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

CE

Certificate of Analysis

(See LOR006 for Methodology)

PRODUCT	A.H.G Elite (Green) Reagent
LOT NUMBER	435124-B1 and all sub-lots (i.e 435124-B2, 435124-B3, 435124-B4, etc)
DATE OF MANUFACTURE	2025-09-10
DATE OF EXPIRY	2027-09-10
DYE	0.002% Patent Blue and 0.002% Tartrazine
STORAGE CONDITIONS	Refrigerate at 2 – 8ºC
BIOBURDEN	Product filtered through a sterile 0.2 µm filter. The reagent is not sterile.
PRESERVATIVE	< 0.1% Sodium Azide w/v

QUALITY CONTROL:

ANTI-IgG POTENCY:	**A.H.G Elite Reagent:**		**AHG Reference Standard:**	
	R_1r Cells	1 in 8	**R_1r Cells**	1 in 8
ANTI-C3d POTENCY:	**A.H.G Elite Reagent:**		**AHG Reference Standard:**	
	EC3d Cells	1 in 8	**EC3d Cells**	1 in 8

QUALITY CONTROL STATEMENT	Source materials used to produce this lot were tested at source and found to be non-reactive for anti-HIV 1+2, anti-HCV and HBsAg. However care must be taken in the use and disposal of each vial and its contents. This lot of A.H.G Elite (Green) meets the potency and specificity requirements as described in the current edition of the Guidelines for the Blood Transfusion Services in the UK

Title	**Lead Quality Assurance Coordinator**
Signature	Joyce Dos Santos Digitally signed by Joyce Dos Santos Date: 2025.10.09 11:32:45 +01'00'
Date:	**09 OCT 2025**

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

Certificate of Analysis

(See LOR006 for Methodology)

PRODUCT	LISS Ready For Use
LOT NUMBER	470212-B1 (Mother Lot)
DATE OF MANUFACTURE	2026-01-28
DATE OF EXPIRY	2027-01-28
STORAGE CONDITIONS	Store at 10–30ºC
BIOBURDEN	Product filtered through a sterile 0.2 µm filter. The reagent is not sterile.

QUALITY CONTROL:

POTENCY: This lot of LISS Ready For Use demonstrated adequate serological potentiation and no haemolysis was observed during testing

PHYSICAL TESTS:

Test	Specifications	Result
pH @ 22ºC	6.50 – 6.90	Pass
Conductivity @ 22ºC	3.40 – 4.00 mS/cm	Pass
Osmolality	285 – 305 mOsmol/kg	Pass

QUALITY CONTROL STATEMENT	This lot of LISS Ready For Use meets potency and physical requirements as described in the current edition of the Guidelines for the Blood Transfusion Services in the UK

Title	**Quality Assurance Coordinator**
Signature	sangeetha natarajan Digitally signed by sangeetha natarajan Date: 2026.02.02 11:58:02 Z
Date:	**02 FEB 2026**

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

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

UL LLC® (UL Solutions) 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 design and manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kits.

UKAS MANAGEMENT SYSTEMS 4426

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A12241	Cycle Start	May 23, 2023
Certificate Number	1458.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

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 Solutions).

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 123789 0004 Rev. 00

Manufacturer:

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

SRN Manufacturer - GB-MF-000029354

Authorized Representative:

Advena Ltd.
Tower Business Centre,
2nd Floor, Tower Street,
Swatar, BKR 4013, MALTA

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V13 123789 0004 Rev. 00

Report No.: 75959970_AR
Valid from: 2025-05-07
Valid until: 2030-05-06

Marta Carnielli
Head of Certification IVD

Issue date: 2025-05-07

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 123789 0004 Rev. 00

Classification:	Class D
Device Group:	IVR 0101 - Immunohaematology (Blood grouping): ABO system
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-

Rev.	Dated	Report	Description
00	2025-05-07	75959970_AR	Initial issuance

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