

Core™ ANTI-A, Core™ ANTI-B, Core™ ANTI-A, B

MONOCLONAL BLOOD GROUPING ANTIBODIES FOR SLIDE AND TUBE TESTS

SUMMARY

Monoclonal antibodies are derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells. Each hybridoma cell line produces homogenous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity.

Human red blood cell antigens can be divided into four groups A, B, AB and O depending on the presence or absence of the corresponding antigens on the red blood cells.

Approximately 41% of the Caucasian population have the A Antigen, 9% have the B Antigen, 4% have both A and B antigens, while the remaining have neither the A nor the B antigen.

PRESENTATION

	Core™ Anti-A	Core™ Anti-B	Core™ Anti-A,B
5 ml	BG- 11/5	BG- 22/5	BG- 12/5
10 ml	BG- 11	BG- 22	BG- 12
Clone	11H5	6F9	11H5 + 6F9

REAGENTS

Core™ Anti-A, Core™ Anti-B, and Core™ Anti-A,B are ready to use solutions of the respective specific antibodies of the immunoglobulin class IgM prepared from the corresponding supernatants of mouse hybridoma cell cultures. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE

Human red blood cells possessing A and/or B antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with Core™ Anti-A, Core™ Anti-B, Core™ Anti-A,B reagents is a positive test result and indicates the presence of the corresponding antigen. Absence of agglutination of red blood cells with Core™ Anti-A, Core™ Anti-B, and Core™ Anti-A, B reagents is a negative test result and indicates the absence of the corresponding antigen.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. To be used by a qualified personnel. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. Reagents are not from human source, hence contamination due to HBsAg and HIV is practically excluded.
5. The shelf life of the reagents is as per the expiry mentioned on the reagent vial labels.
6. It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop.
7. It is advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution.
8. Do not use damaged or leaking reagents.
9. Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8°C if not tested immediately. Do not use haemolysed samples.

Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period:

EDTA or HEPARIN	:	2 days
Sodium citrate or sodium oxalate	:	14 days
ACD or CPD	:	28 days

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85 mm), Test tubes (10 x 75 mm), Pasteur pipettes, Isotonic saline, Centrifuge, Timer, Mixing sticks, test tube rack.

TEST PROCEDURE

Bring reagents and samples to room temperature before testing.

Slide Test

1. Place one drop of Core™ Anti-A or Core™ Anti-B or Core™ Anti-A, B reagent using the reagent vial dropper on a clean glass slide.
2. To each reagent drop, add 50µl of whole blood.
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm².
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at two minutes.

Tube test

1. Prepare a 2-3% suspension of the red cells to be tested in isotonic saline.
2. Place one drop of Core™ Anti-A, Core™ Anti-B, Core™ Anti-A, B reagent using the reagent vial dropper into corresponding labelled test tubes.
3. Pipette into each of the test tubes, 50µl of the test red cell suspension and mix well.
4. Centrifuge for 1 minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g) or incubate at room temperature for 20-30 minutes.
5. Gently suspend the cell button, observing for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and tube tests

Agglutination is a positive test result and indicates the presence of A and/or B antigen. Do not interpret peripheral drying or fibrin strands as agglutination. No agglutination is a negative test result and indicates the absence of A and/or B antigen.

REMARKS

- Core™ Anti-A, Core™ Anti-B, Core™ Anti-A, B reagents do not show a reaction with crypt antigens (T, Tn, Tk activated cells).
 - Core™ Anti-B is truly negative reacting with acquired B characteristics.
 - Due to the use of monoclonal antibodies in Core™ Anti-A reagent usually red cells with weak A-characteristics are detected, A₂ blood provide normal to weak reactions and A₁ bloods weak positive to negative reactions.
- In the tube test procedure, it is recommended that tubes with negative reactions should be recentrifuged and results read again after 5 minutes so that weak antigens are not overlooked.
- As undercentrifugation or overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and determine the time required for achieving the desired results.
- Results of forward grouping obtained by using Core™ Anti-A, Core™ Anti-B, Core™ Anti-A,B reagents should always be confirmed by performing reverse grouping with known red cells. If there is discordance, do not report the result and pursue blood identification in compliance with current recommendations and protocols or forward the sample to an expert laboratory.
- It is strongly recommended that red cells with known ABO characteristics should be occasionally run, preferably on a daily basis to validate the reagent performance.
- After usage the reagents should be immediately recapped and replaced to 2-8°C storage.
- In certain cases (transfusion recipients, certain weak phenotypes A or B (A₃, B₃,...), certain hemopathological modifications, mosaics or chimeras, etc.), an image of a double population may be observed.

PERFORMANCE CHARACTERISTICS

The performance of Core™ Anti A, Core™ Anti B, Core™ Anti A,B comply with the common technical specifications of in-vitro diagnostic medical devices under the recommended methods.

The performance of Core™ Anti-A, Core™ Anti-B, Core™ Anti A,B was evaluated on over 5000 samples (from donors, patients and neonates) drawn on the recommended anticoagulants. The process, techniques and protocols used were as defined in the package insert. The evaluation demonstrated 100% specificity of each reagent versus the expected results with common known phenotypes A₁, A₂, A,B, A₁B, B and O.








WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

- Kohler C. & Milstein C. (1975), Continuous cultures of fused cells secreting antibody of predefined specificity. Nature, 256, 495-497.
- Lee H.H., Rouger P., Germain C., Muller A & Salmon C. (1983). The production and standardisation of monoclonal antibodies as AB blood group typing reagents. Symposium of International Association of Biological Standardisation on monoclonal antibodies.
- Human Blood Groups, by Geoff Daniels, 1st Ed., Blackwell Science, Oxford 1995.

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 Store at 2-8°C	 Manufacturer	 This way up
 Use by (Last day of stated month)	 Consult Instructions for use	REAGENT Description of reagent
 Date of Manufacture	REF Catalogue Number	Clone Identity of antibody clone
LOT Batch Number	IVD <i>In vitro</i> Diagnostic Medical Device	 Xn Harmful if swallowed Do not breathe vapour If swallowed, seek medical advice immediately and show this container or label Avoid release to the environment. Refer to special instructions. NAN, R22 S23-46-61

0110-03/0806/AE/VER-1


CORE DIAGNOSTICS
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CORE
Diagnostics

Core™ ANTI-D (Rho)(IgM)

MONOCLONAL BLOOD TYPING ANTIBODIES FOR SLIDE AND TUBE TESTS

SUMMARY

Monoclonal antibodies are derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells or are derived from a human B cell line through EBV transformation.

Each hybridoma cell line produces homogenous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity.

Human red blood cells are classified as Rho (D) positive or Rho (D) negative depending upon the presence or absence of D (Rho) antigen on them. Approximately 85% of the Caucasian population are Rho (D) positive. The Dⁱ phenotype is a variant of D (Rho) antigen and is recognised by performing the antiglobulin test.

About 60% of the D^s, now classified as weak or partial D^s, may react with Core™ Anti-D (Rho) (IgM) in slide tests and about 90% may be detected by the tube technique.

PRESENTATION

REF	Core™ Anti D (IgM)	Clone
BG-40/5	5 ml	P3x61
BG-40	10ml	P3x61

REAGENT

Core™ Anti-D (Rho) (IgM) is a ready to use reagent, prepared from supernatants of cell cultures with antibody producing B lymphocytes obtained through EBV transformation and is formulation of monoclonal antibodies of immunoglobulin class IgM, having the capability of recognising different epitopes of the human red blood cell antigen D (Rho).

Core™ Anti-D (Rho) (IgM) does not detect all weak and partial D^s. For the confirmation of negative reactions with Core™ Anti-D (Rho) (IgM) further testing with an incomplete Anti-D (Rho) of IgG or Core™ Anti D (Rho) (IgM + IgG) is strongly recommended to confirm the presence or absence of weak/partial D^s. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE

Human red blood cells possessing the D (Rho) antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with Core™ Anti-D (Rho) (IgM) reagent is positive test result and indicates the presence of D (Rho) antigen. No agglutination with the reagent is a negative test result and indicates the absence of D (Rho) antigen. All negative test results should be further tested for Dⁱ (Presence of weak / partial D^s) by performing the Dⁱ test procedure using incomplete Anti-D (Rho) of IgG class, as described later.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. To be used by a qualified personnel. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. Reagents are not from human source, hence contamination due to HBsAg and HIV is practically excluded.
5. The shelf life of the reagents is as per the expiry mentioned on the reagent vial labels.
6. It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop.
7. It is advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution.
8. Do not use damaged or leaking reagents.
9. Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8°C if not tested immediately. Do not use haemolysed samples.

Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period.

EDTA or Heparin	:	2 days
Sodium citrate or sodium oxalate	:	14 days
ACD or CPD	:	28 days

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85 mm), Test tubes (10 x 75 mm), Pasteur pipettes, Isotonic saline, Centrifuge, Timer, Mixing sticks, Anti-D (Rho)(IgG) or Core™ Anti-D (Rho)(IgM + IgG).

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Slide Test

1. Place one drop of Core™ Anti-D (Rho) (IgM) reagent on a clean slide.
2. Pipette 50µl of whole blood on the slide.
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm².
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at the end of two minutes.

Immediate Spin Tube Test

1. Prepare a 5% suspension of red cells to be tested in isotonic saline.
2. Place one drop of Core™ Anti-D (Rho) (IgM) reagent into a labeled test tube.

- Pipette into the test tube 50µl of 5% cell suspension and mix well.
- Centrifuge for one minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
- Gently resuspend the cell button, observing for agglutination macroscopically.

D⁺TEST PROCEDURE

- Prepare a 5% suspension of the red cells to be tested in isotonic saline.
- Place one drop of any incomplete Anti-D (Rho) (IgG class) reagent or Core™ Anti D (Rho)(IgM + IgG) into a labeled test tube.
- Add to the test tube 50µl of the 5% cell suspension and mix well. Incubate at 37°C for 15 minutes.
- Wash the contents of the tube thoroughly, atleast three times, with isotonic saline and decant completely after the last wash.
- Add two drops of Anti Human Globulin reagent and mix well.
- Centrifuge for 1 minute a 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
- Very gently, resuspend the cell button and observe for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and Tube Tests

- Agglutination is a positive test result and indicates the presence of D (Rho) antigen. Do not interpret peripheral drying or fibrin strands as agglutination. No agglutination is a negative result and indicates the absence of D (Rho) antigen.
- Cord cells heavily sensitized with Anti-D (Rho) may give a false negative immediate spin test result.

D⁺Test Procedure

(a) Agglutination indicates the presence of D⁺ antigen (Presence of weak / partial D's). No agglutination indicates the absence of D⁺ antigen (Absence of weak/ partial D's). (b) Mixed field agglutination in the D⁺ test on red cells from a recently delivered woman may indicate a mixture of maternal Rho (D) negative and fetal Rho (D) positive blood. (c) Red cells demonstrating a positive direct antiglobulin test cannot be accurately tested for D⁺ antigen (Presence of weak / partial D's).

REMARKS

- As undercentrifugation and overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required of achieving the results.
- It is strongly recommended that as a routine quality control measure known as Rho (D) positive and Rho (D) s negative red cells be occasionally run, preferably on a daily basis so as to control reagent performance and validation of test results.
- After usage, the reagents should be immediately recapped and replaced to 2-8°C storage.

PERFORMANCE CHARACTERISTICS

The performance of Core™ Anti-D(Rho) (IgM) comply with the common technical specifications of in-vitro diagnostic medical devices under the recommended methods.

The performance of Core™ Anti-D(Rho) (IgM) was evaluated on over 5000 samples (from donors, patients and neonates) drawn on the recommended anticoagulants. The process, techniques and protocols used were as defined in the package insert. The evaluation demonstrated 100% specificity of reagent versus the expected results with common known Rhesus phenotypes.








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BIBLIOGRAPHY

(1) Kohler C. & Milstein C. (1975). Continuous cultures of fused cells secreting antibody of predefined specificity. Nature, 256, 495-497. (2) Lee H.H., Rouger P., Germain C., Muller A & Salmon C. (1983). The production and standardisation of monoclonal antibodies as AB blood group typing reagents. Symposium of International Association of Biological Standardisation on Monoclonal antibodies. (3) Human Blood Groups by Geoff Daniels, 1st Ed., Blackwell Science,

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 Store at 2-8°C	 Manufacturer	 This way up
 Use by (Last day of stated month)	 Consult Instructions for use	REAGENT Description of reagent
 Date of Manufacture	REF Catalogue Number	Clone Identity of antibody clone
LOT Batch Number	IVD <i>In vitro</i> Diagnostic Medical Device	 Xn Harmful if swallowed Do not breathe vapour If swallowed, seek medical advice immediately and show this container or label NAN, R22 S23-60-61 Avoid release to the environment. Refer to special instructions.

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CORE DIAGNOSTICS
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Core™ Anti-D (Rho) (IgM + IgG)

MONOCLONAL BLOOD TYPING ANTIBODIES FOR SLIDE AND TUBE TESTS

SUMMARY

Monoclonal antibodies are derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells or are derived from a human cell line through EBV transformation. Each hybridoma cell line produces homogenous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity.

Human red blood cells are classified as Rho (D) positive and Rho (D) negative depending upon the presence or absence of D (Rho) antigen on them. Approximately 85% of the Caucasian population are Rho (D) positive. The D⁺ phenotype is a traditional definition to describe the weak / partial D's that can be detected with Core™ Anti-D (Rho) (IgM+IgG).

About 60% of the D⁺ (weak / partial D's) may react with Core™ Anti-D (Rho) (IgM+IgG) in slide tests and about 90% may be detected by tube technique.

PRESENTATION

REF	Core™ Anti D Rho (IgM + IgG)	Clone
BG-44/5	5 ml	P3x61 + MCAD 6
BG-44	10 ml	P3x61 + MCAD 6

REAGENT

Core™ Anti-D (Rho) (IgM + IgG) is a ready to use reagent, prepared from supernatants of cell cultures with antibody producing B lymphocytes obtained through EBV transformation and is a blend of monoclonal antibodies of the immunoglobulin class IgM and IgG. These antibodies are monoclonal antibodies of the same specificity but having the capability of recognising different epitopes of the human red blood cell antigen D (Rho).

Core™ Anti-D (Rho) (IgM + IgG) is a blend of IgM and IgG class of Anti-D (Rho) monoclonal, a characteristic which accords versatility to the reagent. It gives an avid saline reacting slide / tube test reagent the capability of detecting D⁺ (weak/partial D's) in the Anti Human Globulin Phase.

Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE

Human red blood cell possessing D antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with Core™ Anti-D (Rho) (IgM + IgG) reagent is a positive test result and indicates the presence of the D (Rho) antigen. No agglutination with Core™ Anti-D (Rho) (IgM + IgG) reagent is a negative test result and indicates absence of D (Rho) antigen. All negative test results should be further tested for D⁺ (weak / partial D's) by performing the D⁺ test procedure, as described later.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. To be used by a qualified personnel. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. Reagents are not from human source, hence contamination due to HBsAg and HIV is practically excluded.
5. The shelf life of the reagents is as per the expiry mentioned on the reagent vial labels.
6. It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop.
7. It is advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution.
8. Do not use damaged or leaking reagents.
9. Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8°C if not tested immediately. Do not use haemolysed samples.

Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period:

EDTA or Heparin	:	2 days
Sodium citrate or sodium oxalate	:	14 days
ACD or CPD	:	28 days

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85 mm), Test tubes (10 x 75 mm), Test tube rack, Pasteur pipettes, Isotonic saline, Centrifuge, Timer, Mixing sticks, Anti Human Globulin (Coombs) reagent.

TEST PROCEDURE

Bring reagents and samples to room temperature before testing.

Slide Test

1. Place one drop of Core™ Anti-D (Rho) (IgM + IgG) reagent on a clean glass slide.
2. Pipette 50µl whole blood below Core™ Anti-D (Rho) (IgM + IgG) reagent on the slide.
3. Mix well the reagent and blood sample with a mixing stick uniformly over an area of approximately 2.5 cm².
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at the end of two minutes.

Tube Test

1. Prepare a 5% cell suspension of the red cells to be tested in isotonic saline.
2. Place one drop Core™ Anti-D (Rho) (IgM + IgG) reagent into a labeled test tube.
3. Pipette 50µl of test red cell suspension into the test tube and mix well.
4. Centrifuge for one minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
5. Gently resuspend the cell button observing for agglutination macroscopically.

D⁺ TEST PROCEDURE

1. Prepare a 5% suspension of the red cells to be tested in isotonic saline.

2. Place one drop of Core™ Anti-D (Rho) (IgM + IgG) reagent into a labelled test tube.
3. Add to the test tube 50µl of cell suspension under test, mix well and incubate at 37°C for 15 minutes.
4. Wash the contents of the tube thoroughly, atleast three times, with isotonic saline and decant completely after the last wash.
5. Add two drops of Anti Human Globulin reagent using the vial dropper and mix well.
6. Centrifuge for 1 minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
7. Very gently, resuspend the cell button and observe for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and Tube Tests

- a) Agglutination with the Core™ Anti-D (Rho) (IgM + IgG) is a positive test result and indicates the presence of D (Rho) antigen. Do not interpret peripheral drying or fibrin strands as agglutination.
- b) No agglutination with Core™ Anti-D (Rho) (IgM + IgG) is a negative test result and indicates the absence of D antigen.

D⁺ Test Procedure

(a) Agglutination with reagent indicates the presence of D⁺ antigen (weak / partial D's). (b) No agglutination with reagent indicates the absence of D⁺ antigen. Negative reactions obtained in Du test must be validated:- add 50µl of coomb's control cells to the reaction mixture. A positive reaction confirms the activity of the coomb's reagent and validates the negative reaction before the addition of the coomb's control cells. (c) Mixed field agglutination in the D⁺ test on red cells from a recently delivered woman may indicate a mixture of maternal Rho (D) negative and fetal Rho (D) positive blood. (d) Red cells demonstrating a positive direct antiglobulin test cannot be accurately tested for D⁺ antigen (weak / partial D's).

REMARKS

1. As undercentrifugation and overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required of achieving the results.
2. It is strongly recommended that as a routine quality control measure with known Rho (D) positive and Rho (D) negative red cells be occasionally run, preferably on a daily basis to validate reagent performance.
3. After usage, the reagents should be immediately recapped and replaced to 2-8°C storage.
4. Cord Cells heavily sensitized with Anti-D (Rho) may give false negative result in immediate spin test.
5. False positive reactions may occur if the test subject has cold agglutinins.
6. Core™ Anti-D (Rho) (IgM + IgG) have the feature of recognizing certain rare antigen motif of type (RoHar) and may thus yield discordant results with polyclonal reagents that may or may not recognize them.
7. Core™ Anti-D (Rho) (IgM + IgG) enables the screening for weak Rh red blood cells in the Du test procedure with coomb's reagent.
8. The tests conducted on particular phenotypes, while satisfactory, cannot ensure recognition of all weak or variant subjects, due to variability of antigen motifs.

PERFORMANCE CHARACTERISTICS

The performance of Core™ Anti-D (Rho) (IgM + IgG) comply with the common technical specifications of in-vitro diagnostic medical devices under the recommended methods.

The performance of Core™ Anti-D (Rho) (IgM + IgG) was evaluated on over 5000 samples (from donors, patients and neonates) drawn on the recommended anticoagulants. The process, techniques and protocols used were as defined in the package insert. The evaluation demonstrated 100% specificity of reagent versus the expected results with common known Rhesus phenotypes.







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 Store at 2-8°C	 Manufacturer	 This way up
 Use by (Last day of stated month)	 Consult Instructions for use	REAGENT Description of reagent
 Date of Manufacture	REF Catalogue Number	Clone Identity of antibody clone
LOT Batch Number	IVD In vitro Diagnostic Medical Device	Xn Harmful if swallowed Do not breathe the vapour If swallowed, seek medical advice immediately and show this container or label Avoid release to the environment. Refer to special instructions. NaN, R22 S23-46-61

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