

## **LORNE LABORATORIES LTD**

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## **CERTIFICATE OF ANALYSIS**

| DESCRIPTION    | LOT NO. | EXPIRY  | PRODUCT<br>CODE |
|----------------|---------|---------|-----------------|
| RPR Carbon Kit | LO16261 | 2023-03 | 044150A         |

**STORAGE:** Refrigerated at  $2 - 8^{\circ}$ 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                                  |                       |                                      | DE0111 T |
|--------------------------------------|---|-----------------------|--------------------------------------|----------|
|                                      | Appearance                                      | Colour                | Functionality                        | RESULT   |
| RPR Carbon Kit                       | Liquid suspension free of macroscopic particles | Grey                  | Tested<br>against kit (+)<br>and (-) | PASS     |
| Positive Control<br>Negative Control | Liquid solution                                 | Clear and transparent | controls                             | 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: 14 April 2021

Eddy Velthuis Technical Director