AVAGEN GENETIC EYE TEST REQUISITION FORM

Please complete ALL sections of this form (back and front).

Laboratory Director: Mir H. Noorbakhsh, PhD, D(ABMM)
CLIA Number: 05D2048075

1. PATIENT INFORMATION *(completed by Patient or Parent/Legal Guardian)*

Patient Identification Number or Name:		**Date of Birth:** *(MM/DD/YYYY)* _____ / _____ / _____
Patient Phone Number:	**Patient Email:**	**Patient State of Residence:**

Patient Ethnicity:

- ☐ Black / African / African-American
- ☐ South Asian
- ☐ Jewish (Sephardic)
- ☐ Pacific Islander
- ☐ East Asian
- ☐ Hispanic (non-white)
- ☐ Middle Eastern
- ☐ Portuguese
- ☐ South East Asian
- ☐ Jewish (Ashkenazi)
- ☐ Native American
- ☐ White / Caucasian / European
- ☐ Other (*please specify*): _____

Sex at Birth:

- ☐ Male
- ☐ Female

2. CLINICAL INFORMATION *(completed by Physician or Clinic/Practice Clinician or Technician)*

Patient Clinical Diagnosis:

- ☐ Keratoconus
- ☐ Corneal Dystrophy
- ☐ Pellucid Marginal Degeneration
- ☐ Post Refractive Surgery Ectasia
- ☐ Known Family History
- ☐ Unknown
- ☐ Other (*describe in Comments section below*)

Comments:

Family History: *Attach a copy of the patient's family/genetic pedigree if available, indicating family member's age and eye condition(s), and submit along with patient buccal sample.*

Any known family history of Keratoconus, Corneal Dystrophy or other eye conditions? ☐ Yes (*specify below*) ☐ No ☐ Unknown

RELATIONSHIP TO PATIENT	MATERNAL	PATERNAL	CONDITION	AGE AT DIAGNOSIS*
	☐	☐	☐ Keratoconus ☐ Corneal Dystrophy ☐ Other (*specify*):	
	☐	☐	☐ Keratoconus ☐ Corneal Dystrophy ☐ Other (*specify*):	
	☐	☐	☐ Keratoconus ☐ Corneal Dystrophy ☐ Other (*specify*):	
	☐	☐	☐ Keratoconus ☐ Corneal Dystrophy ☐ Other (*specify*):	
	☐	☐	☐ Keratoconus ☐ Corneal Dystrophy ☐ Other (*specify*):	

3. TEST SAMPLE INFORMATION *(completed by Physician or Clinic/Practice Clinician or Technician)*

Sample Collection Date: *(MM/DD/YYYY)* _____ / _____ / _____

IMPORTANT: *It is recommended that the patient sample be shipped within seven (7) days from sample collection date if stored at room temperature.*

4. REQUESTING PHYSICIAN/CLINIC INFORMATION *(completed by Physician or Clinic/Practice Clinician or Technician)*

Clinic Name:			
Address:			
City:	**State:**	**Country:** United States	**ZIP:**
Phone Number:	**Ordering Physician Email:**		
Ordering Physician Printed Name: *(Last, First, Middle)*			

Ordering Physician Statement

I, the physician named herein, confirm that I am requesting this AvaGen genetic eye test for the patient identified above. Test results are confidential and will be used with standard clinical assessments to guide patient care decisions. By signing below, I attest that: (1) I am the ordering physician or authorized healthcare provider; (2) I have explained the purpose of test described above; (3) the patient has had the opportunity to ask questions regarding this test and the retention, use, and sharing of their data and sample, and to seek genetic counseling; and (4) the patient has voluntarily decided to have this test performed by Avellino.

Signature of Ordering Physician:	**Date:** *(MM/DD/YYYY)*

Avellino Lab USA, Inc.
1505 Adams Drive, Suite B2, Menlo Park, CA 94025
(650) 396-3741 | infousa@avellino.com | www.avellino.com

5. ABOUT GENETIC TESTING AND AVAGEN

What is genetic testing?

Genetic testing is an important step in diagnosing diseases, such as keratoconus or corneal dystrophies. When your healthcare provider suspects that you may have a condition or could develop one in the future that has a genetic basis, it's important to get tested so you can confirm a diagnosis or risk factors and take appropriate steps.

How does the AvaGen test work?

The AvaGen genetic test analyzes your DNA – the chemical building blocks of genes – to look for changes (mutations) that can cause certain diseases. If your test confirms a risk for developing keratoconus or the presence of corneal dystrophy, you and your healthcare provider may consider creating a management or treatment plan. Your healthcare provider may advise/request professional genetic counseling based on the results of your tests. In this case, Avellino will facilitate genetic counseling at no additional charge to the patient or their healthcare provider.

For more information about the AvaGen genetic test, talk to your healthcare provider or refer to www.avellino.com.

How will I receive my test results?

Avellino's clinical reports are released to the certified healthcare provider(s) ("Ordering Physician") listed on this requisition form. Clinical reports are confidential and will only be shared in accordance with applicable laws. Your healthcare provider will follow up with you to discuss your test results. You should contact your healthcare provider to follow up on the results of your genetic eye test. Your clinical report is available to you from your healthcare provider(s) or upon your written request in accordance with applicable law.

Who should I speak to about my test and results?

You should consult with your healthcare provider before consenting to this test – your healthcare provider can help answer your questions you have about this test and genetic testing. You should discuss your test results with your healthcare provider and/or a genetic counselor.

Will my test results ever change?

As knowledge of genetic information improves over time, new information may become available that potentially could impact the interpretation of your test results. Your healthcare provider may be notified of clinically significant changes to the interpretation of your genetic eye test and may over time receive updated reports containing previously unreported variants in genes that were not associated with disease at the initial time of testing and/or updated variant classifications.

What about the privacy of my DNA?

Genetic information, just like your medical records, is private. When you get tested with the AvaGen genetic test, your DNA will be securely stored within your electronic medical records and also securely within Avellino's HIPAA-compliant database. This information will be available to you upon request to assist with other health conditions in the future. Learn more about Avellino's genetic data usage and privacy practices below or at https://www.avellino.com/en/genetic-data-usage/ and https://www.avellino.com/en/privacy/.

6. PATIENT CONSENT

I hereby consent to participate in the AvaGen *The Genetic Eye Test* for the risk of keratoconus and the presence of corneal dystrophy.

I understand that a biologic specimen (e.g., saliva or tissue) will be obtained from me/my child. I understand that this biologic specimen will be used for the purpose of attempting to determine if I/my child are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease.

It has been explained to me and I understand that:

- This test is specific for identifying the risk of keratoconus and the presence of corneal dystrophy.
- A positive result is an indication that I/my child may be predisposed to or have the specific disease or condition. Further testing may be needed to confirm the diagnosis. I understand I will be given the opportunity to talk with my physician and a genetic counselor about any positive results.
- Familial genetic testing can be a powerful tool in determining the genetic predisposition to a disease in families. I understand that, based on my/my child's positive test result, I will be given the opportunity to talk with my physician to pursue further genetic testing for other family members.
- There is a chance that I/my child may have this genetic condition but that the genetic test results will be negative. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease may not be detected by the test.
- There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition other than the diagnosis that was originally considered.
- In many cases, a genetic test directly detects an abnormality. Molecular testing may detect a change in the DNA (i.e., mutation). Most genetic tests have high analytical sensitivity and specificity. However, clinical sensitivity and specificity are dependent on a still growing body of knowledge in the medical genetic field.
- The tests offered are considered to be the best available at this time. This testing is often complex and utilizes specialized materials. However, there is always a non-zero chance an error may occur.
- Because of the complexity of genetic testing and the important implications of the test results, my/my child's test results will be reported only through a physician, genetic counselor, or other identified healthcare provider. The results are confidential to every extent allowed by law. They will only be released to other medical professionals or other parties with my express written consent or as otherwise required by law. Participation in genetic testing is completely voluntary.
- My/my child's sample will not be used for research purposes without my consent.
- My/my child's de-identified genetic information, PFHI, personal data, and results may also be stored and used for internal quality assurance; internal validation studies; improvement and research and development of all current and future products that Avellino offers; and in publications authored solely by Avellino, disclosing only aggregated and anonymous information.
- Avellino will retain the sample only for the maximum duration permitted under applicable law or regulation ("Retention Period"), after which point it will be destroyed. Samples from New York patients will be destroyed within 60 days after Avellino's receipt of the sample (or upon completion of all Tests). Until such time that your sample is destroyed, Avellino may: (a) store or use it for regulatory compliance purposes, and (b) de-identify your sample and process and analyze it for internal quality assurance, internal validation studies, and internal research and development for all current and future products that Avellino offers.
- Avellino reserves the right to: (a) suggest additional genetic testing if it would help in resolving the patient's clinical genotyping; (b) report additional testing results (other than requested) if they are clinically relevant to the patients and their families; and (c) refuse testing if one of the conditions in the Patient Consent form is not met.

Patient Acknowledgement: I acknowledge that the information provided by me on the test requisition form (TRF) is true and correct. I have read (or have had read to me) all of the above statements and understand the information regarding genetic eye testing and have had the opportunity to ask questions I might have about the testing, the procedure, the risks, and the alternatives prior to my informed consent. My signature below acknowledges my voluntary participation in this test. I understand that the genetic analysis performed by Avellino is specific only for the diseases specified and in no way guarantees my/my child's health, the health of an unborn child, or the health of other family members.

Patient or Legal Guardian Signature:	**Date:** *(MM/DD/YYYY)*
Patient Printed Name: *(Last, First, Middle)*	
Parent/Legal Guardian Printed Name: *(Last, First, Middle)*	

Healthcare Provider's Statement: I have explained genetic testing (including the risks, benefits, and alternatives) to this individual. I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.

Healthcare Provider's Signature:	**Date:** *(MM/DD/YYYY)*
Healthcare Provider Printed Name: *(Last, First, Middle)*	**Clinic Name:**