

Fundus Grading Report

Patient ID

Patient Name

Date of Birth

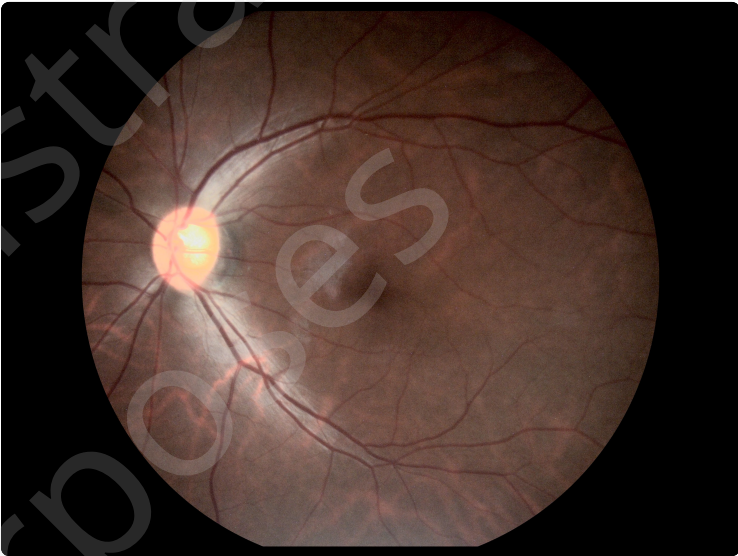
Date and time

Right Eye Results (OD)



Disease type	Status
Glaucoma:	<div>✔ Low risk</div>
Diabetic Retinopathy:	<div>✔ No DR</div>
Age-related Macular Degeneration:	<div>✔ Negative or early</div>

Left Eye Results (OS)



Disease type	Status
Glaucoma:	<div>✔ Low risk</div>
Diabetic Retinopathy:	<div>⚠ Ungradable</div>
Age-related Macular Degeneration:	<div>✔ Negative or early</div>

Refer to the end of the report for definitions of glaucoma, diabetic retinopathy, and age-related macular degeneration used in this analysis.

Warning: Image artifacts may impact results. Examples of artifacts include reflection from the inner limiting membrane typically seen in people less than 40 years old.

Warning: Do not use the thumbnail images above for diagnostic purposes.

Regulatory Disclaimer

Assure Plus is intended to support clinical decision making by classifying retinal diseases (age-related macular degeneration (AMD), diabetic retinopathy (DR), glaucoma) and cardiovascular disease (CVD) risk from color fundus photos. Assure Plus is not intended to replace clinical judgement. Assure Plus outputs should be considered alongside other medical information by appropriately qualified healthcare providers to make diagnostic and referral decisions. Assure Plus is indicated for use in patients at increased risk or who are suspected of having retinal diseases (AMD, DR, glaucoma) or high CVD risk. The software application is not expected to cause any side effects for patients.

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The table below lists possible Assure Plus outputs and defines each classification.

Disease	Product Output	Definition
Diabetic retinopathy (DR) Per International Classification of DR (ICDR)	No DR	Early treatment of diabetic retinopathy (ETDRS) Level 10: No apparent retinopathy
	Mild NPDR	ETDRS Level 20: Very mild DR
	Moderate NPDR	ETDRS Level 35-53: Moderate non-proliferative DR (NPDR)
	Severe NPDR	ETDRS Level 53: Severe NPDR
	Proliferative DR (PDR)	ETDRS Level 60-85: all severities of proliferative DR
Age-related Macular Degeneration (AMD) Per Beckman Initiative for Macular Research	Negative or Early	No AMD pigmentary abnormalities* with either only small drusen ($\leq 63 \mu\text{m}$), or medium drusen ($> 63 \mu\text{m}$ and $\leq 125 \mu\text{m}$)
	Intermediate	Large drusen ($> 125 \mu\text{m}$) and/or any AMD pigmentary abnormalities*
	Late Dry	Geographic atrophy
	Late Wet	Neovascular AMD
	*AMD pigmentary abnormalities are any definite hyper- or hypopigmentary abnormalities associated with the medium or large drusen but not associated with known disease entities	
Glaucoma Per Li et al Ophthalmology 2018	Low Risk	Unlikely glaucoma, defined as neither suspect or certain glaucomatous optic neuropathy (GON) detailed below
	Moderate Risk	Suspect GON, defined as any of the following: <ul style="list-style-type: none"> • $0.7 \leq \text{vertical cut to disc ratio (VCDR)} < 0.9$ • $0.05 \text{ disc diameter (DD)} < \text{rim width} \leq 0.1 \text{ DD}$ • Retinal nerve fiber layer (RNFL) defect • Disc hemorrhage
	High Risk	Certain GON, defined as any of the following: <ul style="list-style-type: none"> • $\text{VCDR} \geq 0.9$ • $\text{Rim width} \leq 0.05 \text{ DD}$ or localized notches • RNFL defect which corresponds to narrowing of rim or localized notches

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