CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

4426

Authorized by

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

Check Certificate Status: here

Digitally signed by Ceaicovschi Tudor
Date: 2023.04.14 11:05:54 EEST
Reason: MoldSign Signature
Location: Moldova

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

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 LLC.

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

LORNE LABORATORIES LTD

Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley, Berkshire, RG6 4UT
United Kingdom

Phone: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com

CERTIFICATE OF ANALYSIS

DESCRIPTION	LOT NO.	EXPIRY	PRODUCT CODE
ASO Latex Kit	**LO16138**	**2024-03**	**031100A**

STORAGE: Refrigerated at 2 – 8ºC. Protect from light. Do not freeze

SHIPPING: This product has data supporting stability tolerance during fluctuations in ambient shipping temperature

This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications

REAGENT	SPECIFICATIONS			RESULT
	Appearance	Colour	Functionality	
ASO Latex Reagent	Homogeneous suspension free of macroscopic or flaky particles	White	Tested against kit (+) and (-) controls	**PASS**
Positive Control Negative Control	Liquid solution	Clear and transparent		**PASS**

If applicable:

- Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. Handle with caution as potentially infectious
- This product was tested by methods described in the manufacturers package insert
- This product is intended for ***In Vitro*** Diagnostic use only

We certify that this product has been released as meeting our acceptance criteria

APPROVED BY: **DATE: 23 June 2022**

Technical Administrator

Lorne Laboratories Ltd.
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley,
Berkshire RG6 4UT, UK

Certificate of Analysis

(See LOR006 for Methodology)

CE

PRODUCT	CRP Latex Kit
LOT NUMBER	LO16164
DATE OF EXPIRY	2024-10
STORAGE CONDITIONS	Refrigerated at 2 – 8ºC. Protect from light. Do not freeze.
SHIPPING	This product has data supporting stability tolerance during fluctuations in ambient shipping temperature

QUALITY CONTROL:

REAGENT	SPECIFICATIONS			RESULT
	Appearance	Colour	Functionality	
CRP Latex reagent	Homogeneous suspension free of macroscopic or flaky particles	White	Tested against kit (+) and (-) controls	**PASS**
Positive Control Negative Control	Liquid solution	Clear and transparent		**PASS**

Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. Handle with caution as potentially infectious
This product was tested by methods described in the manufacturers package insert
This product is intended for In Vitro Diagnostic use only

We certify that this product has been released as meeting our acceptance criteria

QUALITY CONTROL STATEMENT	This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications

Title	**Quality Assurance Associate**
Signature	Angela Lane Digitally signed by Angela Lane Date: 2022.10.25 16:39:41 +01'00'
Date:	**25 October 2022**

Lorne Laboratories Ltd.
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley,
Berkshire RG6 4UT, UK

Certificate of Analysis

(See LOR006 for Methodology)

CE

PRODUCT	RF Latex Kit
LOT NUMBER	LO16272
DATE OF EXPIRY	2024-04
STORAGE CONDITIONS	Refrigerated at 2 – 8ºC. Protect from light. Do not freeze.
SHIPPING	This product has data supporting stability tolerance during fluctuations in ambient shipping temperature

QUALITY CONTROL:

REAGENT	SPECIFICATIONS			RESULT
	Appearance	Colour	Functionality	
RF Latex reagent	Homogeneous suspension free of macroscopic or flaky particles	White	Tested against kit (+) and (-) controls	**PASS**
Positive Control Negative Control	Liquid solution	Clear and transparent		**PASS**

Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. Handle with caution as potentially infectious
This product was tested by methods described in the manufacturers package insert
This product is intended for In Vitro Diagnostic use only

We certify that this product has been released as meeting our acceptance criteria

QUALITY CONTROL STATEMENT	This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications

Title	**Quality Assurance Associate**
Signature	Angela Lane Digitally signed by Angela Lane Date: 2022.10.13 13:48:35 +01'00'
Date:	**13 October 2022**