



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
RF Latex Kit	LO16268	2023-11	830100A

STORAGE: Refrigerated at 2 – 8°C. 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	
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

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: 01 February 2022

Technical Administrator
