BLOOD GROUPING REAGENT
Anti-k (cellano)
ALBAclone®
(Mouse Monoclonal/Direct Agglutinin) For Tube and BioVue® Technique

REF **Z137** CE

INTERPRETATION OF LABELLING SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
REF	Product Code
2 °C – 8 °C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
	Manufacturer

INTENDED USE

The Anti-k reagent is for the *in vitro* detection and identification of the k antigen on human red blood cells by direct agglutination.

SUMMARY AND EXPLANATION

Since the description of the antigen K in 1946 by Coombs *et al* and its allele k in 1949 by Levine *et al*, the Kell blood group system has been shown to be increasingly complex and over 20 antigens are now known to be associated with the system. These are probably controlled from a series of closely linked loci so that Kell antigens, like CDE in the Rh system, are inherited as a haplotype.

The antigens of the Kell blood group system are of further interest in that they tend to occur either very frequently (eg k 99.8%) or relatively infrequently (eg K 8%) and show considerable ethnic variation e.g. the antigen Js^a is extremely rare in whites but is expressed by 20% of black Americans.

The antigens require the presence of disulphide bonds for full expression and are destroyed by treatment with trypsin and chymotrypsin in combination.

Kell system antibodies are capable of causing haemolytic transfusion reactions and haemolytic disease of the newborn and are optimally detected by the indirect antiglobulin technique.

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause the agglutination (clumping) of red blood cells carrying the k (cellano) antigen. Lack of agglutination demonstrates the absence of the k (cellano) antigen.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the immunoglobulin secreting mouse hybridoma Lk1:

Product Name	Product Code	Cell Line
Anti-k	Z137	Lk1

The formulation consists of culture supernatant containing bovine material, potentiators, EDTA and <0.1% (w/v) sodium azide buffered to pH 5.2.

NOTE: The volume delivered by the reagent dropper bottle is approximately 40µL. Care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS

The reagent should be stored at 2-8 °C.

PRECAUTIONS FOR USE AND DISPOSAL

For *in vitro* diagnostic use only
Products should be used by qualified personnel
Does not use beyond the expiration date Do not use if turbid
Do not dilute

The format of the expiration date is expressed as YYYY-MM- DD (Year-Month-Day)

This reagent contains <0.1% (w/v) sodium azide. Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into a sink, flush with a large volume of water to prevent azide build-up.
Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.
This reagent is of animal origin, therefore care must be taken during use and disposal as there is a potential infection risk.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE FOR INFECTIOUS AGENTS.

This reagent is of animal origin (murine and bovine), therefore care must be taken during use and disposal as there is a potential infection risk.

Monoclonal antibodies exhibit a high degree of potency, avidity and specificity. When using such antibodies, great care should be taken to avoid cross contamination.

This product has components (dropper bulbs) containing dry natural rubber.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by a standard collection technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures.

Tube Technique:

Clotted samples, or those collected in EDTA, should be tested within seven days from collection. Donor blood collected in citrate anticoagulant may be tested until the expiration date of the donation.

BioVue® CAT Technique:

Clotted samples, or those collected in EDTA, should be tested within fourteen days from collection. Donor blood collected in ACD, CPD, CPDA -1, CP2D, CP2D with AS-3, CPD with AS-1, and CPD with AS-5 may be tested until the expiration date of the donation.

Special care should be taken if haemolysed samples must be tested. Grossly icteric or contaminated blood specimens should not be used.

MATERIALS

Material provided

1. ALBAclone® Anti-k (cellano)

Materials required but not provided (dependant on technique)

2. PBS pH 7.0 ± 0.2 or isotonic saline
3. Pipettes
4. Reagent red cells suitable for the control of Anti-k
5. 10 x 75 mm or 12 x 75 mm glass test tubes
6. Centrifuge
7. Timer
8. ORTHO BioVue® Neutral Cassettes
9. ORTHO BioVue® Workstation/Centrifuge
10. ORTHO VISION™/VISION™ MAX Analyzer
11. ORTHO Optix™ Reader
12. Cassette Rack

PROCEDURES

This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed. When a test is required to be incubated for a specific time period, a timer should be used.

When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator's manual provided by the device manufacturer.

Tube Technique - NIS 5 Min Incubation/Spin

1. Prepare a 2-3% suspension of red blood cells in PBS pH 7.0 ± 0.2. (Reagent Red Blood Cells may be used directly from the vial or according to manufacturer's instructions).
2. Add 2 drops of blood grouping reagent to a glass test tube.
3. Add 2 drops of red blood cell suspension.
4. Mix the contents of the test tube and incubate at 20°C for 5 minutes.
5. Centrifuge the test tube.
6. NOTE: Suggested centrifugation: 900-1000g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy re-suspension of antigen- negative red blood cells.
7. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
8. Record results.

ORTHO BioVue® - Neutral Cassette, Immediate Spin

1. Prepare a 0.8% or 3-5% red cell suspension from patient or donor cells, using isotonic saline.
2. Allow the cassette and reagent to come to 21-25°C prior to use.
3. Label the cassette appropriately with a sample identifier.
4. Add 40µL of the blood grouping reagent to the appropriate reaction chamber(s) of the opened cassette. Do not touch the pipette to the side of the reaction chamber. If this occurs, change pipette tip before proceeding to the next chamber.
5. Add 50µL of 0.8% red cell suspension or add 10µL of 3-5% red cell suspension to the appropriate reaction chamber(s) of the cassette.
6. Observe that the contents of the reaction chamber(s) are combined. If necessary tap gently.
   NOTE: Assure that the reagents remain in the reaction chamber. There should be no mixing of reactants with reagents in the column prior to centrifugation.
7. Immediately centrifuge the cassette using the ORTHO BioVue® System Centrifuge.
8. Read the front and back of the individual columns for agglutination and/or haemolysis upon test completion.
9. Record the reaction strength.

The use of this reagent on ORTHO VISION™ Analyzer and ORTHO VISION™ Max Analyzer requires use of a User Defined Reagent within the analyser software. For instructions on how to configure the analyser to use ALBAclone® Anti-k (Z137) please refer to the following User Guide/s. ORTHO VISION™ Analyzer ORTHO BioVue® Cassettes User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide and ORTHO VISION™ MAX Analyzer ORTHO BioVue® Cassettes User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide.

STABILITY OF REACTION

Test results should be read, interpreted and recorded immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

Interpretation of ORTHO BioVue test results should be performed as directed by ORTHO BioVue® System Cassettes Interpretation Guide (J39791 EN), Ortho Clinical Diagnostics.

QUALITY CONTROL

Quality control of reagents is essential and should be performed on the day of use.

K+k+ red blood cells should be used as a positive control. K+k- red blood cells should be used as a negative control.

PERFORMANCE LIMITATIONS

Red blood cells from individuals of the Kell phenotype K+k+Kp (a+b+) show a substantially weakened expression of k antigen.

This monoclonal antibody may not detect weak genetic variants of the k antigen.

Kell antigen expression may be dramatically weakened in some cases of Chronic Granulomatous Disease.

DAT positive red blood cells may return false positive reactions.

The expression of certain red blood cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Excessive centrifugation of tube tests can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

Gently re-suspend tube tests before reading. Excessive agitation may disrupt weak agglutination and produce false negative results.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

Suppressed or weak expression of blood group antigens may give rise to false negative reactions.

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAclone® Anti-k (cellano) is tested using recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

BIBLIOGRAPHY

1. British Committee for Standards in Haematology: Guidelines for pre- transfusion compatibility procedures in blood transfusion laboratories, *Trans Med* 2013; 23: 3-35
2. National Blood Service: Guidelines for the Blood Transfusion Services in the United Kingdom, ed 8. TSO, 2013
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012
4. J55673: ORTHO VISION Analyzer ORTHO BioVue® Cassettes User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide

5. J55675: ORTHO VISION MAX Analyzer ORTHO BioVue® Cassettes User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide
6. ORTHO™ BioVue® System Cassette Interpretation Guide (J39791EN), Ortho Clinical Diagnostics

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EC REP

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Las instrucciones de uso están disponibles en el sitio web de Quotient en www.quotientbd.com o puede solicitarlas a su distribuidor local mediante el código de producto pertinente que figura en las etiquetas de productos y en las instrucciones de uso suministradas con el producto.

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Le feuillet technique est disponible sur le site Web de Quotient à l'adresse www.quotientbd.com. Vous pouvez également le demander à votre distributeur local en renseignant le code produit concerné, qui est mentionné sur l'étiquette du produit et dans le feuillet technique fourni avec ce dernier.

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De gebruiksaanwijzing staat op de Quotient-website (www.quotientbd.com) of kan bij uw leverancier worden aangevraagd door de desbetreffende productcode te vermelden. Deze code staat op productlabels en in de gebruiksaanwijzing die bij het product worden geleverd.

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As Instruções de Utilização estão disponíveis no website da Quotient, em www.quotientbd.com. Pode também solicitá-las ao seu Distribuidor local ao fornecer o Código do produto relevante indicado nas etiquetas do produto e nas Instruções de Utilização fornecidas com o mesmo.

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BRUKSANVISNING
Du finner bruksanvisning på Quotient-nettstedet på www.quotientbd.com, eller du kan be om den hos din lokale forhandler ved å oppgi den aktuelle produktkoden som er angitt I produktmerkingen og i bruksanvisningen som fulgte med produktet.

KÄYTTÖOHJEET
Käyttöohjeet ovat saatavilla Quotientin sivustossa osoitteessa www.quotientbd.com, tai ne voi pyytää paikalliselta jälleenmyyjältä antamalla tuotteen tuotemerkinnöissä ja mukana toimitetuissa käyttöohjeissa ilmoitetun tuotekoodin.

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INSTRUKCJA UŻYTKOWANIA
Instrukcja użytkowania jest dostępna na stronie internetowej firmy Quotient pod adresem www.quotientbd.com. Można ją też zamówić u lokalnego dystrybutora, podając odpowiedni kod produktu zawarty na etykietach produktów i w instrukcji użytkowania dostarczonej z produktem.

The linear barcode is provided below for scanning purposes.
Please note the barcode below is lot specific (lot number is displayed immediately under the barcode) - this IFU should be retained with the product vial with which it was supplied.

Den lineære stregkode er angivet nedenfor til scanningsformål.
Bemærk, at nedenstående stregkode er lot-specifik (lot-nummeret vises umiddelbart under stregkoden) – denne brugsanvisning skal opbevares sammen med det medfølgende produkt-hætteglas.

Nachstehend wird der lineare Barcode zum Scannen angegeben.
Beachten Sie bitte, dass der nachstehende Barcode losspezifisch ist (die Losnummer wird direkt unterhalb des Barcodes angezeigt) – diese Gebrauchsanweisung sollte zusammen mit dem Produktfläschchen aufbewahrt werden, mit dem sie geliefert wurde.

Ο γραμμικός κωδικός παρέχεται παρακάτω για σκοπούς σάρωσης.
Παρακαλούμε σημειώστε ότι ο γραμμικός κωδικός που ακολουθεί είναι ειδικός για κάθε παρτίδα (ο αριθμός παρτίδας εμφανίζεται αμέσως κάτω από τον γραμμικό κωδικό) - αυτές οι οδηγίες χρήσης θα πρέπει να φυλαχθούν μαζί με το φιαλίδιο του προϊόντος με το οποίο παρασχέθηκαν.

A continuación encontrará el código de barras lineal para su lectura.
Tenga en cuenta que el siguiente código de barras es específico de un lote (el número de lote se muestra justo debajo del código de barras). Estas instrucciones de uso se deben conservar junto con el vial con el que se suministró el producto.

Le code à barres linéaire est fourni ci-dessous à des fins de lecture.
Veuillez noter que le code à barres ci-dessous est spécifique au lot (le numéro de lot s'affiche immédiatement sous le code à barres) - cette notice d'utilisation doit être conservée avec le flacon de produit avec lequel elle a été fournie.

Di seguito è riportato il codice a barre lineare per la scansione.
Tenere presente che il codice a barre sottostante è specifico per il lotto (il numero di lotto è riportato sotto il codice a barre) - queste IFU devono essere conservate con il flaconcino di prodotto con cui sono state fornite.

De lineaire barcode wordt hieronder weergegeven voor het scannen.
Houd er rekening mee dat de onderstaande barcode batchspecifiek is (het batchnummer wordt direct onder de barcode weergegeven). Deze gebruiksaanwijzing moet worden bewaard bij de productflacon waarmee deze is geleverd.

Den lineære strekkoden befinner seg nedenfor til skanningsformål.
Merk at strekkoden nedenfor er lotspesifikk (lotnummeret vises rett under strekkoden) – denne bruksanvisningen bør beholdes med produkthetteglasset den medfulgte.

O código de barras linear é fornecido abaixo para fins de verificação.
Tenha em atenção que o código de barras abaixo é específico do lote (o número de lote é apresentado imediatamente sob o código de barras) - estas instruções de utilização devem ser mantidas junto do frasco para injetáveis do produto com o qual são fornecidas.

Den linjära streckkoden tillhandahålls nedan i skanningssyften.
Notera att streckkoden nedan är lotspecifik (lotnumren visas direkt under streckkoden). Denna bruksanvisning ska behållas med den produktflaska som den levererades med.

Alla oleva lineaarinen viivakoodi on tarkoitettu luettavaksi.
Huomaa, että oheinen viivakoodi on eräkohtainen (eränumero näkyy heti viivakoodin alapuolella). Tämä käyttöohje on säilytettävä sen tuotepullon yhteydessä, jonka.

Liniowy kod kreskowy na potrzeby skanowania znajduje się poniżej.
Należy pamiętać, że poniższy kod kreskowy jest właściwy dla danej partii (numer partii znajduje się bezpośrednio pod kodem kreskowym). Tę instrukcję użytkowania należy przechowywać wraz z fiolką z produktem, z którą została dostarczona.

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