Micro Typing Systems, Inc.

INSTRUCTIONS FOR USE

Anti-Human Globulin Anti-IgG (Rabbit)
MTS™ Anti-IgG Card

REF MTS084024

Rx ONLY

Intended Use

For Direct and Indirect Antiglobulin Test
Does not contain antibodies to complement components
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

Anti-Human Globulin was described in 1945 by Coombs, Mourant, and Race.[1] Blood group antibodies of the IgG class, that were previously undetectable, reacted in the direct or indirect antiglobulin test (also known as the Coombs test). Anti-IgG reagents remain important tools for determining the presence or absence of IgG on human red blood cells. The reagent is used in the investigation of hemolytic disease of the newborn (refer to Limitations of the Procedure, item 12), transfusion reactions, and autoimmune hemolytic anemia in a direct antiglobulin test (DAT). The DAT detects IgG and/or C3 using either a polyspecific reagent solely or monospecific Anti-IgG and Anti-C3. Indirect antiglobulin tests are employed in compatibility testing, screening tests for donor and patient antibodies, antibody identification procedures, and antigen detection.

Principle of Procedure

The combination of the antiglobulin reagent incorporated into gel, known as the ID-MTS™ Gel Test[2], was first described by Dr. Yves Lapierre.[3] The Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Card can be used in both direct and indirect antiglobulin test systems to detect the presence or absence of IgG on human red blood cells.

In the MTS™ Anti-IgG Card, red blood cells that are coated with IgG due to *in vivo* sensitization are detected with the direct antiglobulin test. The detection of *in vitro* sensitization is determined by the indirect antiglobulin test.

The MTS™ Anti-IgG Card restricts the unbound IgG from moving through the gel during centrifugation. The unbound IgG does not neutralize the Anti-IgG incorporated in the gel.

Red blood cells sensitized with IgG react with the Anti-IgG gel in the microtube during centrifugation. Strongly positive agglutination reactions produce a line of red blood cells layered at the top of the gel. Positive reactions will have varying degrees of visible red blood cell agglutinates suspended in the gel. Uncoated (unsensitized) red blood cells or red blood cells coated only with complement are not agglutinated by the Anti-IgG and will form a button at the bottom of the microtube. Some literature reports indicate that Anti-IgG reagents lacking anti-complement components occasionally fail to detect some antibodies. These antibodies are demonstrable only by the use of a polyspecific antiglobulin reagent. In some cases, those antibodies that are not detected by Anti-IgG may be clinically significant.[4-7]

Reagents

Anti-Human Globulin Anti-IgG (Rabbit) for the MTS™ Anti-IgG Card is prepared from pools of sera obtained from rabbits that have been immunized with human IgG. The serum is adsorbed to remove unwanted heterospecific antibodies and is suspended in a buffered gel solution. The reagent meets present potency and specificity requirements of the FDA.[8]

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

Anti-Human Globulin (Anti-IgG) suspended in a diluent and buffered gel solution is contained in the 6 microtubes of the MTS™ Anti-IgG Card.

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. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.**

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 the ID-Micro Typing System™ Interpretation Guide[9] 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 11).
- 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.**

- Customers who choose to use commercial antisera in an off-label manner 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, Preparation and Storage

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

Samples for Direct Antiglobulin Test (DAT)

- Samples intended for direct antiglobulin testing should be drawn into EDTA to prevent *in vitro* complement binding. If EDTA is unavailable, specimens drawn into ACD, CPD or CPDA-1 are preferable to non-anticoagulated clotted specimens. Red blood cells should be tested within 24 hours after collection. Clotted samples should not be refrigerated. Some samples such as cord blood, blood stored for extended periods of time, or blood that has been incompletely anticoagulated, may develop fibrin clots or particulates. The fibrin clots or particulates may interfere with the ID-MTS™ Gel Test and cause red blood cell entrapment at the top of the microtube. Testing should be repeated using red blood cells that have been washed to remove the clots or particulates.
- Red blood cells that are stored for extended periods of time may become coated *in vitro* with complement and globulin proteins. Those samples coated with IgG will then test as DAT positive with this reagent.
- 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 the ID-MTS™ Gel Test interpretation.[9] 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.[12] Laboratories are advised to consult their approved procedures.
- Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution.

Samples for Indirect Antiglobulin Test

- Fresh serum or plasma collected with or without anticoagulants may be used in indirect antiglobulin procedures 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 transfusion, there is an FDA requirement that the specimen should not be stored for longer than 3 days before testing.[8] Antibodies dependent for their detection upon the binding of complement may not be detected, if aged serum or plasma from an anticoagulated sample is used for antibody detection tests. Serum should be separated from the red blood cells when stored or shipped. Donor blood or commercial reagent red blood cells should be used within their dating period.
- Samples obtained from acid elution procedures can be used if properly neutralized and if centrifuged to remove any debris.[10,11]

- Red blood cells that are direct antiglobulin positive should not be used in the indirect antiglobulin procedure.
- Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution. Grossly lipemic samples containing particulates that clog the gel, as indicated by diffuse blotches of red blood cells in the microtube, may be clarified by centrifugation or filtration and retested.
- 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 the ID-MTS™ Gel Test interpretation.[9] 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.[12] Laboratories are advised to consult their approved procedures.
- The use of enzyme-treated red blood cells with the MTS™ Anti-IgG Card may detect clinically insignificant antibodies. The MTS™ Buffered Gel Card is recommended when using enzyme treated cells.

Reagent Preparation

The MTS™ Anti-IgG Card is provided ready to use. Each microtube contains Anti-IgG 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 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[9] and ID-Micro Typing System™ Implementation Guide and Procedures[13] for additional information.

Materials Provided

Anti-Human Globulin (Anti-IgG) suspended in a final diluent and buffered gel solution is contained in the 6 microtubes of the MTS™ Anti-IgG Card.

Materials Required but not Provided

For manual gel card processing:

- 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
- Pipets: 10 µL, 25 µL and 50 µL
- Pipet Tips
- Test Tubes
- Dispenser pipet capable of delivering 1.0 mL
- 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% 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
- ORTHO VISION™ Analyzer and associated Reference Guide (J40050)
- ORTHO VISION™ Max Analyzer and associated Reference Guide (J55656)

Test Procedure

Direct Antiglobulin Test

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

3. Prepare a red blood cell suspension of approximately 0.8% in MTS™ Diluent 2 (e.g., deliver 1.0 mL of MTS™ Diluent 2 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™ Anti-IgG 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 11).

6. Add 50 µL of red blood cells (cells must be diluted in MTS™ Diluent 2 to approximately 0.8% or be a commercial 0.8% red blood cell in a low ionic strength diluent specifically approved for use in the ID-Micro Typing System™) to each microtube.

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

7. Centrifuge the prepared cards 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. If either side of the microtube is positive, the reaction is to be considered positive. See Diagram 1.

Indirect Antiglobulin Test

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

3. Label the gel card appropriately.
4. Remove the foil seal from the MTS™ Anti-IgG 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 11).

5. Add 50 µL of red blood cells (cells must be diluted in MTS™ Diluent 2 to approximately 0.8% or be a commercial 0.8% red blood cell in a low ionic strength diluent specifically approved for use in the ID-Micro Typing System™) to each microtube.

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

6. Add 25 µL of serum or plasma to each microtube of the MTS™ Anti-IgG Card. The mixture may or may not touch the gel suspension.

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

7. Incubate the MTS™ Anti-IgG Card for 15 minutes at 37±2 °C.

Note:	Incubation times in low ionic strength solutions between 5 minutes and 40 minutes have been recommended in the literature.[14-16] No single incubation time will be optimal for all antibodies.

8. After incubation, centrifuge the prepared cards in the MTS™ Centrifuge or ORTHO™ Workstation at the preset conditions installed by the manufacturer.

9. After centrifugation, remove the MTS™ Anti-IgG Cards 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.

Interpretation of Results

Refer to ID-Micro Typing System™ Interpretation Guide[9] 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.

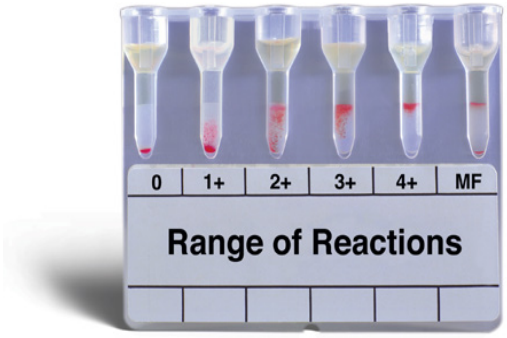
Positive Result–Agglutination and/or hemolysis of the red blood cells is a positive test result. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few red blood cells may form a button in the bottom of the microtube in some positive reactions.

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 6).**

Diagram 1: Examples of Reaction Grades



Stability of Reaction

For best results, it is recommended that reactions 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 °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 over time. This darkening does not interfere with the test result.

Quality Control

To confirm the specificity and reactivity of the MTS™ Anti-IgG 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[9] 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™ Anti-IgG 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. Red blood cells must be suspended in MTS™ Diluent 2 or be a commercial 0.8% red blood cell in a low ionic strength diluent specifically approved for use in the ID-Micro Typing System™.
4. Variations in red blood cell concentration can markedly affect the sensitivity of test results.[12] If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in the antigen/antibody ratio. In addition, red blood 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. 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.
6. Anomalous results may be caused by fresh serum, fibrin, or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube. Anomalous results (i.e., a line of red blood cells on the top of the gel) may be observed with serum samples and can be minimized with the use of EDTA plasma.
7. Red blood cells that test as DAT positive should not be used in an indirect antiglobulin procedure.
8. The MTS™ Anti-IgG Card is not manufactured to detect Anti-C3 cell sensitizations. It may be used in the compatibility test; however, some literature reports indicate that the Anti-IgG may occasionally fail to detect antibodies that are demonstrable by the use of antiglobulin reagents containing Anti-C3.[12]
9. Optimal reaction conditions vary across antibody specificities. No single test method will detect all antibodies. In some low ionic strength test systems, certain antibodies, such as Anti-E and Anti-K, have been reported to be nonreactive.[17-19]
10. There is the potential for IgM antibodies to react in this test. Some patient antibodies that are IgM in nature may react with corresponding antigens in the upper portion of the microtube and be trapped in the top portion of the gel at the time of centrifugation resulting in a positive reaction.
11. False-positive results may occur if a card that shows signs of drying is used in testing.
12. Negative direct antiglobulin test results do not necessarily rule out hemolytic disease of the newborn (HDN), especially if ABO incompatibility is suspected.
13. The Anti-H of Para-Bombay individuals may not be detectable in gel.[20]
14. 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 the ID-MTS™ Gel Test interpretation[9]. 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.[12] Laboratories are advised to consult their approved procedures.
15. Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution.
16. 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™ Anti-IgG Card meets FDA requirements.

The potency of Anti-IgG is verified by tests with red blood cells sensitized with decreasing amounts of Anti-D and Anti-Fy^a according to methods approved by FDA. Additionally, each lot is tested with a known antibody to ensure Anti-IgG sensitivity of 0.1 IU/mL or greater.

The absence of antibodies to C3 and C4 components has been confirmed by methods approved by FDA.[21]

The absence of contaminating heterophile agglutinins has been verified in tests employing group A_1 B, and O red blood cells.

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 antibody being tested. The combined results from all sites are summarized in the following table.

	Total			Positive			Negative		
Test	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**
Antibody Screen	11472	99.6%	99.5%	351	98.3%	96.7%	11121	99.6%	99.5%
Untreated and Ficin treated panels	2589	98.0%	97.5%	525	98.1%	96.8%	2064	98.0%	97.4%
DAT (IgG)	557	98.6%	97.4%	105	100.0%	97.2%	452	98.2%	96.8%
IAT Crossmatch	990	97.4%	96.4%	465	100.0%	99.4%	525	95.0%	93.2%

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. The combined results from all sites are summarized in the following table.

	Total			Positive			Negative		
Test	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**
Antibody Screen	11356	99.8%	99.8%	479	98.3%	97.0%	10877	99.9%	99.8%
Untreated and Ficin treated panels	2537	99.8%	99.5%	675	99.6%	98.9%	1862	99.8%	99.6%
DAT (IgG)	563	99.5%	98.6%	180	98.9%	96.5%	383	99.7%	98.8%
IAT Crossmatch	1024	99.9%	99.5%	466	100.0%	99.4%	558	99.8%	99.2%

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 One Sided 95% CI**	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**	**N**	**% Agreement**	**Lower Bound One Sided 95% CI**
Antibody Screen	5108	99.8%	99.6%	314	98.4%	96.7%	4794	99.9%	99.8%
Antibody Identification	228	99.6%	97.9%	126	99.2%	96.3%	102	100.0%	97.1%

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

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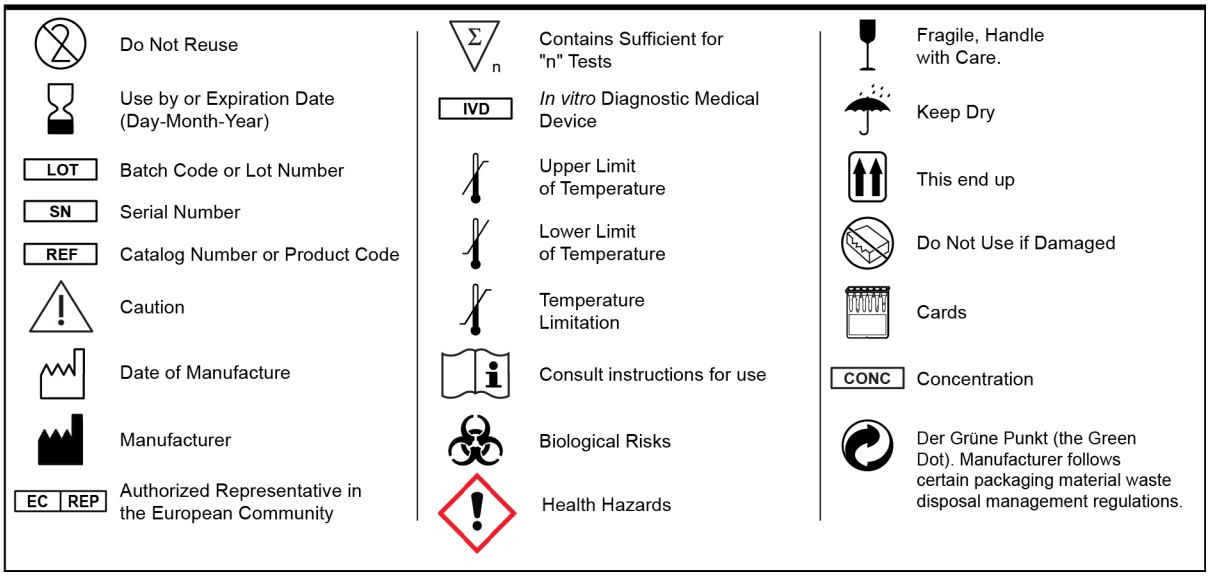
Glossary of Symbols

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



Summary of Revisions

Date of Revision	Version	Section	Description of Technical Changes*
2016-10-05	4.0	Precautions	• Added sodium azide Caution statement.
		Materials Required but not Provided	• Added ORTHO™ Workstation. • Added ORTHO™ VISION Max Analyzer.
		Test Procedure	• Direct Antiglobulin Test: o Step 7: added ORTHO™ Workstation. • Indirect Antiglobulin Test: o Step 8: 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 screen and antibody identification test data.
		Glossary of Symbols	• Updated to add symbols.
		Back Page	• Updated copyright to add date range.
2015-06-01	3.0	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 16, referring user to automated instrument user guide for instrument specific limitations.
		Performance Characteristics on ORTHO VISION™ Analyzer	• New section.
2013-07-17	2.0	Specimen Collection, Preparation and Storage	• Samples for Direct Antiglobulin Test section: Add text: Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution.
		Limitations of the Procedure	• Add Step 15: Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution.
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.
		Test Procedure	• Addition to steps 5 and 4: After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.
2008-12-08	1.0		Replaces PK No. 010-E Revision date: 12-28-04 with the changes below.
		Header	• New product code: MTS084024
		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.
		Principle of Procedure	• "MTS Anti-IgG Gel test" changed to "Anti-Human Globulin Anti-IgG (Rabbit) MTS Anti-IgG Card™"
		Precautions	• Added Note to refer to ID-Micro Typing System™ Interpretation Guide. • Further clarified storage requirement by adding statement not to use gel cards that were not shipped in an upright position.

Date of Revision	Version	Section	Description of Technical Changes*
		Specimen Collection and Preparation	• Added rouleaux statement to Samples for Direct Antiglobulin Test (DAT) section. • Expanded statement regarding rouleaux and added advisory statement for laboratories to consult their approved procedures. • Clarified statement related to the use of enzyme treated cells.
		Procedure	• Added statement to refer to the ID-Micro Typing System™ Interpretation Guide.
		Test Procedure	• Added Notes to Direct Antiglobulin Test and Indirect Antiglobulin Test sections 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.
		Limitations of Procedure	• Added statement regarding rouleaux and included advisory statement for laboratories to consult their approved procedures.
		Specific Performance Characteristics	• Revised statement regarding FDA requirements to provide consistency with other ID-Micro Typing System™ Gel Card Instructions for Use
		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
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