

OMNIHEALTH DIAGNOSTICS, LLC

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PLEASE SUBMIT THE FOLLOWING WITH REQUISITION FO	RM
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Statement of Medical Necessity (Signed by Physician)
Informed Consent Form (Signed by Pt & Physician)

☐ SOAP & Progress Note (Signed by Physician)

COMPREHENSIVE EYE DISORDERS TESTING REQUISITION FORM
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COMPREHENSIVE ETE DISORDERS TESTING REQUISITION FORM								
		P	ATIENT INF	ORMATION				
Patient First Name Pati			Patient	nt Last Name Biological Sex F M				
Date of Birth (MM/DD/YYYY) Phone Number			r Email Address					
Address			City				Zip	
Ethnicity: African American	☐ Asia	an 🗌 Caucas	ian 🗌 Hispar	nic	hkenazi) 🗌	Portuguese [	Other	
PATIENT INSURA	NCE INI	ORMATIO	V	SPECIMEN INFORMATION				
☐ Insurance ☐ Self-Pay ☐ Client Bill			Date Sample Collected (mm/dd/yy) (required)					
Name of the insurance	Secondary Insurance, If any			Medical Rec	Лedical Record#			
Insurance Policy/ID number	er Name of the insured			☐ Buccal Sw	ab			
Insurance Group number Date of Birth of Insured			☐ Other (specify source)					
ORDERIN	G PHYS	ICIAN/SEN	DING FACII	LITY (Each Listed	person will r	eceive a copy of th	ne report)	
Facility Name (Facility Code):			Address	ess: City:				
State/Country:			Zip:	Phone:				
Ordering Licensed Provider Name (Last, First)(Code)			NPI#	PI#			Fax/Email	
		STATEM	ENT OF ME	DICAL NECE	SSITY			
By submission of this test requisition as the ordering provider is authorize requisition form are reasonable and disorder; (iv) the test results will detect (v) have obtained this patient's and reappropriate diagnosis code(s) are in	ed by law t d medicall ermine my relatives', w	o order the test y necessary for patient's medic hen applicable,	(s) requested; (i the diagnosis al management written informe	ii) certify that any and/or treatment t and treatment d	custom pait of a diseast ecisions of t	nel and/or order se, illness, impai his patient's con	ed test(s) requested on this test rment, symptom, syndrome or dition on this date of service;	
Signature of Provider (required)  Date:						Date:		
	IND	<b>ICATIONS F</b>	OR TESTIN	IG (CHECK ALL T	HAT APPLY)			

**CLINICAL PRESENTATION** 

Please indicate any clinical presentations and /or findings that may be relavant to genetic testing:

Will Patient management be changed depending on the test results? ☐ Yes☐ No

- Behavior - Phenotypes

- Conditions- Physical- Pedigree/Family History- Symptoms

There are many presentations which may not seem like a direct association for disease. Please List the most suspected presentations and attach detailed medical records and/or pedigree.

☐ Diagnostic ☐ Family history ☐ Positive or normal control ☐ Other.......

Custom Eye Disorders Panel (Select the genes below) or	Comprehensive Eye Disorders Panel (Test All Genes)
□ ATXN7       □ CTSD       □ KCNQ2       □ PCDH19       □ RPGR       □ ST         □ CACNA1A       □ EYS       □ MECP2       □ PDE6A       □ SCN1A       □ ST         □ CDH23       □ FTL       □ MTRNR1       □ PDE6B       □ SCN1B       □ TG         □ CDKL5       □ GABRG2       □ MYO15A       □ POLG       □ SCN2A       □ TG         □ CFH       □ GJB2       □ MYO7A       □ PRPF31       □ SCN8A       □ TI	GFBI
INDICATION (S) FOR TESTING ICD-10	
Category - 1:	
B73.1 - Onchocerciasis without eye disease   C43.10 - Malignant melanoma of unspecified eyelid, including canthus   C43.10 - Malignant neoplasm of unspecified eyelid, including canthus   C69.00 - Malignant neoplasm of infit conjunctiva   C69.01 - Malignant neoplasm of infit conjunctiva   C69.01 - Malignant neoplasm of left conjunctiva   C69.01 - Malignant neoplasm of infit conjunctiva   C69.01 - Malignant neoplasm of infit cornea   C69.11 - Malignant neoplasm of unspecified cornea   C69.12 - Malignant neoplasm of unspecified retina   C69.21 - Malignant neoplasm of unspecified retina   C69.21 - Malignant neoplasm of unspecified chroid   C69.21 - Malignant neoplasm of infit retina   C69.21 - Malignant neoplasm of infit chroid   C69.31 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.31 - Malignant neoplasm of infit chroid   C69.31 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.31 - Malignant neoplasm of infit chroid   C69.31 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.31 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of infit chroid   C69.32 - Malignant neoplasm of woretapping sites of inspecified eye and adnexa   C69.32 - Malignant neoplasm of unspecified site of unspecified eye   C69.31 - Malignant neoplasm of unspecified site of inspecified eye   C69.31 - Malignant neoplasm of unspecified site of inspecified eye   C69.31 - Malignant neoplasm of unspecified part of right eye   C69.31 - Malignant neoplasm of unspecified site of inspecified eye   C69.31 - Malignant neoplasm of unspecified site of inspecified eye   C69.31 - Malignant neoplasm of unspecified site of inspecified eye   C69.31 - Malig	E11.321-1 Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye  □ E11.321-1 Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye □ E11.3219- Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye □ E11.3219- Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye □ E11.3291- Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, elf eye □ E11.3292- Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye □ E11.3291- Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye □ E11.331- Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye □ E11.331- Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye □ E11.3319- Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, and the view of the v
☐ E10.3511 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	☐ H40.051 - Ocular hypertension, right eye  Continue

INDICATION (S) FOR TESTING	CD-10 Codes					
□ E10.3512 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye □ E10.3519 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye □ E10.3521 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macular edema, right eye □ E10.3522 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macular edema, left eye □ E10.3529 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macular edema, unspecified eye □ E10.3531 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macu □ E10.3532 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macu □ E10.3539 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macu □ E10.3531 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatog □ E10.3541 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatog □ E10.3542 - Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatog □ E10.3551 - Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye □ E10.3553 - Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye □ E10.3559 - Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral □ E10.3559 - Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye □ E10.3592 - Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye □ E10.3592 - Type 1 diabetes mellitus with prol	<ul> <li>H40.052 - Ocular hypertension, left eye</li> <li>H40.053 - Ocular hypertension, unspecified eye</li> <li>H40.059 - Ocular hypertension, unspecified eye</li> <li>H40.061 - Primary angle closure without glaucoma damage, right eye</li> <li>H40.062 - Primary angle closure without glaucoma damage, left eye</li> <li>H40.811 - Glaucoma with increased episcleral venous pressure, right eye</li> <li>H40.812 - Glaucoma with increased episcleral venous pressure, left eye</li> <li>H40.819 - Glaucoma with increased episcleral venous pressure, unspecified eye</li> <li>H40.821 - Hypersecretion glaucoma, right eye</li> <li>H40.822 - Hypersecretion glaucoma, left eye</li> <li>H40.89 - Other specified glaucoma</li> <li>H46.00 - Optic papillitis, unspecified eye</li> <li>H46.01 - Optic papillitis, ight eye</li> <li>H46.10 - Retrobulbar neuritis, inspecified eye</li> <li>H46.11 - Retrobulbar neuritis, right eye</li> <li>H46.12 - Retrobulbar neuritis, left eye</li> <li>H57.00 - Unspecified anomaly of pupillary function</li> <li>H57.01 - Argyll Robertson pupil, atypical</li> <li>H57.02 - Anisocoria</li> <li>H57.03 - Miosis</li> <li>H57.04 - Mydriasis</li> <li>H57.052 - Tonic pupil, right eye</li> <li>H57.053 - Tonic pupil, left eye</li> <li>H57.059 - Tonic pupil, unspecified eye</li> <li>H57.051 - Tonic pupil, unspecified eye</li> <li>H57.051 - Tonic pupil, vight eye</li> <li>H57.051 - Tonic pupil, or eye disorders</li> <li>Z83.51 - Family history of eye disorders</li> <li>Z85.84 - Personal history of other diseases of the nervous system and sense organs</li> </ul>					
Category - 2: ICD10 codes						
<ul> <li>□ T41.0X5A - Adverse effect of inhaled anesthetics, initial encounter</li> <li>□ T41.0X5D - Adverse effect of inhaled anesthetics, subsequent encounter</li> <li>□ T41.0X5S - Adverse effect of inhaled anesthetics, sequela</li> <li>□ T41.0X6A - Underdosing of inhaled anesthetics, initial encounter</li> <li>□ T41.0X6D - Underdosing of inhaled anesthetics, subsequent encounte</li> <li>□ T41.0X6S - Underdosing of inhaled anesthetics, sequela</li> </ul>	☐ T41.1X5S - Adverse effect of intravenous anesthetics, sequela☐ T41.1X6A - Underdosing of intravenous anesthetics, initial encounter					
Additional ICD-10 codes:						

## **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 arelative 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.

**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** its assigned affiliates and authorized representatives for laboratory services furnished to me by **OmniHealth Diagnostics, LLC** I irrevocably designate, authorize and appoint **OmniHealth Diagnostics, LLC** or its 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** immediately upon receipt. I hereby authorize **OmniHealth Diagnostics, LLC** its 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 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 **OmniHealth Diagnostics, LLC** and for all the laboratory services. I understand the acceptance of insurance does not relieve me from any responsibility concerning payment for laboratory services and that I am financially responsible for all charges whether or not they are covered by my insurance.

Signature of Patient or Patient Representative / Relationship to Patient

Date:

## 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

Date: