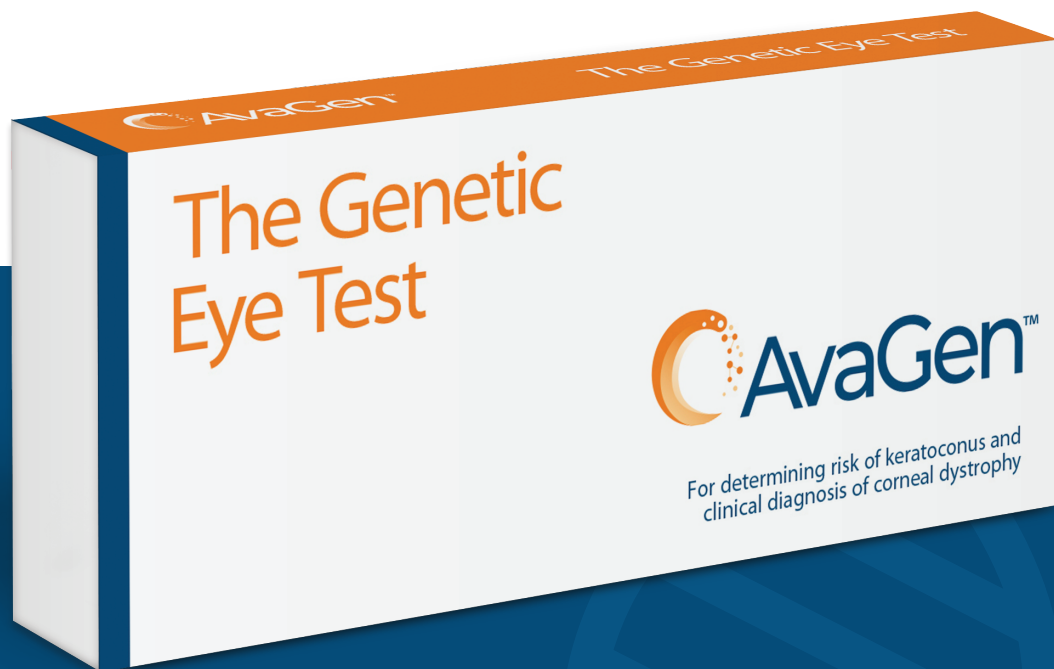


# INSTRUCTIONS FOR **TESTING**



**Know early.  
Act personally.  
Decide confidently.**

# THE AVAGEN GENETIC EYE TEST

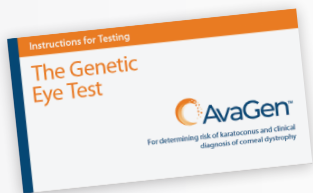
## TEST KIT CONTENTS

Each AvaGen test kit contains the following:



- 1x Instructions for Testing
- 1x Test Requisition Form
- 1x Collection vial, including reagent
- 2x Swab Pouches containing two swabs each (total four swabs)
- 1x Biohazard bag with absorbent pad
- 1x Shipping box with pre-paid USPS shipping label

## INSTRUCTIONS FOR TESTING



The Instructions for Testing (IFT) trifold contains an easy-to-use checklist to confirm that all required steps for sample collection and shipping (as detailed in this Instructions Brochure) are completed.

The IFT also includes a tear-off section with key contact information which may be handed to the patient.

## TEST REQUISITION FORM

The Test Requisition Form (TRF) must be completed online via the web portal ([www.avageneye.com](http://www.avageneye.com)).

- Only if you cannot access the web portal, complete the paper Test Requisition Form available in the test kit. Contact your local account representative or [infousa@avellino.com](mailto:infousa@avellino.com) with any questions about completion or a replacement TRF.
- If using the paper form, it must be signed by the ordering clinician and patient, and the fully completed form must be sent along with the patient sample to Avellino for testing. The clinic may make a copy of the form (both sides) to keep with the patient's medical records.

**Please complete all sections of the TRF, whether electronic or paper (both sides of the form), in full to ensure prompt service and avoid sample rejection.**

## TEST REQUISITION FORM

Carefully review the requirements below for correct completion of each section in the TRF (electronic or paper).

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### Section 1 - Patient Information (pg.1)

*To be completed by Patient or Parent/Legal Guardian.*

- **Patient Identification Number or Name:** Include either the patient identification number assigned to the patient and used in your clinic, or the patient's first and last name. Do NOT use initials.
- **Other Patient Information:** The patient's ethnicity, gender, phone number, email address, and state of residence must also be provided for testing purposes and compliance with U.S. State requirements for genetic sample retention.

### Section 2 - Clinical Information (pg.1)

*To be completed by Physician or Clinic/Practice Clinician or Technician.*

- **In this section, provide clinical information known about the patient.**
  - Check "Unknown" if clinical diagnosis is not known or unavailable.
  - Comments section may be used if clinic wishes to convey information or instructions to the test lab.
  - Attach a copy of clinic notes (if available) for submission along with patient buccal sample.
- **Indicate patient's family history of Keratoconus, Corneal Dystrophy, or other eye conditions.**
  - Indicate family members' ages and eye conditions in the pedigree chart (if available) and attach to the TRF.

### Section 3 - Clinical Information (pg.1)

*To be completed by Physician or Clinic/Practice Clinician or Technician.*

- Provide the date the sample was collected from the patient.

*NOTE: Though DNA is typically very stable, there is always the possibility that storage conditions may affect the quality of the DNA received. Therefore, it is strongly recommended that the patient sample must be shipped within seven (7) days from sample collection date if stored at room temperature from time of collection.*

### Section 4 - Requesting Physician/Clinic Information (pg.1)

*To be completed by Physician or Clinic/Practice Clinician or Technician.*

- This includes clinic name, address, phone number, and email.
- The ordering physician/clinician must review statement in orange and indicate agreement by printing name and signing in the provided sections.

### Sections 5 & 6 - Patient Informed Consent (pg.2)

*To be read and signed by Patient or Parent/Legal Guardian.*

- The consent form includes important information about genetic testing and test results, as well as information about Avellino's privacy policy and practices (learn more at <https://www.avellino.com/en/genetic-data-usage/>).
- In order for patient to proceed with the genetic eye test and to receive genetic counseling services (if requested by ordering physician based on genetic eye test results), patient must review the form for accuracy as well as read and sign the Consent section.

*NOTE: It is the responsibility of the patient's healthcare provider to (1) ensure the purpose of the AvaGen genetic eye test is explained to the patient, and (2) address any questions the patient has regarding this test and the retention, use, and sharing of their data and sample, and to seek genetic counseling.*
- Authorization/consent is provided by patient or parent/legal guardian printing name (first and last name) with signature and date.

## SAMPLE COLLECTION FROM PATIENT

For video instructions, go to  
[www.avellino.com/avagen/video/](http://www.avellino.com/avagen/video/)



### STEP 1

Recently consumed fatty foods, soft drinks, alcohol, butter, cheese, chocolate, or chewing gum may interfere with the quality of the patient's buccal sample and subsequent genetic testing.  
To ensure a clean sample, the patient must rinse their mouth with warm water prior to buccal swabbing to remove any food or beverage residue.

### STEP 2

The physician/clinician must complete steps 2 through 13 to collect the patient's buccal sample.  
**PLEASE USE APPROPRIATE PPE TO PREVENT SAMPLE CONTAMINATION.**

**IMPORTANT:** The patient identifier (i.e., patient identification number or patient first and last name) and date of birth, as noted on the TRF, must be written exactly the same on the vial flag label.

Verify the AVA number on the top right corner of the paper TRF matches the label placed on the vial.

Confirm that the date printed on the iSWAB collection device (vial) and buccal swab pouches are not expired.

**DO NOT USE IF EXPIRED – EXPIRED VIAL WILL BE REJECTED.**



### STEP 3

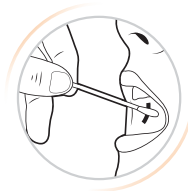
Unscrew the cap from the vial to allow the swab access to the sample suspension solution.

**IMPORTANT:** To avoid losing the solution, take care not to tip the vial.

### STEP 4

Take a new swab pouch. Peel and remove swab.

**IMPORTANT:** Do not touch the swab tip or allow the swab tip to be in contact with any other object.



### STEP 5

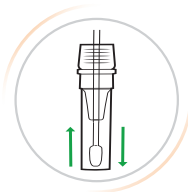
For each swab, apply tip against inside of the cheek and rub firmly against it for at least 20-30 seconds.

**Swab Collection Tips:**

- Rotate swab tip during collection.
- Try to cover the whole side of the cheek from top to bottom and from side to side.

### STEP 6

Insert the swab by twisting downward into the vial with a screw-like motion (clockwise).



### STEP 7

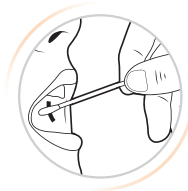
Carefully plunge the tip of the swab approximately ten (10) times into the vial by moving the tip up and down. Be careful not to pull up too high above the insert funnel.

### STEP 8

Remove the swab from the vial by twisting the swab upwards in a unscrewing-like motion (counter-clockwise).

**DO NOT BREAK THE SWAB OFF INTO THE VIAL, IT WILL BE REJECTED.**

**DISCARD THE USED SWAB AS BIOHAZARD WASTE.**



### STEP 9

Repeat steps 4 to 8 until all four swabs provided in the kit are used, alternating between the left and right cheeks.

**PLEASE USE ALL 4 SWABS.**

## SHIPPING PROCEDURE

For video instructions, go to [www.avellino.com/avagen/video/](http://www.avellino.com/avagen/video/)



### STEP 10

Twist on vial cap, making sure that it is snug (tightly closed).

### STEP 11

Place vial (containing patient's collected sample) into provided sealable biohazard bag with absorbent pad.



### STEP 12

Place biohazard bag (with patient sample sealed inside) in shipping box. When the web portal is used, the TRF can be retained at the clinic (with patient name) for reference use. When paper TRF is used, place the completed TRF in the shipping box.



### STEP 13

Seal box by removing the pull-off strip from the box flap, and pressing onto the side of the box, ensuring that it is securely closed.



### STEP 14

Mail by USPS Express Service. The shipping box is marked with a pre-paid USPS shipping label. Sample may be shipped at room temperature for receipt at test lab within seven (7) days from collection.



## Customer Support

For questions, technical support, and to order additional test supplies:



650-396-3741



[infousa@avellino.com](mailto:infousa@avellino.com)



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