Micro Typing Systems, Inc.

INSTRUCTIONS FOR USE

MTS™ Buffered Gel Card

REF MTS085014

Rx ONLY

Intended Use

For the detection of antibodies to 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 combination of a phosphate buffered gel incorporated into plastic cards was first described by Dr. Yves Lapierre.[1,2] This MTS™ Buffered Gel Card can be used in ABO Serum Grouping as well as direct agglutination i.e., cold and warm antibody detection.

Principle of Procedure

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 MTS™ 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

A buffered gel suspension is contained in the 6 microtubes of the MTS™ Buffered Gel 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.
- 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 the ID-MTS™ Interpretation Guide[3] 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 4).
- 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.**

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.***

- Customers who choose to use commercial antisera not licensed for use with the gel test (off-label use) must ensure that the test method is appropriate by validating its intended use.
- 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.

Serum or Plasma

Fresh serum or plasma collected with or without anticoagulants may be used for antibody detection and identification. Testing should be performed as soon as possible. Samples that cannot be tested immediately should be stored at 2–8 °C or frozen. In the case of potential recipients of blood transfusions there is an FDA requirement that the specimen should not be stored for longer than 3 days before testing.[5] AABB Standards imposes more lenient storage limits.[6]

The following blood samples can cause red blood cells to give a false positive result:

- Hemolyzed
- Grossly icteric
- Containing abnormally high concentrations of protein
- From patients who have received plasma expanders of high molecular weight.

Red Blood Cells

All red blood cells must be diluted in the appropriate MTS™ Diluent before use. Fresh red blood cells are preferred for testing and may be collected as clotted samples or in anticoagulants such as CPDA-1, CPD, ACD or EDTA. Clotted samples or those collected in EDTA or ACD may be used for up to 5 days after collection. Donor cells collected in CPDA-1 or CPD may be tested up to the expiration date of the unit. Reagent red blood cells should be used within their dating period according to the manufacturer's instructions. Blood specimens should be stored at 2–8 °C if not used immediately. 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 re-suspended in the appropriate MTS™ Diluent.

Reagent Preparation

The gel card is provided ready to use. Each microtube contains Buffered Gel 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 cards if the liquid level in the microtube is at or below the top of the gel matrix (refer to Precautions).

Procedure

The procedures identified below are 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[3] and ID-Micro Typing System™ Implementation Guide and Procedures[4].

Materials Provided

Buffered Gel is contained in the 6 microtubes of the MTS™ Buffered Gel 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
- 3% ORTHO® Pooled Screening Cells
- 0.8% ORTHO® Pooled Screening Cells
- 3% Selectogen® Reagent Red Blood Cells
- 0.8% Selectogen® Reagent Red Blood Cells
- 3% Surgiscreen® Reagent Red Blood Cells
- 0.8% Surgiscreen® Reagent Red Blood Cells
- 3% Resolve® Panel Reagent Red Blood Cells
- 0.8% Resolve® Panel 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.
- MTS™ Diluent 2

- MTS™ Diluent 2 PLUS
- Pipet: 10 to 12.5 µL, 25 µL and/or 50 µL
- Dispenser pipet capable of delivering 1.0 mL
- Pipet Tips
- Test Tubes
- Marking Pen
- MTS™ Centrifuge or ORTHO™ Workstation
- MTS™ Incubator

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

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

Test Procedure

A. Serum or Plasma ABO Grouping (Reverse Grouping)

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[3] for additional information related to the visual inspection of gel cards before use.

3. Prepare a red blood cell (A_1 and B cell) suspension of approximately 0.8% in MTS™ Diluent 2 *PLUS* (e.g., deliver 1.0 mL of MTS™ Diluent 2 *PLUS* into a test tube and pipet 10 µL packed red blood cells into the diluent), mix gently.
4. Label the gel card appropriately.
5. Remove the foil seal from the MTS™ Buffered 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 4).

6. Blood grouping should always be performed in conjunction with an MTS™ Monoclonal Control Card.
7. Add 50 µL of the red blood cell suspension into the appropriate Buffered Gel microtube. It is not necessary that the red blood cells come into contact with the gel.

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

8. Add 50 µL of serum or plasma to the appropriate microtubes containing red blood cells.
9. Centrifuge the prepared cards 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. If either side of the microtube is positive, the reaction is to be considered positive. See Diagram 1.

B. Antibody Testing (For Cold Agglutinins, Room Temperature, 37 °C and Enzyme Treated Red Blood Cells)

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[3] for additional information related to the visual inspection of gel cards before use.

3. All red blood cells (commercial or fresh) must be diluted in MTS™ Diluent 2 to approximately 0.8%.

Note:	Enzyme treated red blood cells may be used after being washed and re-suspended in MTS™ Diluent 2 *PLUS*.

4. Label the MTS™ Buffered Gel Card appropriately.
5. Remove the foil seal from the MTS™ Buffered 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 4).

6. Add 50 µL of the red blood cell suspension into the appropriate Buffered Gel microtube.

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

7. Add 25 µL of serum, plasma or commercial grouping antisera approved for use with the MTS™ Buffered Gel Card to each microtube in the MTS™ Buffered Gel Card. The mixture may or may not touch gel suspension.

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

8. Incubate the MTS™ Buffered Gel Card at the desired time and temperature.
9. After incubation, centrifuge the prepared cards in the MTS™ Centrifuge or ORTHO™ Workstation at the preset conditions installed by the manufacturer.
10. After centrifugation, remove the MTS™ Buffered Gel Cards, observe, read macroscopically the front and back of each microtube for agglutination or hemolysis and record reactions. If either side of the microtube is positive, the reaction is to be considered positive. See Diagram 1.

Interpretation of Results

Refer to ID-Micro Typing System™ Interpretation Guide[3] 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.

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. Hemolysis may occur due to complement-mediated lysis of the red blood cells. If the quantity of red blood cells remaining is reduced to a level that interferes with the interpretation of the test, the test should be repeated using anticoagulated plasma.

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 antibody status is determined.

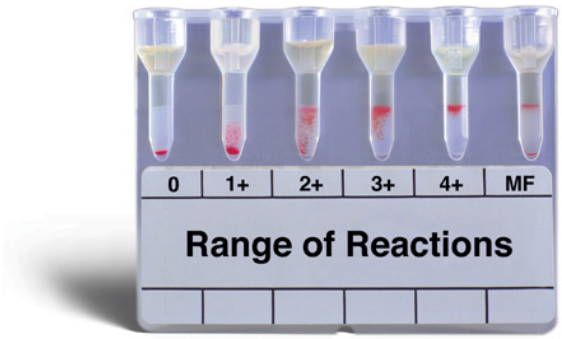
Reaction Grading Guide (Use in conjunction with Diagram 1)

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 14).**

Diagram 1: Examples or Reaction Grades



Interpretation of ABO Serum or Plasma Grouping Results[7]

Reagent Red Blood Cells A_1	Reagent Red Blood Cells B	ABO Blood Group
+	+	O
+	-	B
-	+	A
-	-	AB

Note:	ABO serum or plasma tests should always be performed as an adjunct to ABO red blood cell grouping tests. Any discrepancies between the cell and sera group results must be resolved before the ABO group is assigned. Decreased antibody activity may be seen in disease states, elderly or infants. Umbilical serum may not give reliable results.

Stability of Reaction

For best results, it is recommended that results should be read immediately following centrifugation. Interpretations 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 ^{o}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 red blood cell hemolysis is observed. The age and condition of the red blood cells, as well as the temperature at which the card is stored, will have an effect on how long gel 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 with the passage of time. This darkening does not interfere with the test result.

Quality Control

To confirm the reactivity of the MTS™ Buffered Gel Card, 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 ID-Micro Typing System™ Interpretation Guide[3] **for additional information.**

1. Strict adherence to the procedures and recommended equipment is essential.
2. Proper centrifuge calibration is particularly important to the performance of the MTS™ Buffered Gel Card. 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.
3. False positive or false negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples. Should extended delays in testing occur, red blood cells may lose antigenicity; hemolyze and may have elution of antibodies from in vivo coated red blood cells.

4. False positive results may occur if a card that shows signs of drying is used in testing.
5. Red blood cells must be diluted in the appropriate MTS™ Diluent at the proper concentration before addition to the MTS™ Buffered Gel Card. Variations in cell concentration can markedly affect the sensitivity of test results. When cells 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 cells are too low in concentration they become difficult to visualize and in extreme cases a weak positive can fail to be detected.
6. ABO Serum or plasma tests should always be performed as an adjunct to ABO cell grouping tests. Any discrepancies between the cell and sera grouping results must be resolved before the ABO grouping is assigned.
7. Customers who choose to use commercial antisera not licensed for use with the gel test (off-label use) must ensure that the test method is appropriate by validating its intended use.
8. Hemolyzed and grossly icteric blood samples may be difficult to visually interpret in the ID-Micro Typing System™ and therefore test results should not be used. Grossly lipemic samples containing particulates that clog the gel as indicated by diffuse blotches of red blood cells may be clarified by centrifugation or filtration and retested.
9. 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 Gel Test™ interpretation.[3] False positive results or hazy reactions may occur with these samples but are rare. Samples exhibiting rouleaux should be washed several times in saline and retested.[7] Laboratories are advised to consult their approved procedures.
10. Cold agglutinin testing may be done by pre-chilling and incubating cards at 2–8 °C. However, these reactions will be warmed during the centrifugation, which may result in the weakening of cold agglutination reactions.
11. The MTS™ Buffered Gel Card is not intended for use as the red blood cell control test with MTS™ Blood Grouping Cards.
12. Antibodies to preservatives, medications, disease states, Wharton's jelly, and/or cross-contamination of reaction microtubes may cause false positive reactions.
13. Occasionally, specimens showing incomplete clotting or excess particulates may need to be centrifuged to clarify or red blood cells washed prior to testing.
14. Anomalous results may be caused by fibrin or other particulate matter in blood samples that could stick to the sides of the microtube.
15. Decreased antibody activity may be seen in disease states, elderly or infants. Umbilical serum may not give reliable results.
16. Aged or hemolyzed blood may yield weaker reactions than those obtained with fresh red blood cells.
17. 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™ Buffered Gel Card is tested using the recommended procedure with known positive and negative serum and cells to assure reactivity and specificity.

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. Method comparison testing for Panel C Ficin was performed at one study site. 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 antibody 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**
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%
Panel C Ficin 37C	173	99.4%	97.3%	33	97.0%	86.4%	140	100.0%	97.9%

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 antibody 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**
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%
Panel C Ficin 37C	2334	99.4%	99.1%	569	98.6%	97.5%	1765	99.7%	99.4%

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

Sample interpreted results were also evaluated for agreement between analyzers. For sample interpreted results to be in agreement between the analyzers, interpretations were either both negative or both positive results. 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**
Antibody Identification	206	98.5%	96.3%	109	100.0%	97.3%	97	96.9%	92.2%

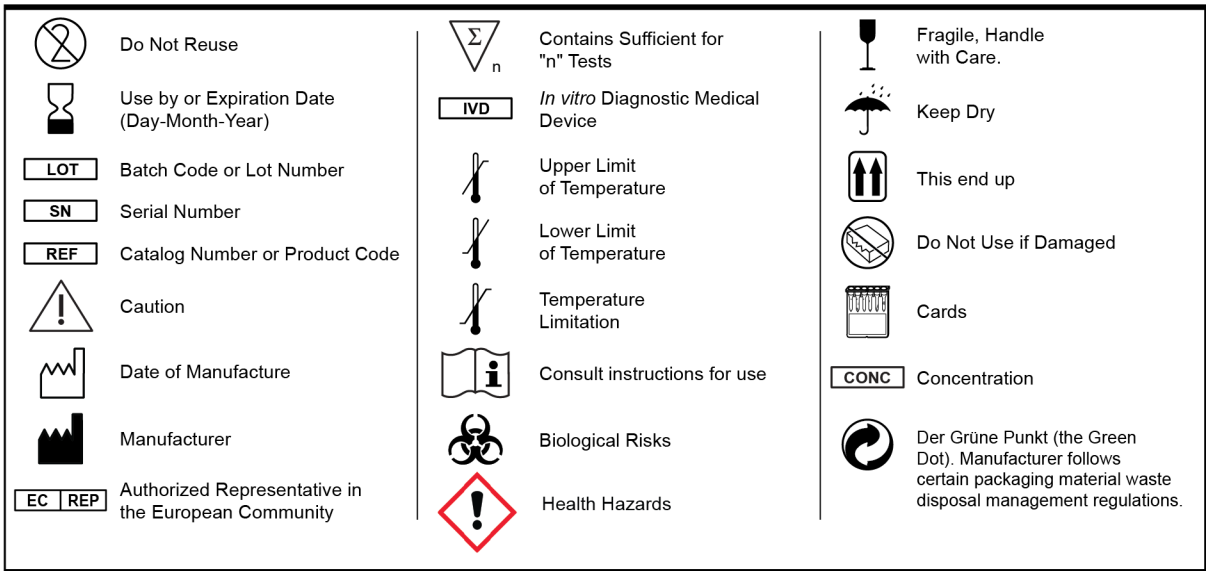
Agreement between two methods does not indicate which method gave the correct results.

Bibliography

1. Y. Lapierre et al. The gel test: a new way to detect red cell antigen-antibody reactions. Transfusion 1990;30: 109-113.
2. Malyska, H., Weiland, D. The Gel Test. Laboratory Medicine 1994;25: 81-85.
3. ID-Micro Typing System™ Interpretation Guide (J6902201), Ortho Clinical Diagnostics.
4. ID-Micro Typing System™ Implementation Guide and Procedures (J6902200), Ortho Clinical Diagnostics.
5. Code of Federal Regulations; FDA, April 1, 2007; 21 CFR 606.151 (b).
6. Widman FK. ed Standards for blood banks and transfusion services. 25th ed. Bethesda 2008; American Association of Blood Banks.
7. Brecher M. (ed) Technical Manual, 16th Ed. Bethesda, MD: American Association of Blood Banks, 2008.

Glossary of Symbols

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



Summary of Revisions

Date of Revision	Version	Section	Description of Technical Changes*
2016-10-05	3.0	Precautions	• Added sodium azide Caution statement.
		Materials Required but not Provided	• Added ORTHO™ Workstation. • Added ORTHO VISION™ Max Analyzer.
		Test Procedure	• Serum or Plasma ABO Grouping o Step 9: added ORTHO™ Workstation. • Antibody Testing • Step 9: added ORTHO™ Workstation.
		Limitations of the Procedure	• Item 2: added ORTHO™ Workstation and ORTHO VISION™ Max Analyzer.
		Specific Performance Characteristics	• Reformatted section. • Added section for ORTHO VISION™ Max Analyzer. o Added antibody identification test data.
		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 RRBC and QC material for manual and automated testing and ORTHO VISION™ for automated testing.
		Limitations of the Procedure	• Added ORTHO VISION™ Analyzer to item 2. • Added item 17, referring user to automated instrument user guide for instrument specific limitations.
		Performance Characteristics on ORTHO VISION™ Analyzer	• New section.
2010-06-09	1.1	All	• Applied trademark symbol correctly. Corrected the trademark statement at the end of the document.
		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. • New bullet: Customers who choose to use commercial antisera not licensed for use with the gel test (off-label use) must ensure that the test method is appropriate by validating its intended use.
		Specimen Collection and Preparation	• Modified last sentence to a bulleted format for clarity.
		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.
		Limitations of the Procedure	• New bullet: Customers who choose to use commercial antisera not licensed for use with the gel test (off-label use) must ensure that the test method is appropriate by validating its intended use.
2008-12-10	1.0		Replaces PK No. 017-E Revision date: 05-08-06 with changes below.
		Intended Use	• New section; previously part of the 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.

Date of Revision	Version	Section	Description of Technical Changes*
		Precautions	• Added Note to refer to ID-Micro Typing System™ Interpretation Guide and ID-Micro Typing System™ Implementation Guide and Procedures. • 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.
		Interpretation of Results	• Corrected typographical error in 2+ reaction definition, by replacing “agglutinates” with “few unagglutinated red blood cells”. • Replaced drawing of range of reactions with photograph. • Added definition of the mixed field reaction (included with new photograph). • Moved Interpretation of ABO Serum or Plasma Grouping results table after Diagram 1.
		Limitations of Procedure	• Added limitation 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.

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.

Micro Typing Systems, Inc.
an Ortho-Clinical Diagnostics Company
1295 S.W. 29th Avenue
Pompano Beach, Florida 33069