STATEMENT

We, **Rapid Labs Limited** having a registered office at Unit 2 & 2A, Hall Farm Business Centre, Church Road, Little Bentley, Colchester, Essex CO7 8SD, United Kingdom assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: March 5th, 2025

Signature: Tracy Wu Rapid Labs Rapid Labs Limited

Digitally signed by Dolgopol Iulian
Date: 2025.12.19 10:15:42 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Unit 2 & 2A, Hall Farm Business Centre,
Church Road, Little Bentley, Colchester,
Essex CO7 8SD, United Kingdom

Certificate of Registration

This certificate has been awarded to

Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Please refer to the Appendix

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by Mukesh Singhal - On behalf of the Schemes Manager

Appendix to Certificate

Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

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Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

Mukesh Singhal - On behalf of the Schemes Manager

Declaration of Conformity

for Blood grouping reagents

Digitally signed by Tricolici Lidia
Date: 2025.08.20 14:35:59 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Blood grouping reagents
Manufacturer:	Rapid Labs Ltd. Unit 2 & 2a Hall Farm Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
Variants:	n/a
Intended Use:	To qualitatively determine the presence or absence of the specific antigens on the red cells of blood donors or patients requiring a blood transfusion .
Intended User:	Professional use
IVD Directive Category:	Annex II List A
Notified Body:	Polskie Centrum Badarí i Certyfikacji S.A, 23A Klobucka Street, 02-699 Warsaw, Poland, Notified Body Number 1434.
CE Certificate Reference:	1434-IVDD-031/2022 and 1434-IVDD-032/2022
IVD Directive Assessment Route:	Annex II List A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Rowland King **Position** Managing Director

Signed **Date** 23rd May 2023

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN 13612:2002	Performance evaluation of in-vitro medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in-vitro diagnostics
EN ISO 15223-1:2016	Medical devices - Symbols
EN ISO 23640:2015	Evaluation of stability

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
BG-A10	Anti-A Monoclonal CE marked	52532
BG-B10	Anti-B Monoclonal CE marked	52538
BG-AB10	Anti-A, B Monoclonal CE marked	46442
BG-D10	Anti-D Monoclonal (IgG + IgM) CE Marked	52647
BG-ABOD10	ABOD Blood grouping Kit CE Marked	43508

Version History

Version	Compiled by	Date	Description
5.0	Emily Swager	08/11/2023	Addition of ABOD blood grouping kit

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

CATALOGUE NUMBER
Anti-A: BG-A10, BG-A10X10
Anti-B: BG-B10, BG-B10X10
Anti-A,B: BG-AB10, BG-AB10X10

INTENDED USE
The intended use of Rapid Biotec ABO blood grouping reagents is to be used in a qualitative method to identify the presence or absence of A or B antigens on the surface of red blood cells in donors or patients who require a blood transfusion.

These reagents are suitable for use by the slide, tube and Bio-Rad ID card and are designed for use by operators trained in serological techniques.

INTRODUCTION
The ABO Blood Group System
In 1900, Landsteiner discovered that the serum of some individuals would agglutinate the red cells of others and that this phenomenon could be used to classify individuals into different blood group phenotypes. Four common phenotypes are recognised – O, A, B and AB. Subgroups of the A and B antigens have since been identified. The ABO phenotype of an individual is usually determined by the agglutination reactions of the individual's red cells with Anti-A, Anti-B and Anti-A,B antisera (forward grouping). In testing blood samples from adults, confirmation of the ABO blood group can be provided by the reactions of the individual's serum with standard A and B red cell suspensions (reverse grouping).

PRINCIPLE
When used by the recommended techniques these reagents will cause agglutination (clumping) of red cells carrying the specific antigen (positive test).
Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).
These reagents have been optimised for use by the recommended techniques without further dilution or additions. These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS
Blood grouping reagents contain monoclonal murine IgM antibodies in a buffer solution. The solution is a phosphate buffer containing sodium chloride, EDTA and bovine material. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-A	Blue	Patent blue	BIRMA-1
Anti-B	Yellow	Tartrazine	LB-2
Anti-A,B	Colourless	None	ES-15/ES-4

Materials needed but not provided:
- Microscope slide/Plastic slides
- Plastic stirrers
- Timer
- Isotonic saline/LISS
- Compatible serum/plasma
- Test tubes
- Centrifuge (1000 rcf)
- Bio-Rad ID Cards (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID-diluent 2

PRECAUTIONS
- The cell lines used to produce these reagents are of murine origin and have been tested and found to be negative for Mouse Antibody Production (MAP) viruses. Care must be taken in the use and disposal of each container and its contents.
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE
For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS
- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.
- Each 10ml vial contains approx number of tests:

Methods	Drop size	No. of tests
Slide & Tube	45µl	<218
	50µl	<200

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.
- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE
SLIDE METHOD:
1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum or in isotonic saline.
2. Add one drop (45-50µl) of either Anti-A, Anti-B or Anti-A,B reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination

TUBE METHOD (recommended for A_x):
1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of either Anti-A, Anti-B or Anti- A,B reagent to an appropriately labelled test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-ABO reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

LIMITATIONS

- The results of red cell grouping should be confirmed by reverse grouping the individual's serum with known A1 and B red cells.
- No recipient should be given AB blood unless the cells of the recipient are clearly positive with Anti-A and Anti- B and the recipient's serum shown to give negative reactions with A1 and B cells (unless the recipient has been shown to be a subgroup of AB with Anti-A1 in the serum).
- Rapid Biotec Anti-A,B does not detect A3 antigens neither does it detect "Acquired B cells"
- Rapid Biotec Anti-B does not react with "Acquired B cells"
- Anti-A blood grouping reagent is not validated to detect all examples of A_x cells. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
- ABO antigens are not fully developed at birth therefore weaker reactions may occur with cord or neonatal samples.
- Using the reagent to detect weak B subgroups may give rise to false negative or weaker reactions when using slide, microtitre plates or gel cards.
- Stored blood may give weaker reactions than fresh blood.
- 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
  - •Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping tested by the recommended techniques against a panel of antigen-positive red cells.
- Anti-A,B can detect A_x antigens however, only through tube technique; see recommended technique in this IFU.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC):
  Anti- A = 03/188
  Anti- B = 03/164
- Rapid Biotec ABO reagents do not detect crypt antigens such as T, Tn or Cad.
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- BG-A, BG-B and BG-A,B have been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-A, Anti-B and Anti-A,B is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Moore, S. *et al.* Vox Sang 47: 427-434 (1984). A Mouse Monoclonal Antibody with Anti-A,(B) Specificity which Agglutinates Ax Cells.
2. McDonald, D.F. and Thompson, J.M. Vox Sang 1991;61:53-58. A New Monoclonal Anti-A Antibody BIRMA-1.
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Index of symbols	
Consult instructions for use	REF Catalogue number
Store between 2-8^{0}C	Manufacturer
IVD For in vitro diagnostic use only	Lot number
Use by	Date of manufacturer

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: CE ABO RB - 04/2024

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

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

RAPID BIOTEC™

CATALOGUE NUMBER
Anti-A: BG-A10, BG-A10X10
Anti-B: BG-B10, BG-B10X10
Anti-A,B: BG-AB10, BG-AB10X10

INTENDED USE
The intended use of Rapid Biotec ABO blood grouping reagents is to be used in a qualitative method to identify the presence or absence of A or B antigens on the surface of red blood cells in donors or patients who require a blood transfusion.

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PRINCIPLE
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Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).
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REAGENTS AND MATERIALS
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Anti-A,B	Colourless	None	ES-15/ES-4

Materials needed but not provided:
- Microscope slide/Plastic slides
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- Timer
- Isotonic saline/LISS
- Compatible serum/plasma
- Test tubes
- Centrifuge (1000 rcf)
- Bio-Rad ID Cards (NaCl, Enzyme tests and cold agglutinins)
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- Bio-Rad ID cell stab or ID-diluent 2

PRECAUTIONS
- The cell lines used to produce these reagents are of murine origin and have been tested and found to be negative for Mouse Antibody Production (MAP) viruses. Care must be taken in the use and disposal of each container and its contents.
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
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- These reagents are for professional *in vitro* diagnostic use only.
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ADVICE TO USERS
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- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.
- Each 10ml vial contains approx number of tests:

Methods	Drop size	No. of tests
Slide & Tube	45µl	<218
	50µl	<200

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.
- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE
SLIDE METHOD:
1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum or in isotonic saline.
2. Add one drop (45-50µl) of either Anti-A, Anti-B or Anti-A,B reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination

TUBE METHOD (recommended for A_x):
1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of either Anti-A, Anti-B or Anti- A,B reagent to an appropriately labelled test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B

CE
1434

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BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-ABO reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

LIMITATIONS

- The results of red cell grouping should be confirmed by reverse grouping the individual's serum with known A1 and B red cells.
- No recipient should be given AB blood unless the cells of the recipient are clearly positive with Anti-A and Anti- B and the recipient's serum shown to give negative reactions with A1 and B cells (unless the recipient has been shown to be a subgroup of AB with Anti-A1 in the serum).
- Rapid Biotec Anti-A,B does not detect A3 antigens neither does it detect "Acquired B cells"
- Rapid Biotec Anti-B does not react with "Acquired B cells"
- Anti-A blood grouping reagent is not validated to detect all examples of A_x cells. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
- ABO antigens are not fully developed at birth therefore weaker reactions may occur with cord or neonatal samples.
- Using the reagent to detect weak B subgroups may give rise to false negative or weaker reactions when using slide, microtitre plates or gel cards.
- Stored blood may give weaker reactions than fresh blood.
- 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
  - •Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping tested by the recommended techniques against a panel of antigen-positive red cells.
- Anti-A,B can detect A_x antigens however, only through tube technique; see recommended technique in this IFU.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC):
  Anti- A = 03/188
  Anti- B = 03/164
- Rapid Biotec ABO reagents do not detect crypt antigens such as T, Tn or Cad.
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- BG-A, BG-B and BG-A,B have been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-A, Anti-B and Anti-A,B is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Moore, S. *et al.* Vox Sang 47: 427-434 (1984). A Mouse Monoclonal Antibody with Anti-A,(B) Specificity which Agglutinates Ax Cells.
2. McDonald, D.F. and Thompson, J.M. Vox Sang 1991;61:53-58. A New Monoclonal Anti-A Antibody BIRMA-1.
3. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology, 4th Edition, Montgomery Scientific Publications, 1998.
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Index of symbols			
	Consult instructions for use	REF	Catalogue number
	Store between 2-8^{0}C		Manufacturer
IVD	For in vitro diagnostic use only	LOT	Lot number
	Use by		Date of manufacturer

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: CE ABO RB - 04/2024

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

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)

CE 1434

RAPID BIOTEC™

CATALOGUE NUMBER
BG-D10
BG-D10X10

INTENDED USE
Rapid Biotec Anti-D (IgG & IgM) is a blood grouping reagent which is intended to be used to qualitatively determine the presence or absence of the RhD antigen 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.

INTRODUCTION
The Rh Blood Group System

RhD (D or RH1), originally identified in 1939, was the first clinically important blood group to be found following the discovery of ABO 39 years earlier. A phenotypic relationship between D and an antigen on human red cells detected by antibodies made in rabbits immunized with rhesus monkey red cells, led to D being inappropriately named the Rhesus antigen. A vestige of that term remains in Rh, the name of the blood group system that contains D.

Approximately 15% of Caucasians lack the RhD antigen and are easily stimulated by an RhD positive pregnancy or blood transfusion to produce anti-D. This may cause haemolytic disease of the fetus and newborn or severe haemolytic transfusion reactions.

The frequency of the D+ phenotype is about 85% in Caucasians, around 95% in sub-Saharan Africa, and greater than 99·5% in eastern Asia (Daniels, 2013).

WEAK AND PARTIAL D
Anti-D (-RH1) of the Rh bloodgroup system is clinically important as it causes haemolytic transfusion reactions and haemolytic disease of the foetus and new-born. Although most people are either D+ or D-, there is a plethora of D variants, often categorized as either weak Dor partial D. These two types are inadequately defined and the dichotomy is potentially misleading. D^{VI} is the D variant most commonly associated with anti-D production and UK guidelines recommend that patients are tested with anti-D reagents that do not react with D^{VI}.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect most examples of weak D by direct agglutination; see the recommended technique stated in this IFU.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect partial D category D^{VI} by indirect agglutination; see the recommended technique stated in this IFU.

PRINCIPLE
When used by the recommended techniques these reagents will cause direct agglutination (clumping) of red cells carrying the specific antigen (positive test) and indirect agglutination of red cells that are classified as D^{VI} in the antiglobulin phase recommended technique. Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

These products are supplied filtered through 0.2 µmfilter.

REAGENTS AND MATERIALS
Blood grouping reagents contain monoclonal human IgM and IgG antibodies in a buffer solution. The solution containing macromolecular chemical potentiators. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-D (IgG &IgM)	Straw/clear	None	MS-26 & RUM-1

Materials needed but not provided:

Slide technique
- Microscope slide/plastic slides
- Isotonic saline, PBS or compatible plasma/serum
- Plastic stirrers
- Timer

Tube technique
- Test tubes 75 x 12mm (glass)
- Isotonic saline
- 37^{0}C incubator (if needed)
- Timer
- Centrifuge (1000 rcf)

Indirect antiglobulin technique
- Anti-Human globulin reagent
- IgG sensitised red cells (Coombs control cells)

Bio-Rad ID Card technique
- Column agglutination technique Bio-Rad ID Card (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID diluent 2

PRECAUTIONS
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- All blood products should be treated as potential infectious. The human donor or cell line used to produce this reagent has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV. No known tests can guarantee that any products derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- Do not use reagent past the expiration date.
- Protective clothing must be worn when handling reagent, such as, disposable gloves and lab coat.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
- 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 HANDLING A SPILLAGE
For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS
- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- The use of the reagent and the interpretation of results must be carried out by properly trained and competent professionals.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Weak and D^{VI} antigens are poorly detected by Bio-Rad ID card and slide techniques. It is recommended that weak D variants should be tested by tube test and D^{VI} should be tested by indirect antiglobulin technique.
- The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- 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^{0}C.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

This reagent has undergone transportation stability studies at 37^{0}C and 2-8^{0}C as described in BS EN ISO 23640:2015.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)

CE 1434

RAPID BIOTEC™

- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum, isotonic saline or PBS.
2. Add one drop (45-50µl) of Anti-D (IgG & IgM) reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination.

TUBE METHOD: (recommended for weak D):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-D (IgG & IgM) reagent.
4. Centrifuge cassette(s) in a Bio-Rad gel card centrifuge.
5. Read macroscopically for agglutination.

INDIRECT ANTIGLOBULIN TECHNIQUE (recommended for D^{VI}):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix well and incubate at 37^0C for 15 minutes.
5. Wash the cells once with isotonic saline, thoroughly decanting saline.
6. Add 2 drops (80-100µl) of Anti-Human Globulin reagent, mix and centrifuge at 1000 rcf for 20 seconds.
7. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
8. Confirm validity of negative results with IgG sensitised red cells

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

LIMITATIONS

- ABO antigens are not fully developed at birth and so weaker reactions may therefore occur with cord or neonatal specimens
- Stored blood may give weaker reactions than fresh blood.
- 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
  - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work optimised best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping reagent is tested by the recommended techniques against a panel of antigen- positive red cells.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC): Anti-D = 99/836
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- Rapid Biotec Anti-D (IgG & IgM) has been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-D (IgG & IgM) is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Kholer, G. and Milstein, C. Continuous culture of fused cells secreting antibody of predefined specificity. Nature. 256 : 495-497 (1975).
2. Race RR, Sanger R. Blood Groups in Man 6th Edition, Oxford, Blackwell Scientific Publishers Chapter 2 (1975).
3. Issitt PD. Applied Blood Group Serology, 3rd Edition, Montgomery Scientific, Miami, Chapter 10 (1985).
4. Mollison PL. Blood Transfusion in Clinical Medicine, 8thEdition, Oxford, Blackwell Scientific Publications, Chapter 7 (1987).
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6. Thompson KM, Hughes-Jones NC. Production and characteristics of monoclonal anti-Rh. Bailliere's Clinical Haematology; (1990).
7. 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 5: 171-184 (1995).
8. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
9. Daniels, G. Variants of RhD – Current Testing and Clinical Consequences, British Journal of Haematology; 161: 461-470 (2013).

	Consult instructions for use	IVD	For *in vitro* diagnostic use only
REF	Catalogue Number	LOT	Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: CE D Blend RB 1 - 04/2024

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

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)

CE 1434

RAPID BIOTEC™

CATALOGUE NUMBER
BG-D10
BG-D10X10

INTENDED USE
Rapid Biotec Anti-D (IgG & IgM) is a blood grouping reagent which is intended to be used to qualitatively determine the presence or absence of the RhD antigen 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.

INTRODUCTION
The Rh Blood Group System

RhD (D or RH1), originally identified in 1939, was the first clinically important blood group to be found following the discovery of ABO 39 years earlier. A phenotypic relationship between D and an antigen on human red cells detected by antibodies made in rabbits immunized with rhesus monkey red cells, led to D being inappropriately named the Rhesus antigen. A vestige of that term remains in Rh, the name of the blood group system that contains D.

Approximately 15% of Caucasians lack the RhD antigen and are easily stimulated by an RhD positive pregnancy or blood transfusion to produce anti-D. This may cause haemolytic disease of the fetus and newborn or severe haemolytic transfusion reactions.

The frequency of the D+ phenotype is about 85% in Caucasians, around 95% in sub-Saharan Africa, and greater than 99·5% in eastern Asia (Daniels, 2013).

WEAK AND PARTIAL D
Anti-D (-RH1) of the Rh bloodgroup system is clinically important as it causes haemolytic transfusion reactions and haemolytic disease of the foetus and new-born. Although most people are either D+ or D-, there is a plethora of D variants, often categorized as either weak Dor partial D. These two types are inadequately defined and the dichotomy is potentially misleading. D^{VI} is the D variant most commonly associated with anti-D production and UK guidelines recommend that patients are tested with anti-D reagents that do not react with D^{VI}.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect most examples of weak D by direct agglutination; see the recommended technique stated in this IFU.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect partial D category D^{VI} by indirect agglutination; see the recommended technique stated in this IFU.

PRINCIPLE
When used by the recommended techniques these reagents will cause direct agglutination (clumping) of red cells carrying the specific antigen (positive test) and indirect agglutination of red cells that are classified as D^{VI} in the antiglobulin phase recommended technique. Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

These products are supplied filtered through 0.2 µmfilter.

REAGENTS AND MATERIALS
Blood grouping reagents contain monoclonal human IgM and IgG antibodies in a buffer solution. The solution containing macromolecular chemical potentiators. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-D (IgG &IgM)	Straw/clear	None	MS-26 & RUM-1

Materials needed but not provided:

Slide technique
- Microscope slide/plastic slides
- Isotonic saline, PBS or compatible plasma/serum
- Plastic stirrers
- Timer

Tube technique
- Test tubes 75 x 12mm (glass)
- Isotonic saline
- 37^{0}C incubator (if needed)
- Timer
- Centrifuge (1000 rcf)

Indirect antiglobulin technique
- Anti-Human globulin reagent
- IgG sensitised red cells (Coombs control cells)

Bio-Rad ID Card technique
- Column agglutination technique Bio-Rad ID Card (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID diluent 2

PRECAUTIONS
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- All blood products should be treated as potential infectious. The human donor or cell line used to produce this reagent has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV. No known tests can guarantee that any products derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- Do not use reagent past the expiration date.
- Protective clothing must be worn when handling reagent, such as, disposable gloves and lab coat.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
- 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 HANDLING A SPILLAGE
For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS
- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- The use of the reagent and the interpretation of results must be carried out by properly trained and competent professionals.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Weak and D^{VI} antigens are poorly detected by Bio-Rad ID card and slide techniques. It is recommended that weak D variants should be tested by tube test and D^{VI} should be tested by indirect antiglobulin technique.
- The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- 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^{0}C.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.

STORAGE AND STABILITY
Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

This reagent has undergone transportation stability studies at 37^{0}C and 2-8^{0}C as described in BS EN ISO 23640:2015.

SPECIMEN COLLECTION AND PREPARATION
- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)

CE 1434

RAPID BIOTEC™

- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum, isotonic saline or PBS.
2. Add one drop (45-50µl) of Anti-D (IgG & IgM) reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination.

TUBE METHOD: (recommended for weak D):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-D (IgG & IgM) reagent.
4. Centrifuge cassette(s) in a Bio-Rad gel card centrifuge.
5. Read macroscopically for agglutination.

INDIRECT ANTIGLOBULIN TECHNIQUE (recommended for D^{VI}):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix well and incubate at 37^0C for 15 minutes.
5. Wash the cells once with isotonic saline, thoroughly decanting saline.
6. Add 2 drops (80-100µl) of Anti-Human Globulin reagent, mix and centrifuge at 1000 rcf for 20 seconds.
7. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
8. Confirm validity of negative results with IgG sensitised red cells

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

LIMITATIONS

- ABO antigens are not fully developed at birth and so weaker reactions may therefore occur with cord or neonatal specimens
- Stored blood may give weaker reactions than fresh blood.
- 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
  - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARATERISTICS

- Reagents will work optimised best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping reagent is tested by the recommended techniques against a panel of antigen- positive red cells.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC): Anti-D = 99/836
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- Rapid Biotec Anti-D (IgG & IgM) has been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-D (IgG & IgM) is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Kholer, G. and Milstein, C. Continuous culture of fused cells secreting antibody of predefined specificity. Nature. 256 : 495-497 (1975).
2. Race RR, Sanger R. Blood Groups in Man 6th Edition, Oxford, Blackwell Scientific Publishers Chapter 2 (1975).
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7. 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 5: 171-184 (1995).
8. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
9. Daniels, G. Variants of RhD – Current Testing and Clinical Consequences, British Journal of Haematology; 161: 461-470 (2013).

	Consult instructions for use	IVD	For *in vitro* diagnostic use only
REF	Catalogue Number	LOT	Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

Manufactured By:
Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester Essex
CO7 8SD United Kingdom

Doc Ref: CE D Blend RB 1 - 04/2024

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