Reagent		Parameters
Anti AB monoclonal reagent 10 ml vials	2050 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies - IgM class. Sensitivity – with the corresponding antigen in heterozygous form;a)avidity in first 15 sec ,plate method;b) Reaction intensity of 3+ to 4+ tube/plate method Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C, visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti D(IgM+IgG) monoclonal reagent 10 ml vials	1600 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies – IgM and IgG class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti D-IgM monoclonal reagent 10 ml vials	1500 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies - IgM class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C, visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti Kell monoclonal reagent 10 ml vials.	1440 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies – IgM class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity – according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent – agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C, visual examination. Aspect – without rolls and precipitated.

LORNE LABORATORIES LIMITED
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Date: 2021.02.08 14:53:11 EET
Reason: MoldSign Signature
Location: Moldova

		Pharmaceutical form – 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti k monoclonal reagent 2ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donor's blood,tub method Properties: Sensitivity - Reaction intensity of 2+ to 3+ with standard erythrocytes with corresponding Ag in heterozygous form.; Specificity - according to Ag without immune haemolyse and false Agglutination reactions; The method of using the reagent - tube incubation at room temperature 15-25 ° C or 37 ° C in the indirect antiglobulin test (TAI), visual examination. Type of antibodies - IgM class or IgG. Aspect - without rolls and precipitated. Packaging form: in bottles of 2 ml,5 ml,10 ml, delivered in secured package, marked and labeled by the manufacturer with the information identification (name, lot/seria number, validity terms, storage conditions).
Anti C monoclonal reagent 5ml vials	300 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies - IgM class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C, visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti c monoclonal reagent 5ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies - IgM class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C, visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti E monoclonal reagent 5ml vials	350 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies - IgM class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T° 15 to 25 °C, visual examination.

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		Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti e monoclonal reagent 5ml vials.	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood. Type of antibodies - IgM class. Sensitivity – a)avidity in first 15 sec with corresponding antigen, plate method;b) Reaction intensity of 3+ to 4+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the well at room T ° 15 to 25 ° C, visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit.
Anti Fya monoclonal reagent 2ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood, tube method. Type of antibodies – IgM or IgG class. Sensitivity –Reaction intensity of 2+ to 3+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit
Anti Fyb monoclonal reagent THIS IS A POLYCLONAL PRODUCT 2ML VIALS	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood, tube method. Type of antibodies – IgM or IgG class. Sensitivity –Reaction intensity of 2+ to 3+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit

Anti Jka monoclonal reagent 2ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood, tube method. Type of antibodies – IgM or IgG class. Sensitivity –Reaction intensity of 2+ to 3+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit
Anti Jkb monoclonal reagent 2ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood, tube method. Type of antibodies – IgM or IgG class. Sensitivity –Reaction intensity of 2+ to 3+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit
Anti S monoclonal reagent 2ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood, tube method. Type of antibodies – IgM or IgG class. Sensitivity –Reaction intensity of 2+ to 3+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit
Anti s monoclonal reagent 2ml vials	80 ml	Usage: for determining the erythrocyte antigens in the donors and patient's blood, tube method. Type of antibodies – IgM or IgG class. Sensitivity –Reaction intensity of 2+ to 3+ tube/plate method with the corresponding antigen in heterozygous form; Specificity - according to Ag without immune haemolyse and false agglutination reactions; The method of using reagent - agglutination on the surface, the tube and the at room T ° 15 to 25 ° C and 37° C in antiglobulinic indirect test (TAI) ,visual examination. Aspect - without rolls and precipitated.

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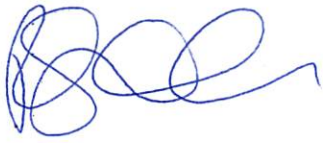
		Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit
Polispecific antiglobulin serum 10ml vials	3130 ml	Destination: provided for the direct and indirect antiglobulinic (COOMBS) test, tube method. Properties: - contains anti-IgG and anti-C3d antibodies that react with immunoglobulins and / or complement on the erythrocyte membrane, causing agglutination of sensitized erythrocytes. Aspect - without rolls and precipitated. Pharmaceutical form - 1ml equivalent to 20 examinations Form of packing: in bottles of 2ml, 5ml or 10 ml, delivered in secure packaging, marked and labeled by the manufacturer to maintain identity data (name, batch number, serial number, product shelf life, storage conditions). Identity data displayed on the box will coincide mandatory with the labeling of each component of the kit



LORNE LABORATORIES LIMITED
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Lower Earley
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United Kingdom

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

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

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CERTIFICATE

EC No 1434-IVDD-134/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

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

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List A

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 649/2019
Module: H7

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No **1434-IVDD-134/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-134/2019

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

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-134/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

CERTIFICATE

EC No 1434-IVDD-132/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

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

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List B

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 22.03.2022

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 648/2019
Module: H7

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No **1434-IVDD-132/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-132/2019

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

Name:	GMDN code:
Anti-Jka Polyclonal 323002	52586
Anti-Jkb Polyclonal 324002	52587
Anti-Fyb Polyclonal 317002	52570
AHG Elite Clear 415010	52731
AHG Elite Green 435010	52731
Anti-Fya Monoclonal 774002	52569
Anti-Human IgG Clear 401010	45811
Anti-Human IgG Green 402010	45811
Anti-Jka Monoclonal 775002	52586
Anti-Jkb Monoclonal 776002	52587

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-132/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

CERTIFICATE

EC No 1434-IVDD-133/2019
EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

Lorne Laboratories Ltd

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

in vitro diagnostic medical devices
List A

Products list in attachments: 1

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 649/2019
Module: H6

mgr Anna Wyroba
Vice-President

Certificate No **1434-IVDD-133/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-133/2019

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

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-133/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-k (Cellano) Monoclonal	325002

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2016
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 04 June 2018.

Eddy Velthuis
Technical Director

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

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-S Monoclonal	770002

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 06 April 2017.

Eddy Velthuis
Technical Director

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www.lornelabs.com

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-s Monoclonal	771002

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 06 April 2017.

Eddy Velthuis
Technical Director

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