



REAGENȚI PENTRU DETERMINAREA GRUPELOR SANGVINE # referință a documentului CEPI690/691/692/693

APLICAȚIILE. Reagentul Anti-C, anti-E, anti-c și anti-e: pentru tehnicile în tub, DiaMed-ID, Ortho BioVue, Microplăci + Slide-uri

SUMAR

Levine și Stetson au descoperit sistemul de sânge Rh în 1940. Separat de D, celelalte antigene majore sunt C, E, c și e. Antigenul D posedă imunogenicitate înaltă; antigenele C și e sunt mai puțin imunogenice decât E și c. Anticorpilor corespunzători posedă semnificație clinică deoarece pot provoca reacții hemolitice de transfuzie, dar și în Boala Hemolitică a Nou-Născuților.

Tabelul 1: frecvențele antigenelor în populația Caucasiană

Antigenele Rh principale

D	C	E	c	e
85	70	30	80	98

PRINCIPII

Reagenții vor cauza aglutinarea directă (agregarea) a celulelor roșii testate, care poartă antigenul Rh corespunzător. Lipsa aglutinării în general indică asupra absenței antigenului Rh corespunzător (a se vedea **Limitările**).

REAGENȚII

Reagenții pentru determinarea grupelor sangvine Monoclonal IgM Anti-Rh de la LORNE reprezintă reagenți de proteine minore, ce conțin anticorpilor umani monoclonali diluate în soluția de clorură de sodiu (0,9 g%) ce conține potențiatori macromoleculari și albumina bovină (6g%). Fiecare din reagenți este în diluție optimă pentru utilizare în toate tehnicile recomandate, menționate mai jos, fără necesitatea de diluții ulterioare sau adaosuri. Pentru identificarea numărului Lotului și a termenului de expirare a se vedea **Eticheta Flaconului**.

Tabelul 2: Liniile celulare/clonile umane IgG utilizate

Reagent	Cell Line / Clone
Anti-C	MS-24
Anti-E	MS-258
Anti-c	MS-33
Anti-e	MS-16 + MS-63

CONDIȚII DE PĂSTRARE

Flacoanele cu reagenți trebuie să fie păstrate la 2 - 8°C la primire. Păstrarea îndelungată la o altă temperatură decât cea menționată poate duce la pierderea rapidă a reactivității reagentului. Acest reagent a fost testat la condiții de transportare +37°C și -25°C, precum menționat în documentul EN13640:2002.

COLECTAREA ȘI PREPARAREA PROBELOR

Probele de sânge colectate cu sau fără anticoagulant pot fi utilizate pentru tiparea antigenului. Dacă testarea se face mai târziu, atunci probele se stochează la 2-8°C. Probele cu EDTA și citrat trebuie să fie testate în timp de 35 zile după colectare. Probele colectate ACD, CPD, CPDA-1 poate fi testat timp de până la 35 zile din data colectării. Toate probele de sânge trebuie să fie spălate cel puțin două ori cu PBS sau soluție izotonică salină înainte de testare. Probele de sânge care prezintă liza pot manifesta rezultate dubioase.

PRECAUȚII

1. Reagenții sunt destinați doar pentru diagnosticul *in vitro*.
2. Dacă flaconul cu reagent este stricat, ne ermetic închis, acesta trebuie să fie aruncat imediat.

3. Nu utilizați reagenții cu termenul expirat (a se vedea pe **Eticheta Flaconului**).
4. Nu utilizați reagenții dacă este prezent precipitatul.
5. Purtați haine de protecție în timpul utilizării reagenților, precum mănuși și halat.
6. Reagenții au fost filtrați prin filtre de 0,2 μ, pentru a înlătura pericolul biologic. Astfel, odată ce flaconul a fost deschis, conținutul poate fi utilizat până la sfârșitul termenului de expirare, dacă nu este prezentă careva turbiditate în flacon, care poate indica asupra prezenței deteriorării sau contaminării.
7. Reagentul conține <0,1% de azid de sodiu. Acesta poate fi toxic la ingerare și poate reacționa cu cupru și staniu plumbuit și forma azide de metale cu efect exploziv. La expunere, spălați abundent cu apă.
8. Materialele utilizate pentru producerea reagenților au fost testate pentru a fi negativi la anticorpilor HIV 1+2, HCV și HBsAg prin metodici microbiologice aprobate.
9. Nici o metodică de testare cunoscută nu poate garanta lipsa agenților infecțioși în produsele derivate din material de origine umană sau biologică. Atenție se ia la utilizarea și distrugerea fiecărui flacon și a conținutului acestuia.

PROCEDURI DE DISTRUGERE A REAGENTULUI ȘI DE PROTECȚIE ÎN CAZUL SCURGERII

Pentru informarea referitor la proceduri de distrugere și decontaminare a locului de scurgere, a se vedea Broșurile cu Date referitor la Siguranța Materialului (Material Safety Data Sheets).

CONTROALE ȘI SFATURI

1. Se recomandă utilizarea în paralel a controalelor pozitiv (ideal celulele heterozigote) și cel negativ la efectuarea testării fiecărui set de probe. Testele trebuie să fie considerat invalid dacă toate controalele nu prezintă rezultatele așteptate.
2. La tiparea celulelor roșii a unui pacient, este important ca să fie inclus reagentul control negativ (Mono Rh Control, Lorne cat. # 640010), deoarece sunt prezenți potențiatori macromoleculari ce poate cauza reacții fals pozitive cu celulele acoperite cu IgG.
3. Antigenele Rhesus cu manifestare slabă pot fi greu detectate prin tehnica gel card, plăcii de microtitrare și slide-ului. Se recomandă ca aceste să fie testate prin tehnica testării în tub.
4. La compartimentul Tehnicile Recomandate, un volum se consideră de cca 50 μl la utilizarea flaconului cu pipetă oferit.
5. Utilizarea reagenților și interpretarea rezultatelor trebuie să fie efectuată de personal antrenat și calificat în concordanță cu cerințele țării unde acești reagenți se folosesc. Utilizatorul trebuie să determine utilitatea reagentului în alte tehnici decât cele menționate.

REAGENȚI ȘI MATERIALE NECESARE

- Bețișoare de aplicare.
- Cititor de plăci automat.

- ID-Carduri DiaMed (Neutre).
- ID-Centrifugea DiaMed
- DiaMed ID-CellStab.
- Lame microscopice de sticlă.
- Tuburi de testare din sticlă (10 x 75 mm or 12 x 75 mm).
- Centrifuga pentru microplăci.
- Casete Ortho BioVue System (Neutre).
- Centrifuga Ortho BioVue System.
- Diluent pentru celule roșii Ortho 0,8%.
- Șeicher pentru plăci.
- Soluția PBS (pH 6,8-7,2) sau soluția salină izotonică (pH 6,5-7,5)
- Control de celule roșii pozitiv și negativ:
 - Monoclonal Anti-C: R1r (control pozitiv) and rr (control negative).
 - Monoclonal Anti-E: R2r (control pozitiv) and rr (control negative).
 - Monoclonal Anti-c: R1r (control pozitiv) and R1R1 (control negative).
 - Monoclonal Anti-e: R2r (control pozitiv) and R2R2 (control negative).
- Centrifuga pentru tuburi de testare.
- Microplăci cu godeurile "U" validate.
- Pipete volumetrice.

TEHNICILE RECOMANDATE

A. Tehnica în Tub

1. Preparati o suspensie de celule roșii spălate 2-3% în PBS sau soluție izotonică salină
2. Adăugați în tubul marcat pentru testare: 1 volum de reagent Lorne Anti-Rh și 1 volum de suspensie de celule roșii de testare.
3. Amestecați minuțios și centrifugați toate tuburile timp de 20 sec la 1000 RCF sau utilizați alți parametri corespunzători de timp și viteză de centrifugare.
4. Resuspendați atent conglomeratul de celule roșii și citiți aglutinarea macroscopic.
5. Orice tub, care manifestă o reacție negativă sau dubioasă, trebuie să fie incubate pentru 15 min la temperatura camerei.
6. Urmează incubarea și se repetă etapele 3 și 4.

B. Tehnica de Microtipare DiaMed-ID

1. Prepararea suspensiei de 0,8% a celulelor roșii spălate în ID-Cellstab.
2. Înlăturați folia de aluminiu de pe tuburi.
3. Plasați în tuburile corespunzătoare: 50μl de soluție suspensie celule roșii de testare și 25μl de reagent Lorne Anti-Rh.
4. Centrifugați ID-Card-urile în centrifuga Diamed ID.
5. Citiți rezultatul aglutinării macroscopic.

C. Tehnica de tipare Ortho BioVue

1. Prepararea suspensiei de 0,8% a celulelor roșii spălate în Ortho Red Cell Diluent.
2. Înlăturați folia de aluminiu de pe tuburi.
3. Plasați în camera de reacție corespunzătoare: 50μl de suspensie de celule roșii și 40μl de reagent Lorne Anti-Rh.
4. Centrifugați casetele timp de 5 minute în centrifuga Ortho BioVue System.
5. Citiți rezultatul aglutinării macroscopic.

D. Tehnica în Microplacă, cu godeurile "U"

1. Preparati o suspensie de celule roșii spălate 2-3% în PBS sau soluție izotonică salină
2. Adăugați în tubul marcat pentru testare: 1 volum de reagent Lorne Anti-Rh și 1 volum de suspensie de celule roșii de testare.

3. Amestecați minuțios, preferabil cu ajutorul unui sheicher pentru microplăci, cu precauție evitând cross-contaminarea între godeuri.
4. Incubați la temperatura camerei pentru 15 minute (timpul dependent de utilizator)
5. Centrifugați microplaca timp de 1 minut la 140 RCF sau utilizați alți parametri corespunzători de timp și viteză de centrifugare.
6. Resuspendați atent conglomeratul de celule roșii utilizând aglutinarea controlată pe un șeicher de microplăci.
7. Citiți rezultatul macroscopic sau cu ajutorul unui cititor automat.
8. Orice tub, care manifestă o reacție slabă trebuie să fie repetate prin tehnica de tub.

E. Tehnica de slide-uri

1. Preparati o suspensie de celule roșii pentru testare 35-45% în ser, plasma și PBS sau soluție izotonică.
2. Plasați în tuburile corespunzătoare: 1 volum de soluție suspensie celule roșii de testare și 1 volum de reagent Lorne Anti-Rh.
3. Utilizând un bețișor de aplicare curat amestecați reagentul și celulele, repartizând pe o suprafață de cca 20X40 cm.
4. Încet răsturnați lama înainte - înapoi timp de 30 sec, cu amestecare ulterioară peste fiecare 2 minute, menținând lama la temperatura camerei.
5. Citiți rezultatul macroscopic peste 2 minute prin lumina difuză; nu confundați fibrele de fibrină cu aglutinarea.
6. Orice reacție slabă trebuie să fie repetată prin tehnica în tub.

INTERPRETAREA REZULTATELOR TESTULUI

1. Pozitiv: aglutinarea celulelor roșii testate constituie rezultatul pozitiv al testării în limitele acceptate a procedurii de testare și indică prezența antigenului Rh corespunzător de pe celulele roșii de testare.
2. Negativ: lipsa aglutinării celulelor roșii de testare constituie rezultatul negativ și în limitele acceptate a procedurii de testare și indică asupra absenței antigenului Rh corespunzător de pe celulele roșii de testare.
3. Rezultatele testării celulelor care au aglutinat utilizând reagentul pentru controlul negativ trebuie să fie excluse, deoarece aglutinarea e probabil că este cauzată de efectul potențiatorilor macromoleculari de pe celulele sensibilizate.

STABILITATEA REACȚIILOR

1. Citiți rezultatele tuturor tuburi și microplăci după centrifugare.
2. Testele pe slide-uri trebuie să fie interpretate timp de 2 minute pentru asigurarea specificității și evitării posibilității rezultatului negativ, ce poate fi interpretat incorect ca unul pozitiv, datorită uscării reagentului.
3. Precauția trebuie să fie luată în interpretarea rezultatelor testului realizat la temperaturile altele decât cele recomandate.

LIMITĂRILE

1. Reagentul Anti-Rh nu este potrivit pentru utilizare cu celulele tratate enzimatic sau pentru utilizare în tehnica antiglobulinică indirectă.
2. Mulți anticorpi anti-Rh IgM monoclonali umani posedă activitate aglutininică anti i/I la rece, în special cu celulele cordului sau cele tratate enzimatic. Aceasta poate deveni evident dacă testele au fost incubate la temperaturile mai mici decât cele recomandate.
3. Unele celule roșii expresează antigenele Rh variante și pot da reacții mai slabe decât observate cu celulele de control

pozitiv selectate randomizat. Anti-C poate da reacții mai slabe cu antigenul C a indivizilor R_2R_z . Similar, Anti-e poate da reacții puțin mai slabe în absența antigenului C, de ex., în cazul R_2r , $r''r$ și rr .

4. Expresia supresată sau diminuată a antigenelor de anumită grupă sanguină pot advers să majoreze numărul de rezultate fals negative și astfel trebuie să fie luate precauții la asocierea genotipului în baza rezultatelor de testare.
5. Rezultatele fals pozitive și fals negative pot apărea datorită:
 - contaminarea materialului de testare
 - păstrarea incorectă, concentrația celulară, timpul de incubare sau temperatura
 - centrifugarea incorectă sau excesivă.
 - abateri de la tehnica recomandată.

CARACTERISTICILE PERFORMANTELOR SPECIFICE

1. reagenții au fost caracterizați prin procedurile menționate în Tehnici Recomandate.
2. Înaintea eliberării, fiecare lot a reagentului monoclonal Anti-C, Anti-E, Anti-c și Anti-e LORNE este testat prin Tehnicile Recomandate contra panelului de celule roșii antigen pozitive pentru asigurarea reactivității corespunzătoare.
3. Specificitatea a anticorpilor monoclonali se demonstrează utilizând panelul de celule antigen negative.
4. Controlul Calității a reagenților a fost realizat prin utilizarea celulelor roșii care au fost spălate dublu cu PBS sau soluție salină izotonică înainte de utilizare
5. Reagenții corepsund cu recomandările incluse în ultima ediție a Ghidului pentru Serviciile de Transfuzie a Sângelui din Marea Britanie.

ACT DE RENUNȚATE (DISCLAIMER)

1. Utilizatorul este responsabil de performanța reagenților fiind utilizate prin alte metode decât cele menționate în Tehnicile Recomandate.
2. Orice deviere de la Tehnicile Recomandate trebuie să fie validată înainte de utilizare.

BIBLIOGRAFIE

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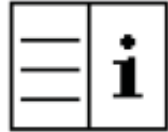
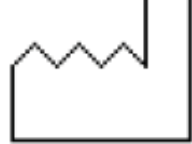
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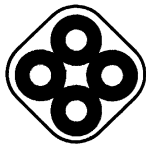
	Volumul flaconului	Număr de catalog
Anti-C Monoclonal	5 ml	690005
	1000 ml	690000*
Anti-E Monoclonal	5 ml	691005
	1000 ml	691000*
Anti-c Monoclonal	5 ml	692005
	1000 ml	692000*
Anti-e Monoclonal	5 ml	693005
	1000 ml	693000*

* Acest format este doar pentru utilizare în producere și astfel nu este cu marcajul CE.

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TABELUL DE SIMBOLURI

	Numărul producerii BATCH NUMBER
	Referința în catalog CATALOG REFERENCE
	Data de expirare EXPIRY DATE
	A se citi manualul de utilizare READ PACK INSERT
	Diagnosticarea in vitro IN-VITRO DIAGNOSTICS
	A se păstra la STORE AT
	Producătorul MANUFACTURER



BLOOD GROUPING REAGENTS DIRECTIONS FOR USE

Anti-C, Anti-E, Anti-c and Anti-e Monoclonal: For Tube, Bio-Rad-ID, Ortho BioVue, Microplate + Slide Techniques.

SUMMARY

Levine and Stetson discovered the Rh blood group system in 1940. Apart from D the other major Rh antigens are C, E, c and e. The D antigen is highly immunogenic; the C and e antigens are less immunogenic than E and c. The corresponding antibodies are all clinically significant since they may cause both Transfusion Reactions and Haemolytic Disease of the Newborn.

INTENDED PURPOSE

The Rh reagents are blood grouping reagents intended to be used to qualitatively determine the presence or absence of Rh antigens 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 reagents contain antibodies to the appropriate Rhesus antigen on human red cells and will cause direct agglutination (clumping) of red cells that carry the corresponding Rh antigen. No agglutination (no clumping) generally indicates the absence of the corresponding Rh antigen (see **Limitations**).

REAGENTS

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 (4.0 g%). The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. Each 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**.

Reagent	Cell Line / Clone
Anti-C	MS-24
Anti-E	MS-258
Anti-c	MS-33
Anti-e	MS-16 + MS-63

STORAGE

Reagent vials should be stored at 2 - 8°C 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 37°C and -25°C 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 reagents are 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 reagents past the expiration date (see **Vial Label**).
4. Do not use the reagents 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 reagents have 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 reagents contain < 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 products 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 patients known or suspected to have auto-antibodies, protein abnormalities or a positive Direct Antiglobulin Test (DAT), it is important that a reagent negative control is tested in parallel. For the reagent negative control, only Lorne Monoclonal Rh Control, catalogue number 640010, must be used.
3. Weak Rh antigens may be poorly detected by the gel card, microtitre plate and slide technique. It is recommended that weak Rh 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 2-8°C.
5. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
6. The use of reagents and interpretation of results must be carried out by properly trained and qualified personnel in accordance with requirements of the country where the reagents are in use. The user must determine suitability of the reagents 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 and negative control red cells:
Monoclonal Anti-C: R₁R (positive control) and rr (negative control).
Monoclonal Anti-E: R₂R (positive control) and rr (negative control).
Monoclonal Anti-c: R₁R (positive control) and R₁R₁ (negative control).
Monoclonal Anti-e: R₂R (positive control) and R₂R₂ (negative control).

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 Lorne Anti-Rh reagent and 1 volume 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 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 the NaCl/Enzyme/Cold agglutinins ID-Card as needed.
3. Place in appropriate microtube: 50µl of red cell suspension and 25µl of Lorne Anti-Rh reagent.
4. Centrifuge the 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 the Neutral cassette as needed.

- Place in appropriate reaction chamber: 50µl of red cell suspension and 40µl of Lorne Anti-Rh reagent.
- Centrifuge cassette(s) for 5 minutes in an Ortho BioVue System Centrifuge.
- Read macroscopically for agglutination.

D. Microplate Technique, using “U” wells

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

E. Slide Technique

- 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.
- Place on a labelled glass slide or card tile: 1 volume of Lorne Anti-Rh reagent and 1 volume of red cell suspension.
- Using a clean applicator stick, mix reagent and cells over an area of about 20 x 40 mm.
- Slowly tilt the slide back and forth for 1-minute, maintaining slide at room temperature.
- Read macroscopically after 1 minute over a diffuse light and do not mistake fibrin strands as agglutination.
- Any weak reactions should be repeated by the tube technique.

INTERPRETATION OF TEST RESULTS

- Positive:** Agglutination of the red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the appropriate Rh antigen on the red cells.
- 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 appropriate Rh antigen on the red cells.
- 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

- Read all tube and microplate tests straight after centrifugation.
- 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.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS

- Lorne Anti-Rh reagents are not suitable for use with enzyme treated cells or for use in indirect antiglobulin techniques.
- Many Monoclonal human IgM anti-Rh antibodies have been shown to possess anti-i/I cold agglutinin activity, particularly with cord cells or enzyme treated cells. This may become apparent if tests are incubated below the recommended temperature.
- Some red cells express variant Rh antigens and may give weaker reactions than seen with randomly selected positive control cells. Anti-C may give weaker reactions with C antigen of R₂R₂ individuals. Similarly, Anti-e may give slightly weaker reactions in absence of C antigen, e.g. R₂r, r⁺r and rr.
- Suppressed or diminished expression of certain blood group antigens may conversely give rise to false negative reactions. For these reasons, caution should always be exercised when assigning genotypes on the basis of test results.
- 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

- Prior to release, each lot of Rh 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.
- Specificity of source Monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
- 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

- The user is responsible for the performance of the reagents by any method other than those mentioned in the **Recommended Techniques**.
- Any deviations from the **Recommended Techniques** should be validated prior to use⁵.

BIBLIOGRAPHY

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- Jones J, Scott ML, Voak D. Monoclonal anti-D specificity and Rh D structure: criteria for selection of monoclonal anti-D reagents for routine typing of patients and donors. Transfusion Medicine 1995, **5**, 171-184
- Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
- 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

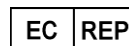
	Vial Size	Catalogue Number	Tests per vial
Anti-C Monoclonal	5 ml	690005	100
	1000 ml	690000*	20,000
Anti-E Monoclonal	5 ml	691005	100
	1000 ml	691000*	20,000
Anti-c Monoclonal	5 ml	692005	100
	1000 ml	692000*	20,000
Anti-e Monoclonal	5 ml	693005	100
	1000 ml	693000*	20,000

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



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Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013, Malta

Glass Test Tube



Glass Test Tube

Test tube, glass test tube, glass culture tube made of borosilicate glass. The tubes provide excellent chemical resistance and durability.

Made of superior quality 3.3 borosilicate glass tubes, suitable for all usual laboratory applications, can withstand high temperature.

Material: 3.3 borosilicate glass or borosilicate glass.

Mouth: plain mouth

Bottom: round bottom

Size: 10x50mm, 10x75mm, 11x70mm, 12x75mm, 12x100mm, 13x100mm, 12x110mm, 12x120mm, 15x100mm, 15x125mm, 16x125mm, 16x100mm, 16x160mm, 20x150mm, 18x150mm, 20x200mm or customized.

Cat No.	Size	Wall thick(mm)	Qty/Case (PCS)
Glass test tube, borosilicate glass, plain, round bottom			
670701	Ø10x50mm,2.5ml	0.8-1.0mm	2000
670702	Ø10x75mm,3.0ml	0.8-1.0mm	2000
670703	Ø11x70mm,3.0ml	0.8-1.0mm	2000
670704	Ø12x75mm,5.0ml	0.8-1.0mm	2000
670705	Ø12x100mm,7.0ml	0.8-1.0mm	2000
670706	Ø13x100mm,7.0ml	0.8-1.0mm	2000
670707	Ø12x110mm,8.0ml	0.8-1.0mm	1000
670708	Ø12x120mm,8.0ml	0.8-1.0mm	1000
670709	Ø15x100mm,10ml	0.8-1.0mm	1000

670710	Ø15x125mm,12ml	0.8-1.0mm	1000
670711	Ø16x125mm,14ml	0.8-1.0mm	1000
670718	Ø10x50mm,2.5ml	0.6mm	2000
670719	Ø10x75mm,3.0ml	0.6mm	2000
670720	Ø11x70mm,3.0ml	0.6mm	2000
670721	Ø12x75mm,5.0ml	0.6mm	2000
670722	Ø12x100mm,7.0ml	0.6mm	2000
670723	Ø13x100mm,7.0ml	0.6mm	2000
670724	Ø12x110mm,8.0ml	0.6mm	1000
670725	Ø12x120mm,8.0ml	0.6mm	1000
670726	Ø15x100mm,10ml	0.6mm	1000
670727	Ø15x125mm,12ml	0.6mm	1000
670728	Ø16x125mm,14ml	0.6mm	1000
670712	Ø16x100mm,10ml	1.0mm	1000
670713	Ø16x150mm,16ml	1.0mm	1000
670714	Ø16x160mm,17ml	1.0mm	1000
670715	Ø20x150mm,20ml	1.0-1.2mm	600
670716	Ø18x200mm,25ml	1.0-1.2mm	600
670717	Ø20x200mm,25ml	1.0-1.2mm	600
Glass test tube, 3.3 borosilicate glass, plain, round bottom			
670801	Ø10x50mm,2.5ml	0.8-1.0mm	2000
670802	Ø10x75mm,3.0ml	0.8-1.0mm	2000
670803	Ø11x70mm,3.0ml	0.8-1.0mm	2000
670804	Ø12x75mm,5.0ml	0.8-1.0mm	2000
670805	Ø12x100mm,7.0ml	0.8-1.0mm	2000
670806	Ø13x100mm,7.0ml	0.8-1.0mm	2000
670807	Ø12x110mm,8.0ml	0.8-1.0mm	1000
670808	Ø12x120mm,8.0ml	0.8-1.0mm	1000
670809	Ø15x100mm,10ml	0.8-1.0mm	1000
670810	Ø15x125mm,12ml	0.8-1.0mm	1000
670811	Ø16x125mm,14ml	0.8-1.0mm	1000
670812	Ø16x100mm,10ml	1.0mm	1000
670813	Ø16x150mm,16ml	1.0mm	1000
670814	Ø16x160mm,17ml	1.0mm	1000
670815	Ø20x150mm,20ml	1.0-1.2mm	600
670816	Ø18x200mm,25ml	1.0-1.2mm	600
670817	Ø20x200mm,25ml	1.0-1.2mm	600

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

BLOOD GROUPING REAGENTS Page

ABO system – Monoclonal Reagents.....	4
Rhesus System – Monoclonal Reagents.....	4
Grouping Reagents for M, N and S Blood Group Systems	5
Grouping Reagents for Kell Blood Group System.....	5
Grouping Reagents for Rare Blood Groups.....	6
Control Reagents.....	7
Anti-Human IgG Reagent.....	7
Anti-Human Globulin Reagent	7
Monoclonal Anti-C3d Reagent.....	7

ENZYMES AND POTENTIATORS Page

Buffered Saline Tablets	8
Papenzyme-plus.....	8
Bromelite	8
LISS Concentrate	8
LISS Ready for use.....	8
LISS-ADD	8
PEG-ADD.....	8
Serological Albumin	8
Accessories	9

RED CELLS Page

Red Cells – Reverse Grouping Cells	10
Red Cells – Antibody Screening Cells.....	10
Red Cells – Identicells.....	10
Red Cells – Coombs Control Cells.....	10
Red Cells Preservative – Preservacell.....	11
Red Cells Preservative – ABO Preservacell.....	11
Alsevers Solution	11
Red Cell Elute	11

DIAGNOSTIC KITS Page

Syphilis Kits	12
Latex Kits.....	13
Febrile Antigens	14
Rose Waaler.....	14

NON CE MARKED BLOOD GROUPING REAGENTS Page

ABO System - Monoclonal Reagents.....	15
Rhesus System - Monoclonal Reagents.....	15



LORNE
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Blood Grouping
Reagents

Enzymes and
Potentiators

Red Cells

Diagnostic Kits

Non CE Marked Blood
Grouping Reagents

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-A₁ 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^v) 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^v) and a high proportion of weak D (D^u) phenotypes when using the slide, tube, gel card and microplate techniques. It will agglutinate D^v cells in the IAT phase of testing.

Anti-D Duoclone Monoclonal	740010	10ml	30 Months
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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
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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
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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 quantities

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-P₁ 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
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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
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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
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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
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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
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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 quantities

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
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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
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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
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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
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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 quantities

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	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	881025	25 Boxes
 The Cardtiles are suitable for a wide range of haemagglutination tests. Each card has twenty 30mm square white test sites.	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.	880120	25 Cards
 The Latex Cardtiles are suitable for all latex agglutination tests. Each card has six 30mm diameter black reaction sites.	880130	25 Cards
 The mini pipettes are 11.5cm in length with one sealed end. The diameter of the tube is 4mm.	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.	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	LAB00027	5 Vial
Flatpacks	LAB00007	10 Vial

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 A₁, A₂ 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 quantities

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
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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
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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
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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
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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
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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
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Lorne Staph Kit is a Latex agglutination 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 quantities

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

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
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All products available in bulk quantities



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