REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
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Klasa: 530-04/16-01/35
Ur. br.: 381-13-07/36-16-02
Zagreb, 10.08.2016.

Biognost d.o.o.,
Republika Hrvatska, Zagreb,
Međugorska 59

POTVRDA O SLOBODNOJ PRODAJI
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Agencija za lijekove i medicinske proizvode Republike Hrvatske ovim putem potvrđuje da niže navedeni medicinski proizvod ispunjava zahtjeve Zakona o medicinskim proizvodima („Narodne novine", br. 76/13.) te Pravilnika o bitnim zahtjevima, razvrstavanju, upisu proizvođača u očevidnik proizvođača, upisu medicinskih proizvoda u očevidnik medicinskih proizvoda te ocjenjivanju sukladnosti medicinskih proizvoda (Narodne novine, br. 84/13.), kojima se prenose direktive o medicinskim proizvodima Europske unije.

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Medicinski proizvod:
Medical Device:

Reagensi za histopatologiju
Klasa rizika in vitro dijagnostika - ostalo / Risk Class – in vitro diagnostics Others

Proizvođač:
Manufacturer:

Biognost d.o.o.,
Republika Hrvatska,
Zagreb,
Međugorska 59

nalazi se u prometu u Republici Hrvatskoj, te se slobodno izvozi.
is marketed in Republic of Croatia, and is free to export.

Ravnatelj Agencije / *Head of Agency*

Izv. prof. dr. sc. Siniša Tomić

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Dostaviti:
1. Naslovu
2. Pismohrana – ovdje.

BIOGNOST ®
FARMACEUTSKI I DIJAGNOSTIČKI PROIZVODI

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Declaration of Conformity Certificate

Izjava o sukladnosti

Certificate No. / broj izjave 0182016-BIOG

BIOGNOST d.o.o.
Međugorska 59
10040 Zagreb, Croatia

ensures and declares with sole responsibility, that following *In Vitro* Diagnostic Medical Devices:
jamčimo i izjavljujemo s potpunom odgovornošću, da naši *In Vitro* dijagnostički medicinski proizvodi:

Laboratory diagnostics and microscopy supplies and reagents
Pribor i sredstva za laboratorijsku dijagnostiku i mikroskopiju

See attached Product List
Popis proizvoda u prilogu

meet the provisions of Council Directive 98/79/EC (IVDD) which apply to us. This declaration is based on approval according to Annex III (excluding III.6) of the Directive.

udovoljavaju svim propisanim zahtjevima Europskog Vijeća - 98/79/EC (IVDD). Ova Izjava temelji se na odobrenju prema Aneksu III (isključujući III.6) direktive.

Signed this day 16 May 2016
Potpisano dana 16. svibnja 2016.

BIOGNOST
BIOGNOST d.o.o., www.biognost.hr
Međugorska 59, 10040 Zagreb, Croatia

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Ivan Marchiotti, MD MSc
Director
BIOGNOST LTD.

Anti-A Anti-B Anti-A,B MonoGnost® reagents

MONOCLONAL REAGENTS FOR ABO BLOOD GROUPING

Name	Product code	Packaging
Anti-A MonoGnost	M01101	1x10 ml
Anti-A MonoGnost	M01110	10x10 ml
Anti-A MonoGnost	M011100	100x10 ml
Anti-B MonoGnost	M01201	1x10 ml
Anti-B MonoGnost	M01210	10x10 ml
Anti-B MonoGnost	M012100	100x10 ml
Anti-A,B MonoGnost	M01301	1x10 ml
Anti-A,B MonoGnost	M01310	10x10 ml
Anti-A,B MonoGnost	M013100	100x10 ml

INSTRUCTIONS FOR USE

Summary

Anti-A, -B and -A,B MonoGnost reagents are intended for ABO blood grouping. Anti-A, -B and -A,B MonoGnost reagents contain murine monoclonal IgM class antibodies. The principle of the test is the agglutination technique, which is based on antigen/antibody reaction. The ABO blood group system is comprised of four blood groups: A, B, AB and O.
Erythrocyte agglutination caused by Anti-A MonoGnost reagent means that the erythrocytes carry the A antigen, while agglutination caused by Anti-B MonoGnost reagent means that the erythrocytes carry the B antigen. Agglutination caused by Anti-A,B MonoGnost reagent means that the erythrocytes carry the A and/or B antigen. Absence of agglutination indicates that the erythrocytes do not carry the antigens reagents are specific to. These reagents meet the requirements of the concerned standards and guidelines. The reagents can be used in either spin tube, or slide method. The inclusion of positive and negative controls with each series of blood group determinations is strongly recommended.
Anti-A MonoGnost reagent contains blue dye, Anti-B contains yellow dye, and Anti-A,B MonoGnost reagent is colorless.

Precautions

For *in vitro* diagnostics use only. Names of clones are printed on the product's label. Expiration date is printed on the product. Reagents should not be used beyond the expiration date. Reagents should be stored at 2-8°C. Marked turbidity may indicate microbiological contamination. Do not use such reagents. Do not freeze. Sodium azide is added as preservative (0.1% w/v). Blood samples should be taken aseptically with or without the addition of anticoagulants. If testing of the blood samples is delayed, storage should be at 2-8°C.

Test procedures

Spin tube method

Tube requirements: round bottom glass tubes; size 75 x 10/12 mm

1. Prepare a 3-5% cell suspension of red cells to be tested in isotonic saline or in their own plasma or serum.
2. Add to a test tube:
   - 1 drop of BioGnost's Anti-A, Anti-B, or Anti-A,B blood grouping reagent
   - 1 drop of the 3-5% cell suspension

and mix well.
3. Incubate at room temperature (~18-25°C) for 60 minutes (sedimentation technique) or centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
4. Resuspend the cells by gentle agitation and read macroscopically for agglutination.

Slide method

1. Place 1 drop of BioGnost's Anti-A, Anti-B, or Anti-A,B blood grouping reagent on a clean glass slide.
2. Add 1 drop of a 35-45% cell suspension of the red blood cells to be tested in isotonic saline or in their own plasma or serum.
3. Mix well using a clean applicator stick over a circular area approximately 20 mm in diameter.
4. Move the slide slowly and observe for agglutination of the red blood cells for a period not exceeding 2 minutes.
5. Read macroscopically for agglutination.

Interpretation of test results

A positive reaction (i.e. agglutination) indicates the presence of the corresponding antigen. A negative reaction (i.e. no visible agglutination) indicates the absence of the corresponding antigen. The ABO blood group is determined by the reaction pattern obtained with the various antisera (see table below).

red cells + blood grouping reagents			serum/plasma + reagent red cells		
anti-A	anti-B	anti-A,B	A1 cells	B cells	blood group (frequency)
0	0	0	+	+	O (46.7%)
+	0	+	0	+	A (41.7%)
0	+	+	+	0	B (8.6%)
+	+	+	0	0	AB (3%)

Limitations of the test procedure

Unexpected positive results due to: polyagglutination, pseudoagglutionation autoagglutination, mixed field reaction, and umbilical cord cells.
Unexpected negative or weak results due to: weak antigens, mixed field reaction, decreased activity of the reagent.

References

1. Race R.R. and Sanger R.; Blood groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issitt P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 6th ed. Blackwell Science, Oxford, 1979.

Anti-A, Anti-B, Anti-A,B MonoGnost reagents, IFU V6 – 5 December 2014

	Refer to supplied instructions	°C	Storage temperature range	REF	Product code		Manufacturer
IVD	For *in vitro* diagnostic use only		Valid until	LOT	Lot number		

BIOGNOST Ltd.
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www.biognost.com

ANTI-A_1 LECTIN REAGENT

(Dolichos biflorus)

REAGENT FOR DETECTING A_1 SUBGROUP OF THE ABO BLOOD GROUP SYSTEM

Name	Product code	Packaging
Anti A_1 Lectin reagent	01401	1x10 ml
Anti A_1 Lectin reagent	01410	10x10 ml

INSTRUCTIONS FOR USE

Introduction

Anti-A1 Lectin reagent is a stabilized extract prepared from the seeds of *Dolichos biflorus*. Around 80% of Caucasians with blood groups A and AB have erythrocytes carrying strong A_1 antigen, and around 20% have weak A_2 antigen or one of even weaker antigens (A_3, A_x, A_m). It is intended for detecting A_1 and A_1B subgroups of the ABO blood groups system using hemagglutination technique, which is based on antigen/antibody reaction. The reagent can be used in spin tube and slide methods. Sodium azide (0.1%) is used as preservative.

Test procedures

Spin tube method

Tube requirements: round bottom glass tubes; size 75 x 10/12 mm

1. Prepare a 3-5% cell suspension of red cells to be tested in isotonic saline or in their own plasma or serum.
2. Add to a test tube:
   - 1 drop of Anti-A_1 Lectin reagent
   - 1 drop of the 3-5% cell suspension

   and mix well.
3. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
4. Resuspend the cells by gentle agitation and read macroscopically for agglutination.

Slide method

1. Place 1 drop of Anti-A_1 Lectin reagent on a clean glass slide.
2. Add 1 drop of a 35-45% cell suspension of the red blood cells to be tested in isotonic saline or in their own plasma or serum.
3. Mix well using a clean applicator stick over a circular area approximately 20 mm in diameter.
4. Move the slide slowly and observe for agglutination of the red blood cells for a period not exceeding 30 seconds.
5. Resuspend the cells by gentle agitation and read macroscopically for agglutination.

Interpretation of test results

1. Erythrocyte agglutination with Anti-A_1 Lectin reagent is a positive result and indicates erythrocytes carrying A_1 antigen.
2. Absence of erythrocyte agglutination with Anti-A_1 Lectin reagent is a negative result and indicates no erythrocytes carrying A_1 antigen.

Marked turbidity or precipitation may indicate microbiological contamination. Do not use such reagent. Do not freeze.

Store at 2-8°C. Expiration date is printed on the product.

References

1. Race R.R. and Sanger R.; Blood groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issitt P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.

	Refer to supplied instructions	°C	Storage temperature range	REF	Product code	CE	European Conformity
IVD	For *in vitro* diagnostic use only		Valid until	LOT	Lot number		Manufacturer

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CE

Anti-D MonoGnost® MG reagent

MONOCLONAL REAGENT FOR D (Rh$_o$) BLOOD GROUP TYPING AND D^u IN TUBE OR ON SLIDE TECHNIQUE BY USING DIRECT OR INDIRECT METHODS

Name	Product code	Packaging
Anti-D MonoGnost MG	M02101	1x10 ml
Anti-D MonoGnost MG	M02110	10x10 ml
Anti-D MonoGnost MG	M021100	100x10 ml

INSTRUCTIONS FOR USE

Summary

The RH$_o$ (D) antigen was first recognized in 1939. Most Rh blood group antibodies are immune, produced in response to stimulation by pregnancy or transfusion. The D (RH1) antigen is highly immunogenic and has been reported to stimulate the production of anti-D in 50-85% of D negative individuals who are exposed to D positive blood. Anti-D is of considerable importance since this antibody can cause severe Rh hemolytic disease of the fetus and newborn (HDFN) and hemolytic transfusion reactions. The D (RH1) antigen and its weakened form - weak D (formerly called D^u) are therefore important factors in the routine selection of blood for transfusion. Optimal detection of weak D antigen using cells by Anti-D Blood Grouping Reagent may require the application of an indirect antiglobulin test procedure. The commonly used terms Rh positive and Rh negative refer specifically to the presence or absence of the D (RH1) antigen. The frequency of Rh positive people in the Caucasian population is ~85%. The principle of the test is the agglutination technique, which is based on antigen/antibody reaction. The reagent can be used in either spin tube or slide method. Anti-D MonoGnost MG reagent is a preparation that contains a blend of monoclonal anti-D IgM and IgG antibodies. The inclusion of positive and negative controls with each series of blood group determinations is strongly recommended. The reagent meets the requirements of the concerned standards and guidelines.

Precautions

For in vitro diagnostics use only. Names of clones are printed on the product's label. Expiration date is printed on the product. Reagents should not be used beyond the expiration date. Reagents should be stored at 2-8°C. Marked turbidity may indicate microbiological contamination. Do not use such reagents. Do not freeze. Sodium azide is added as preservative (0.1% w/v). Blood samples should be taken aseptically with or without the addition of anticoagulants. If testing of the blood samples is delayed, storage should be at 2-8°C. Do not dilute – use as supplied.

Test procedures

Slide method

1. Prepare a 35-45% suspension of test red cells. Red cell suspensions may be prepared in saline or autologous/group compatible serum or plasma (whole blood).
2. Add one drop (~40-50 µL) of Anti-D MonoGnost MG reagent on a slide.
3. Using a transfer pipette, add one or two drops of the prepared 35-45% suspension of red cells to each drop of Anti-D MonoGnost MG reagent.
4. Using clean, separate applicator sticks, thoroughly mix each red cell suspension over an area of approximately 20 x 20 mm.
5. Slowly tilt slide back and forth for up to 2 minutes and examine for macroscopic hemagglutination.
6. At the end of 2 minutes, those tests showing no agglutination may be interpreted as negative. Care should be taken not to mistake peripheral drying or fibrin strands as agglutination.
7. If the test is negative and a test for weak D is required, test according to the weak D Test Method.

Spin tube method

Tube requirements: round bottom glass tubes; size 75 x 10/12 mm

1. Prepare a 3-5% cell suspension of red cells to be tested in isotonic saline or in their own plasma or serum. The same amount of erythrocytes may be applied by stick (using a blood sample).
2. Add to a test tube:
   - 1-2 drops of Anti-D MonoGnost MG reagent into the tube
   - 1 drop of the 3-5% cell suspension

   and mix well.
3. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
4. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
5. If the test is negative and a test for weak D is required, test according to the weak D Test Method.

Weak D test method - indirect antiglobulin test (IAT)

1. Prepare a 3-5% cell suspension of red cells to be tested in isotonic saline or in their own plasma or serum. The same amount of erythrocytes may be applied by stick (using a blood sample).
2. Add to a test tube:
   - 1-2 drops of Anti-D MonoGnost MG reagent into the tube
   - 1 drop of the 3-5% cell suspension

   and mix well.
3. Incubate the tubes in a water bath or incubator for 20-30 minutes at 37°C.
4. Rinse the erythrocytes three times in saline after incubation. Decant the saline.
5. Add 1-2 drops of polyspecific Anti-human globulin or Anti-IgG to the erythrocyte sediment, and mix well.
6. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
7. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
8. If there is no visible agglutination, add 1 drop Coombs control cells and repeat steps 6 and 7. The reaction should now be positive. If the test remains negative the result is invalid and the test should be repeated.

Interpretation of test results

1. Erythrocyte agglutination with Anti-D MonoGnost MG reagent is a positive result and indicates erythrocytes carrying D antigen.
2. Absence of erythrocyte agglutination with Anti-D MonoGnost MG reagent is a negative result and indicates no erythrocytes carrying D antigen.
3. Erythrocyte agglutination during indirect detection of the D^u antigen following a previous negative result using direct method means that erythrocytes carry the D^u antigen.

Limitations of the test procedure

Unexpected positive results due to: polyagglutination, pseudoagglutionation autoagglutination, mixed field reaction, and umbilical cord cells.
Unexpected negative or weak results due to: weak antigens, mixed field reaction, decreased activity of the reagent.
Red cells that have a positive direct antiglobulin test (DAT) produce false positive test results. Use of MonoGnost control reagent is recommended for detection of such invalid test results.
Ineffective washing of the red cells being tested can result in false negative results due to the neutralization of the polyspecific anti-human serum by proteins (IgG) still present in the tube.
BioGnost's monoclonal blood grouping reagents have been optimized for use by the techniques recommended in these instructions for use.

References

1. Race R.R. and Sanger R.; Blood groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issitt P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell Science, Oxford, 1993.

Anti-D MonoGnost MG reagent IFU V8, 3 September 2014

	Refer to supplied instructions	°C	Storage temperature range	REF	Product code		Manufacturer
IVD	For *in vitro* diagnostic use only		Valid until	LOT	Lot number		

BIOGNOST Ltd.
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Anti-K MonoGnost®

REAGENTUL DE GROUP REZULTAT AL SLABELOR MONOCLONALE
PENTRU DETECTAREA ANTIGENELOR K (KELL) PE CELULE RUMANE UMANE

Denumire Codul produsului Ambalare
Anti-K MonoGnost M06105 1x5 ml

INSTRUCTIUNI DE FOLOSIRE

rezumat
Reactivul anti-K MonoGnost este destinat pentru detectarea antigenului K (Kell KEL1) pe celule roșii în sânge prin testul cu tub. De la descoperirea primului anticorp Kell, anti-Kell (numit acum anti-K), de către Coombs, Mourant și Race în 1946, sistemul a devenit aproape la fel de complex ca Rh. Antigenul K în sine, care este prezent pe celulele roșii din sânge, de aproximativ 9% dintre albii și 2% dintre afro-americani, este puternic imunogen. Acest reactiv monoclonal conține anticorpi IgM umani și a fost special selectat și dezvoltat pentru a oferi o alternativă sigură la reactivii policlonali. Acest reactiv îndeplinește cerințele standardelor și orientărilor respective.
Principiul testului este tehnica de aglutinare, care se bazează pe reacția antigen / anticorp.
Reactivii pot fi utilizați în metoda tubului de centrifugare. Includerea controalelor pozitive și negative cu fiecare serie de determinări ale grupurilor de sânge este recomandată.

Măsuri de precauție
Pentru diagnosticarea in vitro numai. Numele clonei este tipărită pe eticheta produsului. Data expirării este tipărită pe produs. Reactivul nu trebuie utilizat după data de expirare. Reactivul trebuie păstrat la 2-8 ° C. Turbiditatea marcată poate indica contaminarea microbiologică. Nu utilizați un astfel de reactiv. Nu înghețа. Azidă de sodiu este adăugată ca conservant (0,1% g / v). Probele de sânge trebuie extrase aseptic cu sau fără adăugarea de anticoagulante. Dacă testarea probelor de sânge este întârziată, depozitarea trebuie să fie de 2-8 ° C.

Proceduri de testare
Metoda tubului spin
Cerințe tuburi: tuburi din sticlă cu fund rotund; dimensiune 75 x 10/12 mm

1. Se prepară o suspensie celulară de 3-5% de celule roșii care urmează să fie testată în soluție salină izotonică sau în plasmă sau ser propriu.
2. Se adaugă la o eprubetă:
   - 1 picătură de reactiv Anti-K de la BioGnost
   - 1 picătură de suspensie celulară 3-5%
și se amestecă bine.
3. Incubează la temperatura camerei (~ 18-25 ° C) timp de 5 minute
4. Se centrifughează timp de 20 de secunde la 1000 rcf sau pentru o perioadă corespunzătoare calibrării centrifugii.
5. Resuspendați celulele prin agitare ușoară și citiți macroscopic pentru aglutinare.

Interpretarea rezultatelor testelor
O reacție pozitivă (adică aglutinare) indică prezența antigenului K. O reacție negativă (adică nici o aglutinare vizibilă) indică absența antigenului K.

Limitările procedurii de testare
Rezultate pozitive neașteptate datorate: pseudoaglutinare, autoaglutinare, reacție de câmp mixt și celule de cordon ombilical.
Rezultatele neașteptate negative sau slabe datorate: antigenelor slabe, reacției de câmp mixt, scăderii activității reactivului.

Referințe
1. Race R. R. și Sanger R .; Grupurile de sânge în om, ed. Oxford Blackwell Scientific Publishers 1975.
2. Issitt P.D .; Applied Blood Group Serology, ed. Montgomery Scientific Publications, Miami, Florida, SUA, 1985.
3. Mollison P.L. și colab .; Transfuzia de sânge în Clinical Medicine, ed. Blackwell Science, Oxford, 1979.

Reactivul anti-K MonoGnost, IFU V2 - 25 noiembrie 2015

Consultați instrucțiunile furnizate
Intervalul temperaturii de depozitare
Codul produsului Conformitatea europeană
BIOGNOST Ltd.
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www.biognost.com

Anti-K MonoGnost® reagent

MONOCLONAL BLOOD GROUPING REAGENT FOR DETECTION OF THE K (Kell) ANTIGEN ON HUMAN RED CELLS

Name	Product code	Packaging
Anti-K MonoGnost	M08105	1x5 ml

INSTRUCTIONS FOR USE

Summary

Anti-K MonoGnost reagent is intended for the detection of the K (Kell KEL1) antigen on red blood cells by tube test. Since the discovery of the first Kell system antibody, anti-Kell (now called anti-K), by Coombs, Mourant and Race in 1946, the system has grown to become almost as complex as Rh. The K antigen itself, which is present on the red blood cells of approximately 9% of whites and 2% African Americans, is strongly immunogenic. This monoclonal reagent contains human IgM antibodies and has been specially selected and developed to provide a reliable alternative to polyclonal reagents. This reagent meets the requirements of the concerned standards and guidelines.
The principle of the test is the agglutination technique, which is based on antigen/antibody reaction.
The reagents can be used in spin tube method. The inclusion of positive and negative controls with each series of blood group determinations is strongly recommended.

Precautions

For *in vitro* diagnostics use only. Name of clone is printed on the product label. Expiration date is printed on the product. Reagent should not be used beyond the expiration date. Reagent should be stored at 2-8°C. Marked turbidity may indicate microbiological contamination. Do not use such reagent. Do not freeze. Sodium azide is added as preservative (0.1% w/v). Blood samples should be withdrawn aseptically with or without the addition of anticoagulants. If testing of the blood samples is delayed, storage should be at 2-8°C.

Test procedures

Spin tube method

Tube requirements: round bottom glass tubes; size 75 x 10/12 mm

1. Prepare a 3-5% cell suspension of red cells to be tested in isolonic saline or in their own plasma or serum.
2. Add to a test tube:
   - 1 drop of BioGnost's Anti-K reagent
   - 1 drop of the 3-5% cell suspension

   and mix well.
3. Incubate at room temperature (~18-25°C) for 5 minutes
4. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
5. Resuspend the cells by gentle agitation and read macroscopically for agglutination.

Interpretation of test results

A positive reaction (i.e. agglutination) indicates the presence of the K antigen. A negative reaction (i.e. no visible agglutination) indicates the absence of the K antigen.

Limitations of the test procedure

Unexpected positive results due to: pseudoagglutionation , autoagglutination, mixed field reaction, and umbilical cord cells.
Unexpected negative or weak results due to: weak antigens, mixed field reaction, decreased activity of the reagent.

References

1. Race R.R. and Sanger R.; Blood groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issitt P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 6th ed. Blackwell Science, Oxford, 1979.

	Refer to supplied instructions	°C	Storage temperature range	REF	Product code		European Conformity
IVD	For *in vitro* diagnostic use only		Valid until	LOT	Lot number		Manufacturer

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