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
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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.
4. Race, R.R. and Sanger, R. Blood Groups in Man 6th Edition Oxford Blackwell Scientific Publishers 1975.
5. Guidelines for the Blood Transfusion Services in the United Kingdom. Current edition.

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.

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

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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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	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).
5. Tippett P. Sub-divisions of the Rh (D) antigen. Medical. Laboratory Science; 45: 88-93 (1988).
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)

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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).
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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

CE 1434

RAPID BIOTEC™

Rapid Labs

CERTIFICATE OF ANALYSIS

Product Description : Anti-A Monoclonal Blood Grouping Reagent

Cat. No. : BG-A10

Lot Number : A0425-28RB

Manufacture Date : 2025-04-28

Expiry Date : 2027-10-28

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti- HIV 1+2, anti-HCV and HBsAg

Dye : 0.005% Patent Blue

Potency

Cells	Tube Test
A_1	1 in 1024
A_2B	1 in 512

Avidity
: A_1 Cells – 1 seconds
: A_2B Cells – 2 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 4+	B Cells	Negative
A_2B Cells	Grade 4+	O Cells	Negative

Bio-Rad ID Card Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 4+	B Cells	Negative
A_2B Cells	Grade 4+	O Cells	Negative

Tube test Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 5	B Cells	Negative
A_2B Cells	Grade 5	O Cells	Negative

For & on behalf of Rapid Labs

Date 15/05/2025

E. Swager

Technical Production Coordinator & quality controller

CE
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RAPID BIOTEC™

Rapid Labs

CERTIFICATE OF ANALYSIS

Product Description : Anti-A,B Monoclonal Blood Grouping Reagent

Cat. No. : BG-AB10

Lot Number : AB0425-30RB

Manufacture Date : 2025-04-30

Expiry Date : 2027-10-30

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti-HIV 1+2, anti-HCV and HBsAg

Dye : None

Potency

Cells	Tube Test
A_1	1 in 1024
A_2	1 in 1024
B	1 in 256

Avidity

:A_1 Cells – 1 second
:A_2 Cells – 2 seconds
:B Cells – 4 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 4+	O cells	Negative
A_2 Cells	Grade 4+		
B Cells	Grade 4+		

Bio-Rad ID card Specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 4+	O cells	Negative
A_2 Cells	Grade 4+		
B Cells	Grade 4+		

Tube test specificity

Positive Phenotypes		Negative Phenotypes	
A_1 Cells	Grade 5	O cells	Negative
A_2 Cells	Grade 5		
A_x Cells	Grade 4		
B Cells	Grade 5		

For & on behalf of Rapid Labs

Date 15/05/2025

E. Swager

Technical Production Coordinator & Quality controller

CE
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RAPID BIOTEC™

Rapid Labs

CERTIFICATE OF ANALYSIS

Product Description : Anti-B Monoclonal Blood Grouping Reagent

Cat. No. : BG-B10

Lot Number : B0425-28RB

Manufacture Date : 2025-04-28

Expiry Date : 2027-10-28

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti- HIV 1+2, anti-HCV and HBsAg

Dye : 0.015% Tartrazine yellow

Potency

Cells	Tube Test
B	1 in 512
A_1B	1 in 256

Avidity
: B Cells – 1 second
: A_1B Cells – 5 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
B Cells	Grade 4+	O cells	Negative
A_1B Cells	Grade 4+	A_1 Cells	Negative

Bio-Rad ID card Specificity

Positive Phenotypes		Negative Phenotypes	
B Cells	Grade 4	O cells	Negative
A_1B Cells	Grade 4	A_1 Cells	Negative

Tube test Specificity

Positive Phenotypes		Negative Phenotypes	
B Cells	Grade 5	O cells	Negative
A_1B Cells	Grade 5	A_1 Cells	Negative

For & on behalf of Rapid Labs

Date 15/05/2025

E. Swager

Technical Production Coordinator & quality controller

CE
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RAPID BIOTEC™

Rapid Labs

CERTIFICATE OF ANALYSIS

Product Description : Anti-D (IgG & IgM) Blood Grouping Reagent

Cat. No. : BG-D10

Lot Number : D0425-30RB

Manufacture Date : 2025-04-30

Expiry Date : 2027-10-30

Preservative : <0.1% w/v Sodium Azide

Sterility : Product filtered through a sterile 0.2µm filter

Storage : REFRIGERATE AT 2 - 8°C

Micro Testing : Source materials used to produce this lot were tested at source and found to be non-reactive for anti- HIV 1+2, anti-HCV and HBsAg

Dye : None

Potency

	Tube Test
OR1r Cells	1 in 256
OR2r Cells	1 in 256

Avidity

: OR1r Cells – 5 seconds
: OR2r Cells – 8 seconds

Slide Specificity

Positive Phenotypes		Negative Phenotypes	
OR1r cells	Grade 4+	rr cells	negative
OR2r cells	Grade 4+	r'r cells	Negative
		r"r cells	Negative

Bio-Rad ID Specificity

Positive Phenotypes		Negative Phenotypes	
OR1r cells	Grade 4	rr cells	negative
OR2r cells	Grade 4	r'r cells	Negative
		r"r cells	Negative

Tube test specificity

Positive Phenotypes		Negative Phenotypes	
OR1r cells	Grade 5	rr cells	negative
OR2r cells	Grade 5	r'r cells	Negative
Weak D (D_u)	Grade 5	r"r cells	Negative

For & on behalf of Rapid Labs

Date 15/05/2025

E. Swager

Technical Production Coordinator and Quality Controller

Digitally signed by Dolgopol Iulian
Date: 2026.08.25 14:18:02 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ