



CERTIFICATE OF REGISTRATION

MiraVista Diagnostics, LLC

4705 Decatur Blvd.
Indianapolis, Indiana 46241 UNITED STATES

D-U-N-S ID No. 130929792

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design, manufacture, and distribution of in vitro diagnostic test kits to aid in the diagnosis of fungal diseases.



Authorized by



Check Certificate
Status: [here](#)

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

File Number	A28254	Cycle Start Date	January 15, 2019
Certificate Number	1078.190115	Effective Date	January 15, 2019
Initial Issue Date	January 23, 2018	Expiry Date	January 14, 2022

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an MDSAP
Recognized Auditing
Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



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Additional Regulatory Requirements

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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