



# EC CERTIFICATE

## Lorne Laboratories Ltd

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

## EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro  
Diagnostic Medical Devices

Scope of Certificate:

**The design and manufacture of in vitro diagnostic reagents for  
identification of blood groups**

Device Classification:

**Annex II, List A and B**

Device Descriptions:

**Please refer to Attachment 1**

Model:

**Please refer to Attachment 1**

File Number A12241  
Certificate No. 354.170425

Cycle Start Date 23 May 2017  
Effective Date 23 May 2017  
Expiry Date 22 May 2022

Authorised by

**B. Rodgers**  
**Certification Manager**  
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.

**Notified Body**

**0843**



# EC CERTIFICATE

## Lorne Laboratories Ltd

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

### Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

| Device Description            | Model                | Classification  |
|-------------------------------|----------------------|-----------------|
| Anti-A Monoclonal             | 600005/600010/600000 | Annex II List A |
| Anti-B Monoclonal             | 610005/610010/610000 | Annex II List A |
| Anti-A,B Monoclonal           | 620005/620010/620000 | Annex II List A |
| Anti-C Monoclonal             | 690005               | Annex II List A |
| Anti-E Monoclonal             | 691005               | Annex II List A |
| Anti-c Monoclonal             | 692005               | Annex II List A |
| Anti-e Monoclonal             | 693005               | Annex II List A |
| Anti-K Monoclonal             | 760005/760010        | Annex II List A |
| Anti-D Clone 2 Monoclonal     | 710010/710000        | Annex II List A |
| Anti-D Clone 1 Monoclonal     | 730010/730000        | Annex II List A |
| Anti-D Duoclonal Monoclonal   | 740010/740000        | Annex II List A |
| Anti-Jka Polyclonal           | 323002/323000        | Annex II List B |
| Anti-Jkb Polyclonal           | 324002/324000        | Annex II List B |
| Anti-Fyb Polyclonal           | 317002/317000        | Annex II List B |
| AHG Elite Clear               | 415010/415100/415000 | Annex II List B |
| AHG Elite Green               | 435010/435100/435000 | Annex II List B |
| Anti-Fya Monoclonal           | 774000/774002        | Annex II List B |
| Anti-C+D+E Monoclonal         | 700005/700010/700000 | Annex II List A |
| Anti-Human IgG Clear          | 401010/401000        | Annex II List B |
| Anti-Human IgG Green          | 402010/402000        | Annex II List B |
| Monoclonal Rh Control         | 640010               | Annex II List A |
| Monoclonal D Negative Control | 650010               | Annex II List A |

File Number A12241  
Certificate No. 354.170425

Cycle Start Date 23 May 2017  
Effective Date 23 May 2017  
Expiry Date 22 May 2022

Authorised by

**B. Rodgers**  
**Certification Manager**  
For and on Behalf of UL International (UK) Ltd

**Notified Body**

**0843**



# 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.

Authorized by



**Michael J. Windler, P.E.**

**Manager of Global Regulatory Service**  
Distinguished Member of the Technical Staff  
Life and Health Sciences, UL LLC



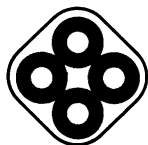
Check Certificate  
Status: [here](#)

|                    |               |                |              |
|--------------------|---------------|----------------|--------------|
| 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](mailto:info@lornelabs.com)



### CERTIFICATE OF ANALYSIS

| DESCRIPTION   | LOT NO. | EXPIRY  | PRODUCT CODE |
|---------------|---------|---------|--------------|
| ASO Latex Kit | LO16126 | 2023-01 | 031100A      |

**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                           |             |
| ASO Latex Reagent                    | Homogeneous suspension free of macroscopic or flaky particles | White                 | Tested against kit (+) and (-) controls | <b>PASS</b> |
| Positive Control<br>Negative Control | Liquid solution   | Clear and transparent |   | <b>PASS</b> |

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**

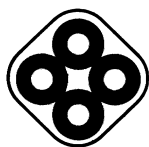
---

**APPROVED BY:**

**Eddy Velthuis**  
Technical Director

**DATE:** 07 April 2021

---



## 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 |
|---------------|---------|---------|--------------|
| CRP Latex Kit | LO16130 | 2023-03 | 850100A      |

**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                           |        |
| CRP Latex reagent                    | Homogeneous suspension free of macroscopic or flaky particles | White                 | Tested against kit (+) and (-) controls | PASS   |
| Positive Control<br>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**

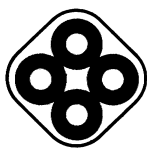
---

**APPROVED BY:**

**DATE:** 16 March 2021

**Eddy Velthuis**  
Technical Director

---



## 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 |
|---------------------------|---------|---------|--------------|
| TPHA Microtitre Plate Kit | LO16146 | 2022-06 | 043100A      |

**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                           |        |
| R1 Test cells<br>R2 Control cells    | Homogeneous suspension free of macroscopic or flaky particles | Dark red              | Tested against kit (+) and (-) controls | PASS   |
| R3 Buffer                            | Liquid solution   | Straw                 |   | PASS   |
| Positive Control<br>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. However handle cautiously 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

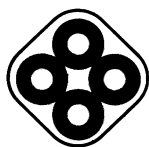
---

APPROVED BY:

Eddy Velthuis  
Technical Director

DATE: 13 January 2021

---



## 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 | LO16258 | 2022-05 | 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 | <b>PASS</b> |
| Positive Control<br>Negative Control | Liquid solution   | Clear and transparent |   | <b>PASS</b> |

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**

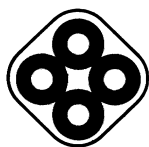
---

**APPROVED BY:**

**DATE:** 08 September 2020

**Eddy Velthuis**  
Technical Director

---



## 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 |
|----------------|---------|---------|--------------|
| RPR Carbon Kit | LO16261 | 2023-03 | 044150A      |

**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                           |        |
| RPR Carbon Kit                       | Liquid suspension free of macroscopic particles | Grey                  | Tested against kit (+) and (-) controls | PASS   |
| Positive Control<br>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:**

**Eddy Velthuis**  
Technical Director

**DATE:** 14 April 2021

---