Micro Typing Systems, Inc.

INSTRUCTIONS FOR USE

Blood Grouping Reagent
MTS™ Monoclonal Rh Phenotype Card

REF MTS080024

Rx ONLY

Intended Use

For the detection of D, C, E, c and e antigens on red blood cells

For *in vitro* diagnostic use only

For use with the ID-Micro Typing System™

Contains: 6 tests per card

Observable Indications

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

Summary and Explanation

The Rh blood group system comprises 48 antigens or antigen complexes, each capable of being defined by its own specific antibody.[1] The five most important antigens in the Rhesus system are D (Rh_o), C (rh'), E(rh''), c(hr') and e(hr''). The frequencies of each of these antigens in the Caucasian population are as follows:

Antigen Nomenclature		Frequency %[2]	
Fisher-Race	**Weiner**	**Rosenfield**	**Caucasian**
D	Rh_o	Rh1	85
C	rh'	Rh2	70
E	rh''	Rh3	30
c	hr'	Rh4	80
e	hr''	Rh5	98

The terms "Rh-positive" and "Rh-negative" refer to the presence or absence of the D (Rh_o) 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.[2,3]

Unlike the ABO system, antibodies of the Rh system do not occur regularly in the serum, but are almost always the result of exposure to the antigen during pregnancy or through transfusion. 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.[4] Most weak D antigen expressions will be detected as weak positive reactions with this reagent. However, the partial D^{VI} 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 Lapierre.[5,6] The ID-MTS™ Gel Test 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 (e.g. Anti-D, Anti-C, Anti-E, Anti-c, Anti-e) 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. 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 in the bottom of the microtube.

Reagents

Monoclonal antibodies of appropriate specificity are provided in a final diluent containing a buffered gel suspension.

All of these antibodies are monoclonal human IgM antibodies secreted by a mouse/human hybridoma. Anti-D is derived from a single cell line MS-201, Anti-C is from a single cell line MS-24, Anti-E is from a blend of 2 cell lines MS-258 and MS-260, Anti-c is from a single cell line MS-33 and Anti-e is from a blend of 3 cell lines MS-16, MS-21 and MS-63, which have been carefully selected to ensure that they will meet present potency and specificity requirements of the FDA when incorporated into the ID-MTS™ Gel Test.

The formulated diluent and gel used in the control microtube is identical to that used in the manufacture of the blood grouping reagent. The monoclonal antibodies are prepared from a cell line produced by another licensed manufacturer.

Sodium Azide (0.1% final concentration) is added as a preservative.

Storage requirements

Store cards upright at 1–8 °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 the gel card is used in testing, it may contain infectious material and should therefore be handled and disposed of as hazardous 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 gel cards if foil seals appear damaged or opened.

Note:	Refer to ID-Micro Typing System™ Interpretation Guide[7] 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 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 EDTA or ACD may be used for up to 5 days after collection. 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.

Reagent Preparation

The gel card is provided ready to use. Each microtube contains monoclonal antibody or control suitable for one test. 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 gels cards if the liquid level in the microtube is at or below the top of the gel matrix (refer to Precautions).

Procedure

The procedure identified below is for manual testing only. 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[7] and ID-Micro Typing System™ Implementation Guide and Procedures[8] for additional information.

Materials Provided

Each MTS™ Monoclonal Rh Phenotype Card contains, sequentially, the following monoclonal products: Anti-D, Anti-C, Anti-E, Anti-c, Anti-e, and Control.

Materials Required but not Provided

For manual gel card processing:

- 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.
- MTS™ Diluent 2 PLUS
- Pipet: 10 to 12.5 µL, 25 µL and/or 50 µL
- Pipet Tips
- Test Tubes
- Marking Pen
- MTS™ Centrifuge or ORTHO™ Workstation
- Dispenser pipet capable of delivering 0.5 mL

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

- 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 gel cards before use. Each microtube should have a clear liquid layer on top of opaque gel.

Caution:	**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[7] for additional information related to the visual inspection of gel cards before use.

3. 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.
4. Label the gel card appropriately.
5. 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).

6. To each microtube add 10–12.5 µL of red blood cells diluted in MTS™ Diluent 2 *PLUS* (as prepared in Step 3). It is not necessary that the cells come into contact with the gel.

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

7. Centrifuge the prepared card(s) in the MTS™ Centrifuge or ORTHO™ Workstation at the preset conditions installed by the manufacturer.
8. 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[7] for additional information.

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

Note: In instances where confirmation of D-negative antigen status is required; negative D reactions obtained with the MTS™ Monoclonal Anti-D microtube 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 red blood 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 sample should be performed before the 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 should be washed several times in warm saline and retested.[3] 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.

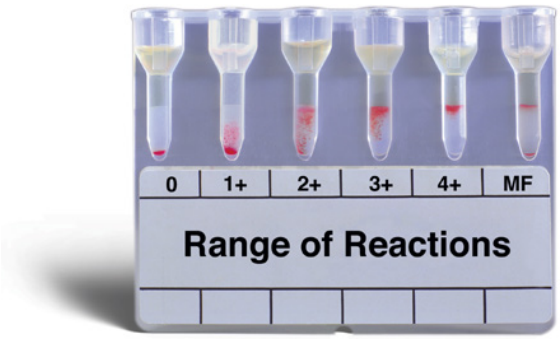
Reaction Grading Guide (Use in conjunction with Diagram 1)

0 Negative	Unagglutinated red blood cells form a well-defined button at the bottom of the microtube.
1+ Reaction	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.
2+ Reaction	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.
3+ Reaction	The majority of red blood cell agglutinates are trapped in the upper half of the gel microtube.
4+ Reaction	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.
Mixed Field	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 11).**

Diagram 1: Examples of Reaction Grades



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 MTS™ Monoclonal Rh Phenotype Card it is recommended that each lot of gel cards be tested on each day of use with antigen positive (preferable heterozygous or weak, i.e. D (D^u)) and antigen 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 agglutinations 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 under the Interpretation of Results section. A control microtube is incorporated into this MTS™ Monoclonal Rh Phenotype Card for this purpose.

Limitations of the Procedure

Refer to ID-Micro Typing System™ Interpretation Guide[7] 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 ID-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[2]. 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.[7] False positive 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 with this card. 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.[3] 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. Very weak expressions of the D, C, E, c, e antigens may not be detected. Example: cells from $r'^S r$, $R_z R_2$ or $r^y r^y$ persons may react more weakly with Anti-C than $R^1 r$ or $r'r$ red cells. The e antigen may be only weakly expressed on the red blood cells of some blacks. The partial D^{VI} 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 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. Anomalous results may be caused by fibrin or other particulate matter in blood samples that could stick to the sides of the microtube.
12. 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. Reactivity of each lot is confirmed in serological tests with cells positive for the respective Rh antigens obtained from different donors. The specificity of the source monoclonal antibodies used in the manufacture of these products has been demonstrated using a panel of cells which lack the antigen against which the reagent is directed.

Very weak expressions of D, C, E, c, e antigens may not be detected by the MTS™ Monoclonal Rh Phenotype Card. The partial D^{VI} epitope variant of the D antigen will not be detected with this Anti-D 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.

	Total			Positive			Negative		
Test	**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-D	6255	100.0%	100.0%	5279	100.0%	99.9%	976	100.0%	99.7%
Anti-C	1301	100.0%	99.8%	838	100.0%	99.6%	463	100.0%	99.4%
Anti-E	1301	100.0%	99.8%	353	100.0%	99.2%	948	100.0%	99.7%
Anti-c	1301	100.0%	99.8%	1045	100.0%	99.7%	256	100.0%	98.8%
Anti-e	1301	100.0%	99.8%	1262	100.0%	99.8%	39	100.0%	92.6%

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.

	Total			Positive			Negative		
Test	**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-D	6406	100.0%	100.0%	5406	100.0%	99.9%	1000	100.0%	99.7%
Anti-C	1300	100.0%	99.8%	752	100.0%	99.6%	548	100.0%	99.5%
Anti-E	1300	100.0%	99.8%	440	100.0%	99.3%	860	100.0%	99.7%
Anti-c	1300	100.0%	99.8%	1006	100.0%	99.7%	294	100.0%	99.0%
Anti-e	1300	100.0%	99.8%	1072	100.0%	99.7%	228	100.0%	98.7%

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

Bibliography

1. Wagner, FF, Flagel WA. Review: the molecular basis of Rh blood group phenotypes. Immunohematology 2004; 20:23-36.
2. Issitt PD, Applied Blood Group Serology, 4th Ed. Durham, NC: Montgomery Scientific Publications, 1998.
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5. Lapierre Y et al. The gel test: a new way to detect red blood cell antigen-antibody reactions. Transfusion 1990;30: 109-113.
6. Malyska, H., Weiland D. The Gel Test. Laboratory Medicine 1994; 25:81-85.
7. ID-Micro Typing System™ Interpretation Guide (J6902201), Ortho Clinical Diagnostics
8. ID-Micro Typing System™ Implementation Guide and Procedures (J6902200), Ortho Clinical Diagnostics

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)	IVD	*In vitro* Diagnostic Medical Device		Keep Dry
LOT	Batch Code or Lot Number		Upper Limit of Temperature		This end up
SN	Serial Number		Lower Limit of Temperature		Do Not Use if Damaged
REF	Catalog Number or Product Code		Temperature Limitation		Cards
	Caution		Consult instructions for use	CONC	Concentration
	Date of Manufacture		Biological Risks		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations.
	Manufacturer		Health Hazards		
EC REP	Authorized Representative in the European Community				

Summary of Revisions

Date of Revision	Version	Section	Description of Technical Changes*
2016-06-09	3.0	Precautions	• Added sodium azide Caution statement.
		Materials Required but not Provided	• Added ORTHO™ Workstation. • Added ORTHO VISION™ Max Analyzer.
		Test Procedure	• Step 7: added ORTHO™ Workstation.
		Limitations of the Procedure	• Item 3: added ORTHO™ Workstation and ORTHO VISION™ Max Analyzer.
		Specific Performance Characteristics	• Reformatted section. • Added section for ORTHO VISION™ Max Analyzer.
		Glossary of Symbols	• Updated to add symbols.
		Back Page	• Updated copyright to add date range.
2015-06-01	2.0	Header	• Added Rx ONLY statement.
		Materials Required but not Provided	• Reorganized section. Added QC material for manual and automated testing and ORTHO VISION™ for automated testing.
		Limitations of the Procedure	• Added ORTHO VISION™ Analyzer to item 3. • Added item 12, referring user to automated instrument user guide for instrument specific limitations.
		Performance Characteristics on ORTHO VISION™ Analyzer	• New section.
2010-06-09	1.1	Precautions	• New bullet: After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.
		Test Procedure	• Addition to step 5: After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.
		Interpretation of Results	• Moved sentence to end of paragraph: Laboratories are advised to consult their approved procedures.
2009-03-09	1.0		Replaces PK No. 172-A Revision date: 03-12-07 with changes below.
		Header	• New product code: MTS080024
		Intended Use	• New section; previously included in header.
		All	• Updated and standardized product references. • Added references to ID-Micro Typing System™ Interpretation Guide and ID-Micro Typing System™ Implementation Guide and Procedures. • Deleted duplicate statements. • Minor editorial changes without affect on technical content.
		Precautions	• Further clarified storage requirement by adding statement not to use gel cards that were not shipped in an upright position.
		Procedure	• Added statement to refer to ID-Micro Typing System™ Interpretation Guide.
		Test Procedure	• Added Note to refer to ID-Micro Typing System™ Interpretation Guide.
		Reagent Preparation	• Deleted duplicate statement related to card configuration already included under Materials Provided.

Date of Revision	Version	Section	Description of Technical Changes*
		Interpretation of Results	• Corrected typographical error in 2+ reaction definition, by replacing “agglutinates” with “few unagglutinated red blood cells”. • Expanded advisory recommending laboratories perform additional testing and consult their approved procedures to resolve false positive control reactions. • Replaced drawing of range of reactions with photograph.
		Quality Control	• Deleted duplicate statements already included in Interpretation of Results section requiring additional testing and use of the control to resolve false positive reactions.
		Limitations of Procedure	• Expanded statement regarding rouleaux and added advisory statement for laboratories to consult their approved procedures.
		Bibliography	• Added ID-Micro Typing System™ Interpretation Guide and ID-Micro Typing System™ Implementation Guide and Procedures. • Updated editions and dates of references listed as appropriate.
		Glossary of Symbols	• Added section.
		Summary of Revisions	• Added section.

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

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5,338,689
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