



Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074
USA

T: +1 207 730 5750
F: +1 207 730 5717

DECLARATION OF CONFORMITY

DoC #: 68 - 2024 - 04

Legal Manufacturer: **Abbott Diagnostics Scarborough, Inc.**
Legal Manufacturer's Address: 10 Southgate Road
Scarborough, ME 04074 U.S.A.

With additional sites at:
14 Washington Avenue
Scarborough, Maine 04074 U.S.A.

6 Lincoln Avenue
Scarborough, Maine 04074 U.S.A.

5 Bradley Drive
Westbrook, Maine 04092 U.S.A.

EC Representative's Name: **EMERGO Europe**
EC Representative's Address: Prinsessegracht 20
2514 AP, The Hague
The Netherlands

declares, that the product
Product Name and Model(s): Determine™ TB LAM Ag (7D2741)

as described above conforms with the Directive 98/79/EC on *in vitro* diagnostic medical devices and pertinent essential requirements.

Additional information:

Management System: A-028, Quality Manual
Conformity Pathway: Annex III
Classification: Self - declaration



Scarborough, Maine, USA
20 December 2021

A handwritten signature in blue ink, appearing to read 'Betsy Graves', positioned above a horizontal line.

Betsy Graves
Director, QA Abbott Diagnostics Scarborough



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22nd February 2023

Addendum to the Declaration of Conformity 68 – 2024 - 04

We, Abbott Diagnostics Scarborough, Inc., located at 10 Southgate Road, Scarborough, Maine, 04074, USA, the legal manufacturer of the device(s) listed below:

Product	SKU
Determine™ TB LAM Ag	7D2741

hereby declare that starting 31 January 2023, the address of our EU Authorized Representative listed in the original Declaration of Conformity has changed.

Old Address	New Address
Name: Emergo Europe B.V. Address: Prinsessegracht 20, 2514 AP The Hague, The Netherlands. Telephone: +31.70.345.8570 Email: EmergoEurope@ul.com	Name: Emergo Europe B.V. Address: Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands. Telephone: +31.70.345.8570 Email: EmergoEurope@ul.com

On behalf of Abbott Diagnostics Scarborough, Inc.

Name: Betsy Graves
Title: Director Quality Assurance
Date : 22nd February 2023

Abbott
Determine
TB LAM Ag
Package Insert

Flat Size: 33.0" x 14.75"
Fold Size: 4.125" x 7.375"



Black

PN: IN02740005
Rev: 1

Date of Last Revision:
1.6 2020/06/26