders placed with federal or state-funded insurance plans (e.g. Medicare, Medicaid, Tricare, etc.), institutional bill, or patient bill (self-pay).

To provide you with the estimated out-of-pocket expenses related to your test, **OmniHealth Diagnostics, LLC** will send you an email and/or text with the link to access your personalized Digital Patient Letter.

In order to send this information, we need your consent and agreement to the following items:

1. can use your email address or mobile phone number solely for the purpose of **OmniHealth Diagnostics**, **LLC** sending your estimated financial obligation. Text message data rates may apply. is not responsible for undelivered messages due to incorrect or illegible contact information.

2. will send you an email and/or text message containing a link to view your personalized Patient Letter that includes the test out-of-pocket estimate. The link is time-sensitive and will only be available for 72 hours from the time the message is sent. In order to view the estimate, you must click the link in the message.

3. If you take no action, **OmniHealth Diagnostics, LLC** will assume that you agree to move ahead with testing and will bill your health insurance. You can approve testing with insurance, switch to self-pay, or cancel the test via the link within the given 72-hour window. In turn, **OmniHealth Diagnostics, LLC** if receives your sample(s) and the billing method hasn't been changed, or the test hasn't been cancelled, we will move ahead with testing as ordered, and you will be responsible for any out-of-pocket costs for the completion of the test(s).

STOP Patient Signature

I hereby assign all rights and benefits under my health plan and all rights and obligations that I and my dependents have under my health plan to **OmniHealth Diagnostics, LLC** is assigned affiliates and authorized representatives for laboratory services furnished to me by **OmniHealth Diagnostics, LLC** I irrevocably designate, authorize and appoint **OmniHealth Diagnostics, LLC** is assigned affiliates and their authorized representatives as my true and lawful attorney-in-fact for the purpose of submitting my claims, obtain a copy of my health plan document. Summary Plan Description, disclosure, appeal, litigation or other remedies in accordance with the benefits and rights under my health plan and in accordance with federal or state laws. If my health plan fails to abide by my authorization and makes payment directly to me, I agree to endorse the insurance check and forward it to **OmniHealth Diagnostics, LLC** is assigned affiliates and authorized representatives to contact me or my health Plan/administrator for billing or payment purposes by phone, text message, or email with the contact information that I have provided to **OmniHealth Diagnostics, LLC**, in compliance with federal and state laws. **OmniHealth Diagnostics, LLC** its assigned affiliates and authorized representatives, my enployer, and my authorized representative my personal health **Diagnostics, LLC**, its assigned affiliates and their authorized representatives may release to my health plan administrator, my employer, and my authorized representative my personal health **Diagnostics, LLC**. It is assigned affiliates and forward it to **OmniHealth Diagnostics, LLC** is assigned affiliates and authorized representatives to contact me or my health plan and in accordance with federal and state laws. **OmniHealth Diagnostics, LLC**, its assigned affiliates and their authorized representatives may release to my health plan administrator, my employer, and my authorized representative my personal health information for the purpose of procuring payment of **OmniHealt**

Signature of Patient or Patient Representative / Relationship to Patient

STOP ORDERING PHYSICIAN SIGN HERE Physician must only order tests that are medically necessory for the diagnosis or treatment of a patient

I attest that this test is medically necessary for the diagnosis or detection of a disease or disorder and that the results will be used in medical management and care decisions for the patient. Furthermore, all information on this Requisition Form is true to the best of my knowledge. I agree to provide the Care Plan notes and Letter of Intent for this order if the insurance requests the lab to gather the medical necessity for any reason

Ordering Physician Signature

Updated: 02/06/2023

Date:

Date: