# CERTIFICATE

## EC Certificate No. 1434-IVDD-074/2022

**EC Design-examination**
**Directive 98/79/EC concerning**
***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**

i.e. *in vitro* diagnostic medical devices
List A

*The list of medical devices covered by this certificate is provided in the Annex 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 the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019

Digitally signed by Ceaicovschi Tudor
Date: 2023.11.17 14:44:09 EET
Reason: MoldSign Signature
Location: Moldova

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 504/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022
Module H6/V1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
**President**

# ANNEX 1 TO THE CERTIFICATE

**VALID ONLY WITH CERTIFICATE**

## No 1434-IVDD-074/2022

*List of medical devices covered by the certificate:*

Anti-A Monoclonal 600010
Anti-B Monoclonal 610010
Anti-A,B Monoclonal 620010
Anti-D Clone 1 Monoclonal 730010
Anti-D Clone 2 Monoclonal 710010
Anti-D Duoclone Monoclonal 740010
Anti-C Monoclonal 690005
Anti-E Monoclonal 691005
Anti-c Monoclonal 692005
Anti-e Monoclonal 693005
Anti-C+D+E Monoclonal 700010
Anti-K Monoclonal 760010

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 504/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022

Aleksandra Kostrzewa
**President**

Digitally signed by Aleksandra Kostrzewa

# CERTIFICATE

## EC Certificate No. 1434-IVDD-075/2022

**Full Quality Assurance System**
**Directive 98/79/EC concerning**
***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 device
List A

*The list of medical devices covered by this certificate is provided*
*in the Annex 1 to EC Design-examination Certificate No. 1434-IVDD-074/2022*

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

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 505/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022
Module H7

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
**President**

# CERTIFICATE

## EC Certificate No. 1434-IVDD-027/2022

**Full Quality Assurance System**
**Directive 98/79/EC concerning**
***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 device
List B

*The list of medical devices covered by this certificate is provided in the Annex 1*

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

Validity of the Certificate: from 23.03.2022 to 27.05.2025

The date of issue of the Certificate: 03.03.2022

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Issued under the Contract No. MD-173/2021
Application No: 577/2022
Certificate bears the qualified signature.
Warsaw, 03/03/2022
Module H7

Aleksandra Kostrzewa

Digitally signed by Aleksandra Kostrzewa

**President**

# 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

# LORNE LABORATORIES LTD.

MAREA BRITANIE

## REACTIVI LECTIN PENTRU DETERMINAREA GRUPEI SANGUINE

INSTRUCŢIUNI DE UTILIZARE

**Anti-$A_1$ Lectin:** Pentru tehnica cu eprubetă:

### REZUMAT

Antigenul $A_1$ este un subgrup al grupului A şi a fost descoperit în 1910. De obicei, Anti-$A_1$ nu este reactiv la 37 ºC; totuşi exemplele reactive la 37 ºC şi predominant IgM pot provoca distrugerea globulelor roşii *in vivo*. Aproximativ 78%[3] din persoanele cu grupa A sunt $A_1$ şi 22%[3] sunt $A_2$, proporţii asemănătoare se aplică persoanelor cu AB.

### SCOPUL PROPUS

Acesta este un reactiv pentru determinarea grupei sanguine, destinat a fi folosit pentru a determina calitativ prezenţa sau absenţa antigenului $A_1$ (ABO4) pe globulele roşii ale donatorilor de sânge sau ale pacienţilor care au nevoie de o transfuzie sanguină în cazul testării conform tehnicilor recomandate şi prezentate în aceste instrucţiuni de utilizare.

### PRINCIPIUL

Reactivul conţine glicoproteine ce provin din sămânţa de *Dolichos biflorus* care provoacă aglutinarea (aglomerarea) globulelor roşii purtătoare ale antigenului $A_1$ după centrifugare. Neaglutinarea (neaglomerarea) indică, în general, absenţa antigenului $A_1$ (consultaţi **Limitări**).

### REACTIV

Reactivul Anti-$A_1$ Lectin Lorne pentru determinarea grupei sanguine este preparat dintr-un extract din seminţe de *Dolichos biflorus*, diluat cu o soluţie de clorură de sodiu ce conţine albumină bovină. Reactivul nu conţine sau nu este compus din substanţe CMR, substanţe perturbatoare pentru sistemul endocrin sau care ar putea provoca sensibilizare sau o reacţie alergică în cazul utilizatorului. Reactivul este furnizat la diluarea optimă pentru utilizare cu toate tehnicile recomandate prezentate mai jos, fără să mai fie necesară diluarea sau adăugarea suplimentară. Pentru numărul de referinţă al lotului şi data de expirare, consultaţi **Eticheta flaconului**.

### DEPOZITARE

Flacoanele cu reactiv trebuie depozitate la temperaturi cuprinse între 2 şi 8 ºC după primire. Depozitarea prelungită la temperaturi în afara acestui interval poate duce la pierderea accelerată a reactivităţii reactivilor. Acest reactiv a fost supus unor studii de stabilitate la transport la 37 $^{o}$C şi –25 $^{o}$C, conform precizărilor din documentul BS EN ISO 23640:2015.

### RECOLTAREA ŞI PREGĂTIREA PROBEI

Probele de sânge pot fi recoltate în EDTA, citrat, anticoagulanţi CPDA sau ca probă coagulată. Probele trebuie testate cât mai curând posibil după recoltare. Dacă survine o întârziere în ce priveşte testarea, păstraţi probele la 2-8 °C. Probele care prezintă o hemoliză intensă sau o contaminare microbiană nu trebuie utilizate pentru testare. Probele de sânge care prezintă semne de liză pot conduce la rezultate neconcludente. Este de preferat (dar nu esenţial) să spălaţi toate probele de sânge cu PBS sau soluţie salină izotonă înainte de testare.

### PRECAUŢII

1. Reactivul este destinat exclusiv diagnosticului *in vitro*.
2. Dacă un flacon cu reactiv este crăpat sau curge, aruncaţi conţinutul imediat.
3. Nu folosiţi reactivul după data de expirare (consultaţi **Eticheta flaconului**).
4. Nu folosiţi reactivul dacă observaţi că s-a format un precipitat.
5. Purtaţi echipament de protecţie când manipulaţi reactivii, cum ar fi mănuşi de unică folosinţă şi un halat de laborator.
6. Reactivul a fost filtrat printr-o membrană de 0,2 µm pentru a reduce încărcătura biologică, dar nu este livrat steril. După deschiderea flaconului, reactivul poate fi folosit până la data de expirare dacă nu se observă o turbiditate marcată, care ar putea indica deteriorarea sau contaminarea reactivului.
7. Reactivul conţine <0,1% de azidă de sodiu. Azida de sodiu poate fi toxică dacă este ingerată şi poate reacţiona cu conductele din plumb sau cupru formând azide metalice explozive. La eliminare, spălaţi cu cantităţi mari de apă.
8. Nu se cunosc teste care să garanteze faptul că produsele derivate din surse umane sau animale nu prezintă agenţi infecţioşi. Fiţi atenţi când utilizaţi şi când eliminaţi un flacon şi conţinutul acestuia.

### ELIMINAREA REACTIVULUI ŞI CUM SE ACŢIONEAZĂ ÎN CAZ DE STROPIRE

Pentru informaţii privind eliminarea reactivului şi metodele de decontaminare a unui loc în caz de stropire, consultaţi **Fişele cu date de securitate ale materialului**, disponibile la cerere.

### MARTORI ŞI RECOMANDĂRI

1. Se recomandă testarea în paralel a unui martor pozitiv (ideal, celule din grupa $A_1B$) şi a unui martor negativ (celule din grupa $A_2$) cu fiecare lot de teste. Testele trebuie considerate nevalide dacă probele martor nu prezintă rezultatele prevăzute.
2. Înainte de utilizare, lăsaţi reactivul să ajungă la temperatura camerei. Imediat după utilizare, depozitaţi reactivul înapoi la o temperatură cuprinsă între 2 şi 8 $^{o}$C.
3. În **Tehnici recomandate,** un volum reprezintă aproximativ 50 µl cu pipeta flaconului furnizată.
4. Utilizarea reactivului şi interpretarea rezultatelor trebuie efectuate de personal calificat şi instruit în mod corespunzător în conformitate cu cerinţele ţării în care se utilizează reactivul.
5. Utilizatorul trebuie să stabilească în ce măsură se poate utiliza reactivul în alte tehnici.

### REACTIVI ŞI MATERIALE CARE SUNT NECESARE, DAR NU SUNT FURNIZATE

- Eprubete de sticlă (10 x 75 mm sau 12 x 75 mm).
- Soluţie PBS (pH 6,8–7,2) sau soluţie salină izotonă (pH 6,5–7,5).
- Globule roşii martor pozitiv (grupa $A_1B$) şi negativ (grupa $A_2$).
- Centrifugă pentru eprubete.
- Pipete volumetrice.

### TEHNICĂ RECOMANDATĂ

#### A. Tehnica cu eprubetă

1. Pregătiţi o suspensie de 2-3% din globulele roşii în PBS sau soluţie salină izotonă.
2. Puneţi într-o eprubetă etichetată: 1 volum de reactiv Anti-$A_1$ Lorne şi 1 volum de suspensie de globule roşii.
3. Amestecaţi bine şi apoi centrifugaţi toate eprubetele timp de 20 de secunde la 1000 rcf sau la un alt raport adecvat între timp şi forţă.
4. Resuspendaţi uşor butonul de hematii şi efectuaţi citirea macroscopică pentru aglutinare

### INTERPRETAREA REZULTATELOR TESTULUI

1. **Pozitiv:** Aglutinarea globulelor roşii constituie un rezultat pozitiv şi, în limitele acceptate ale procedurii de testare, indică prezenţa antigenului $A_1$ pe globulele roşii.
2. **Negativ:** Neaglutinarea globulelor roşii constituie un rezultat negativ şi, în limitele acceptate ale procedurii de testare, indică absenţa antigenului $A_1$ pe globulele roşii.
3. **Discrepanţe:** Dacă rezultatele obţinute cu grupul cu metoda inversă nu corespund cu grupul cu metoda directă, sunt necesare investigaţii suplimentare.

### STABILITATEA REACŢIILOR

1. Citirea testelor cu eprubetă trebuie realizată imediat după centrifugare. Orice întârziere poate provoca disocierea complexelor antigen-anticorp, generând reacţii fals negative sau slab pozitive.
2. Aveţi grijă la interpretarea rezultatelor testelor efectuate la alte temperaturi decât cele recomandate.

### LIMITĂRI

1. Anti-$A_1$ poate reacţiona cu eritrocitele Tn-poliaglutinabile sau Cad-pozitive
2. Sângele de la nivelul cordonului ombilical şi specimenele de la nou-născuţi nu pot fi tipizate cu precizie cu Anti-$A_1$ Lectin deoarece antigenul $A_1$ nu este pe deplin dezvoltat la globulele roşii până la vârsta de şase luni.
3. În cazul pacienţilor cu vârsta mai mare de şase luni, rezultatele determinării grupei ABO trebuie confirmate prin testarea serului sau plasmei acestora în raport cu globulele din grupa $A_1$ şi B cunoscută înainte de a confirma în cazul lor grupa sanguină ABO.
4. Sângele stocat poate genera reacţii mai slabe decât sângele proaspăt.
5. Rezultatele fals pozitive sau fals negative pot fi generate şi de:
   - Contaminarea materialelor folosite în testare
   - Depozitarea, concentraţia celulară, timpul sau temperatura de incubaţie necorespunzătoare
   - Centrifugarea necorespunzătoare sau excesivă
   - Abaterea de la tehnicile recomandate

### CARACTERISTICI DE PERFORMANŢĂ SPECIFICE

1. Înainte de a fi pus pe piaţă, fiecare lot de reactiv a fost testat conform metodelor de testare recomandate şi enumerate în aceste instrucţiuni de utilizare. Testele corespund cerinţelor de testare prezentate în numărul/versiunea curentă a „Guidelines for the Blood Transfusion Services in the United Kingdom” (Orientări pentru Serviciile de transfuzii sanguine din Regatul Unit).

2. Controlul calităţii reactivilor a fost efectuat cu globule roşii cu fenotipuri care au fost verificate de un centru pentru transfuzii sanguine din Regatul Unit şi care au fost spălate cu PBS sau soluţie salină izotonă înainte de utilizare.

## DECLINAREA RESPONSABILITĂŢII

1. Utilizatorul este singurul responsabil pentru performanţa reactivului în cazul utilizării altor metode decât cele menţionate în **Tehnici recomandate**.
2. Orice abatere de la **Tehnicile recomandate** trebuie validată înainte de utilizare[5].

## BIBLIOGRAFIE


1. AABB Technical Manual, 16th edition, AABB 2008.
2. Marion E.Reid & Christine Lomas-Francis, Blood Group Antigens & Antibodies, SBB Books, New York 2007.
3. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; capitolul 6, pagina 146.
4. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
5. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, **5**, 145-150.


## DIMENSIUNI REACTIV DISPONIBILE

| Mărime flacon | Număr de catalog | Teste per flacon |
|---|---|---|
| 5 ml | 116005 | 100 |
| 1000 ml | 116000* | 20.000 |

***Această mărime este valabilă numai pentru utilizare de fabricaţie suplimentară (FFMU) şi, prin urmare, nu are marcajul CE.**


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# EC DECLARATION OF CONFORMITY

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

| Product Name | Catalogue Number |
|---|---|
| Anti-$A_1$ Lectin | 116005 |

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 04 April 2017.

_____

Eddy Velthuis
Technical Director



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# LORNE LABORATORIES LTD.
GREAT BRITAIN

**LECTIN BLOOD GROUPING REAGENTS**
DIRECTIONS FOR USE

**Anti-$A_1$ Lectin:** For Tube Technique.

## SUMMARY

$A_1$ antigen is a subgroup of A and was discovered in 1910. Anti-$A_1$ is usually non-reactive at 37ºC, however examples reactive at 37ºC and predominately IgM can cause *in vivo* red blood cell destruction. About 78%[3] of group A people are $A_1$ and 22%[3] are $A_2$, similar proportions apply among AB people.

## INTENDED PURPOSE

This reagent is a blood grouping reagent intended to be used to qualitatively determine the presence or absence of the $A_1$ antigen (ABO4) on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

## PRINCIPLE

The reagent contains glycoproteins of *Dolichos biflorus* seed origin that will cause agglutination (clumping) of red cells that carry the $A_1$ antigen, after centrifugation. No agglutination (no clumping) generally indicates the absence of the $A_1$ antigen (see **Limitations**).

## REAGENT

Lorne Anti-$A_1$ Lectin blood grouping reagent is prepared from an extract of *Dolichos biflorus* seeds, diluted with a sodium chloride solution containing bovine albumin. The reagent does not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. The reagent is supplied at optimal dilution for use with all recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see **Vial Label**.

## STORAGE

Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. This reagent has undergone transportation stability studies at 37ºC and –25ºC as described in document BS EN ISO 23640:2015.

## SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA, citrate, CPDA anticoagulants or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8°C. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results. It is preferable (but not essential) to wash all blood samples with PBS or Isotonic saline before being tested.

## PRECAUTIONS

1. The reagent is intended for *in vitro* diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent past the expiration date (see **Vial Label**).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 µm capsule to reduce the bio-burden, but is not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagent contains < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
8. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

## DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

## CONTROLS AND ADVICE

1. It is recommended a positive control (ideally group $A_1B$ cells) and a negative control (group $A_2$ cells) be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
3. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
4. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.
5. User must determine suitability of the reagent for use in other techniques.

## REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Positive (group $A_1B$) and negative (group $A_2$) control red cells.
- Test tube centrifuge.
- Volumetric pipettes.

## RECOMMENDED TECHNIQUES

### A. Tube Technique

1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume Lorne Anti-$A_1$ reagent and 1 volume red cell suspension.
3. Mix thoroughly and then centrifuge all the tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination

## INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of red cells constitutes a positive test result and within the accepted limitations of the test procedure, indicates the presence of $A_1$ antigen on the red cell.
2. **Negative:** No agglutination of red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of $A_1$ antigen on the red cells.
3. **Discrepancies:** If the results obtained with reverse group don't correlate with forward group, further investigation is required.

## STABILITY OF THE REACTIONS

1. Tube tests must be read immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes leading to false negative, or weak positive reactions.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

## LIMITATIONS

1. Anti-$A_1$ may react with Tn-polyagglutinable or Cad-positive cells
2. Cord blood and specimens from infants cannot be accurately typed using Anti-$A_1$ Lectin since the $A_1$ antigen is not fully developed on red blood cells until the age of six months.
3. Individuals older than six months should have their ABO blood-grouping results confirmed by testing their serum or plasma against known group $A_1$ and B cells before their ABO blood group can be confirmed.
4. Stored blood may give weaker reactions than fresh blood.
5. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage, cell concentration, incubation time or temperature
   - Improper or excessive centrifugation
   - Deviation from the recommended techniques

## SPECIFIC PERFORMANCE CHARACTERISTICS

1. Prior to release, each lot of reagent was tested using the recommended test methods listed in this IFU. The tests complied with the test requirements as stated in the current version/issue of the "Guidelines for the Blood Transfusion Services in the United Kingdom".
2. The Quality Control of the reagents was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed with PBS or Isotonic saline prior to use.

## DISCLAIMER

1. The user is responsible for the performance of the reagent by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations from the **Recommended Techniques** should be validated prior to use[6].

## BIBLIOGRAPHY


1. AABB Technical Manual, 16th edition, AABB 2008.
2. Marion E.Reid & Christine Lomas-Francis, Blood Group Antigens & Antibodies, SBB Books, New York 2007.
3. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6, page 146.
4. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
5. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, **5**, 145-150.

## AVAILABLE REAGENT SIZES

| Vial Size | Catalogue Number | Tests per vial |
|---|---|---|
| 5 ml | 116005 | 100 |
| 1000 ml | 116000* | 20,000 |

***This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.**

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# SAFETY DATA SHEET

**Document reference number: MSDSMonoRhesus+K**
**Issue number: 9/10/2015**

**ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830**

## 1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

**1.1 Product identifier**

| | |
|---|---|
| Product code(s) & Product Name | 690 Anti-C monoclonal reagent<br>691 Anti-E monoclonal reagent<br>692 Anti-c monoclonal reagent<br>693 Anti-e monoclonal reagent<br>700 Anti-C+D+E monoclonal reagent<br>760 Anti-K monoclonal reagent |
| CAS No. | Mixture |
| EINECS No. | Mixture |
| Product Description | A solution containing specific clones (antibodies derived from culture supernatants of antibody producing human B lymphocyte cell lines), diluted in a solution containing bovine serum albumin, buffer salts, and potentiators. |

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

| | |
|---|---|
| Identified Use(s) | Blood grouping reagents. |
| Uses Advised Against | Anything other than the above. |

**1.3 Details of the supplier of the safety data sheet**

| | |
|---|---|
| Company Identification | Lorne Laboratories Ltd<br>Unit 1 Cutbush Park Industrial Estate<br>Danehill<br>Lower Earley<br>Berkshire RG6 4UT<br>United Kingdom |
| Telephone | +44(0) 0118 921 2264 |
| Fax | +44(0) 0118 986 4518 |
| E-Mail (competent person) | Info@lornelabs.com |

**1.4 Emergency telephone number**

| | |
|---|---|
| | +44(0) 0118 921 2264<br>Available 0900 – 1700 (GMT) |
| Languages spoken | English |

## 2. SECTION 2: HAZARDS IDENTIFICATION

**2.1 Classification of the substance or mixture**

**2.1.1 Regulation (EC) No. 1272/2008 (CLP)** Not classified as hazardous for supply/use.

**2.2 Label elements** According to Regulation (EC) No. 1272/2008 (CLP)

| | |
|---|---|
| Hazard Pictogram(s) | None assigned |
| Signal Word(s) | None assigned |
| Hazard Statement(s) | None assigned |
| Precautionary Statement(s) | None assigned |

**2.3 Other hazards** None known.

## 3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.2 Mixtures** Substances in preparations / mixtures

EC Classification Regulation (EC) No. 1272/2008 (CLP)

| Chemical identity of the substance | %W/W | CAS No. | EC No. | REACH Registration No. | Hazard Statement(s) |
|---|---|---|---|---|---|
| Sodium Azide | 0.09 | 26628-22-8 | 247-852-1 | Not yet assigned in the supply chain | Acute Tox. 2; H300<br>Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410 |

## 4. SECTION 4: FIRST AID MEASURES

**4.1 Description of first aid measures**

Inhalation — Remove from exposure. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Keep warm and at rest. Get medical advice/attention if you feel unwell.

Skin Contact — Wash affected skin with soap and water. Remove contaminated clothing and wash clothing before reuse. If irritation (redness, rash, blistering) develops, get medical attention.

Eye Contact — Flush eyes with water for at least 15 minutes while holding eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Ingestion — Rinse mouth. Give plenty of water to drink. Do not give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

**4.2 Most important symptoms and effects, both acute and delayed** — None known.

**4.3 Indication of any immediate medical attention and special treatment needed** — Treat symptomatically.

## 5. SECTION 5: FIRE-FIGHTING MEASURES

**5.1 Extinguishing media**

Suitable Extinguishing Media — Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry powder or CO2.

Unsuitable extinguishing Media — Do not use water jet. Direct water jet may spread the fire.

**5.2 Special hazards arising from the substance or mixture** — Combustion or thermal decomposition will evolve toxic vapours.

**5.3 Advice for fire-fighters** — Fight fire with normal precautions from a reasonable distance. Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Avoid all contact. Do not allow run-off from fire fighting to enter drains or water courses.

## 6. SECTION 6: ACCIDENTAL RELEASE MEASURES

**6.1 Personal precautions, protective equipment and emergency procedures** — Ensure adequate ventilation. Avoid all contact. Ensure suitable personal protection during removal of spillages. See Section: 8

**6.2 Environmental precautions** — Avoid release to the environment.

**6.3 Methods and material for containment and cleaning up** — Absorb spillage in suitable inert material.Transfer to a lidded container for disposal or recovery. Ventilate the area and wash spill site after material pick-up is complete. Avoid release to the environment.

**6.4 Reference to other sections** — See Section: 8, 13

## 7. SECTION 7: HANDLING AND STORAGE

**7.1 Precautions for safe handling**
Avoid all contact. Use personal protective equipment as required. Ensure adequate ventilation. Keep good industrial hygiene. Wash hands thoroughly after handling. Contaminated clothing should be thoroughly cleaned.

**7.2 Conditions for safe storage, including any incompatibilities**
Keep only in the original container/package in a cool well-ventilated place. Keep away from food, drinks and animal food.

Storage temperature
Storage temperature should be controlled to between 2 and 8°C.

Storage life
Keep only in the original container/package in a cool well-ventilated place.

Incompatible materials
None known.

**7.3 Specific end use(s)**
See Section: 1.2

## 8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1 Control parameters**

**8.1.1 Occupational Exposure Limits**

| SUBSTANCE | CAS No. | LTEL (8 hr TWA ppm) | LTEL (8 hr TWA mg/m³) | STEL (ppm) | STEL (mg/m³) | Source |
|---|---|---|---|---|---|---|
| Sodium azide (as NaN3) | 26628-22-8 | - | 0.1 | - | 0.3 | WEL |

Source: WEL: Workplace Exposure Limit (UK HSE EH40)

**8.1.2 Biological limit value**
Not established.

**8.1.3 PNECs and DNELs**
Not established.

**8.2 Exposure controls**

**8.2.1 Appropriate engineering controls**
Ensure adequate ventilation. Good hygiene practices and housekeeping measures.

**8.2.2 Individual protection measures, such as personal protective equipment (PPE)**
Use personal protective equipment as required. Avoid all contact. Keep good industrial hygiene. Wash hands before breaks and after work. Keep work clothes separately. Wash contaminated clothing before reuse. Do not eat, drink or smoke at the work place.

Eye/face protection

Not normally required. Recommended: Wear eye protection with side protection (EN166).

Skin protection

Prolonged, direct contact: Wear impervious gloves (EN374).

Respiratory protection

Not normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protective equipment should conform to the appropriate EN standard.

Thermal hazards
None anticipated.

**8.2.3 Environmental Exposure Controls**
Avoid release to the environment.

## 9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**9.1 Information on basic physical and chemical properties**

Appearance
Liquid, Straw coloured

Odour
Not established.

| | |
|---|---|
| Odour Threshold | Not established. |
| pH | 7 |
| Melting Point/Freezing Point | Not established. |
| Initial boiling point and boiling range | Not established. |
| Flash Point | Not established. |
| Evaporation Rate | Not established. |
| Flammability (solid, gas) | Not established. |
| Upper/lower flammability or explosive limits | Not applicable. |
| Vapour pressure | Not established. |
| Vapour density | Not established. |
| Relative density | Not established. |
| Solubility(ies) | Miscible with water. |
| Partition coefficient: n-octanol/water | Not established. |
| Auto-ignition temperature | Not established. |
| Decomposition Temperature | Not established. |
| Viscosity | Not established. |
| Explosive properties | Not explosive |
| Oxidising properties | Not oxidising. |

**9.2 Other information** None known.

## 10. SECTION 10: STABILITY AND REACTIVITY

| | | |
|---|---|---|
| **10.1** | **Reactivity** | Stable under normal conditions. |
| **10.2** | **Chemical stability** | Stable for 24 months after the date of production when stored at between 2 and 8°C. |
| **10.3** | **Possibility of hazardous reactions** | None known. Hazardous polymerisation will not occur. |
| **10.4** | **Conditions to avoid** | Keep away from heat, sources of ignition and direct sunlight. |
| **10.5** | **Incompatible materials** | Strong acids. |
| **10.6** | **Hazardous decomposition product(s)** | Combustion or thermal decomposition will evolve toxic vapours. |

## 11. SECTION 11: TOXICOLOGICAL INFORMATION

**11.1 Information on toxicological effects (Substances in preparations / mixtures)**

**Acute toxicity**

| | |
|---|---|
| Ingestion | Based on available data, the classification criteria are not met.<br>Acute Toxicity Estimate Mixture Calculation: LD50 >5000 mg/kg bw/day |
| Inhalation | Based on available data, the classification criteria are not met.<br>Acute Toxicity Estimate Mixture Calculation: LD50 >20 mg/l. |
| Skin Contact | Based on available data, the classification criteria are not met.<br>Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day |
| **Skin corrosion/irritation** | Based on available data, the classification criteria are not met. |
| **Serious eye damage/irritation** | Based on available data, the classification criteria are not met. |
| **Respiratory or skin sensitization** | Based on available data, the classification criteria are not met. |
| **Germ cell mutagenicity** | Based on available data, the classification criteria are not met. |
| **Carcinogenicity** | Based on available data, the classification criteria are not met. |
| **Reproductive toxicity** | Based on available data, the classification criteria are not met. |
| **STOT - single exposure** | Based on available data, the classification criteria are not met. |
| **STOT - repeated exposure** | Based on available data, the classification criteria are not met. |
| **Aspiration hazard** | Based on available data, the classification criteria are not met. |

**11.2 Other information** None known.

## 12. SECTION 12: ECOLOGICAL INFORMATION

| | | |
|---|---|---|
| **12.1** | **Toxicity** | Based on available data, the classification criteria are not met.<br>Estimated LC50 (96 hour) Fish > 100 mg/l |
| **12.2** | **Persistence and degradability** | Not established. Some of the ingredients are expected to be resistant to biodegradation. |

| | | |
|---|---|---|
| **12.3** | **Bioaccumulative potential** | Not established. Predicted to be be unlikely. |
| **12.4** | **Mobility in soil** | The product has high mobility in soil. Miscible with water. |
| **12.5** | **Results of PBT and VPVB assessment** | Not classified as PBT or vPvB. None of the substances in this product fulfil the criteria for being regarded as a PBT or vPvB substance. |
| **12.6** | **Other adverse effects** | None known. |

## 13. SECTION 13: DISPOSAL CONSIDERATIONS

| | | |
|---|---|---|
| **13.1** | **Waste treatment methods** | Dispose of contents in accordance with local, state or national legislation. |
| **13.2** | **Additional Information** | Empty containers may contain hazardous residues. Containers shall be disposed of by incineration as soon as possible. |

## 14. SECTION 14: TRANSPORT INFORMATION

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'.

| | | **ADR/RID** | **IMDG** | **IATA/ICAO** |
|---|---|---|---|---|
| **14.1** | **UN number** | None assigned. | None assigned. | None assigned. |
| **14.2** | **UN proper shipping name** | None assigned. | None assigned. | None assigned. |
| **14.3** | **Transport hazard class(es)** | None assigned. | None assigned. | None assigned. |
| **14.4** | **Packing group** | None assigned. | None assigned. | None assigned. |
| **14.5** | **Environmental hazards** | Not classified. | Not classified. | Not classified. |
| **14.6** | **Special precautions for user** | See Section: 2 | | |
| **14.7** | **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | Not applicable. | Not applicable. | Not applicable. |
| **14.8** | **Additional Information** | None. | | |

## 15. SECTION 15: REGULATORY INFORMATION

| | | |
|---|---|---|
| **15.1** | **Safety, health and environmental regulations/legislation specific for the substance or mixture** | |
| **15.1.1** | **EU regulations** | |
| | Authorisations and/or Restrictions On Use | None. |
| **15.1.2** | **National regulations** | |
| | Germany | Water hazard class: 1 |
| **15.2** | **Chemical Safety Assessment** | None. |

## 16. SECTION 16: OTHER INFORMATION

**The following sections contain revisions or new statements:** 1-16.

**References:** Existing Safety Data Sheet (SDS). Existing ECHA registration for Sodium Azide (CAS No. 26628-22-8).

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830.

**LEGEND**

| | |
|---|---|
| LTEL | Long Term Exposure Limit |
| STEL | Short Term Exposure Limit |
| DNEL | Derived No Effect Level |
| PNEC | Predicted No Effect Concentration |
| PBT | PBT: Persistent, Bioaccumulative and Toxic |
| vPvB | vPvT: very Persistent and very Toxic |
| OECD | Organisation for Economic Cooperation and Development |

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

**Disclaimers**
Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Lorne Laboratories Ltd gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. Lorne Laboratories Ltd accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

**Annex to the extended Safety Data Sheet (eSDS)**
Not applicable

**Date of First Issue**
21 August 2001

# LORNE LABORATORIES LTD.

GREAT BRITAIN

CE 1434

## MONOCLONAL BLOOD GROUPING REAGENTS

DIRECTIONS FOR USE

**Anti-K Monoclonal:** For Tube, Bio-Rad-ID, Ortho BioVue, Microplate and Slide Techniques.

### SUMMARY

The K antigen was reported in 1946. The antigen is fully developed at birth and can be strongly immunogenic. Anti-K has been implicated in Haemolytic Transfusion Reactions and Haemolytic Disease of the Newborn.

| Anti-K | Anti-k | Phenotype | Caucasians[1] | Afro-Americans[1] |
|---|---|---|---|---|
| + | 0 | **K+k-** | 0.2% | Rare |
| + | + | **K+k+** | 8.8% | 2% |
| 0 | + | **K-k+** | 91% | 98% |
| 0 | 0 | **$K_o$** | Very Rare | |

### INTENDED PURPOSE

The reagent is a blood grouping reagent intended to be used to qualitatively determine the presence or absence of the Kell antigen (KEL1) on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

### PRINCIPLE

The reagent contains antibodies to the K antigen on human red cells and causes direct agglutination (clumping) of human red cells that carry the Kell antigen. No agglutination (no clumping) generally indicates the absence of the Kell antigen (see **Limitations**).

### REAGENT

Lorne Monoclonal Anti-K blood grouping reagent is a low protein reagent containing the monoclonal IgM antibody, Clone MS-56, diluted in a phosphate buffer containing sodium chloride, bovine albumin and macromolecular potentiators (4.0 g%). The reagent does not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. The reagent is supplied at optimal dilution for use with all recommended techniques stated below without need for further dilution or addition. For lot reference number and expiry date see **Vial Label**.

### STORAGE

Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. This reagent has undergone transportation stability studies at 37ºC and –25ºC as described in document BS EN ISO 23640:2015.

### SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA, citrate, CPDA anticoagulants or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8°C. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results. It is preferable (but not essential) to wash all blood samples with PBS or Isotonic saline before being tested.

### PRECAUTIONS

1. The reagent is intended for *in vitro* diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent past the expiration date (see **Vial Label**).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 µm capsule to reduce the bio-burden, but is not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagent contains < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
8. Materials used to produce the reagent were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

### DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

### CONTROLS AND ADVICE

1. It is recommended a positive control (ideally heterozygous) and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. When typing red cells from a patient it is important that a reagent negative control (Mono Rh Control, Lorne catalogue number 640010) is included since the macromolecular potentiators in the reagent may cause false positive reactions with IgG coated cells.
3. Weak K antigens may be poorly detected by the gel card, microtitre plate and slide technique. It is recommended that weak K antigens are tested using the tube test technique.
4. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
5. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
6. The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
7. The user must determine suitability of reagent for use in other techniques.

### REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

#### Tube Technique

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Centrifuge capable of spinning at 1000 g for 20 seconds.
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Positive (ideally Kk) and negative (kk) control red cells.

#### Bio-Rad-ID Micro Typing Technique

- Bio-Rad ID-Cards (NaCl, Enzyme tests and Cold Agglutinins).
- Bio-Rad ID-Centrifuge.
- Bio-Rad ID-CellStab or ID-Diluent 2.

#### Ortho BioVue Typing Technique

- Ortho BioVue System Cassettes (Neutral).
- Ortho BioVue System Centrifuge.
- Ortho 0.8% Red Cell Diluent.

#### Microtitre plate Technique

- Validated “U” well microtitre plates.
- Microtitre plate centrifuge.
- Microtitre plate shaker.

#### Slide Technique

- Glass microscope slides or white card tiles.
- Applicator sticks.
- Timer or stopwatch

#### All Techniques

- Volumetric pipettes.

### RECOMMENDED TECHNIQUES

#### A. Tube Technique

1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume of Lorne reagent and 1 volume of red cell suspension.
3. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination
5. Any tubes, which show a negative or questionable result, should be incubated for 15 minutes at room temperature.
6. Following incubation, repeat steps 3 and 4.

#### B. Bio-Rad ID Technique (NaCl, Enzyme tests and Cold Agglutinins cards)

1. Prepare a 0.8% suspension of red cells in ID-CellStab or ID-Diluent 2.
2. Remove aluminium foil from as many microtubes on a NaCl, Enzyme tests and Cold Agglutinins ID-Card(s) as needed.
3. Place in appropriate microtube: 50µl of red cell suspension and 25µl of Lorne reagent.
4. Centrifuge ID-Card(s) in a Bio-Rad ID centrifuge.
5. Read macroscopically for agglutination.

#### C. Ortho BioVue Technique (Neutral cassettes)

1. Prepare a 0.8% suspension of red cells in 0.8% Ortho Red Cell Diluent.
2. Remove aluminium foil from as many reaction chambers on Neutral cassette(s) as needed.
3. Place in appropriate reaction chamber: 50µl of red cell suspension and 40µl of Lorne reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

## D. Microplate Technique, using "U" wells

0. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
1. Place in the appropriate well: 1 volume Lorne reagent and 1 volume red cell suspension.
2. Mix thoroughly, preferably using a microplate shaker, taking care to avoid cross-well contamination.
3. Incubate at room temperature for 15 minutes (time dependant on user).
4. Centrifuge the microplate for 1 minute at 140 rcf or for a suitable alternative time and force.
5. Resuspend the cell buttons using carefully controlled agitation on a microplate shaker
6. Read macroscopically or with a validated automatic reader.
7. Any weak reactions should be repeated by the tube technique.

## E. Slide Technique

1. Prepare a 35-45% suspension of red cells in serum, plasma or PBS or Isotonic saline. If this is not possible, whole anti-coagulated blood may also be used as the sample.
2. Place on a labelled glass slide or card tile: 1 volume of Lorne reagent and 1 volume of red cell suspension.
3. Using a clean applicator stick, mix reagent and cells over an area of about 20 x 40 mm.
4. Slowly tilt the slide back and forth for 1 minute, maintaining slide at room temperature.
5. Read macroscopically after 1 minute over a diffuse light and do not mistake fibrin strands as agglutination.
6. Any weak reactions should be repeated by the tube technique.

## INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of the red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the K antigen on the red cells.
2. **Negative:** No agglutination of the red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the K antigen on the red cells.
3. Test results of cells that are agglutinated using the reagent negative control shall be excluded, as the agglutination is most probably caused by the effect of the macromolecular potentiators in the reagent on sensitised cells.

## STABILITY OF THE REACTIONS

1. Read all tube and microplate tests straight after centrifugation.
2. Slide tests should be interpreted within one minute to ensure specificity and to avoid the possibility a negative result may be incorrectly interpreted as positive due to drying of the reagent.
3. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

## LIMITATIONS

1. Stored blood may give weaker reactions than fresh blood
2. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage, cell concentration, incubation time or temperature
   - Improper or excessive centrifugation
   - Deviation from the recommended techniques

## SPECIFIC PERFORMANCE CHARACTERISTICS

1. Prior to release, each lot of this reagent was tested using the recommended test methods listed in this IFU. The tests complied with the test requirements as stated in the current version/issue of the "Guidelines for the Blood Transfusion Services in the United Kingdom" and the "Common Technical Specifications.
2. Specificity of source monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
3. The Quality Control of the reagent was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed with PBS or Isotonic saline prior to use.

## DISCLAIMER

1. The user is responsible for the performance of the reagent by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations from the **Recommended Techniques** should be validated prior to use[5].

## BIBLIOGRAPHY


1. Marion E.Reid & Christine Lomas-Francis, Blood Group Antigens & Antibodies, SBB Books, New York 2007; Page 186.
2. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 12.
3. AABB Technical Manual, 16th edition, AABB 2008.
4. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
5. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, **5**, 145-150.


## AVAILABLE REAGENT SIZES

| Vial Size | Catalogue Number | Tests per vial |
|---|---|---|
| 10 ml | 760010 | 200 |
| 1000 ml | 760000* | 20,000 |

***This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.**


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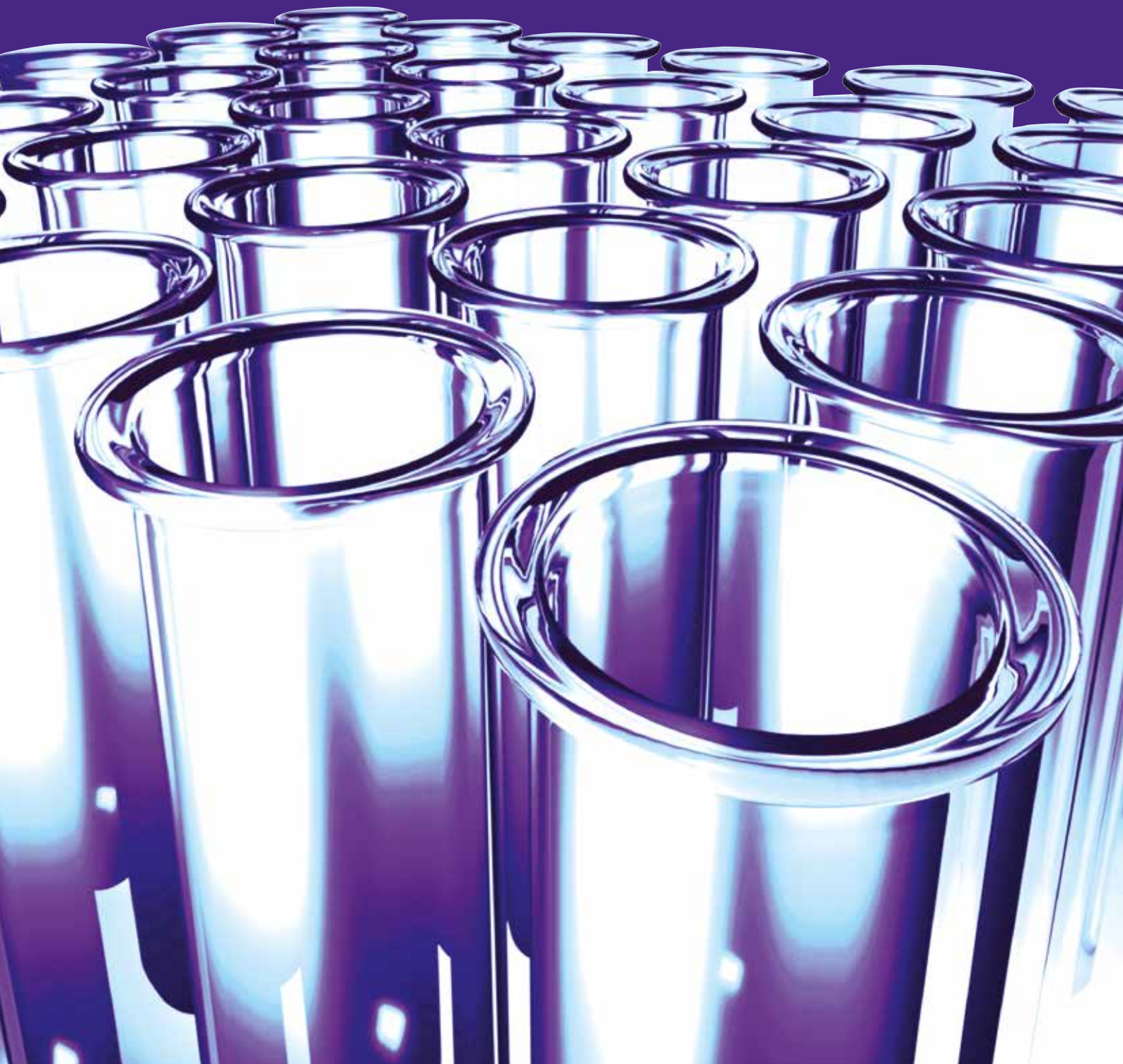
LORNE LABORATORIES

# Blood Reagents and Diagnostic Kits

Quality blood reagents and diagnostic kits delivered worldwide

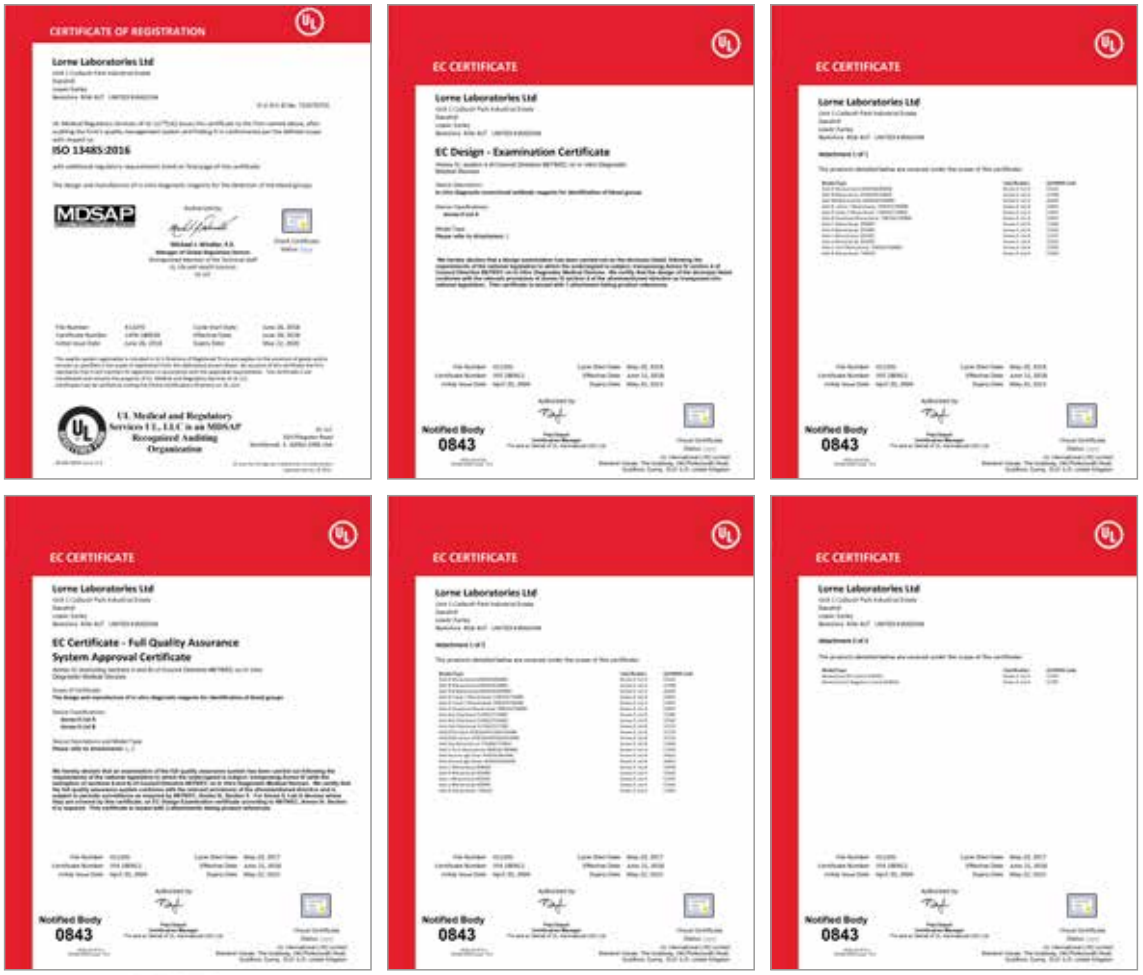


LORNE LABORATORIES

Lorne Laboratories provides high quality blood-grouping reagents and diagnostic kits. We do so at affordable prices and back this up with excellent customer service.

For over forty four years, Lorne has seen that philosophy transform the company from a small UK operation to one that spans the globe. The Lorne name is known and respected in over 110 countries around the world and it has come to mean ‘quality’ to the many blood transfusion professionals who use the products, both in the UK and across the five continents in which we operate.

Lorne has achieved ISO 13485 and MDSAP accreditation and our reagents and diagnostic kits are all CE marked. A significant number of our blood-grouping reagents are also registered with Health Canada.




# Contents



LORNE LABORATORIES

www.lornelabs.com

## ABO SYSTEM – MONOCLONAL REAGENTS

Lorne Monoclonal IgM ABO blood grouping reagents contain mouse monoclonal antibodies diluted in a phosphate buffer containing sodium chloride, EDTA and bovine albumin. Each reagent is supplied at optimal dilution for use by slide, tube, gel card and microplate techniques.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-A Monoclonal | 600010 | 10ml | 36 Months |
| Anti-B Monoclonal | 610010 | 10ml | 36 Months |
| Anti-A,B Monoclonal | 620010 | 10ml | 36 Months |

Lorne Anti-$A_1$ Lectin blood grouping reagent is prepared from an extract of *Dolichos biflorus* seeds, diluted with a sodium chloride solution containing bovine albumin. The reagent is supplied at optimal dilution for use by tube technique.
Lorne Anti-H Lectin blood grouping reagent is prepared from an extract of *Ulex europaeus* seeds, diluted with a sodium chloride solution containing bovine albumin. The reagent is supplied at optimal dilution for use by tube technique.

| | | | |
|---|---|---|---|
| Anti-$A_1$ Lectin | 116005 | 5ml | 24 Months |
| Anti-H Lectin | 115002 | 2ml | 24 Months |

## RHESUS SYSTEM – MONOCLONAL REAGENTS

Lorne Monoclonal IgM Anti-D Clone 1 and Clone 2 blood grouping reagents are low protein reagents containing a human monoclonal IgM antibody diluted with sodium chloride, bovine albumin and macromolecular potentiators. When typing patient samples, each reagent will directly agglutinate Rh D positive cells, including the majority of variants (but not $D^{VI}$) and a high proportion of weak D ($D^u$) phenotypes when using the slide, tube, gel card and microplate techniques.

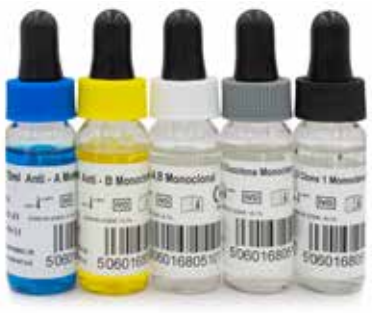
| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-D Clone 1 Monoclonal | 730010 | 10ml | 30 Months |
| Anti-D Clone 2 Monoclonal | 710010 | 10ml | 30 Months |

Lorne Monoclonal Anti-D Duoclone blood grouping reagent is a low protein, blended reagent containing human monoclonal IgM and IgG Anti-D, diluted in a phosphate buffer containing sodium chloride, bovine albumin and macromolecular potentiators. When typing patient samples, this reagent will directly agglutinate Rh D positive cells, including the majority of variants (but not $D^{VI}$) and a high proportion of weak D ($D^u$) phenotypes when using the slide, tube, gel card and microplate techniques. It will agglutinate $D^{VI}$ cells in the IAT phase of testing.

| | | | |
|---|---|---|---|
| Anti-D Duoclone Monoclonal | 740010 | 10ml | 30 Months |

Lorne Monoclonal IgM Anti-Rh blood grouping reagents are low protein reagents containing human monoclonal antibodies diluted with sodium chloride, bovine albumin and macromolecular potentiators. Each reagent is supplied at optimal dilution for use by slide, tube, gel card and microplate techniques.

| | | | |
|---|---|---|---|
| Anti-C Monoclonal | 690005 | 5ml | 24 Months |
| Anti-$C^w$ Monoclonal | 750002 | 2ml | 24 Months |
| Anti-E Monoclonal | 691005 | 5ml | 24 Months |
| Anti-c Monoclonal | 692005 | 5ml | 24 Months |
| Anti-e Monoclonal | 693005 | 5ml | 24 Months |
| Anti-C+D+E Monoclonal | 700010 | 10ml | 24 Months |



All pack inserts are available on **www.lornelabs.com**

## GROUPING REAGENTS FOR M, N AND S BLOOD GROUP SYSTEMS

Lorne Human Anti-M blood grouping reagent is prepared from human serum diluted in a sodium chloride solution containing bovine albumin. The reagent is supplied at optimal dilution for use by tube and gel card techniques.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-M Polyclonal | 311002 | 2ml | 24 Months |

Lorne Anti-N Lectin blood grouping reagent is prepared from an extract of *Vicia*, diluted with a sodium chloride solution containing bovine albumin. The reagent is supplied at optimal dilution for use by tube and gel card techniques.

| | | | |
|---|---|---|---|
| Anti-N Lectin | 312002 | 2ml | 24 Months |

Lorne Monoclonal Anti-S and Anti-s blood grouping reagents contain human monoclonal antibodies diluted in a phosphate buffer containing sodium chloride and bovine albumin. They are supplied at optimal dilution for use by indirect Coombs tube test and gel card techniques.

| | | | |
|---|---|---|---|
| Anti-S Monoclonal | 770002 | 2ml | 24 Months |
| Anti-s Monoclonal | 771002 | 2ml | 24 Months |

## GROUPING REAGENTS FOR KELL BLOOD GROUP SYSTEM

Lorne Monoclonal Anti-K blood grouping reagent is a low protein reagent containing the monoclonal IgM antibody, diluted in a phosphate buffer containing sodium chloride, bovine albumin and macromolecular potentiators. The reagent is supplied at optimal dilution for use by slide, tube, gel card and microplate techniques.

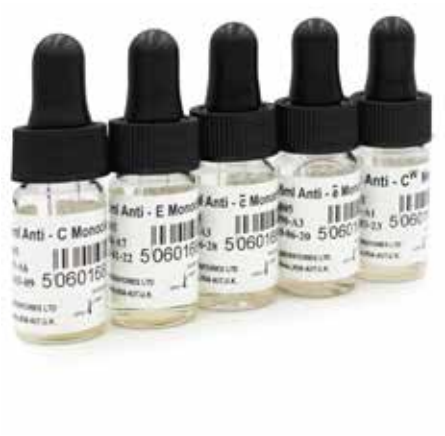
| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-K Monoclonal | 760010 | 10ml | 24 Months |

Lorne Monoclonal Anti-k (Cellano) blood grouping reagent contains monoclonal IgG antibody diluted in sodium chloride containing macromolecular potentiators and bovine albumin. Each reagent is supplied at optimal dilution for use by indirect Coombs tube and gel card techniques without the need for further dilution or addition.

| | | | |
|---|---|---|---|
| Anti-k (Cellano) Monoclonal | 325002 | 2ml | 24 Months |

Lorne Human Anti-Kp$^a$ and Anti-Kp$^b$ blood grouping reagents are prepared from human serum diluted in sodium chloride containing macromolecular potentiators and bovine albumin. Each reagent is supplied at optimal dilution for use by indirect Coombs tube and gel card techniques without the need for further dilution or addition.

| | | | |
|---|---|---|---|
| Anti-Kp$^a$ Polyclonal | 321002 | 2ml | 24 Months |
| Anti-Kp$^b$ Polyclonal | 322002 | 2ml | 24 Months |



All products available in bulk quantites

## GROUPING REAGENTS FOR RARE BLOOD GROUPS

Lorne Monoclonal Fy$^a$ blood grouping reagent contains human monoclonal antibodies diluted in a phosphate buffer containing sodium chloride and bovine albumin.
Lorne Human Anti-Fy$^b$ blood grouping reagent is prepared from human serum diluted in a sodium chloride solution containing macromolecular potentiators and bovine albumin. Each reagent is supplied at optimal dilution for use by indirect Coombs tube test and gel card techniques.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-Fy$^a$ Monoclonal | 774002 | 2ml | 24 Months |
| Anti-Fy$^b$ Polyclonal | 317002 | 2ml | 24 Months |

Lorne Anti-Jk$^a$ and Anti-Jk$^b$ Monoclonal reagents contain human monoclonal IgM antibodies, sodium chloride, phosphate buffer and bovine albumin. When typing red cells in accordance with the instructions for use, the reagents will directly agglutinate either Jk$^a$ positive cells or Jk$^b$ positive cells. Both reagents are supplied at optimal dilution for use by the test tube technique.

| | | | |
|---|---|---|---|
| Anti-Jk$^a$ Monoclonal | 775002 | 2ml | 24 Months |
| Anti-Jk$^b$ Monoclonal | 776002 | 2ml | 24 Months |

Lorne Human Anti-Lu$^a$ and Anti-Lu$^b$ blood grouping reagents are prepared from human serum diluted in a sodium chloride solution containing macromolecular potentiators and bovine albumin. Each reagent is supplied at optimal dilution for use by indirect Coombs tube test and gel card techniques.

| | | | |
|---|---|---|---|
| Anti-Lu$^a$ Polyclonal | 330002 | 2ml | 24 Months |
| Anti-Lu$^b$ Polyclonal | 331002 | 2ml | 24 Months |

Lorne Monoclonal IgM Anti-$P_1$ blood grouping reagent contains mouse monoclonal IgM antibodies, diluted in a solution containing sodium chloride and bovine albumin. The reagent is supplied at optimal dilution for use by tube and gel card techniques.

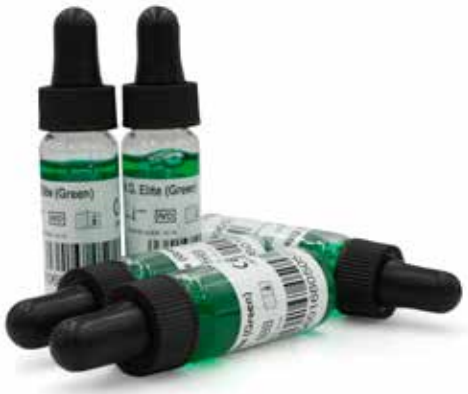
| | | | |
|---|---|---|---|
| Anti-$P_1$ Monoclonal | 315002 | 2ml | 24 Months |

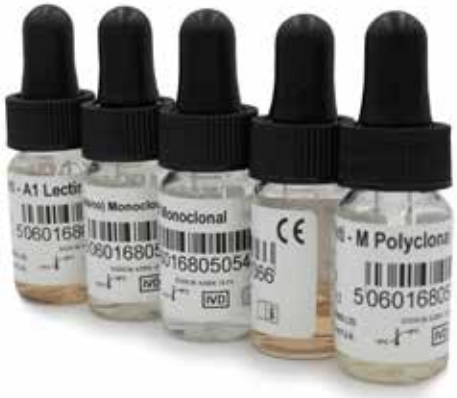
Lorne Monoclonal Anti-Le$^a$ contains human monoclonal IgM and Anti-Le$^b$ contains mouse monoclonal IgM antibodies, diluted in a phosphate buffer containing sodium chloride, EDTA, bovine albumin and macromolecular potentiators. Each reagent is supplied at optimal dilution for use by the tube technique. The Anti-Le$^a$ reagent can also be used for gel card techniques.

| | | | |
|---|---|---|---|
| Anti-Le$^a$ Monoclonal | 632002 | 2ml | 24 Months |
| Anti-Le$^b$ Monoclonal | 631002 | 2ml | 24 Months |

Lorne Human Anti-Di$^a$ blood grouping reagent is prepared from human serum diluted in a sodium chloride solution containing macromolecular potentiators and bovine albumin. The reagent is supplied at optimal dilution for use by indirect Coombs tube test and gel card techniques.

| | | | |
|---|---|---|---|
| Anti-Di$^a$ Polyclonal | 328002 | 2ml | 24 Months |






All pack inserts are available on **www.lornelabs.com**

## CONTROL REAGENTS

Lorne Monoclonal Rh Control is formulated with the same levels of potentiators and protein as Lorne Monoclonal Rh Grouping Reagents with the blood group antibodies omitted. The reagent is supplied at optimal dilution for use by slide, tube, gel card and microplate techniques.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Monoclonal Rh Control | 640010 | 10ml | 24 Months |

Lorne Monoclonal D Negative Control is for the control of Monoclonal Anti-D reagents and is formulated with the same concentrations of phosphate buffer, sodium chloride, bovine albumin and macromolecular potentiators as Lorne Monoclonal Anti-D reagents with the antibodies omitted. The reagent is supplied at optimal dilution for use by slide, tube, gel card and microplate techniques.

| | | | |
|---|---|---|---|
| Monoclonal D Negative Control | 650010 | 10ml | 30 Months |

Lorne Inert AB Serum is prepared from pooled human serum. No potentiators or any other chemicals have been added to the reagent. This reagent is supplied at optimal dilution for use by the techniques recommended for the reagent to be controlled.

| | | | |
|---|---|---|---|
| Inert AB Serum | 110010 | 10ml | 24 Months |

Lorne Precise Weak Anti-D Control Reagent is prepared from pools of human serum containing low activity Anti-D. The pool is diluted in inert serum to give a final concentration of 0.09 IU/ml Anti-D. ABO antibodies are not absorbed. This polyclonal reagent is supplied at the optimal dilution, for use by the techniques recommended for the reagent to be controlled.

| | | | |
|---|---|---|---|
| Precise Weak Anti-D | 209005 | 5ml | 24 Months |

## ANTI-HUMAN IgG REAGENT

Lorne Monospecific Anti-Human IgG Clear and Anti-Human IgG Green reagents contain anti-human IgG derived from rabbits. All non-specific activity is removed by absorption. These monospecific reagents are supplied at optimal dilution, for use by spin tube technique.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-Human IgG (Clear) | 401010 | 10ml | 24 Months |
| Anti-Human IgG (Green) | 402010 | 10ml | 24 Months |

## ANTI-HUMAN GLOBULIN REAGENT

Lorne Polyspecific Anti-Human Globulin Elite Clear and Anti-Human Globulin Elite Green reagents contain anti-human IgG derived from rabbits with non-specific activity removed by absorption and mouse monoclonal IgM Anti-C3d, Clone BRIC-8. The antibodies are diluted in a buffered solution containing bovine albumin. These polyspecific reagents are supplied at optimal dilution, for use by spin tube technique.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| A.H.G Elite (Clear) | 415010 | 10ml | 24 Months |
| A.H.G Elite (Green) | 435010 | 10ml | 24 Months |

## MONOCLONAL ANTI-C3d REAGENT

Lorne Monoclonal IgM Anti-C3d blood grouping reagent contains mouse monoclonal Anti-C3d, Clone BRIC-8. The reagent is supplied at optimal dilution, for use by direct tube technique.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-C3d Monoclonal | 427002 | 2ml | 24 Months |

All products available in bulk quantites

## ENZYMES AND POTENTIATORS

Lorne Phosphate Buffered Saline Tablets provide a safe, standardised saline solution for transfusion serology. Each tablet makes 1 litre of solution.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Buffered Saline Tablets | 490025 | 25 | 24 Months |
| | 490250 | 250 | 24 Months |

Lorne Papenzyme-plus reagent is a ready to use liquid preparation of stabilised papain. The reagent is standardised by serological methods for use in blood group antibody investigations. The reagent is supplied at optimal dilution for use by tube technique.

| | | | |
|---|---|---|---|
| Papenzyme-plus | 441010 | 10ml | 12 Months |

Lorne Bromelite reagent is a ready to use liquid preparation of stabilised bromelin. The reagent is standardised by serological methods for use in blood group antibody investigations. The reagent is supplied at optimal dilution for use by tube technique.

| | | | |
|---|---|---|---|
| Bromelite | 443010 | 10ml | 12 Months |

Lorne LISS Concentrate is a solution of glycine, phosphate buffer and 0.3 M sodium chloride. The solution is supplied at a stronger concentration than needed for serological use. It must be diluted 10 times in de-ionised water before being used by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| LISS Concentrate | 460500 | 500ml | 24 Months |
| | 460025 | 2500ml | 24 Months |

Lorne LISS ready for use is a low ionic strength solution containing glycine, sodium chloride and phosphate buffer. The reagent is supplied at the optimal dilution ready for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| LISS Ready for use | 470020 | 20 x 250ml | 12 Months |
| | 470250 | 4 x 250ml | 12 Months |
| | 470025 | 2500ml | 12 Months |

Lorne LISS-ADD is a low ionic strength solution containing glycine, sodium chloride, phosphate buffer and bovine albumin. The reagent is supplied at the optimal dilution, for use by all the recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| LISS-ADD | 480010 | 10ml | 24 Months |

Lorne PEG-ADD is a low ionic strength solution contains glycine, a phosphate buffer and polyethylene glycol. The reagent is supplied at optimal dilution for use by all the recommended techniques stated in the pack insert without the need for further dilution or addition.

| | | | |
|---|---|---|---|
| PEG-ADD | 485010 | 10ml | 24 Months |

Lorne 22% and 30% Serological Albumin is prepared from a mixture of bovine serum albumin and buffered saline. No artificial avidity enhancers or high molecular weight agglutination potentiators are added to any BSA preparation. None of the BSA reagents contain sodium caprylate. Each BSA reagent is supplied at optimal dilution for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| Serological Albumin 22% | 451010 | 10ml | 24 Months |
| Serological Albumin 30% | 452010 | 10ml | 24 Months |

All products available in bulk quantites

## ACCESSORIES

| Item | Product Code | Size |
|---|---|---|
|  The Essex Blockfile is a sturdy box for the storage of up to 200 cassette type histology blocks in each box. Delivered flat in packs of 25, they are easily assembled when needed and provide convenient and economical long-term storage for tissue samples. Dimensions – (L) 390mm x (D) 200mm x (H) 45mm | | |
| The 'Essex' Blockfile | 882025 | 25 Boxes |
|  The Brighton Slidestak is a sturdy box for the storage of over 1000 microscope slides upright in each box. Delivered flat in packs of 25, they are easily assembled and provide convenient and economical long-term storage. Dimensions – (L) 310mm x (D) 170mm x (H) 80mm | | |
| The 'Brighton' Slidestak | 881025 | 25 Boxes |
|  The Cardtiles are suitable for a wide range of haemagglutination tests. Each card has twenty 30mm square white test sites. | | |
| Cardtiles | 880100 | 100 Cards |
|  The Mini-Cardtiles are specially laminated cards suitable for VDRL and similar agglutination tests requiring a white background. Each card has ten 20mm diameter white test sites that are slightly compressed to form shallow wells. | | |
| Mini-Cardtiles | 880120 | 25 Cards |
|  The Latex Cardtiles are suitable for all latex agglutination tests. Each card has six 30mm diameter black reaction sites. | | |
| Latex-Cardtiles | 880130 | 25 Cards |
|  The mini pipettes are 11.5cm in length with one sealed end. The diameter of the tube is 4mm. | | |
| Mini Pipettes | 044000 | 500 |
|  We use these products in our own production. The 5ml vials are glass and the 10ml vials are plastic. Each vial is supplied with its own dropper. The 10ml vials are supplied in a sterile format in multiples of 1224 while all the other products are supplied individually and require autoclaving. | | |
| Vials and Droppers | LAB00002 | 5ml |
| Vials and Droppers | LAB00036 | 10ml |
|  We use these products in our own production. They are not branded. We supply flatpacks that hold 5 or 10 vials | | |
| Flatpacks | LAB00027 | 5 Vial |
| Flatpacks | LAB00007 | 10 Vial |

All pack inserts are available on **www.lornelabs.com**

## RED CELLS - REVERSE GROUPING CELLS

These Grouping Cells are made from red cells that have been washed to remove all traces of blood group antibodies and then resuspended in a preservative solution of buffered saline containing adenine, inosine, chloramphenicol and neomycin sulphate. The preservative solution does not interfere with complement-mediated haemolysis. Each group $A_1$, $A_2$ and B vial contains a 2.5-3.0% red cell suspension derived from the blood of a single donor, whereas the group O vial contains a 2.5-3.0% suspension of pooled group O red cells from two donors in equal proportions. Antigens for which the O cells have been typed are noted on the antigen profile accompanying each lot. NB: Some antigens are present on only 50% of the cells in each lot.

| Item | Product Code | Size | Minimum Shelf Life |
|---|---|---|---|
| Reverse Grouping $A_1$ + B Cells | 910020 | 2 x 10ml | 30 Days |
| Reverse Grouping $A_1$ + $A_2$ + B Cells | 910030 | 3 x 10ml | 30 Days |
| Reverse Grouping $A_1$ + $A_2$ + B + O Cells | 910040 | 4 X 10ml | 30 Days |
| Reverse Grouping $A_2$ Cells | 920002 | 1 x 10ml | 30 Days |

## RED CELLS – ANTIBODY SCREENING CELLS

Maxi-Screen 3 red cells are for antibody screening. Each reagent vial contains a 2.5-3.0% suspension of red cells derived from the blood of a single group O donor. The donor red cells have been washed to remove blood group antibodies and then resuspended in a preservative solution containing adenine and inosine to help preserve carbohydrate metabolism and chloramphenicol and neomycin sulphate as preservatives.

| Item | Product Code | Size | Minimum Shelf Life |
|---|---|---|---|
| Maxi-Screen 3 | 950030 | 3 x 10ml | 30 Days |

## RED CELLS – IDENTICELLS

Identicells are made up of 10 vials which each contain a 2.5-3.0% suspension of red cells derived from the blood of a single group O donor. The donor cells have been washed to remove blood group antibodies and then resuspended in a preservative solution containing adenine, inosine, chloramphenicol and neomycin sulphate as preservatives.

| Item | Product Code | Size | Minimum Shelf Life |
|---|---|---|---|
| Identicells | 960050 | 10 x 5ml | 30 Days |

## RED CELLS – COOMBS CONTROL CELLS

Coombs Control Cells are made up of a 3.8-4.2% suspension of single donor group O red cells washed to remove all blood group antibodies and then resuspended in a preservative solution. The preservative solution contains neomycin sulphate and chloramphenicol as preservatives. The cells are then sensitised with IgG.

| Item | Product Code | Size | Minimum Shelf Life |
|---|---|---|---|
| Coombs Control Cells | 970010 | 10ml | 30 Days |

**Deliveries take place every 28 days.**

As well as the standard Red Cell products above, we can also supply other products for special standing orders only. These include 0.8% panels and screening cells for use with column agglutination systems and Papainised red cell panels. Contact us with full details of your requirements for a quotation.

All the above Red Cell products are CE marked and comply with the Red Book.

All pack inserts are available on **www.lornelabs.com**

They are not Lorne labelled products.

## RED CELLS PRESERVATIVE – PRESERVACELL

Lorne Preservacell is a phosphate buffered solution containing glucose, calcium chloride and purine bases, with chloramphenicol, gentamycin sulphate and neomycin sulphate as antibiotics. The reagent is supplied at optimal dilution.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Preservacell | 980500 | 500ml | 12 Months |

## RED CELLS PRESERVATIVE – ABO PRESERVACELL

Lorne ABO Preservacell is a phosphate buffered solution containing glucose, calcium chloride and purine bases, with chloramphenicol, gentamycin sulphate and neomycin sulphate as antibiotics. EDTA is added to stop complement binding so that potent ABO haemolysins act as simple agglutinins. The reagent is supplied at optimal dilution.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| ABO Preservacell | 981500 | 500ml | 12 Months |

## ALSEVERS SOLUTION

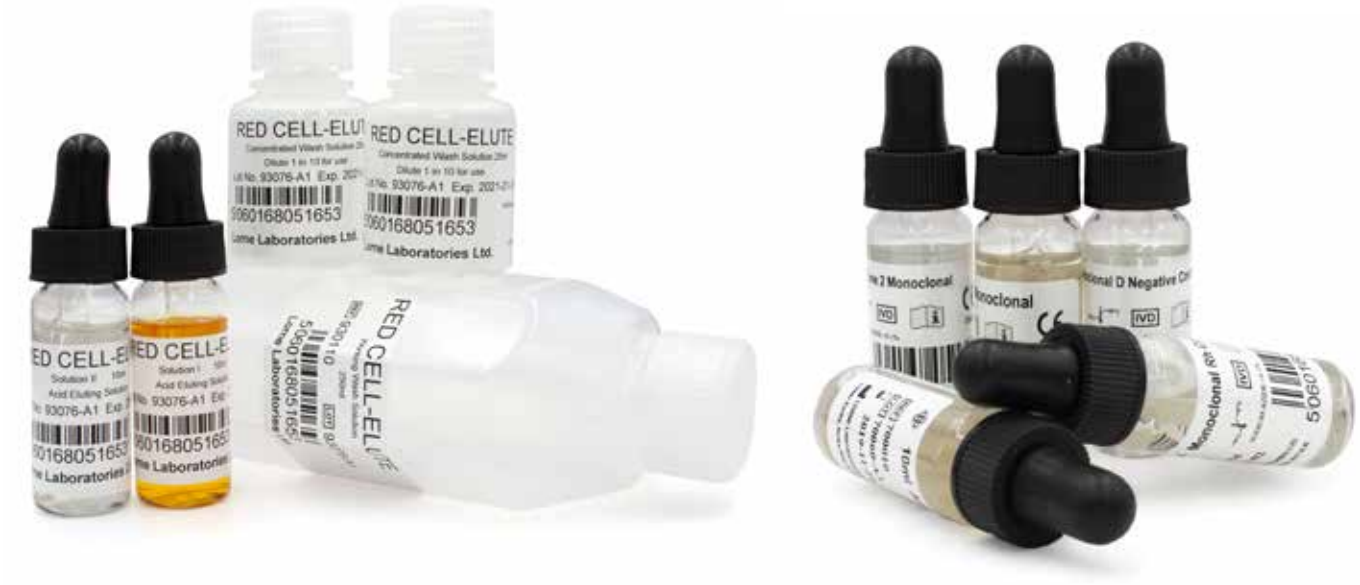
Alsevers Solution is an isotonic, balanced salt solution that is routinely used as an anticoagulant/blood preservative, which permits the storage of whole blood at refrigerator temperatures for approximately 10 weeks. The solution contains antibiotics and other chemicals that ensure maximum viability of stored red cells.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Alsevers Solution | 983000 | 1000ml | 12 Months |

## RED CELL ELUTE

Lorne Red Cell Elute is an acid elution kit. The kit consists of Concentrated Wash Solution, which is used to minimise antibody dissociation during washing, Acid Eluting Solution, which is a low pH glycine buffer containing a colouring agent and a Base Buffering Solution, Tris solution containing bovine albumin. The Concentrated Wash Solution requires dilution and all the other solutions are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Red Cell Elute | 930110 | Kit | 30 Months |




All products available in bulk quantites

## SYPHILIS KITS

Lorne TPHA Kit detects antibodies to *T. pallidum*. Test Cells are preserved avian erythrocytes coated with antigenic components of pathogenic *T. pallidum* (Nichol's strain). Any non-specific reactions are detected using the Control Cells; avian erythrocytes not coated with T. pallidum antigens. Non-specific reactions can also be absorbed out using Control Cells. Antibodies to non-pathogenic treponemes are absorbed by an extract of Reiter's treponemes in the cell suspension. Reagents are supplied at optimal dilution for use by the recommended techniques in the pack insert.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| TPHA Microtitre Plate Kit | 043100A | 100 Tests | 18 Months |

The VDRL test is a non-treponemal slide agglutination test for the qualitative and semi-quantitative detection of plasma reagins. The antigen suspension, a lipid complex, is agglutinated when mixed with samples containing reagins of patients affected by syphilis. The reagent is supplied ready to use.

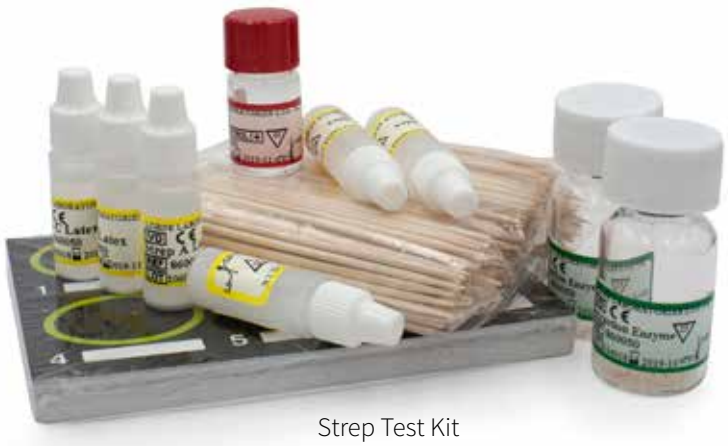
| | | | |
|---|---|---|---|
| VDRL Stabilised Reagent Kit | 046511A | 250 Tests | 30 Months |

RPR Carbon Antigen contains micro particulate carbon, which aids in the microscopic reading of results. Lorne provides reagents, controls and kits. All the reagents are supplied at optimum dilution for use by all recommended techniques without the need for further dilution or addition.

| | | | |
|---|---|---|---|
| RPR Carbon Antigen | 045005A | 100 Tests | 30 Months |
| RPR Carbon Positive Control | 047001A | 1ml | 30 Months |
| RPR Carbon Kit | 044150A | 150 Tests | 30 Months |
| | 044500A | 500 Tests | 30 Months |

RPR Carbon Kit

TPHA Microtitre Plate Kit



Strep Test Kit

All pack inserts are available on **www.lornelabs.com**

## LATEX KITS

Lorne ASO Latex Kit is a serologic test for the detection of ASO antibodies. All the reagents are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| ASO Latex Kit | 031100A | 100 Tests | 30 Months |

Lorne RF Latex Kit is for the detection of Rheumatoid Factor. The latex reagent is a suspension of latex particles coated with human gamma globulins, which agglutinate in the presence of Rheumatoid Factor. All latex reagents are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| RF Latex Kit | 830100A | 100 Tests | 30 Months |

Lorne CRP Latex Test Kit is for the detection of CRP. The test reagent consists of latex particles coated with either goat or rabbit Anti-CRP (IgG). All the latex reagents are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| CRP Latex Kit | 850100A | 100 Tests | 30 Months |

Lorne IM Latex Test Kit is for detection of the heterophile antibody associated with Infectious Mononucleosis. The test reagent consists of latex particles coated with partially purified glycoprotein from bovine red cells. All reagents are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| IM Latex Kit | 041050A | 50 Tests | 30 Months |

Lorne LE Latex Kit is for the detection of nuclear proteins in Systemic Lupus Erythematosus (SLE or LE). The test reagent consists of DNP coated latex particles. All the reagents are supplied at optimal dilution for use by recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| LE Latex Test Kit | 840050 | 50 Tests | 24 Months |

Lorne Strep Kit is a Latex agglutination grouping kit for the identification of Streptococci of Lancefield groups A, B, C, D, F and G by agglutination of specific antibody coated latex particles in the presence of enzymatically-extracted antigen. All the reagents are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| Strep Test Kit | 860050 | 6 x 50 Tests | 18 Months |

Lorne Staph Kit is a Latex aggulation kit for the identification of *Staph. aureus.* Includes latex reagent, control reagent and agglutination slides. All the reagents are supplied at optimal dilution for use by all recommended techniques in the pack insert.

| | | | |
|---|---|---|---|
| Staph Test Kit | 870050 | 50 Tests | 18 Months |
| | 870100 | 100 Tests | 18 Months |

ASO Latex Kit

All products available in bulk quantites

## FEBRILE ANTIGENS

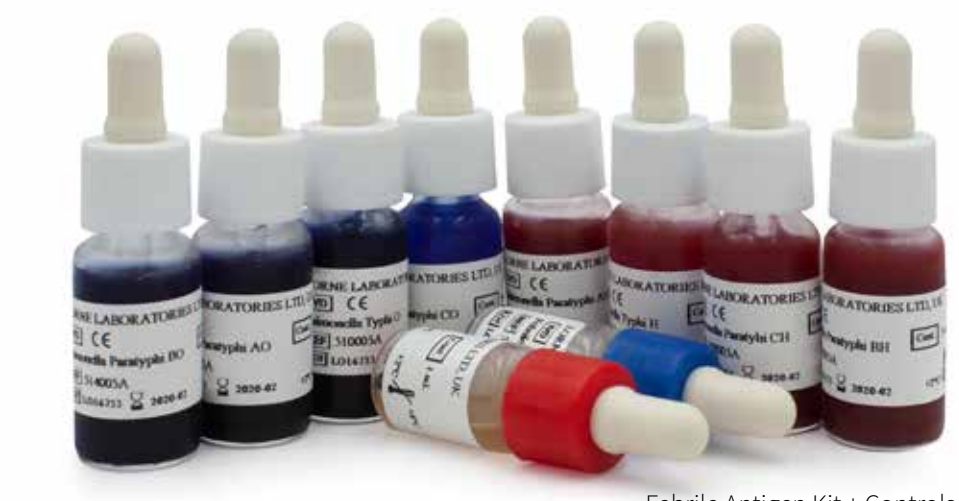
Lorne Stained Febrile Antigens are for the detection of certain Salmonellae, Richettsiae and Brucellae pathogens. The antigens are suspensions of killed bacteria, stained to enhance the reading of agglutination tests. The blue stained antigens are specific to the somatic "O" antigens and the red stained antigens are specific to the flagellar "H" antigens. Suspensions of Proteus OX2, OX19 and OXK are used to detect rickettsial antibodies.
Rose Bengal is a slide agglutination test for the qualitative and semi-quantitative detection of anti-Brucella antibodies in human and animal serum. The stained bacterial suspension agglutinates when mixed with samples containing specific IgG or IgM antibodies present in the patient sample.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Salmonella Typhi H | 502005A | 100 Tests | 30 Months |
| Salmonella Paratyphi AH | 504005A | 100 Tests | 30 Months |
| Salmonella Paratyphi BH | 506005A | 100 Tests | 30 Months |
| Salmonella Paratyphi CH | 508005A | 100 Tests | 30 Months |
| Salmonella Typhi O | 510005A | 100 Tests | 30 Months |
| Salmonella Paratyphi AO | 512005A | 100 Tests | 30 Months |
| Salmonella Paratyphi BO | 514005A | 100 Tests | 30 Months |
| Salmonella Paratyphi CO | 516005A | 100 Tests | 30 Months |
| Brucella Abortus | 518005A | 100 Tests | 30 Months |
| Brucella Melitensis | 520005A | 100 Tests | 30 Months |
| Proteus OX2 | 522005A | 100 Tests | 30 Months |
| Proteus OX19 | 524005A | 100 Tests | 30 Months |
| Proteus OXK | 526005A | 100 Tests | 30 Months |
| Febrile Antigen Kit + Controls | 532042A | 8x100 Tests and 2x1ml | 30 Months |
| Febrile Positive Control | 536001A | 1ml | 30 Months |
| Febrile Negative Control | 537001A | 1ml | 30 Months |
| Rose Bengal | 155050A | 50 Tests | 30 Months |

## ROSE WAALER

Rose Waaler is a technique of passive haemagglutination for qualitative and semi-quantitative detection of human serum Rheumatoid Factor. Sheep red blood cells are coated with a concentration of antiserum to sheep red blood cells that is too low to cause agglutination. The addition of serum from a patient with Rheumatoid Factor will cause agglutination.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Rose Waaler | 156050A | 50 Tests | 30 Months |



Febrile Antigen Kit + Controls

All pack inserts are available on **www.lornelabs.com**

## ABO SYSTEM – MONOCLONAL REAGENTS

Lorne Monoclonal IgM ABO Standard Grade blood grouping reagents contain mouse monoclonal antibodies diluted in a phosphate buffer containing sodium chloride, EDTA and bovine albumin. Each reagent is supplied at optimal dilution for use by slide, tube, gel card and microplate techniques.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-A Monoclonal - Standard Grade | 600010E | 10ml | 36 Months |
| Anti-B Monoclonal - Standard Grade | 610010E | 10ml | 36 Months |
| Anti-A,B Monoclonal - Standard Grade | 620010E | 10ml | 36 Months |

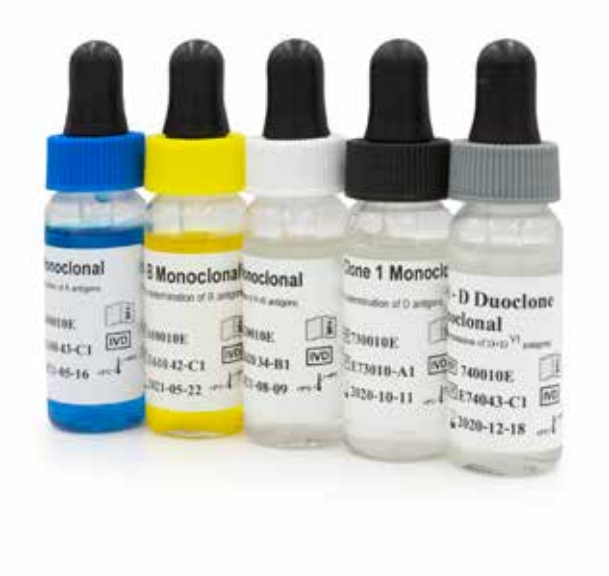
## RHESUS SYSTEM – MONOCLONAL REAGENTS

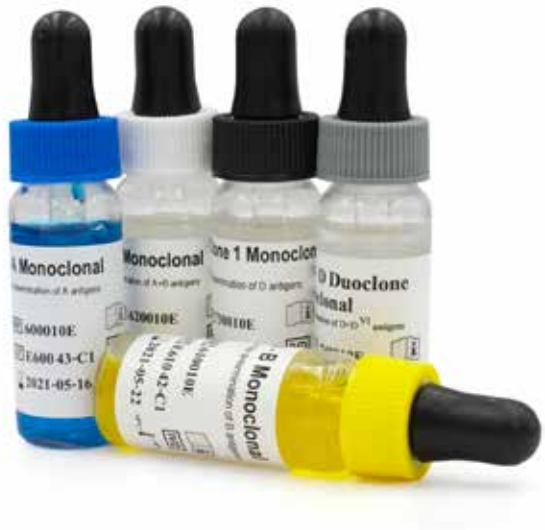
Lorne Monoclonal IgM Anti-D Clone 1 Standard Grade blood grouping reagent is a low protein reagent containing a human monoclonal IgM antibody diluted with sodium chloride, bovine albumin and macromolecular potentiators. When typing patient samples, the reagent will directly agglutinate Rh D positive cells, including the majority of variants (but not $D^{VI}$) and a high proportion of weak D ($D^{u}$) phenotypes when using the slide, tube, gel card and microplate techniques.

| Item | Product Code | Size | Maximum Shelf Life |
|---|---|---|---|
| Anti-D IgM Monoclonal - Standard Grade | 730010E | 10ml | 30 Months |

Lorne Monoclonal Anti-D Duoclone Standard Grade blood grouping reagent is a low protein, blended reagent containing human monoclonal IgM and IgG Anti-D, diluted in a phosphate buffer containing sodium chloride, bovine albumin and macromolecular potentiators. When typing patient samples, this reagent will directly agglutinate Rh D positive cells, including the majority of variants (but not $D^{VI}$) and a high proportion of weak D ($D^{u}$) phenotypes when using the slide, tube, gel card and microplate techniques. It will agglutinate $D^{VI}$ cells in the IAT phase of testing.

| | | | |
|---|---|---|---|
| Anti-D Duoclone Monoclonal - Standard Grade | 740010E | 10ml | 30 Months |





All products available in bulk quantites

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