

# INSTRUCTIONS FOR USE

## Blood Grouping Reagent MTS™ A/B/D Monoclonal and Reverse Grouping Card

REF MTS080515

Rx ONLY

### Intended Use

For the performance of a forward and reverse ABO and D antigen grouping on a single Gel Card  
For use with the ID-Micro Typing System™  
For *in vitro* diagnostic use only

### Observable Indications

Drying, discoloration, bubbles, crystals, other artifacts, opened or damaged seals may indicate product alteration.

### Summary and Explanation

#### ABO

The ABO blood group system, which was the first human blood group system to be discovered by Landsteiner<sup>1</sup>, remains the most important in transfusion practice.<sup>2</sup> The ABO blood group system is unique in that a person lacking the A and/or B antigens from the red blood cells usually has antibody in the serum directed at the missing antigen or antigens. A person's blood group is determined directly by testing the red blood cells with Anti-A and Anti-B (red blood cell or forward grouping). Confirmation of the test results is provided by testing the serum with known group A<sub>1</sub> and group B red blood cells (serum or reverse grouping).

MTS™ Gel Cards containing Anti-A, Anti-B, and Anti-A,B are used to test patient or donor red blood cells for the presence or absence of the A and/or B antigens.

Testing with both Anti-A and Anti-B is necessary to determine if red blood cells possess or lack A and/or B blood group antigens. Agglutination is a positive test result indicating the presence of the corresponding antigen. Absence of agglutination is a negative test result indicating the absence of the corresponding antigen.

Anti-A,B reagent agglutinates red blood cells possessing A and/or B blood group antigens. Group O red blood cells will not react with the reagent. In addition, Anti-A,B is particularly useful in detecting some weak subgroups of A and B which may not agglutinate with Anti-A or Anti-B reagents.

The results of red blood cell grouping should be confirmed by reverse (serum) grouping, i.e., testing the individual's serum with known A<sub>1</sub> and B red blood cells.

#### D (Rh<sub>o</sub>)

The terms "Rh-positive" and "Rh-negative" refer to the presence or absence of the D (Rh<sub>o</sub>) red blood cell antigen. The D antigen is one of many that comprise the Rh blood group system. Approximately 85% of random donors have inherited the D gene and will phenotype as D-positive.<sup>1,2</sup>

Testing for the D antigen is an important laboratory routine to avoid immunization to the D antigen and to assure the identification of all recipients who should be given only D-negative blood.

The term, weak D, describes weaker forms of the D antigen, which may require an indirect antiglobulin test for their detection.<sup>3</sup> Most weak D antigen expressions will be detected as weak positive reactions with this reagent. However, the partial D<sup>VI</sup> epitope variant of the D antigen will not be detected with this monoclonal reagent.

### Principle of Procedure

The combination of the blood group antibodies incorporated into gel was first described by Dr. Yves Lapiere.<sup>3,4</sup> The ID-MTS™ Gel Test procedure is based on the principle of hemagglutination in which a red blood cell antigen will react with its corresponding antibody resulting in red blood cell agglutination. In the ID-MTS™ Gel Test, the specific antibody (Anti-A, Anti-B, or Anti-D) is incorporated into the gel. This gel has been pre-filled into the microtubes of the plastic card. As the red blood cells pass through the gel, they come in contact with the antibody. Red blood cells with the specific antigen will agglutinate when combined with the corresponding antibody in the gel during the centrifugation step.

Human serum or plasma containing a specific antibody to antigens on red blood cells react and cause the red blood cells to agglutinate. The agglutinated red blood cells are trapped in the buffered gel during centrifugation.

Strongly positive agglutination reactions produce a red line of cells layered at the top of the gel. Positive reactions will have varying degrees of visible red blood cell agglutinates suspended in the gel. Non-agglutinated cells are not trapped by the gel and will form a button of red blood cells at the bottom of the microtube.

## Reagents

Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal) and Anti-D (Monoclonal) (IgM) blood grouping reagents are provided in a final diluent contained in a buffered gel suspension. Anti-A, derived from the single cell line BIRMA-1, has been colored with FD & C Blue #1. Anti-B, derived from the single cell line LB-2, has been colored with FD & C Yellow #5

Anti-D is derived from a single cell line, MS-201, a monoclonal human IgM Anti-D secreted by a mouse/human hybridoma. These monoclonal antibodies are prepared from cell lines produced by another licensed manufacturer.

Each clone is carefully selected to ensure that it meets present potency and specificity requirements of the FDA. Anti-A clone BIRMA-1 was selected because it has not demonstrated problems relating to the B(A) phenotype. Anti-B clone LB-2 was selected because it did not react with acquired B cells.

The MTS™ Monoclonal Control is manufactured using the same diluent formula as used in the MTS™ Monoclonal Blood Grouping Cards. A positive reaction in the MTS™ Control microtube indicates a false positive reaction may have occurred in the corresponding blood grouping microtube, thus invalidating the blood grouping tests.

A buffered gel suspension is contained in two (2) microtubes of the MTS™ A/B/D Monoclonal and Reverse Grouping Card. Sodium Azide (0.1% final concentration) is added as a preservative.

## Storage Requirements

Store cards upright at 2–25 °C.

## Precautions

- Do not use beyond expiration date.
- Do not freeze or expose cards to excessive heat.
- Use reagents as furnished.

**Caution** All blood products should be treated as potentially infectious.

**Caution:** Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide buildup.

**Warning:** Once a gel card is used in testing, it may contain infectious material and should therefore be handled and disposed of as biohazard waste.

- A clear liquid layer should appear on top of the opaque gel in each microtube. Do not use gel cards if the gel matrix is absent or the liquid level in the microtube is at or below the top of the gel matrix. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts. Do not use cards if foil seals appear damaged or opened.

**Note:** Refer to ID-Micro Typing System™ Interpretation Guide<sup>6</sup> for additional information related to the visual inspection of gel cards before use.

- Do not remove foil seal until ready to use. Foil should be removed immediately before testing or within 1 hour of testing. Once opened, the gel may begin to dry out which could affect test results (refer to Limitations of the Procedure, item 2).
- After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.

**Caution:** The pipet tip should not touch the gel card. Erroneous results due to carryover may occur.

- Do not pipet by mouth. The absence of murine virus has not been determined.
- Do not use gel cards that have not been shipped in an upright position.

## Specimen Collection and Preparation

No special preparation of the patient is required prior to specimen collection. Collect all blood samples using acceptable phlebotomy techniques.

Fresh red blood cells are preferred for testing and may be collected as clotted samples or in anticoagulants. Clotted samples or those collected in ACD may be used for up to 5 days after collection. EDTA and sodium citrate should be tested within 14 days. Samples in heparin or oxalate may be used within 2 days. Donor blood collected in CPD, CPDA-1, and CP2D may be tested up to the expiration date of the unit. Blood specimens should be stored at 2–8 °C if not used immediately. Bacterial contamination of the specimen may cause false test results. Some blood samples, e.g., cord blood, can occasionally develop fibrin clots when diluted, which may interfere with the ID-Micro Typing System™. If this problem occurs, these samples should be washed to remove the clots and resuspended in MTS™ Diluent 2 PLUS.

All red blood cells must be diluted in MTS™ Diluent 2 PLUS before use.

# INSTRUCTIONS FOR USE

## Reagent Preparation

### Reagent Preparation

The gel card is provided ready to use. Each card contains monoclonal antibody, monoclonal control, and buffered gel for one forward and reverse ABO and D antigen grouping. The gel card is heat-sealed with aluminum foil to preserve the integrity of the reagents. Variations in the liquid and/or gel levels between microtubes may normally be observed. However, do not use cards if the liquid level in the microtube is at or below the top of the gel matrix (refer to Precautions).

### Test Procedures and General Instructions

The MTS™ A/B/D Monoclonal and Reverse Grouping Card allows the performance of forward and reverse ABO and D antigen grouping simultaneously on a single gel card. The Anti-A, Anti-B, Anti-D and control microtubes are used when performing ABO and D antigen forward grouping. The Buffered Gel microtubes are used when performing the ABO serum (Reverse) Grouping.

When performing forward and reverse grouping using this gel card, add serum or plasma to the reverse grouping microtubes first then prepare the red blood cell dilution for the forward grouping in MTS™ Diluent 2 PLUS. This practice will prevent mixing of the sedimented red blood cells in the bottom of the tube with the serum or plasma.

When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer. Laboratories must follow their approved validation procedures and are advised to consult the appropriate regulatory agencies to determine validation requirements. Refer to ID-Micro Typing System™ Interpretation Guide<sup>6</sup> and ID-Micro Typing System™ Implementation Guide and Procedures<sup>7</sup> for additional information.

#### Materials Provided

Each MTS™ A/B/D Monoclonal and Reverse Grouping Card contains, sequentially, the following products:

- Anti-A (Murine Monoclonal)
- Anti-B (Murine Monoclonal)
- Anti-D (Monoclonal)(IgM)
- Monoclonal Control
- Buffered Gel
- Buffered Gel

Refer to the MTS™ Diluent 2 PLUS package insert for further details relative to products referenced but not included with the MTS™ A/B/D Monoclonal and Reverse Grouping Card.

#### Materials Required but not Provided

For manual gel card processing:

- 3% Affirmagen® Reagent Red Blood Cells
- 0.8% Affirmagen® Reagent Red Blood Cells
- 0.8% Affirmagen® 3 Reagent Red Blood Cells
- Quality Control Material known to give the appropriate positive and negative test results for each reagent requiring quality control. Examples include, but are not limited to, AlbaQ-Chek® Simulated Whole Blood Controls.
- Dispenser pipet capable of delivering 0.5 mL
- MTS™ Diluent 2 PLUS
- Pipet: 10 to 12.5 µL, 25 µL and/or 50 µL
- Pipet Tips
- MTS™ Centrifuge or ORTHO™ Workstation
- Test Tubes
- Marking Pen

For automated gel card processing with the ORTHO VISION™ Analyzer or ORTHO VISION™ Max Analyzer:

- 0.8% Affirmagen® Reagent Red Blood Cells
- AlbaQ-Chek® Simulated Whole Blood Controls
- MTS™ Diluent 2 PLUS
- ORTHO VISION™ Analyzer and associated Reference Guide (J40050)
- ORTHO VISION™ Max Analyzer and associated Reference Guide (J55656)

#### Test Procedure

1. Bring samples and reagents to room temperature (18–25 °C).
2. Visually inspect each gel card before use. Each microtube should have a clear liquid layer on top of the opaque gel.

**Caution:** Do not use gel cards if the gel matrix is absent or if the liquid level in the microtube is at or below the top of the gel matrix. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts. Do not use cards if foil seals appear damaged or opened.

**INSTRUCTIONS FOR USE****Interpretation of Results**

**Note:** Refer to ID-Micro Typing System™ Interpretation Guide<sup>6</sup> for additional information related to the visual inspection of gel cards before use.

3. Label the gel card with the appropriate sample identification.
4. Remove the foil seal from the MTS™ Gel Card or from the individual microtubes to be used for testing. After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.

**Note:** Foil should be removed immediately before testing or within 1 hour of testing. Once opened, the gel may begin to dry out which could affect test results (refer to Limitations of the Procedure, item 2).

5. Add 50 µL of each of the 0.8% suspensions of reagent A<sub>1</sub> and B red blood cells to the labeled Buffered Gel microtubes. It is not necessary that the red blood cells come into contact with the gel.

**Caution:** The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.

6. Add 50 µL of serum or plasma to the Buffered Gel microtubes.

**Caution:** The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.

7. Dilute the donor or patient red blood cells to 4% ± 1% in MTS™ Diluent 2 PLUS (e.g., deliver 0.5 mL of MTS™ Diluent 2 PLUS into a test tube and pipet 50 µL whole blood or 25 µL packed red blood cells into the diluent). Mix gently to resuspend.
8. Add 10–12.5 µL of 4% ±1% red blood cells diluted in MTS™ Diluent 2 PLUS to the Anti-A, Anti-B, Anti-D and Control microtubes.

**Caution:** The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.

9. Centrifuge the gel card(s) in the MTS™ Centrifuge or ORTHO™ Workstation at the preset conditions installed by the manufacturer.
10. After centrifugation, remove the gel card(s) from the centrifuge. Observe, read macroscopically the front and back of each microtube for agglutination and/or hemolysis and record reactions. See Diagram 1. If either side of the microtube is positive, the reaction is to be considered positive.

**Interpretation of Results**

Refer to ID-Micro Typing System™ Interpretation Guide<sup>6</sup> for additional information.

**Negative Result**—No agglutination and no hemolysis of the red blood cells and complete sedimentation of all cells in the bottom of the microtube is a negative result.

**Note:** In instances where confirmation of D-negative antigen status is required; negative D reactions obtained with the MTS™ Anti-D (Monoclonal) (IgM) Card should be retested with an Anti-D reagent licensed for antiglobulin phase testing.

**Positive Result**—Agglutination and/or hemolysis of the red blood cells is a positive test result. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few cells may form a button in the bottom of the microtube in some positive reactions.

**Note:** A very weak reaction on one or both sides of the microtube is not an expected result. It may indicate that a false positive or a very weak/partial expression of the antigen is present. Further investigation of this cell should be performed before the ABO and Rh status is determined.

This product does not contain ingredients that enhance spontaneous agglutination of immunoglobulin-coated red blood cells, but a false positive test result may still 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 MTS™ Monoclonal Blood Grouping Reagents. If all blood grouping results for a given sample are positive, a control will be necessary to rule out false positive reactions due to spontaneous agglutination of the red blood cells. If the control test is positive, the test cells should be washed several times in warm saline and retested.<sup>5</sup> 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. Laboratories are advised to consult their approved procedures.

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## Stability of Reaction

### Reaction Grading Guide (Use in conjunction with Diagram 1)

<b>0 Negative</b>	Unagglutinated red blood cells form a well-defined button at the bottom of the microtube.
<b>1+ Reaction</b>	Red blood cell agglutinates are observed predominantly in the lower half of the gel microtube. Unagglutinated red blood cells form a button in the bottom of the microtube.
<b>2+ Reaction</b>	Red blood cell agglutinates are dispersed throughout the length of the gel microtube. Few unagglutinated red blood cells may be observed in the bottom of the microtube.
<b>3+ Reaction</b>	The majority of red blood cell agglutinates are trapped in the upper half of the gel microtube.
<b>4+ Reaction</b>	Solid band of red blood cell agglutinates on top of the gel. A few agglutinates may filter into the gel but remain near the predominant band.
<b>Mixed Field</b>	Red blood cell agglutinates at the top of the gel or dispersed throughout the gel microtube accompanied by a button of negative red blood cells in the bottom of the microtube. See Note below.

**Note:** Caution must be taken in interpreting a reaction as mixed field. Additional patient history and testing will be necessary for resolution. However, not all mixed cell situations have a sufficient minor population to be detected.

**Caution:** Clots, particulates or other artifacts may cause some red blood cells to be entrapped at the top of the gel that may cause an anomalous result in a negative test (refer to Limitations of the Procedure, item 13).

Diagram 1: Examples of Reaction Grades



**Note:** Serum grouping tests (except those on infants) performed in conjunction with cell grouping should always agree. Discrepancies between serum and cell grouping should be resolved before determination of the blood group.

Expected reactions with Anti-A, Anti-B, and Anti-D reagents, and reverse grouping with A<sub>1</sub> and B cells with proper interpretation are shown in the following table.

Forward Grouping				Reverse Grouping		Interpretation	
Anti-A Microtube	Anti-B Microtube	Anti-D Microtube	Control Microtube	Buffered Gel Microtube with A <sub>1</sub> Cells	Buffered Gel Microtube with B Cells	Blood Group	
						ABO	D
0	0	+	0	+	+	O	Positive
0	0	0	0	+	+	O	Negative
+	0	+	0	0	+	A	Positive
+	0	0	0	0	+	A	Negative
0	+	+	0	+	0	B	Positive
0	+	0	0	+	0	B	Negative
+	+	+	0	0	0	AB	Positive
+	+	0	0	0	0	AB	Negative

- If the Control microtube is positive, the results cannot be used.
- If the Forward and Reverse Grouping do not give concordant results, further investigation and testing should be performed to verify the correct ABO Grouping.
- Weak expressions of the A or B antigen may not be detected. Improved reactivity with these weak antigen expressions may be obtained by including the MTS™ Anti-A,B (Murine Monoclonal Blend) Cards in your testing.
- Very weak expressions of the D antigen may not be detected. The D<sup>VI</sup> epitope expression of the D antigen is not detected with this reagent.

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## Stability of Reaction

### Stability of Reaction

For best results, it is recommended that reactions should be read immediately following centrifugation. Interpretation may be affected by the drying out of the gel, hemolysis of the red blood cells, and slanting of the reaction patterns due to storage in a non-upright position. Reactions stored in the refrigerator (2–8 °C) and effectively protected from evaporation were able to be interpreted for more than 14 days. Gel cards should not continue to 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 have an effect on how long cards can be interpreted before red blood cells will start to hemolyze. The presence of sodium azide in the gel may cause the red blood cells to become darker in color over time. This darkening does not interfere with the test result.

### Quality Control

To confirm the reactivity and specificity of the microtubes containing Anti-A and Anti-B, it is recommended that each lot of cards be tested each day of use with antigen positive and antigen negative red blood cells. If available, antigen positive red blood cells that exhibit weakened expression of the antigen should be used, e.g., A<sub>2</sub>B cells. Alternately, red blood cells possessing a single dose of the antigen are acceptable.

To confirm the reactivity and specificity of the microtubes containing Anti-D, it is recommended that each lot of gel cards be tested on each day of use with D-positive or weak D-positive, and D-negative red blood cells. Alternately, red blood cells possessing a single dose of the antigen are acceptable.

Reagents can be considered to be satisfactory if only antigen-positive cells are agglutinated.

A control test to detect spontaneous agglutination of immunoglobulin-coated cells as a source of false positive test results is not essential in routine testing with MTS™ Monoclonal Blood Grouping Cards, because these are prepared in a low protein diluent that does not potentiate this phenomenon. The use of a control test may be appropriate in certain situations, as discussed in the Interpretation of Results section.

To confirm the reactivity of the microtubes containing MTS™ Buffered Gel, it is recommended that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red blood cells. Reactivity must be present with the positive sample only.

### Limitations of the Procedure

Refer to the ID-Micro Typing System™ Interpretation Guide<sup>6</sup> for additional information.

1. False positive or false negative test results may occur from bacterial or chemical contamination of test materials, aged blood specimens, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples.
2. False positive results may occur if a card that shows signs of drying is used in testing.
3. Proper centrifuge calibration is particularly important to the performance of the MTS™ Gel Cards. The MTS™ Centrifuge, ORTHO™ Workstation, ORTHO VISION™ Analyzer and ORTHO VISION™ Max Analyzer have been exclusively designed to provide the correct time, speed and angle.
4. Red blood cells must be diluted to 4% ± 1% in MTS™ Diluent 2 PLUS before addition to the microtubes. Variations in red blood cell concentration can markedly affect the sensitivity of test results<sup>5</sup>. If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in the antigen/antibody ratio. In addition, cells may fail to completely migrate to the bottom of the microtube and could cause a false positive interpretation. When red blood cells are too low in concentration, they become difficult to visualize, and, in extreme cases, a weak positive can fail to be detected.
5. Aged or hemolyzed blood may yield weaker reactions than those obtained with fresh red blood cells.
6. Strict adherence to the procedures and recommended equipment is essential.
7. Rouleaux caused by serum or plasma with abnormally high concentrations of protein (such as in patients with multiple myeloma or Waldenstrom's macroglobulinemia or from patients who have received plasma expanders of high molecular weight) may infrequently cause difficulties in ID-MTS™ Gel Test interpretation.<sup>6</sup> False positives results or hazy reactions may occur with these samples but are rare. If false positive reactions (e.g., rouleaux, cells coated with immunoglobulins, etc.) occur in the control gel, the blood group cannot be established. Additional testing will be necessary to resolve this false positive reaction. If the control test is positive, the test cells should be washed several times in warm saline and retested.<sup>5</sup> If the control test again gives a positive reaction, a valid interpretation of the results obtained cannot be made. Laboratories are advised to consult their approved procedures.
8. Some weak subgroups of the A and B antigen may not be detected by these MTS™ Anti-A and Anti-B reagents. The use of the MTS™ Anti-A,B (Murine Monoclonal Blend) Card may better detect these weak antigens. Very weak expressions of the D antigen may also not be detected. The partial D<sup>VI</sup> epitope variant of the D antigen has not been found positive with this reagent. Other rare cells with very low copy numbers of the D antigen may need to be tested with antiglobulin and will be negative with this Anti-D reagent.
9. Antibodies to preservatives, medications, disease states, Wharton's jelly, and/or cross-contamination of reaction microtubes may cause false positive reactions.
10. Occasionally, specimens showing incomplete clotting or excess particulates may need to be washed prior to testing.
11. Suppressed or diminished expression of certain blood group antigens may give rise to false negative reactions. For this reason, caution should always be exercised when assigning the ABO phenotype. The results of forward grouping (red blood cell) testing should be confirmed by reverse grouping (serum) testing.

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## Specific Performance Characteristics

12. In some patients (e.g., newborns, elderly or immunocompromised patients) the expected ABO antibodies may be weak or missing. For any recipient whose ABO group cannot be accurately determined, group O red blood cells should be considered as a transfusion alternative.
13. Anomalous results may be caused by fibrin or other particulate matter in blood samples that could stick to the sides of the microtube.
14. The interpretation of reactions obtained when testing infant blood may be complicated by the fact that the infant's serum does not necessarily contain antibody for any antigen absent from the cells, and passive anti-A and/or Anti-B from the mother's circulation may yield conflicting reactions when tests are performed on cord blood specimens. Cord blood specimens may also give weaker than normal reactions in the cell grouping test. Imperfect development of the ABH antigens at birth may lead to false negative results, particularly with Anti-A reagents.
15. When using automated instruments, refer to the limitations contained in the operator's manual provided by the device manufacturer.

## Specific Performance Characteristics

Each lot of MTS™ Blood Grouping Reagents meets FDA requirements. The reactivity and identity of each lot is demonstrated in tests with the recommended procedure using cells from different donors. The specificity of the source murine monoclonal antibodies used in the manufacture of these products has been demonstrated using a panel of cells that lack the antigen against which the reagent is directed. Specificity test results submitted to the FDA for release of product will be furnished upon request.

Testing performed prior to lot release includes evaluation against at least 10 red blood cell samples positive for the relevant antigen in order to assure adequate reactivity. Each lot of Monoclonal Anti-A is tested with at least 3 examples of cells with the A<sub>2</sub>B phenotype. Some weak subgroups of the A or B antigen will not be detected by gel cards containing Monoclonal Anti-A, Anti-B and Anti-A,B gel. MTS has tested some weak B antigens that gave negative results with Monoclonal Anti-B gel.

Very weak expressions of D may not be detected by the MTS™ Anti-D (Monoclonal) (IgM) Card. The partial D<sup>VI</sup> epitope variant of the D antigen will not be detected with this reagent.

### Performance Characteristics on ORTHO VISION™ Analyzer

Method comparison testing was performed at five sites (four external and one internal site), that routinely perform immunohematology testing. Patient specimens were tested on the ORTHO VISION™ Analyzer and the ORTHO ProVue® Analyzer. Individual microtube results were evaluated for agreement between analyzers. For microtube reaction grades to be in agreement between the analyzers, microtube reaction grades were either both negative or both positive (1+ through 4+) depending on the antigen being tested. Microtube results for a given test were combined across applicable ID-MTS™ Gel Cards. The combined results from all sites are summarized in the following table.

Test	Total			Positive			Negative		
	N	% Agreement	Lower Bound of One Sided 95% CI	N	% Agreement	Lower Bound of One Sided 95% CI	N	% Agreement	Lower Bound of One Sided 95% CI
Anti-A	5083	99.9%	99.7%	2154	100.0%	99.9%	2929	99.8%	99.6%
Anti-B	5083	100.0%	99.9%	893	100.0%	99.7%	4190	100.0%	99.9%
Anti-D	6255	100.0%	100.0%	5279	100.0%	99.9%	976	100.0%	99.7%
A1 Cells	4885	99.7%	99.6%	2806	99.7%	99.4%	2079	99.8%	99.6%
B Cells	4885	99.9%	99.7%	4035	99.9%	99.8%	850	99.6%	99.1%

Agreement between two methods does not indicate which method gave the correct results.

**Performance Characteristics on ORTHO VISION™ Max Analyzer**

Method comparison testing was performed at five sites (four external and one internal site), that routinely perform immunohematology testing. Patient specimens were tested on the ORTHO VISION™ Max Analyzer and the ORTHO VISION™ Analyzer. Individual microtube results were evaluated for agreement between analyzers. For microtube reaction grades to be in agreement between the analyzers, microtube reaction grades were either both negative or both positive (1+ through 4+) depending on the antigen being tested. Microtube results for a given test were combined across applicable ID-MTS™ Gel Cards. The combined results from all sites are summarized in the following table.

Test	Total			Positive			Negative		
	N	% Agreement	Lower Bound of One Sided 95% CI	N	% Agreement	Lower Bound of One Sided 95% CI	N	% Agreement	Lower Bound of One Sided 95% CI
Anti-A	5127	100.0%	99.9%	2224	100.0%	99.9%	2903	100.0%	99.9%
Anti-B	5127	100.0%	99.9%	802	100.0%	99.6%	4325	100.0%	99.9%
Anti-D	6406	100.0%	100.0%	5406	100.0%	99.9%	1000	100.0%	99.7%
A1 Cells	5105	100.0%	99.9%	2898	100.0%	99.9%	2207	100.0%	99.9%
B Cells	5105	99.9%	99.8%	4299	100.0%	99.9%	806	99.6%	99.0%

























Agreement between two methods does not indicate which method gave the correct results.

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**Glossary of Symbols**

The following symbols may have been used in the labeling of this product.

	Do Not Reuse		Contains Sufficient for "n" Tests		Fragile, Handle with Care.
	Use by or Expiration Date (Day-Month-Year)		In vitro Diagnostic Medical Device		Keep Dry
	Batch Code or Lot Number		Upper Limit of Temperature		This end up
	Serial Number		Lower Limit of Temperature		Do Not Use if Damaged
	Catalog Number or Product Code		Temperature Limitation		Cards
	Caution		Consult instructions for use		Concentration
	Date of Manufacture		Biological Risks		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations.
	Manufacturer		Health Hazards		
	Authorized Representative in the European Community				



# INSTRUCTIONS FOR USE

## Summary of Revisions

### Summary of Revisions

Date of Revision	Version	Section	Description of Technical Changes*
2016-06-09	3.0	Precautions	<ul style="list-style-type: none"> <li>Added sodium azide Caution statement.</li> </ul>
		Materials Required but not Provided	<ul style="list-style-type: none"> <li>Added ORTHO™ Workstation.</li> <li>Added ORTHO VISION™ Max Analyzer.</li> </ul>
		Test Procedure	<ul style="list-style-type: none"> <li>Step 9: added ORTHO™ Workstation.</li> </ul>
		Limitations of the Procedure	<ul style="list-style-type: none"> <li>Item 3: added ORTHO™ Workstation and ORTHO VISION™ Max Analyzer.</li> </ul>
		Specific Performance Characteristics	<ul style="list-style-type: none"> <li>Reformatted section.</li> <li>Added section for ORTHO VISION™ Max Analyzer.</li> </ul>
		Glossary of Symbols	<ul style="list-style-type: none"> <li>Updated to add symbols.</li> </ul>
		Back Page	<ul style="list-style-type: none"> <li>Updated copyright to add date range.</li> </ul>
2015-06-01	2.0	Header	<ul style="list-style-type: none"> <li>Added Rx ONLY statement.</li> </ul>
		Materials Required but not Provided	<ul style="list-style-type: none"> <li>Reorganized section. Added RRBC and QC material for manual and automated testing and ORTHO VISION™ for automated testing.</li> </ul>
		Limitations of the Procedure	<ul style="list-style-type: none"> <li>Added ORTHO VISION™ Analyzer to item 3.</li> <li>Added item 15, referring user to automated instrument user guide for instrument specific limitations.</li> </ul>
		Performance Characteristics on ORTHO VISION™ Analyzer	<ul style="list-style-type: none"> <li>New section.</li> </ul>
2010-06-09	1.1	All	<ul style="list-style-type: none"> <li>Applied trademark symbol correctly. Corrected the trademark statement at the end of the document.</li> </ul>
		Precautions	<ul style="list-style-type: none"> <li>New bullet: After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.</li> </ul>
		Test Procedure	<ul style="list-style-type: none"> <li>Addition to step 4: After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.</li> </ul>
		Interpretation of Results	<ul style="list-style-type: none"> <li>Moved sentence to end of paragraph: Laboratories are advised to consult their approved procedures.</li> </ul>
2008-12-11	1.0		Consolidates and replaces PK No. 229-A Revision Date 02-02-07, PK No. 123-B Revision date: 12-27-05, PK. No. 124-B Revision date: 03-10-06, PK No. 126-A Revision date: 06-16-06 and PK No. 228-A Revision Date: 04-18-06 with changes below.
		Header	<ul style="list-style-type: none"> <li>New product code: MTS080515.</li> </ul>
		Intended Use	<ul style="list-style-type: none"> <li>New section; previously part of the header.</li> </ul>
		All	<ul style="list-style-type: none"> <li>Updated and standardized product references.</li> <li>Added references to ID-Micro Typing System™ Interpretation Guide and ID-Micro Typing System™ Implementation Guide and Procedures.</li> <li>Deleted duplicate statements.</li> <li>Minor editorial changes without affect on technical content.</li> </ul>
		Principle of Procedure	<ul style="list-style-type: none"> <li>Added 2<sup>nd</sup> paragraph.</li> </ul>
		Precautions	<ul style="list-style-type: none"> <li>Added Note to refer to ID-Micro Typing System™ Interpretation Guide.</li> <li>Further clarified storage requirement by adding statement not to use gel cards that were not shipped in an upright position.</li> </ul>
		Test Procedures and General Instructions	<ul style="list-style-type: none"> <li>Added statement to refer to the ID-Micro Typing System™ Interpretation Guide.</li> </ul>
		Test Procedure	<ul style="list-style-type: none"> <li>New section.</li> </ul>

# INSTRUCTIONS FOR USE

## Summary of Revisions

Date of Revision	Version	Section	Description of Technical Changes*
		Interpretation of Results	<ul style="list-style-type: none"> <li>Corrected typographical error in 2+ reaction definition, by replacing “agglutinates” with “few unagglutinated red blood cells”.</li> <li>Expanded advisory recommending laboratories perform additional testing and consult their approved procedures to resolve false positive control reactions.</li> <li>Replaced drawing of range of reactions with photograph.</li> </ul>
		Quality Control	<ul style="list-style-type: none"> <li>Edited “gel cards” to “microtubes”.</li> <li>Deleted duplicate statements already included in Interpretation of Results section requiring additional testing and use of the control to resolve false positive reactions.</li> </ul>
		Limitations of Procedure	<ul style="list-style-type: none"> <li>Expanded statement regarding rouleaux and added advisory statement for laboratories to consult their approved procedures.</li> </ul>
		Specific Performance Characteristics	<ul style="list-style-type: none"> <li>Changed “Anti-A”, “Anti-A, Anti-B and Anti-A,B gel” and “Anti-B” to “Monoclonal Anti-A”, “Monoclonal Anti-A, Anti-B and Anti-A,B gel” and “Monoclonal Anti-B”.</li> </ul>
		Bibliography	<ul style="list-style-type: none"> <li>Added ID-Micro Typing System™ Interpretation Guide and ID-Micro Typing System™ Implementation Guide and Procedures.</li> <li>Updated editions and dates of references listed as appropriate.</li> </ul>
		Glossary of Symbols	<ul style="list-style-type: none"> <li>Added section.</li> </ul>
		Summary of Revisions	<ul style="list-style-type: none"> <li>Added section.</li> </ul>

\* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

Made under one or more of the following U.S. Patents:

5,338,689

5,460,940

5,512,432

5,863,802

6,114,179

Other Patents Pending

Micro Typing Systems, Inc.

U.S. License No. 1177



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