

Ocular Imaging Research and Reading Center

Device Certificate

Certificate Id: OIRRC-01-541c0f83-G
Transmission Numbers:
Issue Date: Apr 15, 2021
Valid until: May 15, 2025

Phase 1/2a Study of the Safety and Bioactivity of AXT107 in Subjects with Diabetic Macular Edema (DME)

Sponsor: Asclepix

Site: Texas Retina Associates - Arlington
Address: 801 West Randol Mill Road, Arlington, TX, United States
Site Code: USA132

Device Information	
Device Modality	Optical Coherence Tomography
Device Manufacture	Optos, Inc.
Device Model	200TX
Device Serial Number	860-11510
Software Version	

The sample images submitted to the OIRRC (transmission #) relevant to the abovementioned device are compliant with requirements and standards of **Congo** imaging manual. The Ocular Imaging Research and Reading Center (OIRRC) is hereby issuing a certificate for the above-mentioned device for the use to obtain images in the **Congo** study.

This certificate is valid for **4 years** from the time it is issued provided that no major modifications, upgrades, updates, or repairs are made during that period. It is the responsibility of the PI and the study team at the Study Site to maintain the integrity of the certification status of the above- mentioned device. Please, communicate with the OIRRC regarding such modifications or other conditions that can possibly affect or compromise the certification status of the device.

Certification Officer



26/03/2021

Super Admin