AMD

Management of "Pre-Clinical" and Early Phases of Age-related Macular Degeneration (AMD)

And how you can play a role in preserving vision

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Disclosure
Dr. Eiden

(consulting, lecturer, research, or financial interest*)

Alcon
Allergan
Avellino
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Cooper Vision
Euclid
Heru
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LENZ
Nevakar
Notal Vision
Novartis
Oculus
Optovue
Percept
Sight Sciences
Sight Glass
Special Eyes
SynergEyes
Visible Genomics*
VTI
EyeVis Eye and Vision Research*

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Keratoconus Specialists of Illinois
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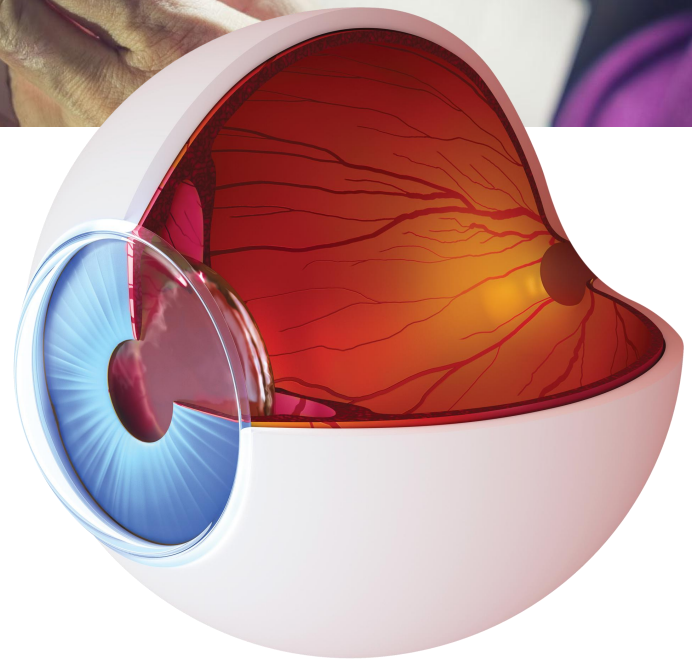
Comprehensive AMD Management Approach

- **Risk Assessment**
  - Modifiable: UV exposure, smoking, obesity, levels of protective photopigments, etc.
  - Non-modifiable: Age, Family History/Genetic Risk, Race, Eye Color, etc.
- **Steps for Prevention**
  - Addressing modifiable risk factors
- **Office Based Diagnostics (Key: Early Dx)**
  - Genetic Testing, Dark Adaptometry, Contrast Sensitivity, MPOD, +Macula OCT, OCT-A
  - Dilated retinal exam, Retinal Photography, NaFl Angiography
  - **Home Based Diagnostics:** Hyperacuity Perimetry, Home OCT*
- **Medical Therapy & Visual Rehabilitation** (Low Vision Rehab.***)
  - Anti-VegF therapy, laser therapy, developing technologies (eg. Stem Cell)

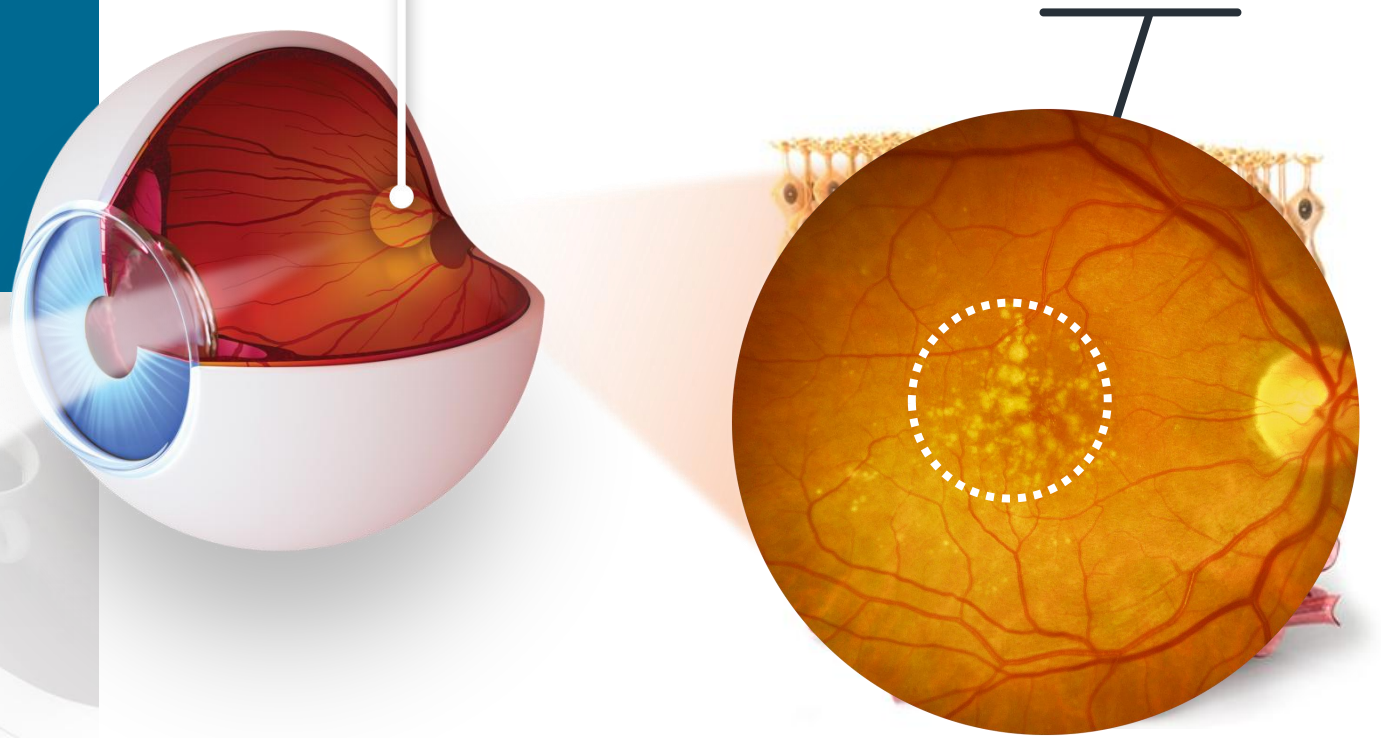
AMD Basics

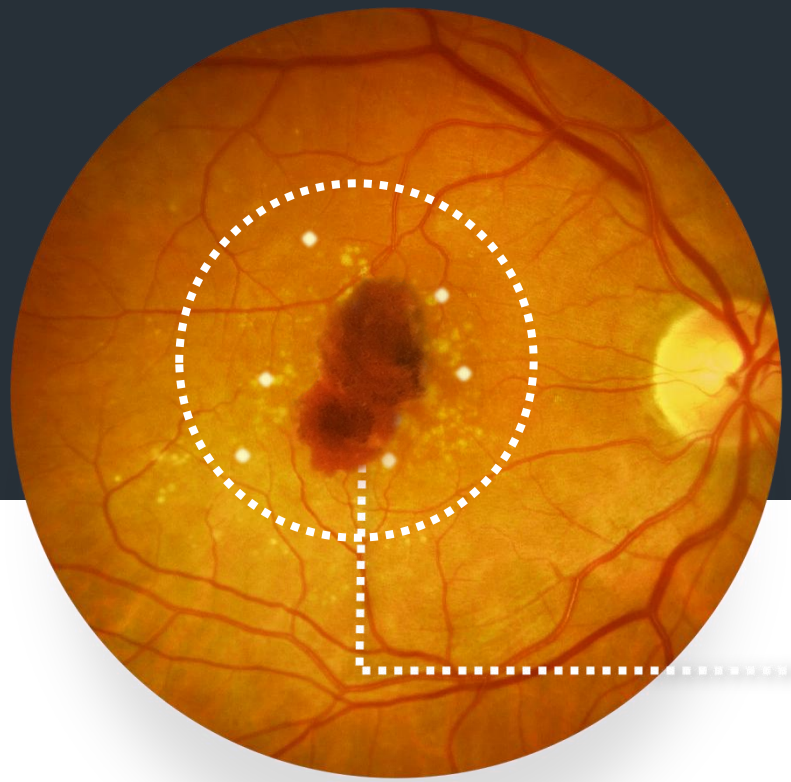


Atrophic/Dry AMD

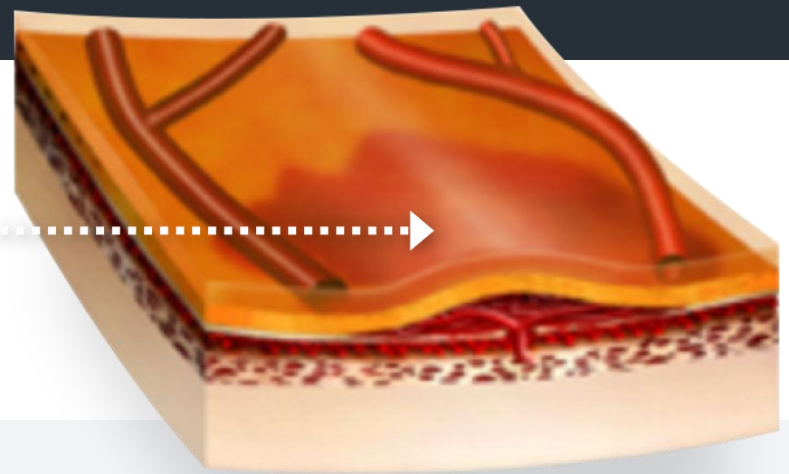
Dry AMD affects the macula, responsible for detailed central vision

Can express from mild/asymptomatic to Advanced Geographic Atrophy w/severe vision loss



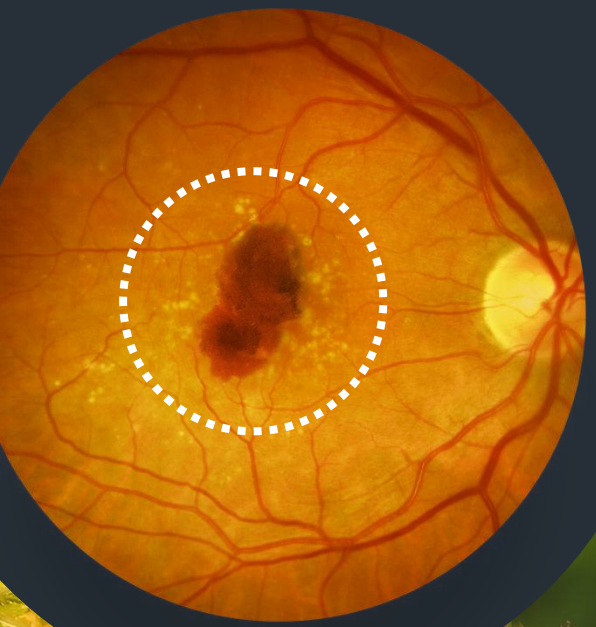


As Atrophic AM progresses, so does the risk of developing "Exudative" or "Wet AMD"



Dry AMD can suddenly change to wet AMD without advance notice

Patients may not notice changes until significant vision loss has occurred



When wet AMD occurs, **significant vision loss can be rapid and severe**

Both Forms of Advanced AMD(Geographic or Exudative) can lead to legal blindness

Atrophic AMD (dry) accounts for approximately

10%

OF SEVERE VISION LOSS ASSOCIATED WITH AMD

10 to 15% of patients with dry AMD convert to wet AMD

Choroidal neovascular (CNV) AMD (wet) accounts for approximately[3]

90%

OF SEVERE VISION LOSS ASSOCIATED WITH AMD

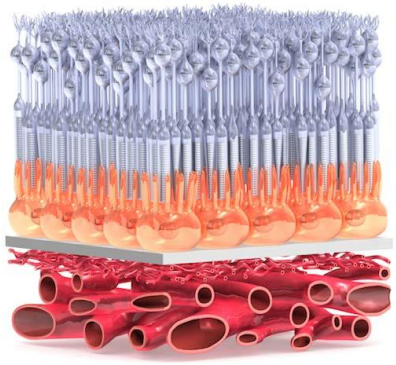
Conversion to CNV can be sudden, with vision loss being rapid and severe.

Burden of a missed conversion

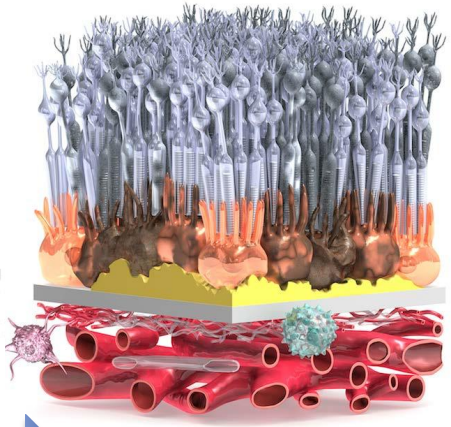
- Leads to delayed therapeutic intervention
- Potential for irreversible central vision loss

Ref avail upon request

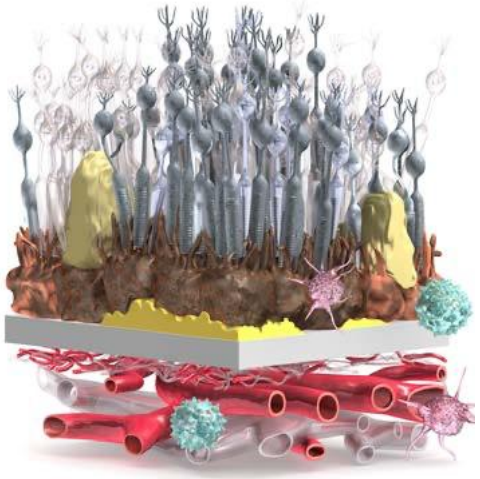
Progression From Early to Advanced AMD With Central Vision Loss



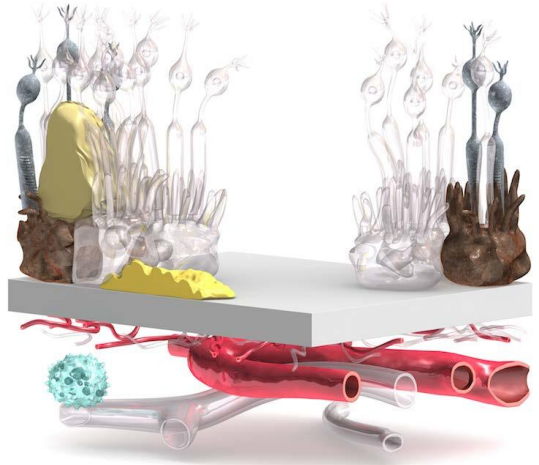
Normal Retina



Chronic, Oxidative Stress, Visual Cycle Toxic Byproducts, Impaired Lipid Metabolism

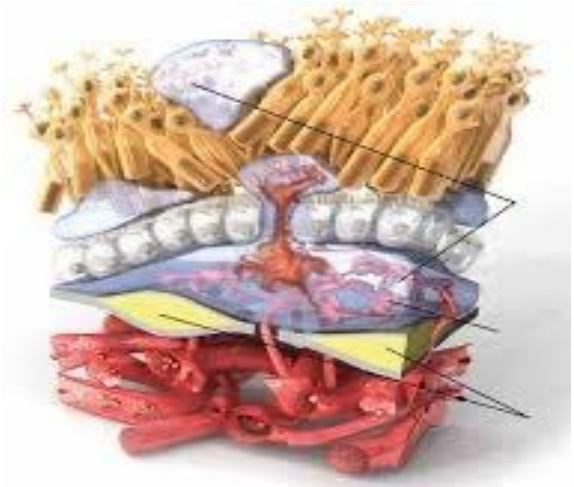


Alternative Complement Pathway Dysregulation, BRB Breakdown; Capillary Dropout



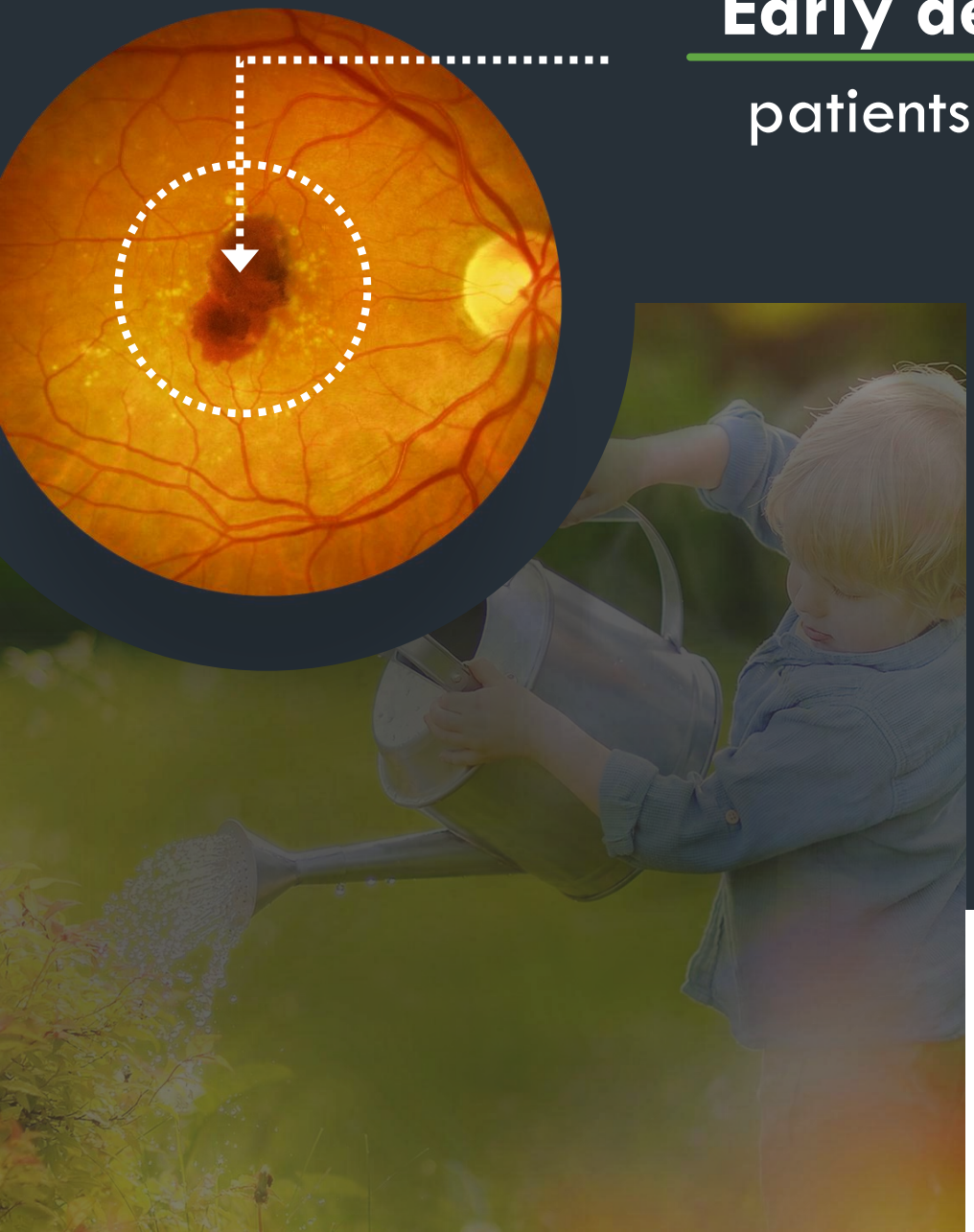
Geographic Atrophy
(RPE and Photoreceptor Cell Death)

Slowly Progressing (Years)



Wet AMD
(Leaky Blood Vessels and Fluid Accumulation)

Acute, Fast Progressing (Weeks)



Early detection provides best chance of helping patients maintain good vision and independence

- **Once wet AMD starts, it will continue to advance until treatment is initiated**
- **Irreversible damage can occur within days to weeks and before symptoms are noticed**
- **Once symptoms of visual impairment are noticed, vision loss may have already occurred**

Early Detection and Management is the Key to Preserving Vision!

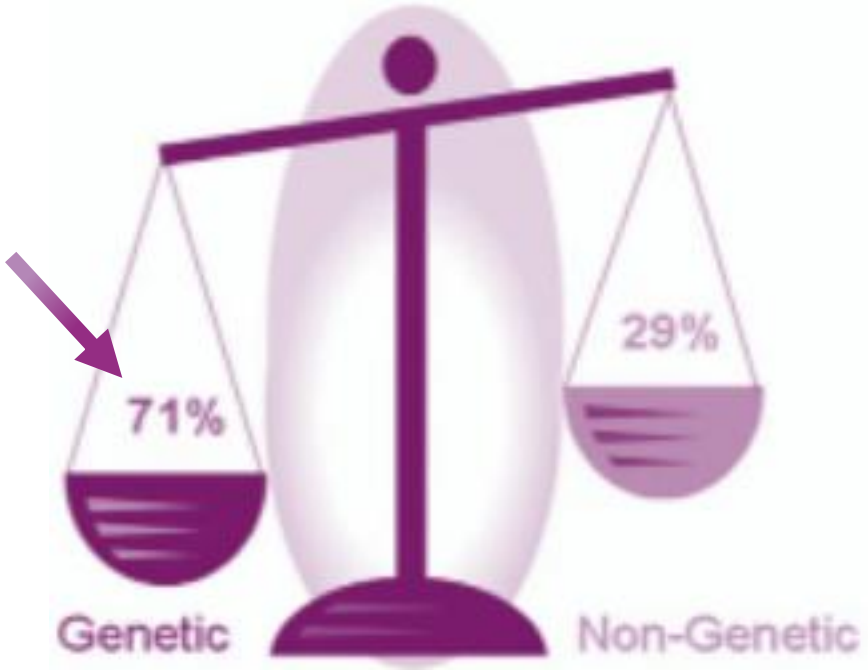
Comprehensive AMD Management Approach
Pre/Sub-Clinical & Early Stage Diagnostics

- **Genetic Testing**
- **CSF Screening**
- **Dark Adaptometry**
- **Macula Pigment Optical Density (MPOD)**
- **Retinal Imaging:**
  - **High resolution photography**
  - **Macula OCT & OCT-A**
- **Home Based Testing:**
  - **Hyperacuity Perimetry**
  - **Home OCT** (in development*)

Genetic Testing & Heritability of Advanced AMD

INTERPLAY OF GENES AND ENVIRONMENT ("Epi-Genetics")

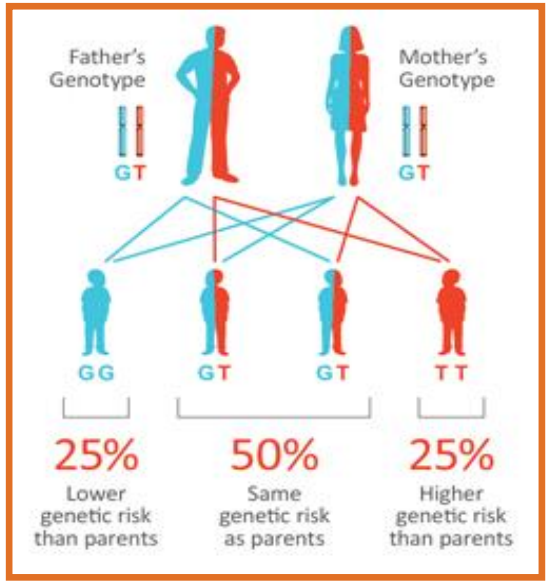
71% GENETIC CAUSE



FOR COMPARISON:

Obesity	54%
CVD	49%
Prostate cancer	42%
Breast cancer	27%
Type 2 diabetes	26%

Progression to advanced AMD is based on multiple factors, modifiable and non-modifiable.



MODIFIABLE RISK FACTORS

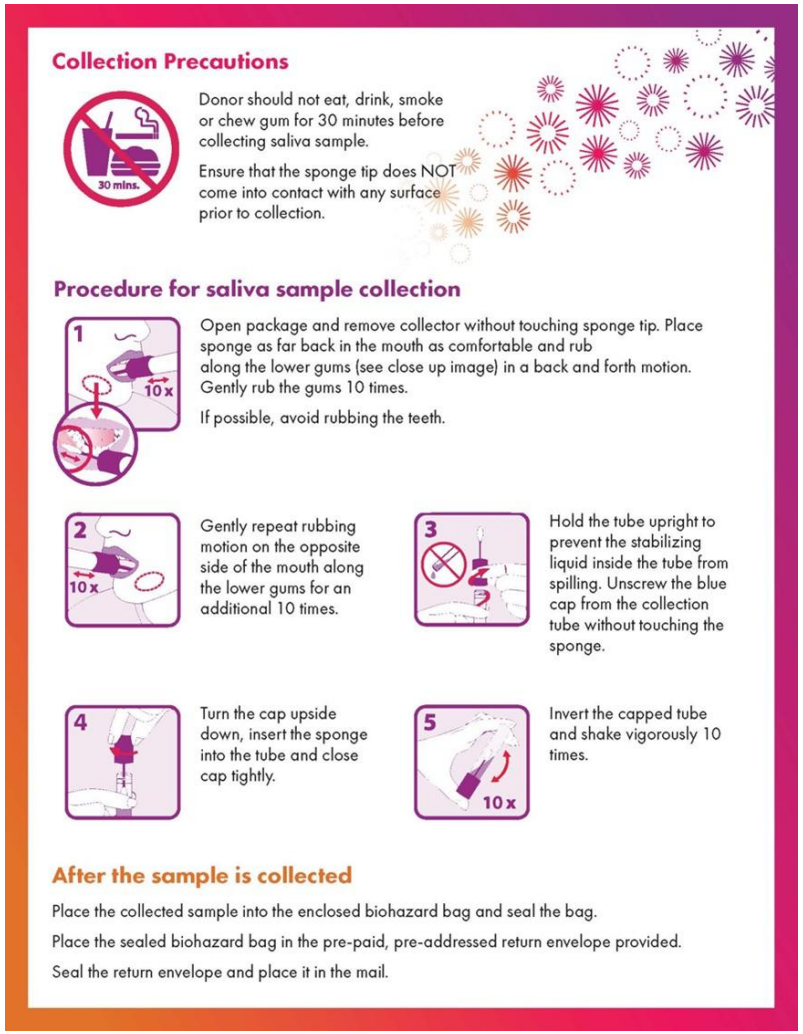
- lifestyle (smoking + diet)
- weight/ body mass index (BMI)
- Protective photopigments

NON-MODIFIABLE RISK FACTORS

- age, sex, race
- family risk (genetic variation)

IN AMD: GENETIC VARIATION IS THE MOST IMPORTANT NON-MODIFIABLE RISK FACTOR.

Simple In Office or Home Cheek Swab Sample Review Outcomes in Office or Virtual



Collection Precautions

Donor should not eat, drink, smoke or chew gum for 30 minutes before collecting saliva sample.

Ensure that the sponge tip does NOT come into contact with any surface prior to collection.

Procedure for saliva sample collection

Open package and remove collector without touching sponge tip. Place sponge as far back in the mouth as comfortable and rub along the lower gums (see close up image) in a back and forth motion. Gently rub the gums 10 times.

If possible, avoid rubbing the teeth.

Gently repeat rubbing motion on the opposite side of the mouth along the lower gums for an additional 10 times.

Hold the tube upright to prevent the stabilizing liquid inside the tube from spilling. Unscrew the blue cap from the collection tube without touching the sponge.

Turn the cap upside down, insert the sponge into the tube and close cap tightly.

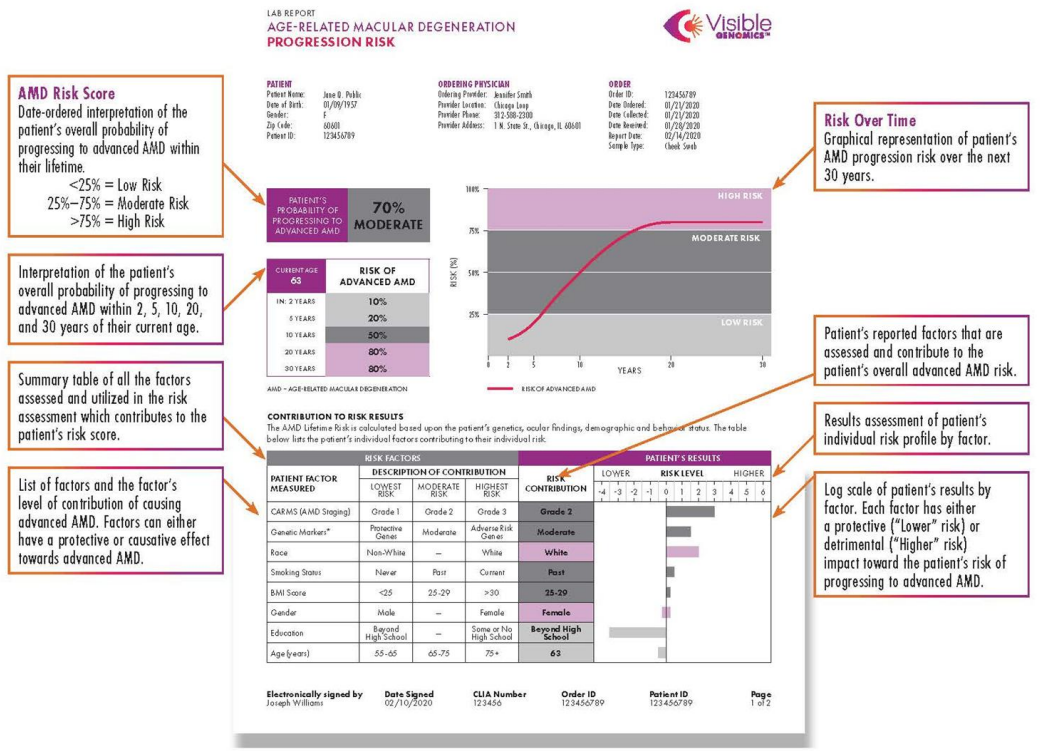
Invert the capped tube and shake vigorously 10 times.

After the sample is collected

Place the collected sample into the enclosed biohazard bag and seal the bag.

Place the sealed biohazard bag in the pre-paid, pre-addressed return envelope provided.

Seal the return envelope and place it in the mail.



AMD Risk Score
Date-ordered interpretation of the patient's overall probability of progressing to advanced AMD within their lifetime.
<25% = Low Risk
25%–75% = Moderate Risk
>75% = High Risk

Interpretation of the patient's overall probability of progressing to advanced AMD within 2, 5, 10, 20, and 30 years of their current age.

Summary table of all the factors assessed and utilized in the risk assessment which contributes to the patient's risk score.

List of factors and the factor's level of contribution of causing advanced AMD. Factors can either have a protective or causative effect towards advanced AMD.

Risk Over Time
Graphical representation of patient's AMD progression risk over the next 30 years.

Patient's reported factors that are assessed and contribute to the patient's overall advanced AMD risk.

Results assessment of patient's individual risk profile by factor.

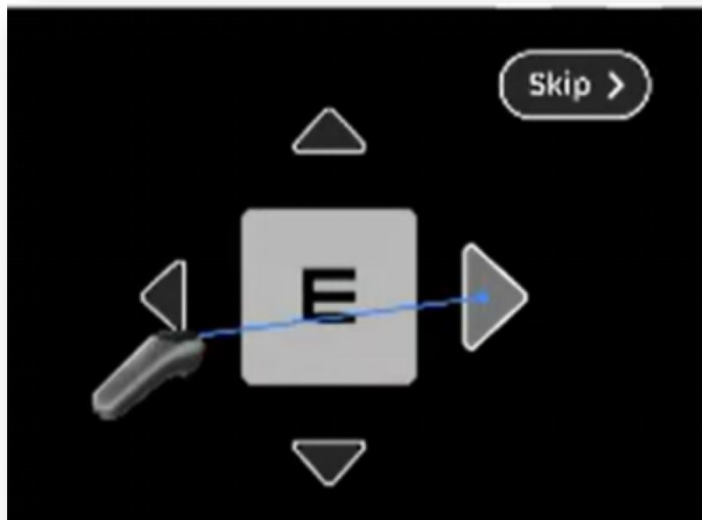
Log scale of patient's results by factor. Each factor has either a protective ("Lower" risk) or detrimental ("Higher" risk) impact toward the patient's risk of progressing to advanced AMD.

Contrast Sensitivity & Dark Adaptation in Early / "Sub-Clinical" AMD Dx

- **What is sub-clinical AMD?** Even though no structural changes can be observed, AMD has already impaired the function of the macula
- **Contrast sensitivity (CS)** and **dark adaptation (DA)**:
  - **DA and CS testing may be more representative of the patient's visual function in everyday life:** allowing for better evaluation and care for patients.
  - **Affected in early AMD, and there is evidence that they may degrade prior to observable structural changes in the retina**

Contrast Sensitivity

- **CS** is **strongly correlated** with **real-world visual function** and its potential to **reveal damage before there are physical manifestations.**[1]
- Often **overlooked** as a functional test for AMD.
- In one AMD study, **increases in central drusen were correlated with decreasing CS results**, yet all subjects maintained 20/20 VA.[2]
- When AMD leads to significant visual dysfunction, CS testing can give **insight into the level of difficulty a patient is likely to encounter in activities of daily living.** [3]

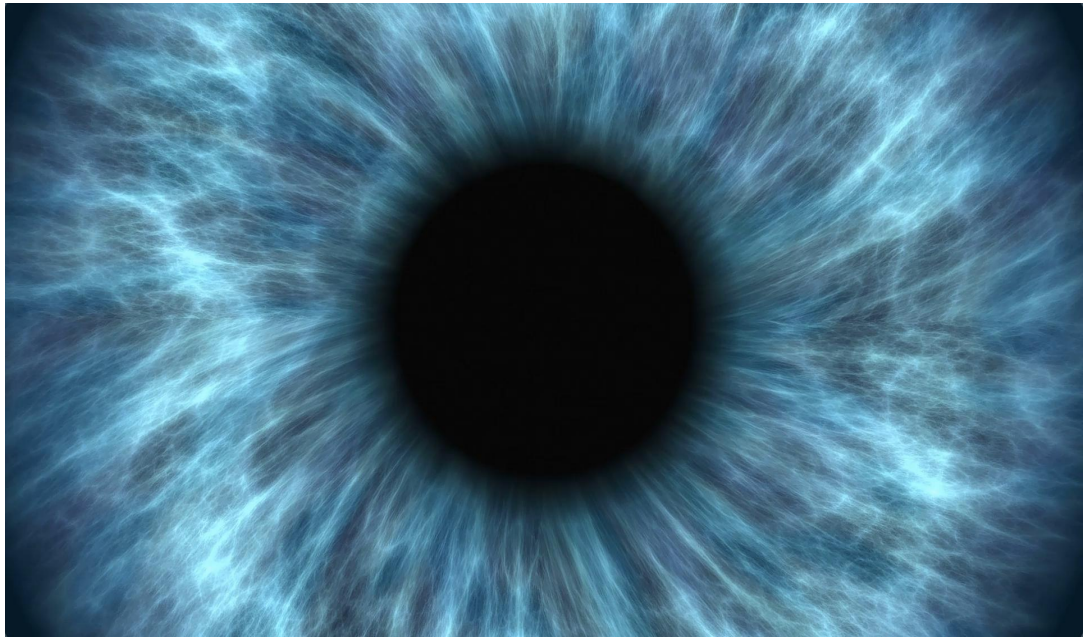


New VR Technology: CS Test time is **15 – 20 seconds per eye**.

1, 2, 3. Roark, M.W., *Add Contrast Sensitivity Testing for AMD*. (2020). Optometric Management - Add Contrast Sensitivity Testing for AMD

Dark Adaptation

- **Onset of AMD:** drusen accumulates, depriving the cones and rods of nutrients which eventually leads to the degeneration of photoreceptor cells.
- **This leads to impaired dark adaptation function**
- *Dark adaptation* ***measures the function of rod photoreceptors***
- Research shows that dark adaptation weakens at the earliest stages of age-related macular degeneration:
  - Studies have shown that dark adaptation may aid in the detection of AMD-related changes **up to three years before drusen are visible**, allowing for earlier intervention and management of the disease.

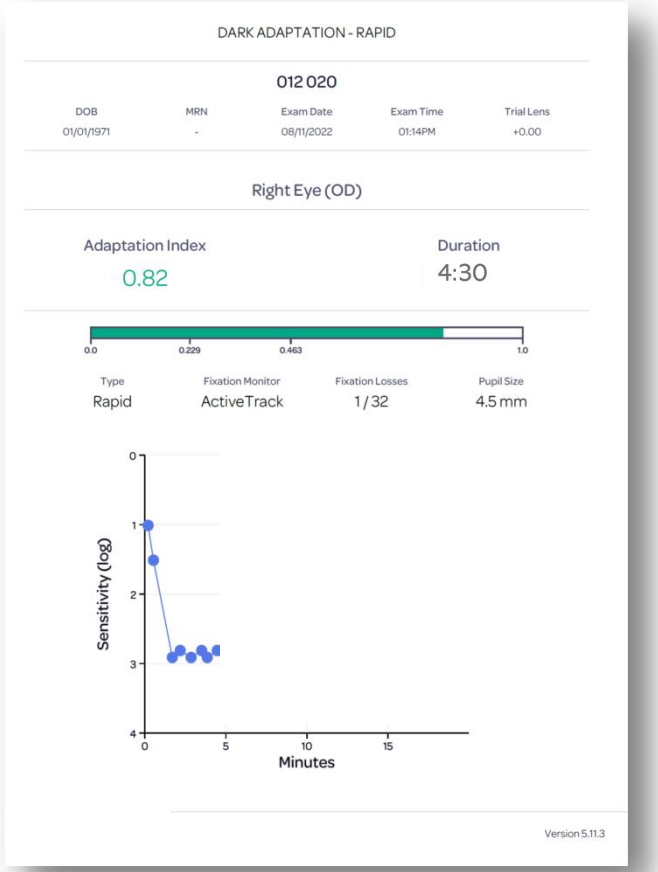


New VR Technology provide:
Rapid Test: 4.5 minutes | Extended Test: 20 minutes.

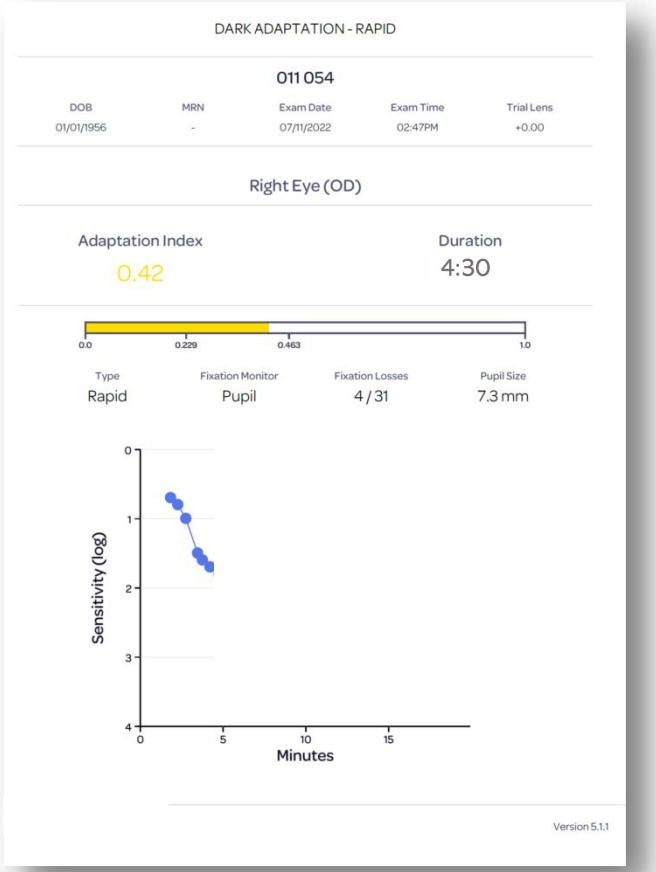
“Rapid” Dark Adaptation: Egs.

- **DA indices** reflect the slope of DA functions, which is the change in threshold over time, where **higher values indicated faster DA functions and vice versa.**

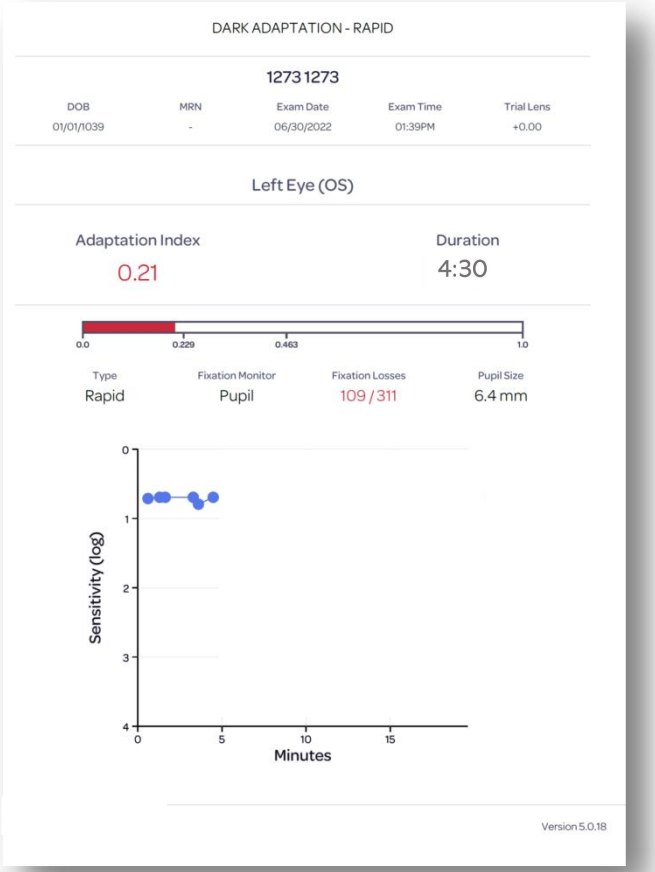
A 50 yr. old person with healthy retina



A 66 yr. old person with Dx of early dry AMD



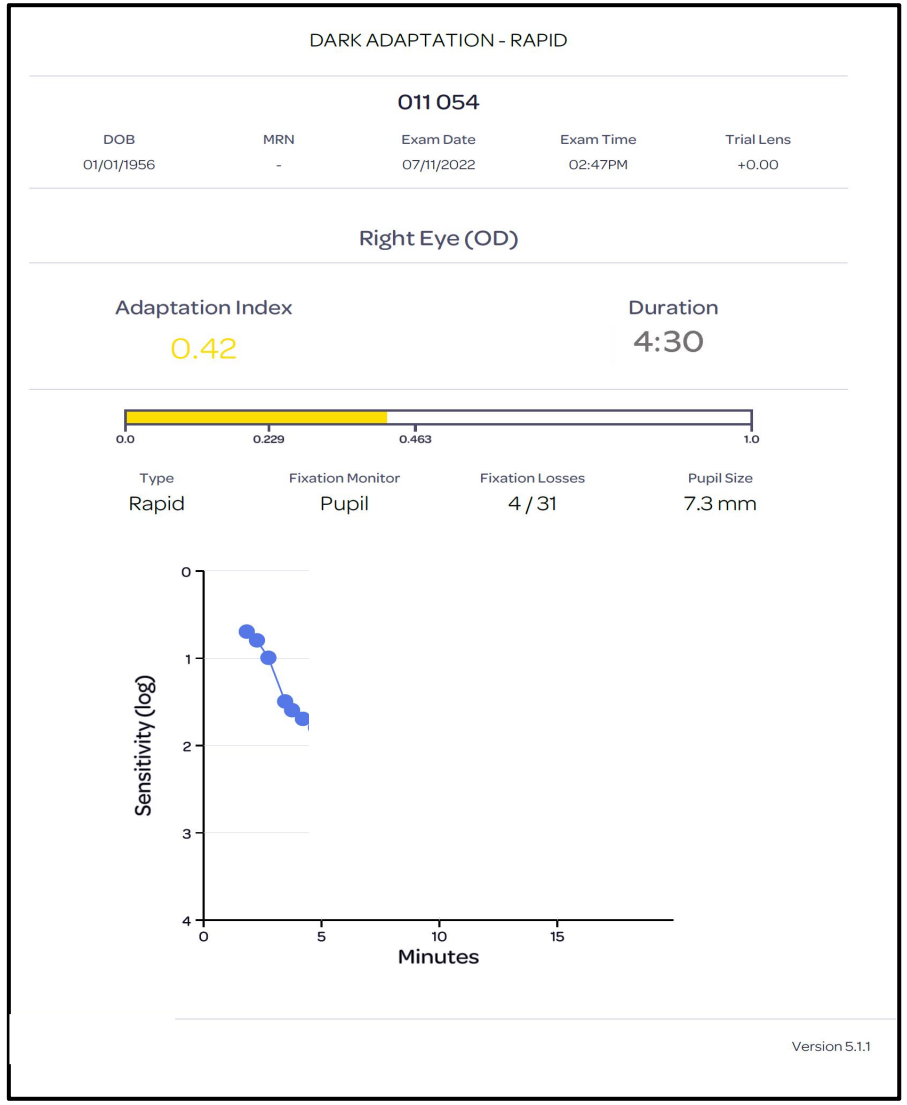
An 82 yr. old with Dx of severe dry AMD

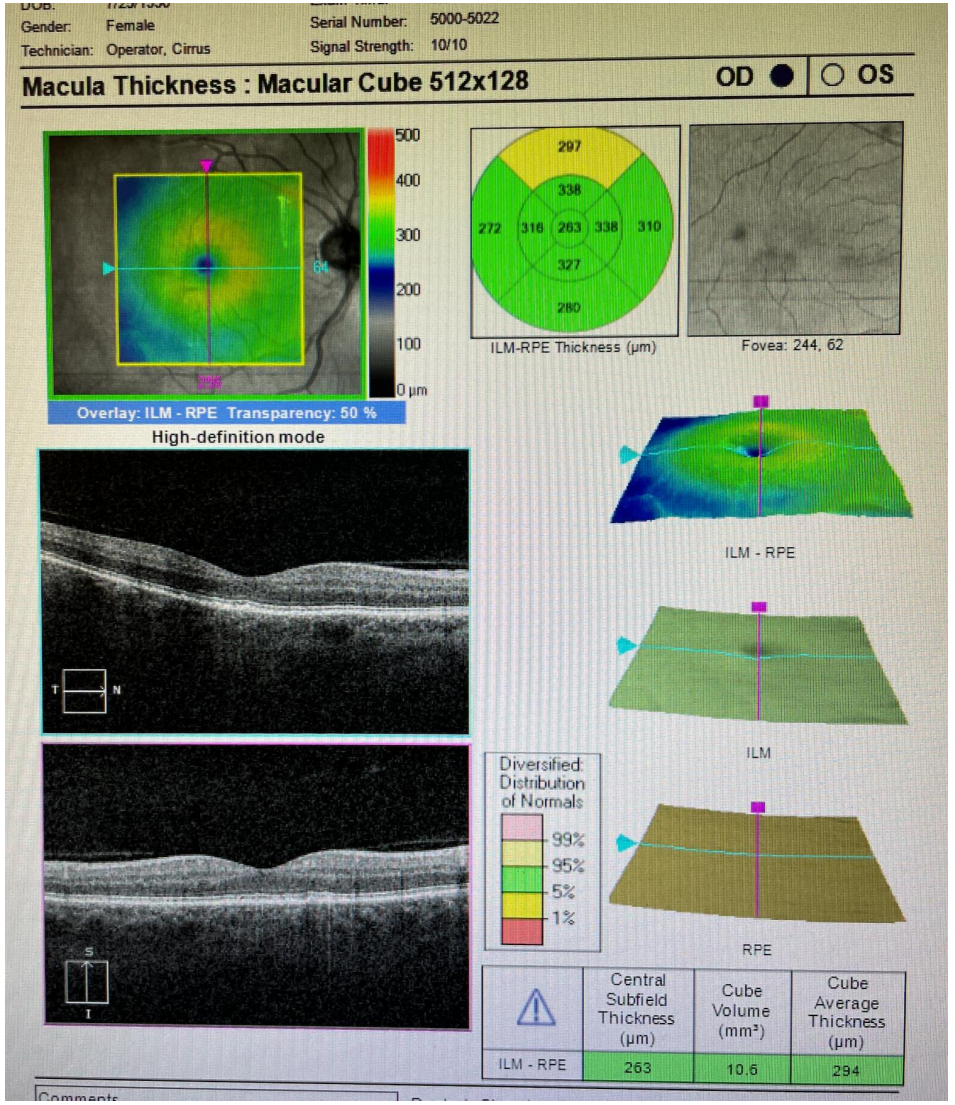


Heru

This test will check your eye's ability to adjust from bright to dark rooms.

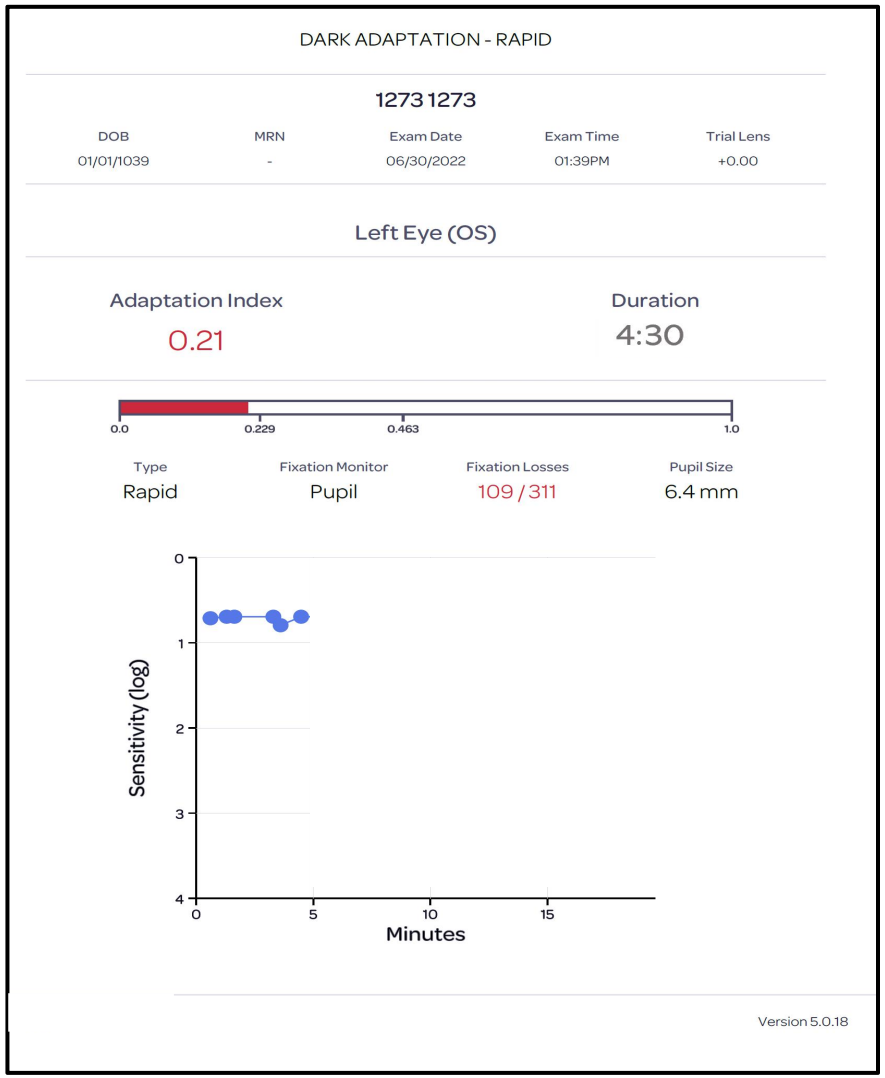
Case 01: 66 YO with Early Dry AMD

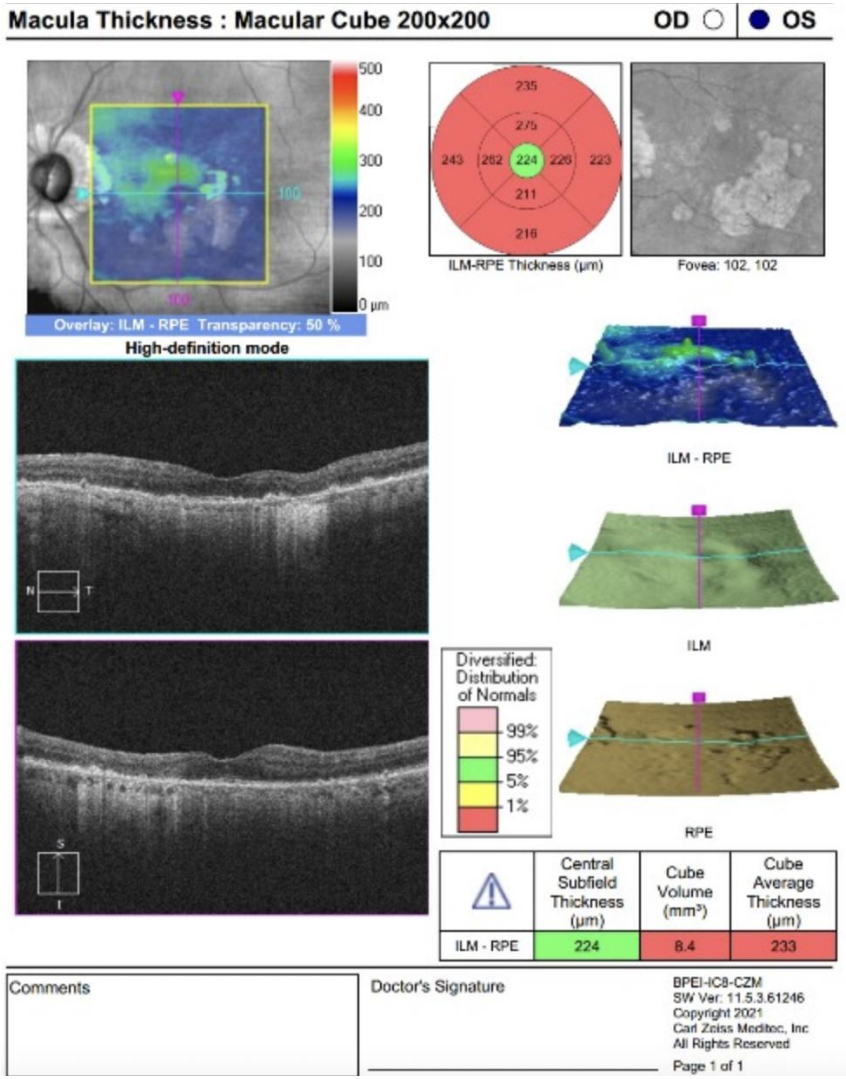




Case Studies courtesy of Heru

Case 02: 82 YO with Diagnosis of **Severe Dry AMD**





Case Studies courtesy of Heru

Indications for Dark Adaptation Testing

- **Patients with issues seeing or driving at night:**

night vision difficulty is often the first symptom of AMD, all patients who have issues seeing or driving at night should be tested for dark adaptation impairment.
Ask the question (intake form or verbally):
“Have you experienced problems seeing or driving at night?”

- **Patients who are at risk of AMD:** Patients over 50 who

are at high risk of developing AMD should be tested annually, even if they do not experience night vision problems. Risk factors include age, family history, smoking, obesity and overall cardiovascular
issues (heart disease, high blood pressure or high cholesterol).

- **Patients with AMD to monitor disease progression:**

Extended Test every six months or more to monitor disease progression. There are several ICD-10 codes that can be used to justify an extended dark adaptation test.

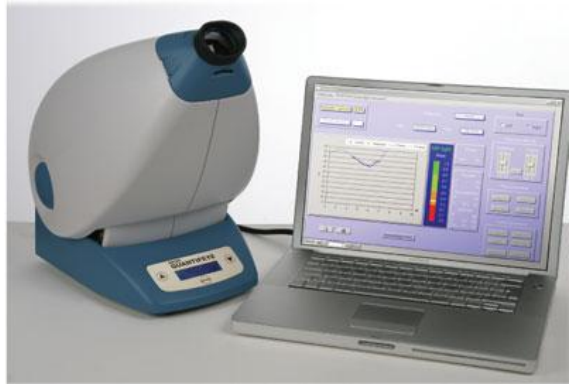
Dark Adaptation Billing & Coding

- Dark adaptation is reported with **CPT Code 92284**.

- The **Extended Test** is billable to insurance and is supported by multiple ICD-10 codes.
  - H35.31XX Non-exudative age-related macular degeneration
  - H35.32XX Exudative age-related macular degeneration
  - H35.36X Drusen (degenerative) of macula
  - H53.61 Abnormal dark adaptation curve
  - H53.62 Acquired night blindness
  - H53.69 Other night blindness
  - *Rapid test is considered screening test – no insurance coverage, out of pocket fee (use of ABN)
- **Co-billable** with visual fields, OCT, fundus imaging and/or office visits.

Macular Pigment Optical Density ("MPOD")

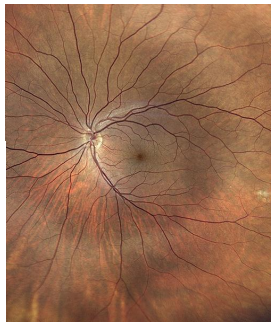
- **MPOD** is a measurement of the attenuation of blue light by macular pigment and is linearly **related to the amount of lutein and zeaxanthin in the macula**
  - Role of Lutein and Zeaxanthin in the macula:
  - epidemiological studies conclude that **levels of lutein and zeaxanthin are associated with reduced risk for AMD**; however, controlled intervention studies will be necessary to establish a causal relationship*
  - Supplements have significantly greater influence vs. dietary changes on MPOD levels.
  - No insurance coverage – out of pocket expense (use of ABN)

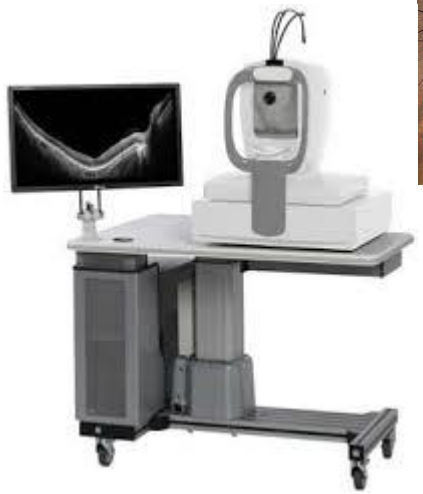


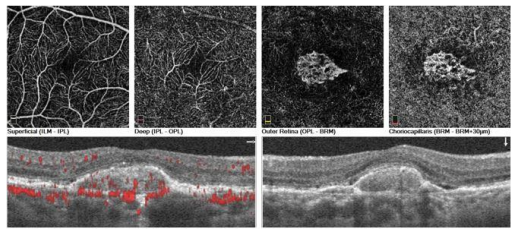
*Bernstein PS, Delori FC, Richer S, van Kuijk FJ, Wenzel AJ.
The value of measurement of macular carotenoid pigment optical densities and distributions in age-related macular degeneration and other retinal disorders. Vision Res. 2010 Mar 31;50(7):716-28.

Retinal Imaging

- **Traditional Color Retinal Photography**
- **Widefield Retinal Imaging**
  - Color/Red Free/Auto Florescence
- **Confocal Scanning Laser Ophthalmoscopy (SLO)**
  - Color/Red Free/Auto Florescence
- **Macula Optical Coherence Tomography** (OCT)
  - Central Grid or other cross sectional imaging
  - OCT Angiography (OCT-A)

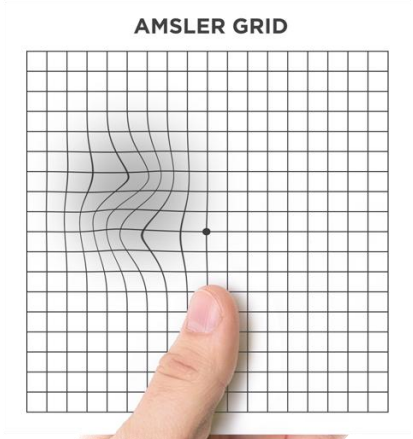






Home Based Monitoring of AMD

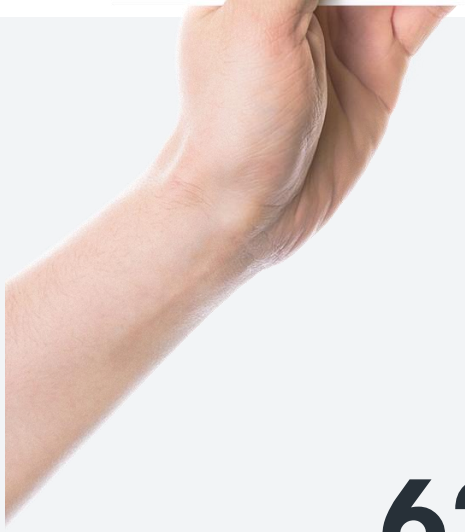
(**Hyperacuity Perimetry** for early detection of conversion to exudative AMD)



1945

VS

2022



Standard of Care

Distortions you see could mean that vision loss has already occurred

62%

including regular eye exams and using the Amsler grid at home

Home® AMD Monitoring

home monitoring, which can be sensitive to small distortions

94%

when Home HP testing was added to regular eye exams and using the Amsler grid

Maintained driving vision at time of diagnosis

(20/40 or better)[1]

1. Chew EY, Clemons TE, Bressler SB, et al; AREDS2-HOME Study Research Group. Randomized trial of a home monitoring system for early detection of choroidal neovascularization home monitoring of the Eye (HOME) study. Ophthalmology. 2014;121(2):535-544.

Home AMD Monitoring

Daily Home Based Hyperacuity Perimetry Testing

Data from each test is sent to the Manufacturer of the test for evaluation and then results are provided to the prescribing ECP

If a change in test scores is detected, the prescribing **ECP is immediately notified** (via e mail) and the ECPs practice will contact the patient to manage care from there (typically an urgent care visit for specific differential diagnosis and management)

Little to no out-of-pocket costs for the majority of Medicare patients

FDA Cleared

Medicare Covered

$0

for the majority of Medicare patients w/ supplemental insurance

$Small Amount

PER MONTH

For patients without supplemental insurance

Patients with Medicare and a secondary supplement plan could have out-of-pocket costs as low as $0 per month

Patients with Medicare and **no secondary supplement plan** will pay a small fee per month once their yearly Medicare Fee-for-Service Part B deductible is met*

*Does not apply to patients enrolled in Medicare Advantage Plans.

Patient Financial Assistance Program is available for qualifying patients

Management of “Pre-Clinical” and Early Phases of Age-related Macular Degeneration (AMD)

And how you can play a role in preserving vision

Thank You!