Blood Grouping Reagents

MTS™ Anti-A (Murine Monoclonal) Card
MTS™ Anti-B (Murine Monoclonal) Card
MTS™ Anti-A,B (Murine Monoclonal Blend) Card

INSTRUCTIONS FOR USE

REF

MTS080014
MTS080015
MTS080016

Rx ONLY

Intended Use

For *in vitro* diagnostic use only
For the detection of A or B antigens on red blood cells
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 of the Test

The ABO blood group system, which was the first human blood group system to be discovered by Landsteiner, [1] remains the most important in transfusion practice. [2] 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_1 and group B red blood cells (serum or reverse grouping).

MTS™ Gel Cards containing Monoclonal 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^1 and B red blood cells.

Principles of the Procedure

The combination of the blood group antibodies incorporated into gel was first described by Dr. Yves Lapierre. [3, 4] 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, Anti A,B) 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 at the bottom of the microtube.

Reagents

Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal) and Anti-A,B (Murine Monoclonal Blend) 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-A,B is derived from a blend of antibodies from cell lines ES-4 and ES-15 and does not contain dye. 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 blend of ES-15 (Anti-A,B) and ES-4 (Anti-B) was selected to ensure that these cell lines are different from the cell lines used in the Anti-A and Anti-B. This formulation provides an independent confirmation of the A and/or B antigen status.

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

Storage Requirements

Store cards upright at 2–25 °C.

Warnings and Precautions

DANGER:	***This product contains 1-Imidazole (CAS 288-32-4)*** [5, 6] ***H360: May damage fertility or the unborn child. P280: Wear protective gloves, Eye protection. P308 + P313: If exposed or concerned: Get medical advice/attention.*** ***Refer to www.Orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.***

DANGER

- Do not use beyond expiration date.
- Do not freeze or expose cards to excessive heat.
- Use reagents as furnished.
- Do not use gel cards that have not been shipped in an upright position.

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 the ID-Micro Typing System™ Interpretation Guide [7] for additional information related to the visual inspection of gel cards before use.

INSTRUCTIONS FOR USE

Specimen Collection and Preparation

- 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 pipette tip should not touch the gel card. Erroneous results due to carryover may occur.** **Do not pipette by mouth. The absence of murine virus has not been determined.**

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.

Reagent Preparation

The gel card is provided ready to use. Each microtube contains monoclonal antibody 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 [7] and ID-Micro Typing System™ Implementation Guide and Procedures [8] for additional information.

Materials Provided

The MTS™ Anti-A (Murine Monoclonal) Card contains 6 microtubes of Anti-A Gel (Murine Monoclonal); the MTS™ Anti-B (Murine Monoclonal) Card contains 6 microtubes of Anti-B Gel (Murine Monoclonal); the MTS™ Anti-A,B (Murine Monoclonal Blend) Card contains 6 microtubes of Anti-A,B Gel (Murine Monoclonal Blend).

Materials Required but Not Provided

For manual gel card processing:

- MTS™ Monoclonal Control Card (used for red blood cell control purposes)
- 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 pipette capable of delivering 0.5 mL
- MTS™ Diluent 2 *PLUS*
- pipette: 10 to 12.5 µL, 25 µL and/or 50 µL
- pipette Tips
- ORTHO® Workstation
- ORTHO Optix™ Reader
- Test Tubes
- Marking Pen

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

- MTS™ Monoclonal Control Card (used for red blood cell control purposes)
- AlbaQ-Chek® Simulated Whole Blood Controls

- MTS™ Diluent 2 *PLUS*
- ORTHO VISION® Analyzer
- ORTHO VISION® Max Analyzer

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 pipette 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. Blood grouping should always be performed in conjunction with the MTS™ Monoclonal Control Card.
6. 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).

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

8. Centrifuge the prepared card(s) in the ORTHO® Workstation at the preset conditions installed by the manufacturer.
9. 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 and complete sedimentation of all cells in the bottom of the microtube is a negative result.

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 red blood cell should be performed before the ABO 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 the control test is positive, the test cells should be washed several times in warm saline and retested. [9] 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.

INSTRUCTIONS FOR USE

Stability of Reaction

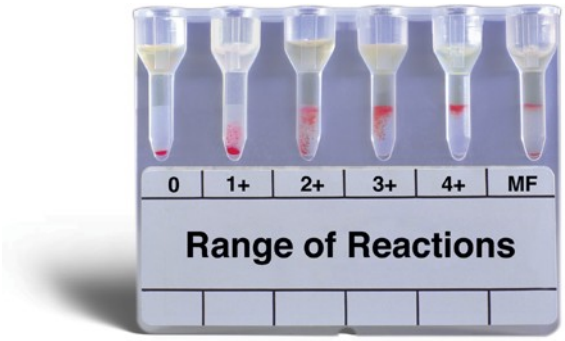
Reaction Grading Guide (Use in conjunction with Diagram 1)

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 13).**

Diagram 1: Examples of Reaction Grades



Expected reactions with Anti-A, Anti-B, and Anti-A,B reagents, and reverse grouping with A_1 and B cells with proper interpretation are shown in the following table.

Reaction with					Blood Group	Frequency [9]	
Anti-A	Anti-B	Anti-A,B	A_1 cells	B cells		Whites	Blacks
0	0	0	+	+	O	45	49
+	0	+	0	+	A	40	27
0	+	+	+	0	B	11	20
+	+	+	0	0	AB	4	4

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.

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, Anti-B and Anti-A,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_2B 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.

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 MTS™ Gel Test. The 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. [9] 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 the 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. 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. [9] 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.
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.
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

which 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_2B phenotype. Monoclonal Anti-A,B gel was tested with A_x cells and 5 of 6 examples gave positive reactions. However, future individual lots of Monoclonal Anti-A,B gel will not be routinely tested with A_x cells. 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.

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. Anti-A,B results are derived from whole blood control samples tested as part of a reproducibility study conducted at three sites. Individual microtube results were evaluated for agreement between analyzers. For microtube reaction grades to be in agreement with expected results, microtube reaction grades were either negative in the absence of A or B antigens or positive (1+ through 4+) in the presence of A or B antigens. 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 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-A,B	300	100.0%	99.0%	200	100.0%	98.5%	100	100.0%	97.0%

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 with expected results, microtube reaction grades were either negative in the absence of A or B antigens or positive (1+ through 4+) in the presence of A or B antigens. 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 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-A,B	1127	100.0%	99.7%	441	100.0%	99.3%	686	100.0%	99.6%

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

Performance Characteristics on ORTHO Optix™ Reader

Method comparison testing was performed at three sites (two external and one internal site), that routinely perform immunohematology testing. Individual microtube results were evaluated for agreement between ORTHO Optix™ Reader and the ORTHO VISION® Analyzer. For microtube reaction grades to be in agreement between the systems, microtube reaction grades were either both negative or both positive (1+ through 4+). 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 One Sided 95% CI	N	% Agreement	Lower Bound One Sided 95% CI	N	(%) Agreement	Lower Bound One Sided 95% CI
Anti-A	3637	100.0%	99.9%	1584	100.0%	99.8%	2053	100.0%	99.9%
Anti-B	3637	100.0%	99.9%	541	100.0%	99.4%	3096	100.0%	99.9%
Anti-A,B	1105	100.0%	99.7%	441	100.0%	99.3%	664	100.0%	99.5%

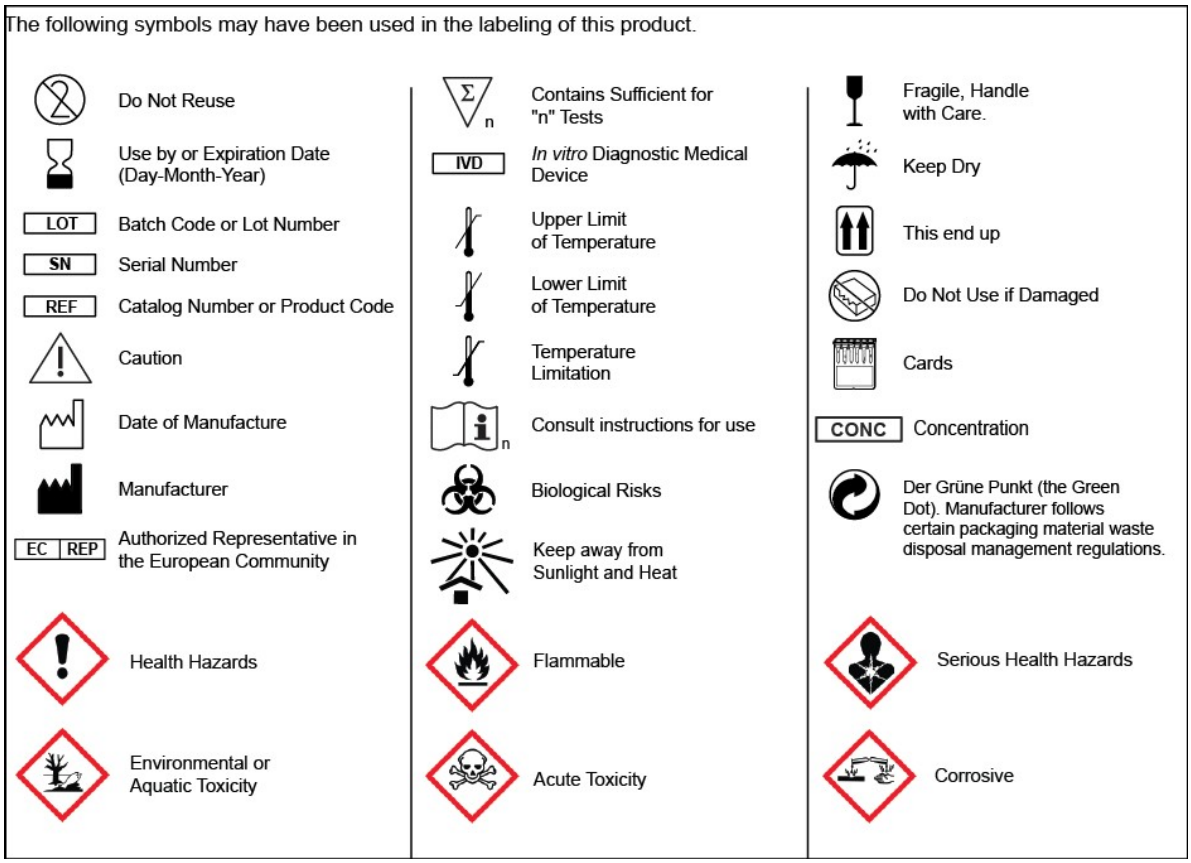
Agreement between two methods does not indicate which method gave the correct results.

References

1. Race RR, Sanger R. Blood groups in man. 6th ed. Oxford: Blackwell Scientific Publications. 1975.
2. Mollison PL, Englefriet CP, Contreras M. 10th ed. Blood Transfusion in Clinical Medicine. London: Blackwell Scientific Publications, 1997.
3. Lapierre Y, Rigal D, Adam J, et al. The gel test: a new way to detect red cell antigen-antibody reactions. *Transfusion* 1990;30:109-113.
4. Malyska H, Weiland D. The gel test. *Laboratory Medicine* 1994;25:81-85.
5. US Department of Labor - Occupational Safety and Health Administration 29 CFR 1910.1020 - Hazard Communication (HazCom 2012).
6. Canada Hazardous Products Regulations (SOR/2015-17).
7. ID-Micro Typing System™ Interpretation Guide (6902201), Ortho Clinical Diagnostics.
8. ID-Micro Typing System™ Implementation Guide and Procedures (6902200), Ortho Clinical Diagnostics.
9. 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.



Revision History

Date of Revision	Version	Description of Technical Changes*
2020-11-12	5.0	• Removed reference to MTS™ Centrifuge throughout document. • Corrected trademark for ORTHO Workstation from (™) to (®) throughout document • Materials Required but not Provided: Added ORTHO Optix™ Reader • Specific Performance Characteristics: Added Performance Characteristics for ORTHO Optix™ Reader

* 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.
an Ortho-Clinical Diagnostics Company
1295 S.W. 29th Avenue
Pompano Beach, Florida 33069
U.S. License No. 1177

MTS, ID-MTS and ID-Micro Typing System are trademarks of Micro Typing Systems, Inc.
© Micro Typing Systems, Inc., 2008–2020

Ortho Clinical Diagnostics

Micro Typing Systems, Inc.