



Preserve Vision with Early AMD Detection



Impaired dark adaptation: the earliest indicator of AMD

Numerous clinical studies have shown that dark adaptation is dramatically impaired from the earliest stages of age-related macular degeneration (AMD), retinitis pigmentosa (RP) and other retinal diseases, with increasing impairment as the disease progresses.

Until now, devices for measuring dark adaptation (the time it takes for the eye to adjust from bright light to darkness) required lengthy preadaptation and testing times, while delivering suboptimal sensitivity and specificity. Today, the AdaptDx delivers a faster and more sensitive functional assessment through precise control of the primary variables affecting dark adaptation kinetics.

The AdaptDx® provides ophthalmologists and optometrists:

An objective and sensitive measurement

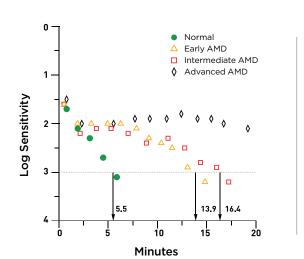
The AdaptDx measures a proprietary parameter called the Rod Intercept (RI) as an indicator of impaired dark adaptation. RI is the recovery time of scotopic sensitivty (or night vision) to a benchmark level, providing an objective and sensitive measurement of retinal function. RI serves as a straightforward vital sign similar to blood pressure, body temperature or intraocular pressure (IOP).

A functional measurement that complements existing imaging technology

The AdaptDx provides functional information that adds to the structural information obtained from retina cameras and OCT imaging. This information is particularly valuable for early assessment, as biological function is often affected before structural changes can be identified.

A simplified assessment

The AdaptDx is patient-friendly, easy to use and easy to interpret. Testing with the AdaptDx is non-invasive and fits neatly into a comprehensive eye exam, providing an objective output with no need for subjective interpretation. For the patient and technician, the experience is similar to routine visual field testing for glaucoma. For the physician, the results are clear. An RI below 6.5 is normal. An RI greater than 6.5 is an early indicator of retinal disease, requiring additional testing.



Measuring and monitoring a patient's RI can aid in tracking progression of AMD.



Sensitive, specific and reproducible results

Multiple studies have demonstrated that the AdaptDx is a sensitive indicator of AMD. In particular, a multi-site study at Harvard, Johns Hopkins and Penn State established that the AdaptDx can discriminate subjects with AMD from healthy subjects across the entire spectrum from early to advanced disease using a rapid testing protocol (≤ 6.5-minute test time). The study compared two cohorts of elderly adults: 127 having early-to-advanced AMD and 21 having normal retinas (as determined by fundus photography grading). Diagnostic sensitivity and specificity were 90.6% and 90.5%, respectively. Additionally, the AdaptDx was proven to have excellent reliability with a test-retest agreement of 94.7% between the first and second visits.

Patient friendly

The test is non-invasive and does not require pre-adaptation or pupil dilation.

Technician friendly

The touch-screen interface with patient eye display is easy to use and offers automated testing and data management.

Easy to interpret

Automatic calculation and display of the rod intercept (RI) provides a simple, objective measure of dark adaptation speed.

Reimbursable

US - CPT 92284

DE - GOA 1233

FR - CCAM BLOP005

CH - TARMED 08.1290

FDA 510(k) Cleared



Sensitivity			9			
Sp	Specificity			90.5%		
Re	produci	94.7%				
0%	20%	40%	60%	80%	100%	

High sensitivity, specificity and reproducibility of the AdaptDx for the diagnosis of AMD

Product specifications

Bleaching wavelength:	505 nm			
Bleaching range:	20% to 95% effective bleach (0.01 to 6,000 scot lx sec)			
Stimulus wavelength:	505 nm			
Stimulus duration:	100 to 300 msec			
Stimulus size:	2°			
Stimulus location:	$5^{\circ},8.5^{\circ}$ and 12° at eight azimuthal locations			
Stimulus maximum intensity:	7.4 scot mlx			
Stimulus dynamic range:	105			
Dimensions:	17" (H) \times 23" (W) \times 22" (D)/43 cm (H) \times 58 cm (W) \times 56 cm (D)			
Weight:	46 lbs/21 kg			
Electrical:	100-240 VAC / 50-60 Hz / 2.25 A			

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