Blood Grouping Reagent
IH-Card ABD(DVI+)-Conf
A-B-D(DVI+) / A-B-D(DVI+)

English, B186354, Version 09, 2019.04

FOR IN VITRO DIAGNOSTIC USE
Gel card for use with the IH-System
MEETS FDA POTENCY REQUIREMENTS
U.S. LICENSE NUMBER: 1845

Product-Identification: 71080

IH-Card ABD(DVI+)-Conf:	VOL 12 cards per box	REF 813 190 100
	VOL 48 cards per box	REF 813 191 100
	VOL 288 cards per box	REF 813 192 100

INTENDED USE

The IH-Card ABD(DVI+)-Conf is intended for the detection of A (ABO1), B (ABO2) and D (RH1) antigens on human red blood cells using the IH-System.

SUMMARY

Between 1900 and 1902, Karl Landsteiner and associates discovered the ABO system of red blood cell antigens. The importance of this discovery is the recognition that antibodies are present when the corresponding antigens are lacking. The ABO system is the only blood group system in which the reciprocal antibodies are consistently and predictably present in most people. ABO blood group typing, using Anti-A and Anti-B antisera to detect A (ABO1) and B (ABO2) antigens, is known as direct or forward grouping.

The Rhesus blood group system was first described by Landsteiner and Wiener in 1940. The antigen discovered by Landsteiner and Wiener is known as the ˝D˝ antigen. The terms ˝Rh-positive˝ and ˝Rh-negative˝ refer to the presence or absence of the D (RH1) red blood cell antigen. The D antigen is one of many that comprise the Rh blood group system. Approximately 85% of random donors in Caucasian populations have inherited the D gene and will phenotype as D positive.

The D antigen is probably the most important antigen outside of the ABO blood group system. Most D negative individuals will make anti-D when sensitized by the D antigen. Additionally, D negative females can become sensitized during pregnancy as a result of a fetal-maternal hemorrhage. The sensitization can lead to destruction of fetal red blood cells.

The D antigen is composed of many epitopes. Most of the D positive red blood cells have a conventional RhD protein. Weak D types are defined by reduced amounts of D antigen and can be classified in different types reflecting the number of D antigens on the red blood cells, which may require an indirect antiglobulin test for their detection. Red cells of individuals with partial D types are lacking one or more epitopes of the D antigen. This means that individuals with partial DVI may develop anti-D to the missing epitope if exposed to red cells that possess the complete D antigen.

The IH-Card ABD(DVI+)-Conf is suitable for the detection of ABO/ RhD antigens. Most D variant expressions will be detected with this reagent although reaction strengths may vary. The DVI epitope of the D antigen will be detected.

PRINCIPLES OF THE TEST

The test combines the principles of hemagglutination and gel filtration for detection of blood group antigen-antibody reactions.

The test sample (red blood cell suspension) is distributed into the microtubes containing the appropriate reagent(s). After centrifugation non-agglutinated red blood cells are collected at the bottom of the microtube while the agglutinates are dispersed throughout the length of the gel, depending upon their size. Their position in the gel determines the intensity of the reaction.

REAGENTS

IVD
OBSERVABLE INDICATIONS
Bubbles trapped in the gel, drying of the gel, artifacts, or open or damaged seals may indicate product alteration.
NOTE: INSPECT THE CONDITION OF THE CARDS BEFORE USE (SEE PRECAUTIONS).

IH-Card ABD(DVI+)-Conf consists of six microtubes containing Anti-A, Anti-B, Anti-D (DVI+). Anti-A, Anti-B and Anti-D blood grouping reagents are provided in a final buffered gel suspension. Anti-A has been colored with FD & C Blue #1 and Anti-B has been colored with FD & C Yellow #5. Anti D is a blend of monoclonal human IgM secreted by mouse/human hybridoma. The Anti-B monoclonal antibody (X9) does not react with acquired B cells. This reagent contains bovine albumin.

Reagent	Source	Antibody Class	Cell lines	Manufacturer
Anti-A	Murine Monoclonal	IgM	15750F7	Bio-Rad
Anti-B	Murine Monoclonal	IgG3	X9	Bio-Rad
Anti-D	Human Monoclonal	IgM	BS226/ESD1M	Bio-Rad/ Alba Bioscience Limited

Preservative: Sodium Azide (0.1%)

The bovine albumin used for the production of this reagent is purchased from BSE-free sources.

Each card contains six microtubes. Depending on the test profile, individual wells of this card can be used by carefully peeling off the aluminum foil from the individual microtubes.

STORAGE REQUIREMENTS

• Store at 18 to 25 °C.
• Do not use beyond expiry on the label, which is expressed as YYYY-MM-DD (Year-Month-Day).
• Store in an upright position.
• Do not freeze or expose cards to excessive heat.
• Do not store near any heat, air conditioning sources or ventilation outlets.

PRECAUTIONS

• All IH-System reagents and test samples must be brought to room temperature (18 to 25 °C) prior to use.
• Do not use cards showing signs of drying, discoloration, bubbles, crystals or other artifacts.
◄
• Do not use cards with damaged foil strips.
• Use reagents as furnished.
• Do not use gel cards if the gel matrix is absent or if the liquid level in the microtube is not at or below the gel matrix. A clear liquid layer should be visible on top of the uniform gel matrix in each microtube.
• Cards with dispersed drops observed at the top of the microtube, due to improper storage or shipping conditions, have to be centrifuged with the **IH**-Centrifuge L or **IH**-Reader 24 with preset time and speed before use. If drops are still observed on top of the microtube after one centrifugation it is recommended to not use the card.
• The use of diluents other than IH-LISS for the red blood cell suspension may modify the reaction and lead to incorrect test results.
• The use of volumes and/or red blood cell suspension in concentrations other than those indicated in the method may modify the reaction and lead to incorrect test results, i.e., false positive or false negative results.
• Once the IH-Card has been used for testing, it may contain infectious material and should therefore be handled and disposed of as biohazardous waste in accordance with local, state, and national regulations.
• Warning: Contains sodium azide, which may react with lead or copper plumbing to form explosive azides. If discarded in the sink, flush with large amounts of water to prevent the buildup of explosive metal azides.

SPECIMEN COLLECTION AND PREPARATION
No special preparation of the patient or donor is required prior to specimen collection. Blood samples should be collected following general blood sampling guidelines.

Fresh blood samples collected in anticoagulant are acceptable. Samples should be tested as soon as possible post collection. If testing is delayed, EDTA samples may be stored at 2 to 8 °C for up to ten (10) days when tested manually and five (5) days when tested on automated systems.

On automated systems if testing is delayed, donor blood collected in CPD or CP2D may be tested up to expiration date of the unit when stored at 1 to 8 °C. Donor blood stored in additive solutions AS-1 or AS-3 may be tested up to thirty (30) days post collection when stored at 1 to 8 °C. Cord blood samples may be stored at 2 to 8 °C up to five (5) days post collection for automated testing.

For manual testing, if testing is delayed, donor blood collected in CPD, CP2D and CPDA-1 and donor blood stored in additive solutions AS-1 or AS-3 may be tested up to expiration date indicated on the label of the unit when stored at 1 to 8 °C. Cord blood samples may be stored at 2 to 8 °C up to ten (10) days post collection for manual testing.
Do not use grossly hemolyzed, lipemic or icteric samples.

A distinct separation of red blood cells and plasma is recommended for optimal results. This can be achieved through centrifugation at 10 minutes at 2000g or at a time and speed that consistently produces a distinct cell/plasma interface. Donor segments do not require centrifugation.

TEST PROCEDURE FOR MANUAL AND AUTOMATED SYSTEMS

Material provided
• IH-Card ABD(DVI+)-Conf

Materials required but not provided
• IH-LISS Rack or IH-LISS Solution
• Dispenser pipette capable of delivering 1 mL
• Pipettes: 10 µL, 50 µL and 1 mL
• Disposable pipette tips
• Glass or plastic test tubes
• **IH**-Centrifuge L or **IH**-Reader 24 to centrifuge the IH-Cards at 85g with pre-set time for manual testing

• **IH**-1000 or **IH**-500 for full automation

Method for automation
Please refer to the **IH-**1000, **IH**-500 and **IH**-Com User Manual for U.S. for testing and reagent handling instructions.

Method for manual testing
Refer to the **IH**-Centrifuge L User Manual U.S. or **IH**-Reader 24 User Manual and **IH**-Com User Manual U.S. for equipment operating instructions.

Immediately prior to use prepare a red blood cell suspension of approximatively 1% to be tested in IH-LISS.

- Transfer 1 mL of IH-LISS Solution to a labelled disposable tube
- Add 10 µL of red blood cell pellet
- Mix gently
- The red blood cell suspension is ready for use

1. Allow reagents and samples to reach room temperature (18 to 25 °C) before use.
2. Inspect the condition of the cards before use (see Warnings and Precautions)
3. Label the gel card appropriately.
4. Withdraw the entire foil seal from the card or from the individual microtubes to be used for testing. Carefully peel off the aluminium foil to prevent cross-contamination of the microtube contents.
   Note: Once the foil has been removed from the microtubes, testing must be initiated to prevent drying of the gel.
5. Ensure the resuspension of the red blood cells before use.
6. Distribute 50 µL of red blood cell suspension (approximately 1%) into the appropriate wells of microtubes 1, 2 and 3.
   Note: Carefully dispense the red blood cell suspension and the serum or plasma, avoiding contact of the pipette tip with the contents of the microtubes to prevent carryover.
7. Centrifuge in the **IH**-Centrifuge L or **IH**-Reader 24 at the pre-set conditions as determined by the manufacturer.
8. Read the reactions by visual inspection or automatically with the **IH**-Reader 24.

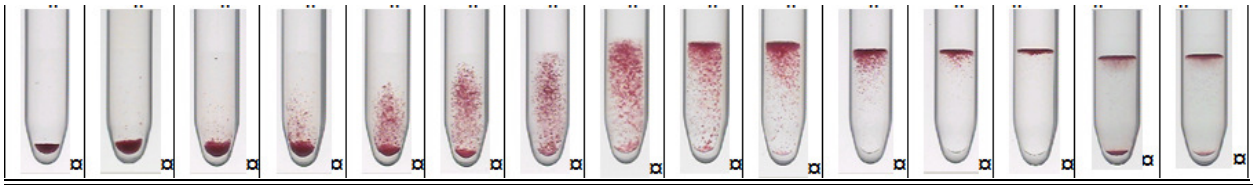
INTERPRETATION OF RESULTS

For visual interpretation

• **Positive result** - Agglutinates on the surface of or dispersed through the gel. Report as a positive test result if hemolysis is present in the microtube but not in the sample column. Red blood cells may remain suspended on the top of the gel or dispersed throughout the gel in varying degrees. A few cells may form a button in the microtube bottom in some positive reactions.

• **Negative result** - A compact button of red blood cells at the microtube bottom is a negative test result.

Refer to the IH-System Interpretation Guide for additional information



Neg (-)	(?)	Positive* (+/- and +)	Positive (++)	Positive (+++)	Positive (++++)	Mixed Field (DP)

*A very weak reaction is not an expected result for antigen testing. It may indicate that a false positive or a very weak/partial expression of the antigen is present. Further investigation of this sample should be performed before the antigen status is determined.

For automated reading

Below is a description of the various reaction grades and how the software uses that well reaction to determine the result interpretation. Please refer to the **IH**-Reader 24 User Manual or **IH**-1000, **IH**-500 and **IH**-Com User Manual U.S for further information.

Well Reaction Grade	Result Interpretation	Reaction Description
-	Negative	A compact, pellet of RBCs* with a smooth surface at the bottom of the well with no visible agglutination.
+/-	Blood Grouping, Antisera, and Phenotyping including Anti-D Blend, = Not interpretable For Reverse (serum) ABO Testing = Positive Direct Antiglobulin Test, Antibody Detection, Autocontrol = Positive Antibody Identification= no overall result interpretation, only well result shown as +/- For Crossmatching = Incompatible	A pellet of RBCs at the bottom of the well with a very few agglutinated RBCs visible above the pellet or an irregular pellet.

Well Reaction Grade	Result Interpretation	Reaction Description
1+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Not interpretable For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	A pellet of RBCs at the bottom of the well with agglutinated RBCs visible in the lower half of the gel column.
2+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Positive For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	Agglutinated RBCs distributed throughout the entire length of the gel column, with no line of RBCs on the top of the well.
3+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Positive For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	Most agglutinated RBCs concentrated at the top of the gel or upper half of the gel column.
4+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend =Positive For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	Agglutinated RBCs concentrated as a line on the top of the gel column with a few agglutinated RBCs just underneath the gel surface.
Mixed Field (DP)	Blood Grouping, Antisera, and Phenotyping including Anti-D Blend, = Not interpretable For Reverse (serum) ABO Testing = Positive Direct Antiglobulin Test, Antibody Detection, Autocontrol = Positive Antibody Identification= no overall result interpretation, only well result shown as DP For Crossmatching = Incompatible	Agglutinated RBCs as a line at the top of the gel or dispersed in upper part of the gel and non-agglutinated RBCs forming a pellet at the bottom of the well. The instrument interpretation software displays “DP” (double population) for a mixed field result.
?	For Blood Grouping including Reverse ABO Testing, Antisera, and Phenotyping including Anti-D Blend, Antibody Detection and Identification, Direct Antiglobulin Testing = Not interpretable For Crossmatching = Incompatible	Ambiguous result.

* RBCs = Red Blood Cells

Expected reactions with Anti-A, Anti-B, Anti-D(DVI+) and their interpretation are shown in the following table:

Blood Grouping Anti-A	Blood Grouping Anti-B	Blood Grouping Anti-D(DVI+)	Interpretation of the result ABO	Interpretation of the result D
positive	negative	positive	A	**Positive**
positive	negative	negative	A	**Negative**
negative	positive	positive	B	**Positive**
negative	positive	negative	B	**Negative**
positive	positive	positive	AB	**Positive**
positive	positive	negative	AB	**Negative**
negative	negative	positive	O	**Positive**
negative	negative	negative	O	**Negative**

• A control test to detect spontaneous agglutination is not essential in routine testing because the IH-System Monoclonal Blood Grouping Reagents do not contain ingredients that enhance spontaneous agglutination of immunoglobulin-coated red blood cells. In some circumstances, a false positive test result may occur due to strong cold autoagglutinins or to a protein imbalance causing the formation of rouleaux. In such cases, similar phenomena would be likely to occur in tests with all the IH System Monoclonal Blood Grouping Reagents. If all blood grouping results for a given sample are positive, a control may be indicated. The IH-Card Control can be used for this purpose. If the control test is positive, laboratories are advised to consult their approved site-specific procedures. The test cells can be washed several times in warm saline and retested.[1] If the control test again gives a positive reaction, a valid interpretation of the results obtained cannot be made. Additional testing will be necessary to resolve the false positive reaction according to site-specific procedures.

• Caution must be taken in interpreting a reaction as a mixed field. Additional patient history and testing may be necessary for resolution. Not all mixed field populations have a sufficient minor population to be detected.

STABILITY OF REACTIONS

For visual reading of reactions, best results are obtained within six (6) hours of centrifugation. Interpretation may be affected by drying of the gel, hemolysis of red blood cells and slanting of reaction patterns due to storage in a non-upright position. Processed cards that are stored in the refrigerator (2 to 8 ℃) and properly sealed to protect from evaporation may be interpreted for up to one (1) day. Gel cards should not be interpreted after the first sign of drying, or if hemolysis is observed. The age and condition of red blood cells, as well as the temperature at which the card is stored, will affect how long cards can be stored. The presence of sodium azide in the gel may cause the red blood cells to become dark in color over time. This darkening does not interfere with the test result.

QUALITY CONTROL

On each day of use, the reactivity of all Blood Grouping Reagents should be confirmed by testing with known positive and negative samples. For example, the Blood Grouping Reagents contained on this card could be controlled by testing group AB RhD positive and group O Rh D negative samples. Other combinations of ABO and Rh types are possible as long as there is a positive and negative control for each reagent. Each reagent is satisfactory for use if positive and negative samples react as expected. For additional information, please consult the **IH**-1000, IH-500 and the **IH**-Com User Manual U.S., Quality Control Sections.

LIMITATIONS

Erroneous and abnormal results may be caused by:

- Bacterial or chemical contamination of the blood specimens, reagents, supplementary materials and/or equipment.
- Patient medication or disease yielding a cross-reaction.
- A red blood cell concentration or suspension medium different from that recommended.
- Incomplete re-suspension of the red blood cells.
- Sample hemolysis prior to testing.
- Contamination between microtubes through pipetting errors.
- Use of procedure other than the one described above.

• Grossly icteric blood samples, blood samples with abnormally high concentrations of protein or blood samples from patients who have received plasma expanders of high molecular weight may give false positive results.
• Fibrin, clots, particulates or other artifacts may cause some red blood cells to be trapped at the top of the gel and cause an anomalous result. They may appear as a pinkish layer. In a negative reaction the false appearance of a mixed field could lead to misinterpretation.
• A weak reaction is not an expected result for antigen typing and may be indicative of a false positive or weak/partial expression of the antigen. Further investigations may be warranted per site-specific procedures.
• Very weak ABO subgroups may not be detected with the Anti-A and Anti-B reagents used in this gel card.
• If red blood cells (pellet at the microtube bottom) are too low in concentration they become difficult to visualize, and, in certain cases, a weak positive reaction may not be detected.
• The Anti-B reagent does not react with the acquired B antigen.
• Very weak expressions of the D antigen may not be detected. The DVI epitope of the D antigen will be detected with this reagent. If the detection of weak D is required, the samples producing negative results with this Anti-D reagent should be further tested with an Anti-D reagent known to detect weak D antigen expression (i.e. IH-Anti-D (RH1) Blend).
• The performance characteristics of this product with chemically modified, frozen/thawed or enzyme treated red blood cells have not been established.

Please refer to the **IH**-Reader 24 User Manual or **IH**-1000, **IH**-500 and **IH**-Com User Manual U.S. for instrument specific assay limitations.

SPECIFIC PERFORMANCE CHARACTERISTICS

The final release testing is performed according to the product specific Standard Operating Procedures. As part of the lot release process, each lot of Bio-Rad Blood Grouping Reagents is tested against antigen positive and negative samples to ensure suitable reactivity and specificity.

Performance characteristics using the IH-1000 ◄

Testing to determine the performance characteristics of the Bio-Rad IH Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) was performed at four different US clinical sites and included patient, cord blood and donor samples. The positive and negative percent agreements were calculated for the Bio-Rad IH Blood Grouping Reagents in comparison to the FDA-licensed reference reagents.

Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL) are listed in the data table below. Note: See the **IH**-1000 User Manual U.S and **IH**-Com User Manual U.S. for more information on verification of results.

Results from Clinical Trials

Test	Negative Agreement N	Negative Agreement one-sided Exact 95% LCL	Positive Agreement N	Positive Agreement one-sided Exact 95% LCL
Anti-A	4,392	99.91% (99.79%)	2,942	99.93% (99.79%)
Anti-B	6,172	100% (99.95%)	1,161	99.83% (99.46%)
Anti-D(DVI+)	672	99.40% (98.64%)	3,169	100% (99.91%)

Agreement between the methods does not imply which method obtained the correct result. The above results do not reflect any discrepancy resolution between the methods.

Reproducibility was evaluated at two external sites and one internal site by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 1 operator x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days using the **IH**-1000 Analyzer. Reproducibility was demonstrated for the Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) within run, between runs and between sites.

A precision study was conducted internally using three reagent lots x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days using the **IH**-1000 Analyzer. Precision was demonstrated with all three lots of Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+).

Performance characteristics using the IH-500

Testing to determine the performance characteristics of the Bio-Rad IH Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) was performed at three different US clinical sites and included patient and donor samples. The positive and negative percent agreements were calculated for the Bio-Rad IH Blood Grouping Reagents in comparison to the FDA-licensed reference reagents.

Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL) are listed in the data table below. Note: See the **IH**-500 User Manual U.S. and **IH**-Com User Manual U.S. for more information on verification of results.

Results from Clinical Trials

Test	Sample types	Negative Agreement N	Negative Agreement one-sided Exact 95% LCL	Positive Agreement N	Positive Agreement one-sided Exact 95% LCL
Anti-A	Random samples	1,270	100% (99.76%)	993	100% (99.70%)
Anti-A	Known group B	255	100% (98.83%)	NA	NA
Anti-A	All samples	1,525	100% (99.80%)	993	100% (99.70%)
Anti-B	Random samples	1,914	99.95% (99.75%)	349	100% (99.15%)
Anti-B	Known group B	NA	NA	255	100% (98.83%)
Anti-B	All samples	1,914	99.95% (99.75%)	604	100% (99.51%)
Anti-D(DVI+)	Random samples	131	100% (97.74%)	691	100% (99.57%)
Anti-D(DVI+)	Known group RhD neg	255	100% (98.83%)	NA	NA
Anti-D(DVI+)	All samples	386	100% (99.23%)	691	100% (99.57%)

Agreement between the methods does not imply which method obtained the correct result. The above results do not reflect any discrepancy resolution between the methods.

Reproducibility was evaluated at three external sites by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 1 operator x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days. Reproducibility for the Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) using the **IH**-500 was demonstrated within run, between runs and between sites.

Performance characteristics for manual testing

Testing to determine the performance characteristics of the Bio-Rad IH Blood Grouping Reagents Anti-A, Anti-B and Anti-D (DVI+) was performed at five different US clinical sites and one internal site and included patient, cord blood and donor samples. The positive and negative percent agreements were calculated for the Bio-Rad IH Blood Grouping Reagents in comparison to the FDA-licensed reference reagents. Microtube results for a given reagent were combined across applicable IH-Cards.

Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL), are listed in the data table below:

Results from Clinical Trials

Test	Negative Agreement N	Negative Agreement one-sided Exact 95% LCL	Positive Agreement N	Positive Agreement one-sided Exact 95% LCL
Anti-A	1,506	100% (99.80%)	1,060	100% (99.72%)
Anti-B	1,999	99.95% (99.76%)	567	100% (99.47%)
Anti-D(DVI+)	466	99.79% (98.99%)	893	100% (99.67%)

Agreement between the methods does not imply which method obtained the correct result. The above results do not reflect any discrepancy resolution between the methods.

Reproducibility was evaluated at three external sites by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 2 operators x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days. Reproducibility for the Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) using the **IH**-Centrifuge L was demonstrated within run, between runs and between sites.

Performance characteristics using the IH-Reader 24

Testing to determine the performance characteristics of the Bio-Rad IH Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) was performed at five different US clinical sites and one internal site and included patient and donor samples. The positive and negative percent agreements were calculated for the Bio-Rad IH Blood Grouping Reagents in comparison to the FDA licensed reference reagents. Microtube results for a given reagent were combined across applicable IH-Cards.

Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL) are listed in the data table below. Note: See the **IH**-Reader 24 User Manual and **IH**-COM User Manual U.S. for more information on verification of results.

Results from Clinical Trials

Test	Negative Agreement N	Negative Agreement one-sided Exact 95% LCL	Positive Agreement N	Positive Agreement one-sided Exact 95% LCL
Anti-A	1,503	99.93% (99.68%)	1,063	99.91% (99.55%)
Anti-B	2,003	99.80% (99.54%)	563	100% (99.47%)
Anti-D(DVI+)	471	99.79% (99.00%)	888	100% (99.66%)

Agreement between the methods does not imply which method obtained the correct result. The above results do not reflect any discrepancy resolution between the methods.

Reproducibility was evaluated at three external sites by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 2 operators x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days. Reproducibility for the Blood Grouping Reagents Anti-A, Anti-B and Anti-D(DVI+) using the **IH**-Reader 24 was demonstrated within run, between runs and between sites.

For technical support or further product information, contact Bio-Rad Laboratories, Inc. at 800-224-6723.

GLOSSARY OF SYMBOLS

Symbol	Definition	Symbol	Definition
LOT	Batch Code	IVD	*In vitro* diagnostic medical device
	Caution, consult accompanying documents		Consult instructions for use.
	Manufacturer		Use by YYYY-MM-DD
	Contains sufficient quantity for <n> tests.	REF	Catalog number
	Temperature limitation	VOL	Volume

BIBLIOGRAPHY

1. John D. Roback, MD et al. Technical Manual 17th Edition, Bethesda, MA: AABB, 2011.
2. Kankura T., Kurashina S., Nakao M.: A gel filtration technique for separation of erythrocytes from human blood. J Lab Clin Med 1974;83:840-844.
3. Rouger Ph., Salmon Ch.: La pratique de l'agglutination des érythrocytes et du test de Coombs. Masson 1981.
4. Lapierre Y., Rigal D., Adam J. et al : The gel test : a new way to detect red cell antigen-antibody reactions. Transfusion 1990;30:109-113.
5. Salmon Ch., Cartron J.P., Rouger Ph.: Les groupes sanguins chez l'homme, 2e éd. Masson 1991.
6. Agre P.C., Cartron J.P.: Protein blood group antigens of the human red cell. Structure, function and clinical significance. The John Hopkins University Press 1992.
7. Third international workshop and symposium on monoclonal antibodies and related antigens. Section Rh TCB 1996;6:331-404.
8. Reid M.E., Lomas-Francis C.: The Blood Group Antigen Facts Book. Academic Press 1997.
9. Third international workshop and symposium on monoclonal antibodies and related antigens. Section ABO. TCB 1997;1:13-54.
10. Issitt P.D.: Applied Blood Group Serology. 4th ed. Miami: Montgomery Scientific Publications, 1998.

Key: **Underline** = Addition of changes ◄ = Deletion of text

Bio-Rad Medical Diagnostics GmbH
Industriestraße 1
D-63303 Dreieich, Germany