

Certificate of Registration

Certificate number

1078.250115

File number

A28254

Initial issue date

2018-01-23

Cycle start date

2025-01-15

Effective date

2025-01-15

Expiry date

2028-01-14

**MiraVista Diagnostics, LLC**4705 Decatur Blvd.
Indianapolis, Indiana 46241 UNITED STATES

Facility ID: F001415

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016/A11:2021

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

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh

Operations manager – Medical Regulatory



Check certificate status: [here](#)

This quality system registration is included in UL's Product IQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization

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

Addendum 1

Site	Company Name	Location	Performing
1-1	MiraVista Diagnostics, LLC	4705 Decatur Blvd Indianapolis Indiana 46241 UNITED STATES Facility ID: F001415	All applicable QMS activities

Additional Regulatory Requirements

MiraVista Diagnostics, LLC

4705 Decatur Blvd.

Indianapolis, Indiana 46241 UNITED STATES

Facility ID: F001415

United States:

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