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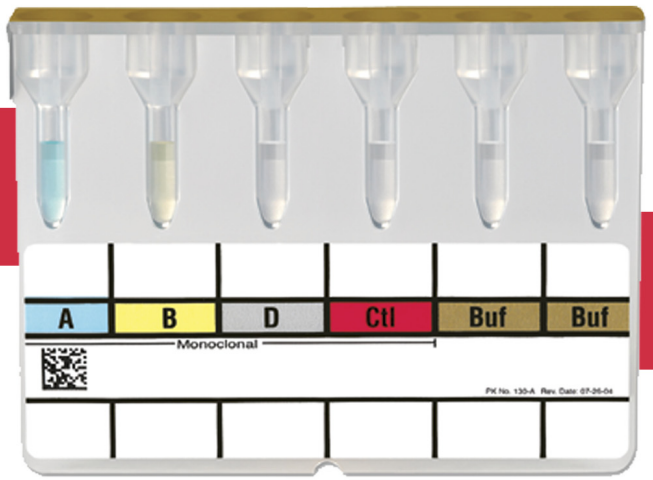
ID-MTS™ Gel Cards

Interpretation Guide



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Ortho Clinical Diagnostics

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Table of Contents

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Chapter 1: Introduction

Ortho Clinical Diagnostics (Ortho) prepared the ID-Micro Typing System™ (ID-MTS™) Interpretation Guide to provide assistance with ID-MTS™ Gel Test training and to provide a tool for the maintenance of technologists' competency levels. This guide provides illustrations of typical gel test agglutination reactions and a troubleshooting section. If you have specific questions not addressed in this guide, contact Ortho Care™ Technical Solutions Center (1-800-421-3311).

NOTE: Illustrations and images used within this guide depict specific examples; however, other variations of appearance may occur. Images used are sourced from automated analyzers and manual method.
This guide is intended to be viewed and printed in color. To obtain a color copy, please contact your Ortho representative to order.

Instructions for Use

Additional information is available in the Instructions for Use for each of the ID-MTS™ gel cards.

- Instructions for Use (IFU) can be downloaded at www.orthoclinicaldiagnostics.com.
- Paper copies of Instructions for Use can be ordered by contacting Ortho Care™ Technical Solutions Center at 1-800-421-3311.

Product Storage

Store cards upright following requirements indicated in the gel card IFU.

Overview of the ID-MTS™ Gel Test

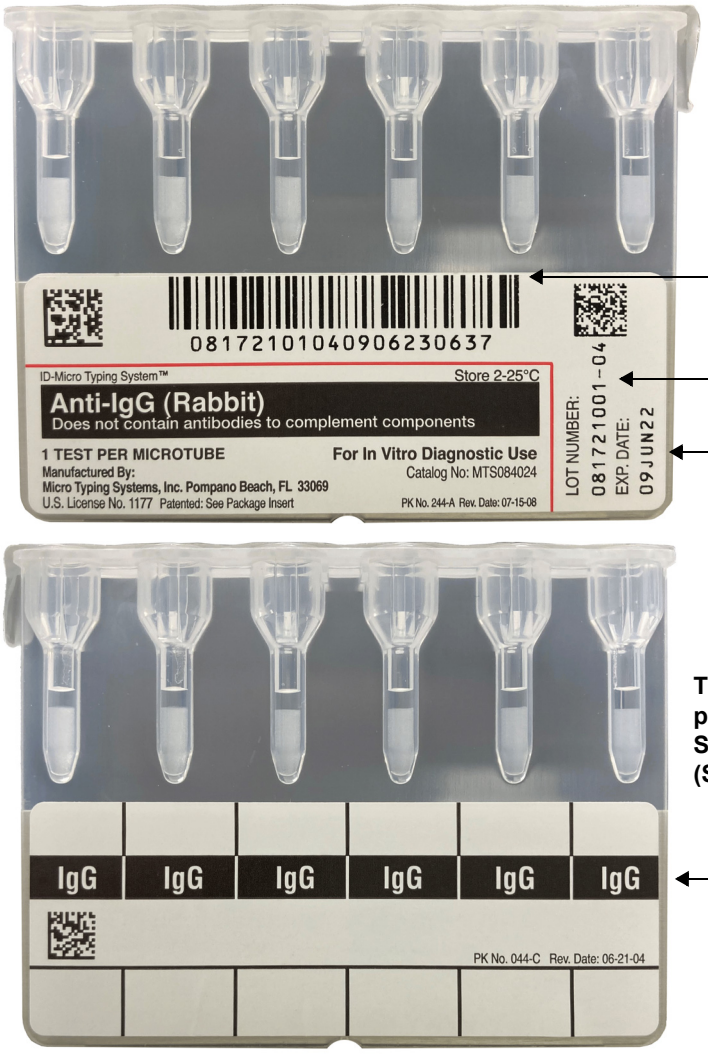
Since its introduction in North America in 1995, the ID-MTS™ Gel Test has widely replaced traditional tube technology for a broad range of blood bank applications. The ID-MTS™ Gel Test provides standardized and simplified procedures. The gel test, licensed in North America as the ID-Micro Typing System™, utilizes dextran acrylamide gel particles that are pre-dispensed into specially designed microtubes manufactured in plastic cards.

The gel card measures 2 x 3 inches, approximately the size of a credit card, and contains 6 microtubes. Each microtube consists of an upper reaction chamber that is wider than the microtube and a long narrow section that contains the pre- dispensed gel and reagents. The top of the gel card is sealed with a foil strip to prevent spillage or drying of the microtube contents.

In the ID-MTS™ Gel Test, measured volumes of red blood cells and plasma/serum are first added to the reaction chamber of the microtube. The reaction chamber provides an area for red blood cell sensitization during the incubation of any indirect antiglobulin test. With the exception of the MTS™ Buffered Gel Card and the MTS™ Monoclonal Control Card, specific antibody is incorporated into the gel. The centrifugation step allows sufficient time for the contact of the red blood cells with the antisera and gel particles, resulting in the separation of agglutinated red blood cells from unagglutinated red blood cells. During this controlled centrifugation, the gel matrix functions as a molecular sieve to trap agglutinated red blood cells.

Agglutinated red blood cells become trapped in the gel at various levels within the microtube, depending on the size of the agglutinates. Free unagglutinated red blood cells pass through the gel and form a button of red blood cells on the bottom of the microtube.

Gel Card with 6 Microtubes



Barcode

Lot Number

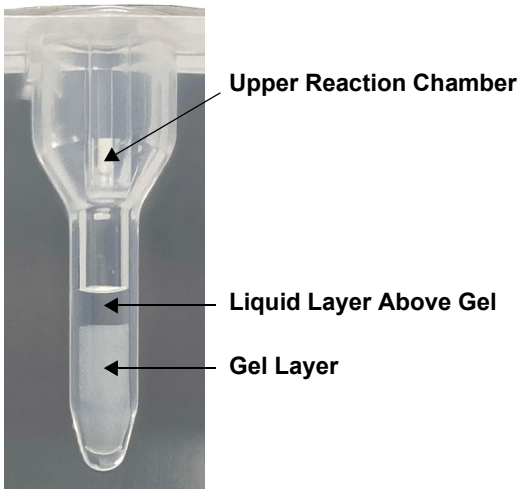
Expiration Date

This side is to be used for labeling purposes according to the Standard Operating Procedures (SOPs) within your facility.

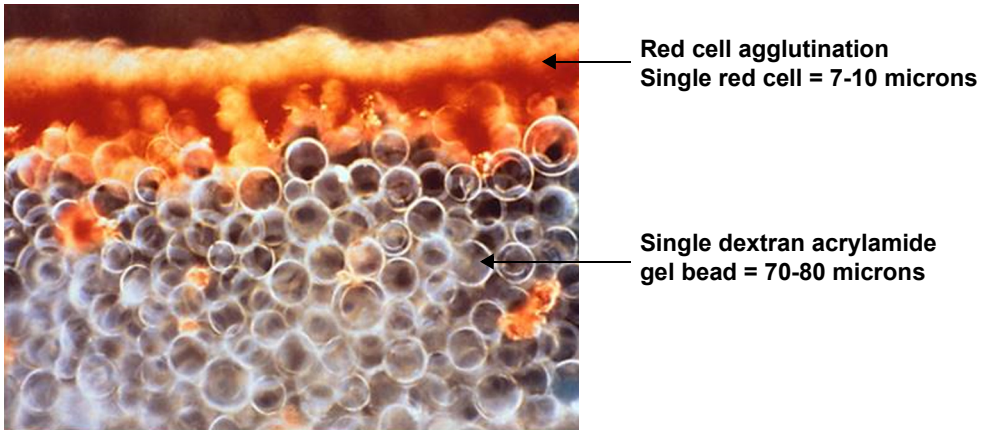
Reagent Identification

Microtube Enlarged

Each microtube has a gel layer and a liquid layer above the gel.



Dextran Acrylamide Gel Particles with Agglutinated Cells



The red upper band is a mass of agglutinated red cells representative of a 4+ reaction. The clear beads are single gel beads.

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Chapter 2: Visual Inspection of Gel Cards Prior to Use

Before performing the ID-MTS™ Gel Test, visually inspect all gel cards for any damage during shipment or handling.

A clear liquid layer should appear on top of the opaque gel in each microtube. Variations in the liquid and/or gel levels between microtubes may normally be observed. 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.

CAUTION: Acceptable microtubes should not have an adverse impact on product performance.
Unacceptable microtubes may have an adverse impact on product performance.

Acceptable Microtubes

Microtube Levels

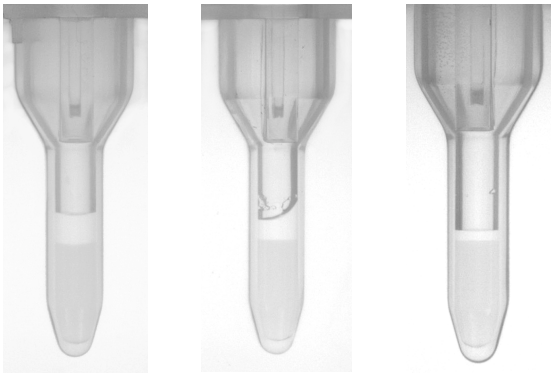
When visually inspecting microtubes in a gel card, a typical microtube should contain an opaque gel layer with a clear liquid layer on the top of the gel.

Gel cards with low liquid layer (and no other artifacts present) are considered acceptable for use, but should be carefully examined.

Do not use cards if the liquid level in the microtube is at or below the top of the gel matrix.

Examples of Acceptable Microtube Liquid Levels.

Acceptable Typical Gel Microtube



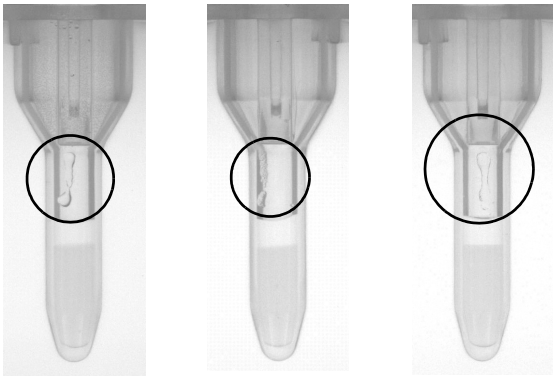
Typical **Slanted** **Low**

Acceptable Variations in Liquid Level

Residue

Gel cards are filled using an automated process. Six (6) stainless steel needles are used to deliver a measured volume of the gel-liquid mixture into each microtube. After filling, the cards are sealed and labeled and then inspected using a state-of-the-art optical inspection system designed to reject cards containing unacceptable defects, such as bubbles, cracks, debris, unacceptable fluid/gel levels, and labeling issues. During the filling process, the filling needles may touch the side of the microtube leaving a residue of gel and/or liquid. Gel cards with residue are acceptable for use.

Examples of Microtubes with Residue



Liquid Drops Above the Liquid Layer

Liquid drops above the liquid layer (as described in the *Microtube Levels* section above) and/or on the underside of the foil may occur as a result of handling and/or storage of the product within the product claims. Gel cards with liquid drops above the liquid layer are acceptable for use. If liquid drops are observed with additional artifacts (e.g. no liquid layer, low (or no) gel layer, signs of drying (dried/cracked gel) or bubbles in the liquid/gel layer) refer to the *Unacceptable Microtubes* section of this guide.

The following are examples of microtubes with liquid drops above the liquid layer that are acceptable for use.

Liquid Drops in the Upper Reaction Chamber and Above the Liquid Layer

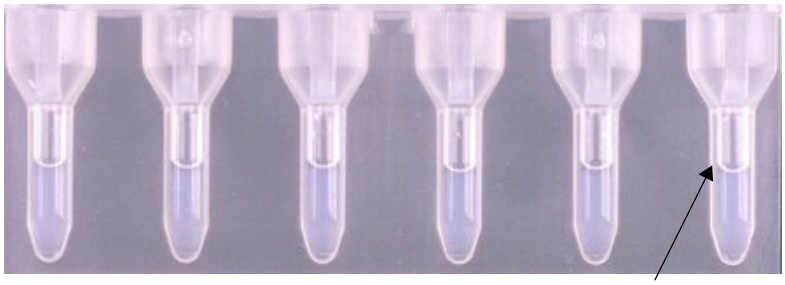
Liquid Drops Above the Liquid Layer

Acceptable Microtubes with Liquid Drops

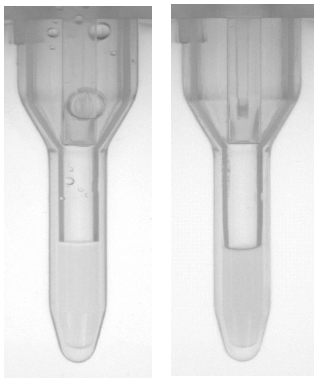
Unacceptable Microtubes

No Liquid Layer

Microtubes in which the liquid level is at or below the top of the gel matrix, prior to use should not be used in testing.



No liquid layer present



No Liquid Layer

Low Gel Level

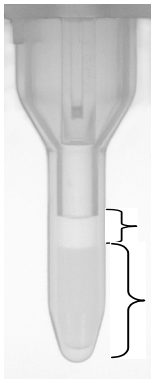
When visually inspecting microtubes in a gel card, a typical microtube should contain a gel layer with a liquid layer on the top of the gel.

The gel layer should occupy approximately half of the microtube.

Do not use microtubes in testing that have low gel levels.

Using microtubes with low gel levels may impact the results of the gel test by generating false-positive or false-negative results.

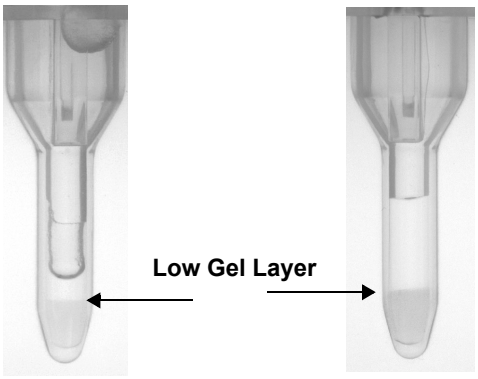
Acceptable Typical Gel Microtube



Liquid Layer

Gel Layer

Unacceptable Microtubes with Low Gel Levels



Low Gel Layer

Total Volume Reduced

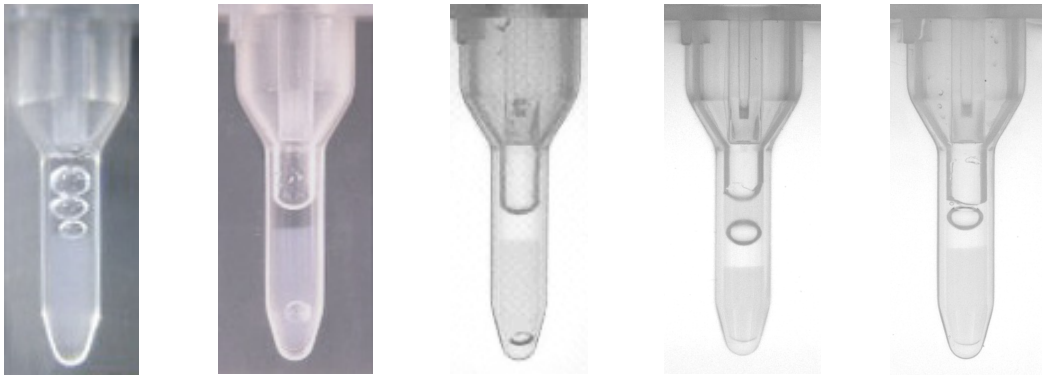
Disproportionate Gel Layer and Liquid Layer

Bubbles in the Microtubes

Bubbles in the card microtubes represent air entrapped in the gel matrix and/or liquid layer; also referred to as a column break if air is entrapped between two layers of liquid, prior to use.

Bubbles may appear in the liquid level above the gel or within the gel itself. Do not use gel cards containing bubbles in the microtubes.

Bubbles can interfere with the downward migration of red blood cells, which may yield a false positive test result.

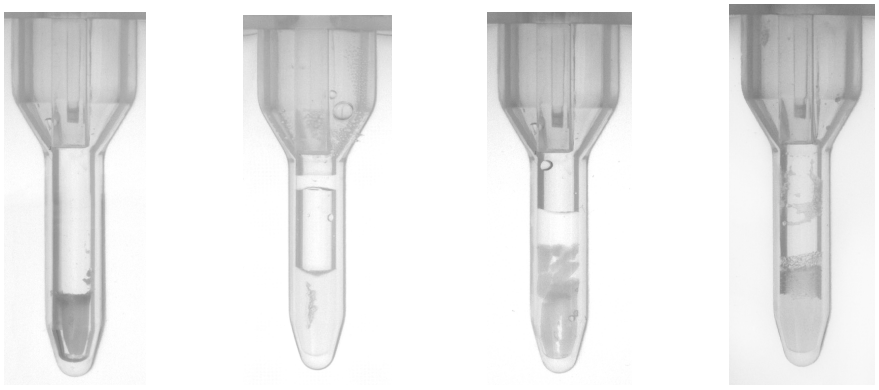


Signs of Drying in the Gel Matrix

Gel cards may show signs of drying due to improper storage, handling, or compromised integrity of the foil seal. Drying of the gel matrix may be observed with or without liquid present.

False-positive results may occur if a card that shows signs of drying is used in testing.

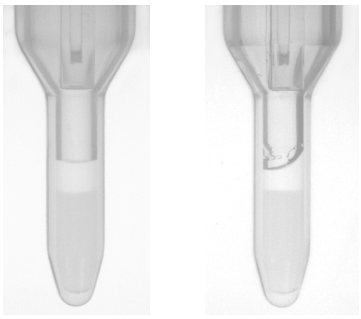
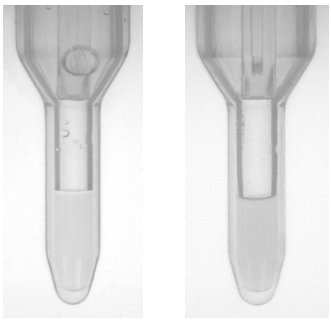
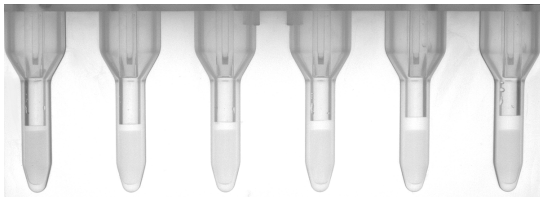
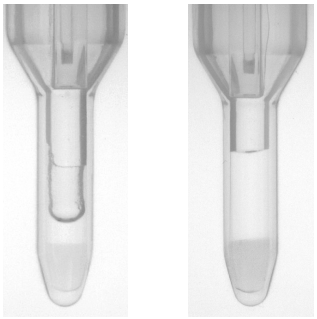
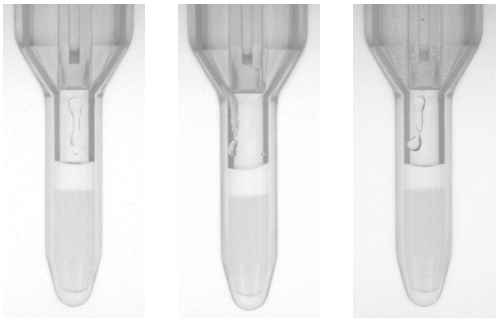
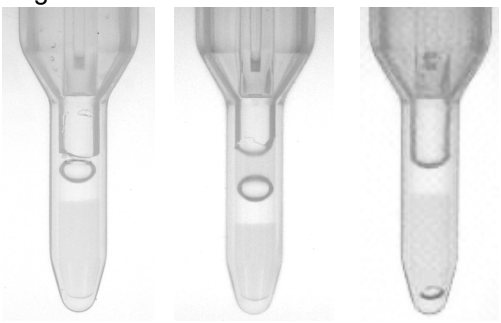
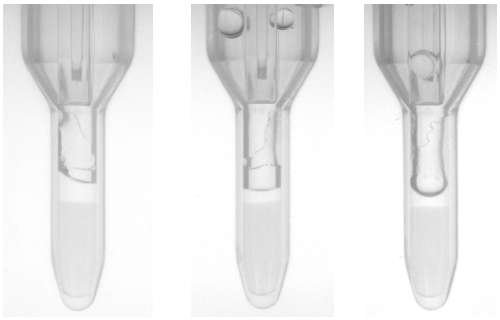
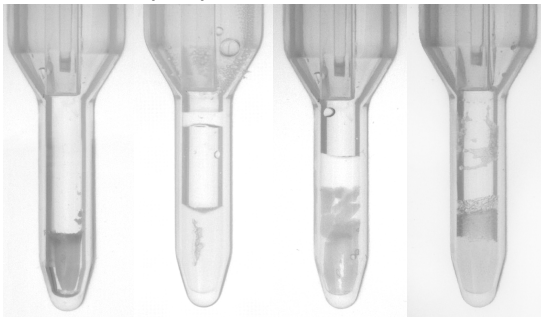
Signs of drying include visible cracks in the gel layer and crystallized amorphous material present in the microtube.



Dried Gel **Cracked Gel** **Cracked Gel with Liquid Layer** **Crystallized Amorphous Material**

Acceptability of Gel Cards

The following images show the various artifacts users may encounter during visual inspection and their acceptability classification.

Acceptable for Use	Unacceptable for Use
Microtube with a clear liquid layer above the gel matrix. 	Liquid layer in microtube is at or below the gel matrix. 
Variations in the liquid and or gel level between microtubes.  **All Acceptable**	Low gel level that occupies less than half the microtube. 
Residue with visible liquid layer above gel matrix. 	Bubbles trapped in the liquid layer or within the gel. 
Liquid drops above the liquid layer without additional artifacts. 	Dried or cracked gel. May be observed with or without liquid present. 

Debris

Cards should be inspected for dust/debris prior to use. If dust/debris is observed on the outside of the gel card, remove using a dry lint-free wipe.

Refer to ORTHO VISION® and ORTHO VISION® Max Analyzers, ORTHO Optix™ Reader or ORTHO ProVue® Analyzers customer documentation for more information on the impact of debris.

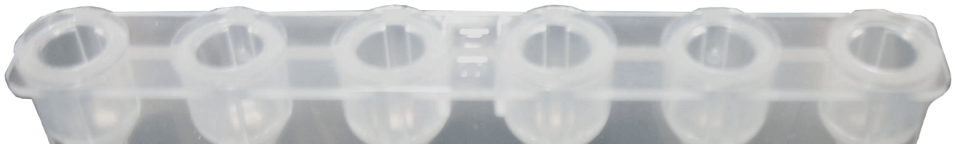
Inspection of Gel Cards after Removal of Foil

When testing manually, do not remove the foil seal until ready to use. Foil should be removed immediately before testing or within 1 hour of testing. Remove the foil with care. Forceful removal of the foil may result in inadvertent transfer of reagents from one microtube to the other or exposure to the user.

Once removed, the gel may begin to dry out which could affect test results. False-positive results may occur if a card that shows signs of drying is used in testing.

Visually inspect all gel cards to ensure that residual film does not block the opening of any microtube after removal of the foil.

Microtubes exhibiting residual film. This card is unacceptable for use.



Microtubes with no residual film. This card is acceptable for use.

Chapter 3: Test Reactions

Reading Gel Test Reactions

Read macroscopically the front and back of each microtube for agglutination and/or hemolysis. Record the reactions. If either side of the microtube is positive, the reaction is to be considered positive. Agglutination and/or hemolysis of the red blood cells is a positive test result. If hemolysis is observed, consult your facility's approved procedures.

Interpreting Gel Test Reactions

NOTE: Before interpreting reactions, the clinical history of the patient and the type of testing performed should be considered. Additional patient history and testing may be required for final interpretation.

Because agglutination reactions are stabilized within the gel matrix, the ID-MTS™ Gel Test provides a definitive end point. The strength of the agglutination reaction determines the extent of migration of the agglutinated red blood cells in the gel. The agglutination reactions may be graded in a similar fashion as observed in traditional tube tests using a scale of 0 to 4+. The grading system for agglutination is based upon the position of the agglutinated red blood cells within the microtube.

Reaction Grades	Interpretation Description
0 (Negative)	Unagglutinated red blood cells form a well-defined button at the bottom of the microtube.
1+ Reaction	Agglutinated red blood cells 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	Agglutinated red blood cells are dispersed throughout the length of the gel microtube. A few unagglutinated red blood cells may be observed in the bottom of the microtube.
3+ Reaction	The majority of agglutinated red blood cells are trapped in the upper half of the gel microtube.
4+ Reaction	Solid band of red cell agglutinates on top of the gel. A few agglutinates may filter into the gel but remain near the predominant band.
Mixed Field	Agglutinated red blood cells 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. 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. This may cause an anomalous result in a negative test.

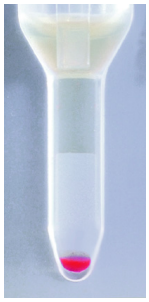
Range of Reactions in the ID-MTS™ Gel Test

Negative Reactions

Unagglutinated red blood cells form a well-defined button in the bottom of the microtube.

Negative Reaction

Negative Reaction



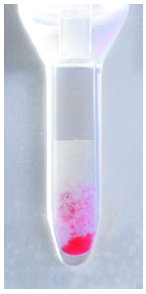
Negative Reaction

Negative reactions are represented by unagglutinated red blood cells traveling through the gel forming a button in the bottom of the microtube. Debris, fibrin, or other artifacts associated with plasma/serum, cord blood, or frozen samples may cause a few unagglutinated red blood cells to trap on top of the gel, but these tests should be interpreted as negative. For more information, refer to the *Troubleshooting* section.

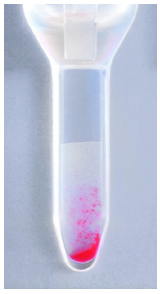
1+ Reactions

Characterized by red blood cell agglutinates predominantly observed in the lower half of the gel microtube.

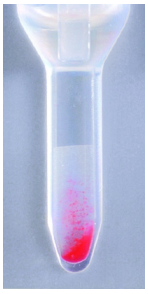
Unagglutinated red blood cells form a button in the bottom of the microtube.



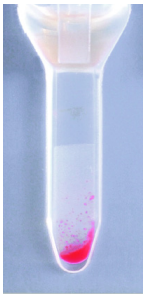
1+ Reaction



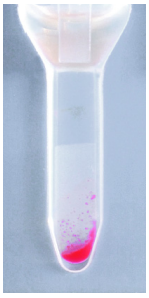
1+ Reaction



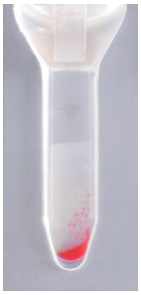
1+ Reaction



1+ Reaction



1+ Reaction



1+ Reaction

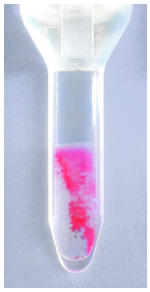
Weaker reactions may be represented by few agglutinated red blood cells in the gel microtube in the area just above the red blood cell button near the bottom of the microtube. The button associated with these weaker reactions is often disrupted.

2+ Reactions

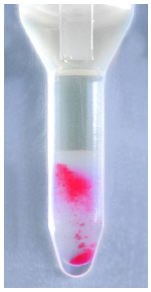
Characterized by red blood cell agglutinates dispersed throughout the length of the gel microtube.

A few unagglutinated red blood cells may be observed in the bottom of the microtube.

2+ Reaction

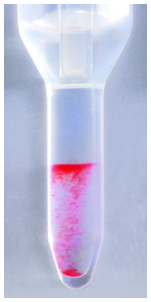


2+ Reaction

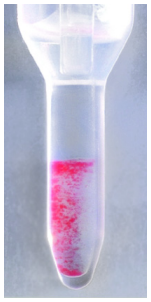


2+ Reaction

2+ Reaction



2+ Reaction

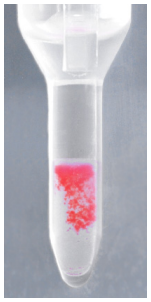


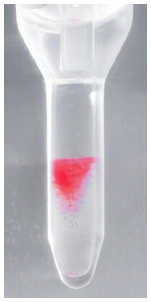
2+ Reaction

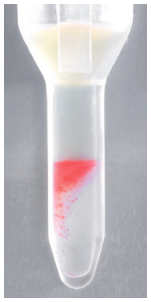
In a 2+ reaction, the agglutinated red blood cells are dispersed vertically throughout the gel in the microtube. The horizontal position of the agglutinated cells within the microtube (i.e., their relative location front-to-back or side-to-side) should not be considered. The size of red blood cell buttons in the bottom of the microtube may vary.

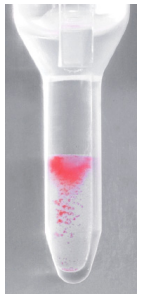
3+ Reactions

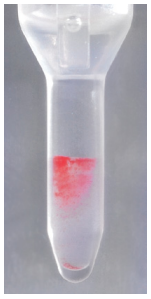
Characterized by the majority of agglutinated red blood cells trapped in the upper half of the gel microtube.

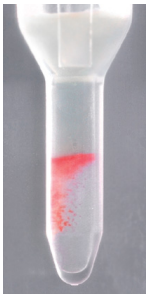

3+ Reaction


3+ Reaction


3+ Reaction


3+ Reaction

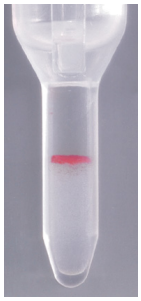

3+ Reaction

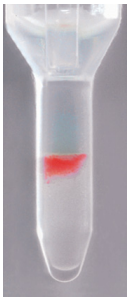

3+ Reaction

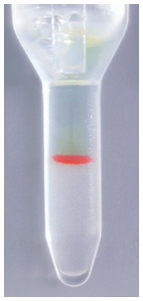
A 3+ reaction appears as a thick group of agglutinated red blood cells, or band, with some red blood cells dispersed below the predominant band in the upper half of the gel microtube.
A 3+ reaction may also be characterized by an even distribution of agglutinated red blood cells in the upper portion of the gel. Occasionally, a few unsensitized red blood cells may migrate to the bottom of the microtube.

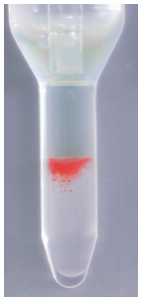
4+ Reactions

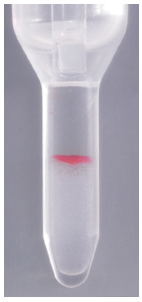
Characterized by a solid band of agglutinated red blood cells on top of the gel. A few agglutinated red blood cells may filter into the gel but remain near the predominant band.

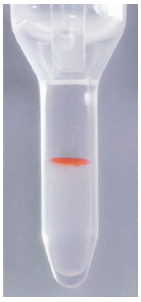

4+ Reaction


4+ Reaction


4+ Reaction

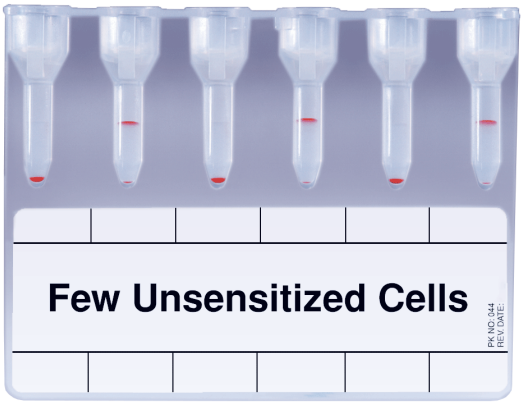

4+ Reaction


4+ Reaction


4+ Reaction

Strong 4+ reactions form a band of agglutinated red blood cells and become trapped on or near the top of the gel. The size of these agglutinated red blood cells makes it difficult for red blood cells to migrate into the gel. Occasionally, a few unsensitized red blood cells may migrate to the bottom of the microtube but the middle of the gel should remain free from agglutinated red blood cells.

Strongly Positive Result with a Few Nonreactive Red Blood Cells



Gel tests exhibiting 3+ or 4+ reactions may also contain a small number of unagglutinated red blood cells that form a small red blood cell button in the bottom of the microtube.

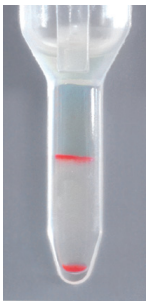
These results could represent a mixed-field reaction in which the majority of red blood cells present in the test sample are strongly reactive and the minority of red blood cells nonreactive.

If the red blood cells used for testing are from a single source (i.e., reagent screening or panel red blood cells), this reaction cannot be the result of a true mixed-field reaction. If red blood cells are not sensitized during incubation, no antigen-antibody complex will form. These nonreactive red blood cells will travel through the gel microtube and form a small red blood cell button in the bottom of the microtube.

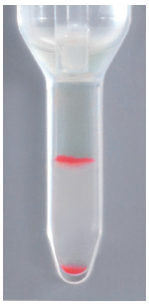
Care must be exercised in interpretation if the sample used for testing was an incompletely clotted whole blood sample. In such cases, the red blood cells noted above the gel microtube may be trapped within a large fibrin aggregate. Tests should be repeated, either with a different blood sample that avoids coagulation difficulty (plasma), or by using serum that is completely clotted and well spun.

Mixed-Field Reactions

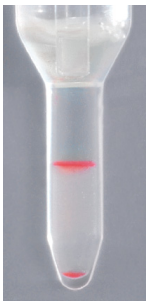
Characterized by agglutinated red blood cells on top of the gel or dispersed throughout the microtube and accompanied by a button of unagglutinated red blood cells in the bottom of the microtube.



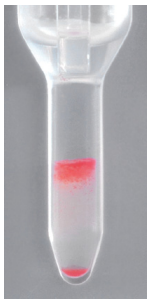
Mixed-Field Reaction



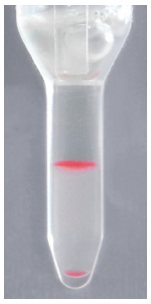
Mixed-Field Reaction



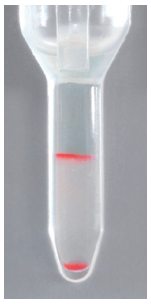
Mixed-Field Reaction*



Mixed-Field Reaction



Mixed-Field Reaction*

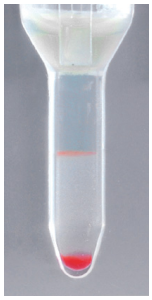


Mixed-Field Reaction

Before interpreting reactions as mixed-field, the clinical history of the patient and the type of testing performed should be considered. Additional patient history and testing will be required for resolution (see section *Troubleshooting: Reactions Associated with Recently Transfused Patients* for information about recently transfused patients).
*Not all mixed-field situations have a sufficient minor population to be detected.

Fibrin

Fibrin



Fibrin

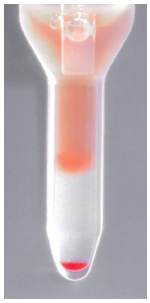
Fibrin may be observed in tests where plasma or serum is added. Anomalous results may be caused by fibrin or other particulate matter in blood samples that could stick to the sides of the microtube.

Use caution to not misinterpret this as mixed field as the patterns may appear similar.

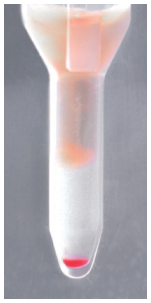
Hemolysis, Weak Reactions, Abnormal Position of Agglutinated Cells

As with any test method, other results may occur that may not appear as typical negative, 1+, 2+, 3+, or 4+ reactions. If hemolyzed samples are used, the liquid portion above or just into the gel will appear pink or red, depending upon the degree of hemolysis.

1. Grossly Hemolyzed Sample

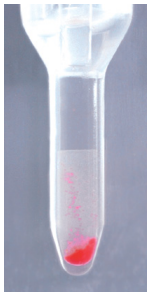


2. Hemolyzed Sample



3. Hemolyzed Sample

Illustrations 1, 2, and 3 demonstrate negative test results using hemolyzed samples of varying degrees. If a hemolytic reaction occurs during an indirect antiglobulin test, the microtube may appear similar with the exception that few to no red blood cells will appear in the gel.

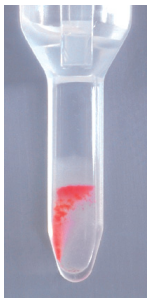


4. Weak Positive Reaction

5. Weak Positive Reaction

Some antigen-antibody reactions may appear weak. Refer to Illustrations 4 and 5.

These positive reactions contain a few agglutinated red blood cells in the middle of the gel or a few agglutinated red blood cells just above the disrupted red blood cell button. These are considered positive and should be graded 1+.



6. Positive Reaction, Abnormal Position of Red Blood Cell Agglutinates

Positive reactions that show agglutinated red blood cells beginning in the middle of the gel may occur if users wait longer than 10-15 minutes prior to initiating incubation or centrifugation of the gel cards. Refer to Illustration 6. Since red blood cell agglutinates are dispersed throughout the gel, the reaction should be graded 2+.

ABO and Rh Card Interpretations

Monoclonal cards for ABO grouping and Rh typing are available in various configurations.

MTS™ A/B/D Monoclonal and Reverse Grouping Card

This gel card is capable of testing the forward and reverse types on a single card.

The reagents are pre-dispensed (Monoclonal Anti-A, Monoclonal Anti-B, Monoclonal Anti-D, Monoclonal Control, and MTS™ Buffered Gel in the last two microtubes).

Diluted patient/donor cells and plasma are added as well as 0.8% reverse grouping red blood cells.

Reaction grading is identical to all other gel card grading.

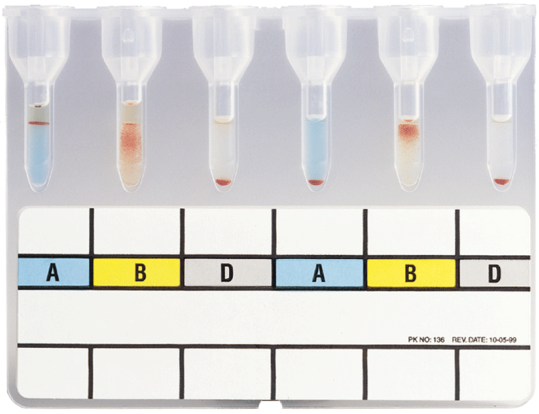
MTS™ A/B/D Monoclonal and Reverse Grouping Card:
Group O Rh-negative is shown

MTS™ A/B/D Monoclonal Grouping Card

This gel card provides two forward types in a single card.

The reagents are pre-dispensed (Monoclonal Anti-A, Monoclonal Anti-B, Monoclonal Anti-D, Monoclonal Anti-A, Monoclonal Anti-B, Monoclonal Anti-D), and the diluted donor/patient cells are added prior to centrifugation.

Reaction grading is identical to all other gel card grading.



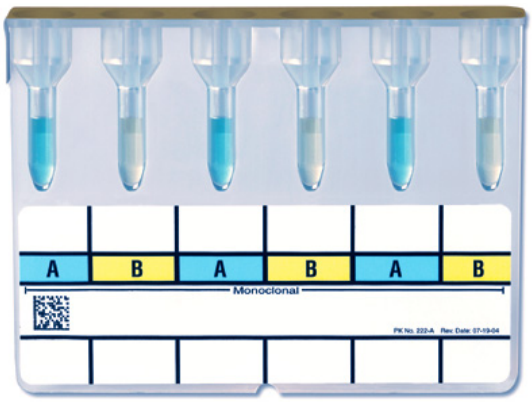
MTS™ A/B/D Monoclonal Grouping Card:
Group AB Rh-negative and Group B Rh-negative are shown

MTS™ A/B Monoclonal Grouping Card

This gel card provides three ABO forward groupings in a single card.

The reagents are pre-dispensed (Monoclonal Anti-A, Monoclonal Anti-B, Monoclonal Anti-A, Monoclonal Anti-B, Monoclonal Anti-A, Monoclonal Anti-B), and the diluted red blood cells are added prior to centrifugation.

Reaction grading is identical to all other gel card grading.



MTS™ A/B Monoclonal Grouping Card:
No reaction shown.

NOTE: Most blood types will demonstrate 4+ reactions with weaker reactions potentially representing weak subgroups or weak representations of naturally occurring Anti-A and Anti-B. ABO discrepancies are resolved in the usual manner according to the facility's Standard Operating Procedures (SOPs). No control is necessary when using monoclonal reagents, except when a Group AB Rh-positive is tested. 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.

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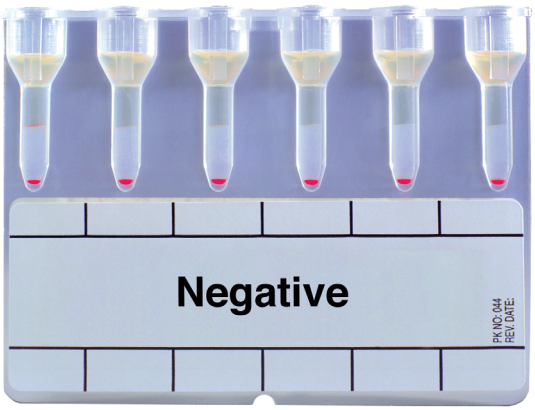
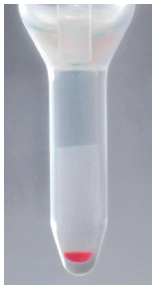
Chapter 4: Troubleshooting

Reactions Associated with Sample Quality Issues

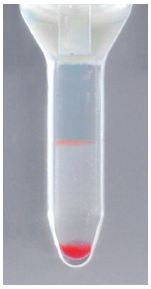
A few unagglutinated red blood cells may be observed on the top of the gel with some negative reactions. These reactions may be associated with the following sample quality issues:

- Samples with clots, particulates, or other artifacts
- Freshly collected plasma/serum samples or fibrin
- Samples previously frozen

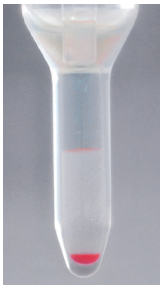




1. Negative Reaction, No Top Line Observed



2. Negative Reaction, Top Line Observed



3. Negative Reaction, Top Line Observed

Samples should be free from debris or particulates prior to use in the gel system. A typical negative reaction is shown in Illustration 1.

Clots, particulates, or other artifacts may cause some red blood cells to become trapped at the top of the gel.

Freshly collected plasma/serum samples may have a line/circle of unagglutinated red blood cells at the top of the gel. These red blood cells will appear very pink and faint and do not have the same red, clumping appearance as a positive test result. See Illustrations 2 and 3. These results should not be considered a mixed-field. Fibrin may be observed in tests where plasma or serum is added. Anomalous results may be caused by fibrin or other particulate matter in blood samples that could stick to the sides of the microtube. Use caution to not misinterpret this as mixed field as the patterns may appear similar.

Samples previously frozen should be mixed well and centrifuged before use.

Reactions Associated with Recently Transfused Patients

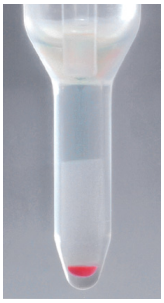
The potential exists for unexpected or mixed field results (see section *Test Reactions: Mixed Field Reactions*) in samples from recently transfused patients, bone marrow transplant patients, and patients with blood group chimerism[1] due to the existence of two distinct, separable populations of red blood cells in the sample. Mixed field and unexpected reactions due to transfusion last only for the life of the transfused red blood cells. After hematopoietic transplantation, the mixed-field reaction usually disappears when the patient's own red blood cells are no longer produced. Mixed-field reactions that arise through blood group chimerism may persist throughout the life of the individual.

1.Fung, Mark K., et al. (ed) Technical Manual, 19th Ed. Bethesda, MD: American Association of Blood Banks, 2017; Chapter 10, ABO Discrepancies (Red Cell Testing Problems), pg. 275.

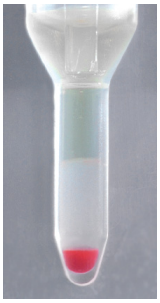
Too Many or Too Few Red Blood Cells in a Negative Reaction

Too many or too few red blood cells in the microtube may be a direct result of using an improperly prepared red blood cell suspension, or adding incorrect quantities of red blood cells to the upper reaction chamber of the microtube.

Variations in red blood cell concentration may affect the sensitivity of the test.



4. Negative Reaction, Typical Red Blood Cell Button



5. Negative Reaction, Too Many Red Blood Cells

6. Negative Reaction, Too Few Red Blood Cells

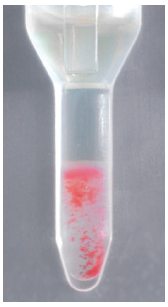
Typical Red Blood Cell Button: Illustration 4 shows the appearance of a typical red blood cell button. This button was derived by adding 50 µL of a 0.8% red blood cell suspension to the gel card as part of the indirect antiglobulin test procedure.

Negative Reaction With Too Many Red Blood Cells: Illustration 5 shows a large red blood cell button caused by adding red blood cells from an improperly prepared red blood cell suspension. Too many red blood cells may cause difficulty making correct test interpretations. If the red blood cell button is large enough, weak reactions may be missed due to masking of red blood cell agglutinates in the bottom portion of the microtube.

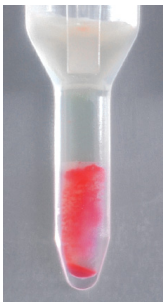
Negative Reaction With Too Few Red Blood Cells: Illustration 6 shows a small red blood cell button caused by adding red blood cells from a very weak red blood cell suspension. If too few red blood cells are added to the gel card, there may not be enough red blood cells to make a valid test interpretation.

Too Many or Too Few Red Blood Cells in a Positive Reaction

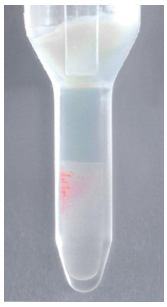
Too many or too few red blood cells in the microtube may be a direct result of using an improperly prepared red blood cell suspension, poor mixing of red blood cell suspension, or adding incorrect quantities of red blood cells to the upper reaction chamber of the microtube. Variations in red blood cell concentration may affect the sensitivity of the test.



7. Positive Reaction Typical 2+ Reaction



8. Positive Reaction, Too Many Red Blood Cells



9. Positive Reaction, Too Few Red Blood Cells

Typical 2+ Positive Reaction: Illustration 7 shows a typical 2+ reaction. This was derived by adding 50 µL of a 0.8% red blood cell suspension, along with plasma/serum containing antibody, to the gel card as part of the indirect antiglobulin test procedure.

Positive Reaction With Too Many Red Blood Cells: Illustration 8 shows a 2+ reaction with too many red blood cells. This was caused by adding red blood cells from an improperly prepared red blood cell suspension. Too many red blood cells may cause difficulty making correct test interpretations. It is possible when red blood cell suspensions are too concentrated that weaker reactions may be observed due to the increase in the antigen-antibody ratio.

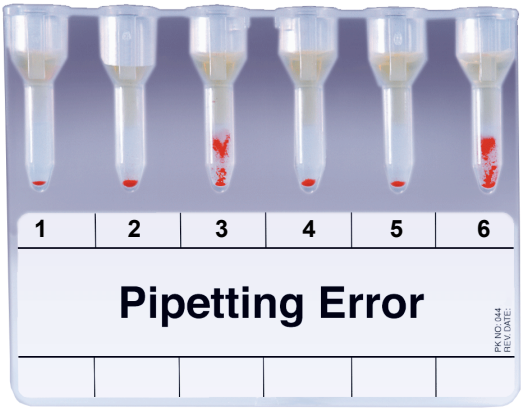
Positive Reaction With Too Few Red Blood Cells: Illustration 9 shows a 3+ reaction with too few red blood cells caused by adding red blood cells from a very weak red blood cell suspension. When red blood cells are too low in concentration, they become difficult to see.

Pipetting Errors

Indirect AHG tests should have a total of 75 µL of reactants added to the reaction chamber, 50 µL of the red blood cell suspension and 25 µL of the test sample.

- If a pipetting error of plasma/serum occurs, the microtube will exhibit a difference in the liquid levels in the upper reaction chamber following centrifugation.
- If a red blood cell suspension pipetting error occurs, the size of the red blood cell button may be incorrect.

Illustration 10 shows the effect of pipetting errors in microtubes 1 and 2; however microtubes 3, 4, 5, and 6 show no visible pipetting errors.



10. Pipetting error visible in microtubes 1 and 2.

Microtube 1
Too few red blood cells

Microtube 2
No serum/plasma added

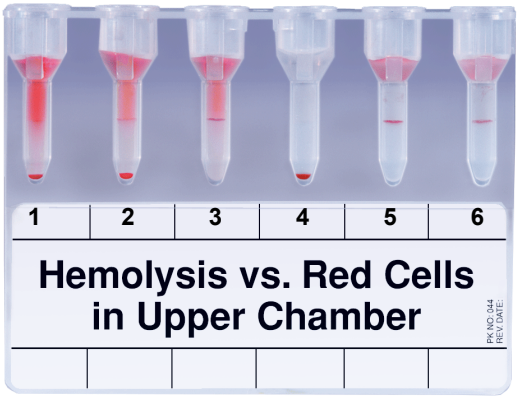
Microtube 5
Correct volumes of reactants

If a pipetting error is recognized, the test must be repeated.

CAUTION: The pipette tip should not touch the gel card or erroneous results due to carryover may occur.

Hemolyzed Sample vs. Red Blood Cells in the Upper Chamber

A pink or red appearance in the upper chamber that extends to the top of the gel microtube is most likely indicative of hemolysis, either from the use of a hemolyzed sample or as a result of complement binding during incubation. A pink or red appearance noted only in the upper chamber is more apt to be due to the presence of intact red blood cells.



CAUTION: Hemolyzed test results should be used with caution.

The first two microtubes in this gel card demonstrate the appearance of hemolysis. See Illustration 11. The red blood cells are in a button at the bottom of the microtube; no agglutinins are noted in the gel microtube.

- If the red blood cell button is of normal size and the original sample is noted to be hemolyzed, these two tests should be interpreted as negative.
- If the red blood cell button is decreased and the original test sample is free of hemolysis, these tests may be indicative of a positive test due to in-vitro hemolysis and further investigation should be performed.

The third microtube demonstrates a 4+ reaction and the original sample is noted to be hemolyzed.

The fourth microtube shows a normal negative gel test, i.e., red blood cell button at the bottom of the microtube, with no hemolysis or red blood cells noted in the upper chamber (see Illustration 12).

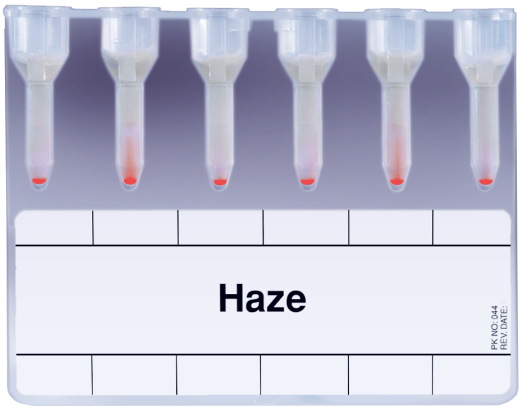
The fifth and sixth microtubes contain intact red blood cells adhering to the walls of the upper reaction chambers (see Illustration 13). The red blood cells that came in contact with the Anti-IgG reagent in the gel microtube have agglutinated and resulted in a 4+ reaction. Those red blood cells remaining in the upper chamber have adhered to the side of the reaction chamber. This adherence may occur because there is a high protein level in the sample being tested or because there is increased static electricity in an environment with low humidity.

11. Hemolysis in Microtube 1

12. Negative Test in Microtube 4

13. Red Blood Cells in Upper Chamber in Microtube 5

Haze or Pink Color in Gel



Occasionally, gel tests may appear hazy or pink with no evidence of red blood cell agglutination. These reactions differ from typical positive or negative results.

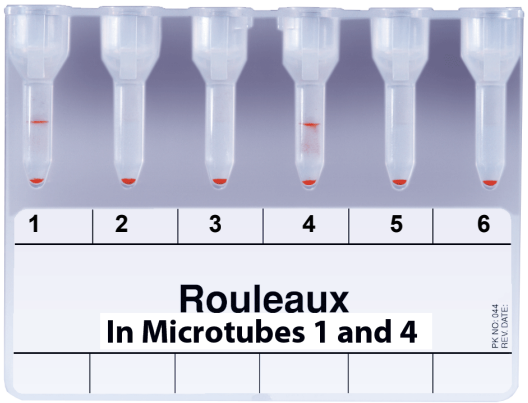
Hazy or pink color in gel tests may be induced by high levels of abnormal proteins in the patient's plasma or serum which may also present as rouleaux (such as in patients with multiple myeloma or Waldenstrom's macroglobulinemia or from patients who have received plasma expanders of high molecular weight). Information regarding the patient's diagnosis and total serum protein may help confirm this explanation. Rouleaux caused by plasma or serum with abnormally high concentrations of protein may infrequently cause difficulties in ID-MTS™ Gel Test interpretation.

Haze

Haze

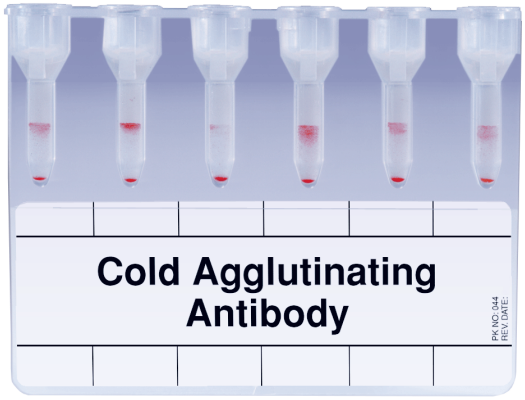
Haze

False positive or hazy reactions in the forward grouping 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. 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.



Direct Agglutinating Antibody

In antibody detection or identification tests, samples containing strong, direct agglutinating antibodies may give the appearance of a mixed-field reaction. As illustrated in the photo to the right, the most common direct agglutinins are cold-enhanced IgM antibodies.



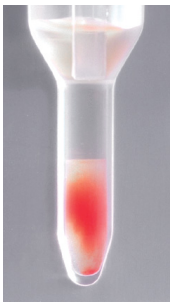
Direct agglutinins may give a mixed-field appearance in Anti-IgG gel antibody detection or identification tests. It may be helpful to perform a room temperature or 37°C test procedure using the MTS™ Buffered Gel Card. Reactivity in these tests indicates the presence of direct agglutinating antibody. Reactivity only at room temperature or reactivity that is stronger at room temperature would be consistent with a strong IgM cold agglutinin in the test sample.

Cold Agglutinin

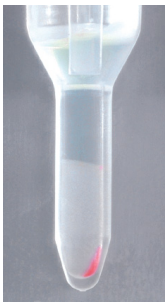
Cold Agglutinin

Improper Centrifugation

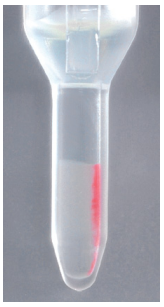
When centrifugation cycles are interrupted or cards are not spun at the proper angle or speed, all six microtubes of a gel card will have a similar appearance. These reactions differ from typical positive or negative results.



14. Interruption in Centrifugation; No Result Determined



15. Incorrect Card Position During Centrifugation; No Result Determined



16. Incorrect Card Position During Centrifugation; No Result Determined

If all microtubes in a card or all cards in the same run appear the same this may indication of a mechanical issue. If a mechanical issue is suspected repeat testing. If the problem persists refer to the Workstation Reference Guide for additional troubleshooting.

If all microtubes do not appear the same in the card, this may be an indication of a sample related issue. Consult standard operating procedures for handling anomalous reactions.

If the centrifugation cycle is interrupted, unagglutinated red blood cells may be observed in the gel. These red blood cells will appear dark pink and hazy. See Illustration 14. Because all six microtubes within a gel card are centrifuged under the same conditions, improper centrifugation is easily recognized by all six microtubes showing the same or similar appearance.

Additionally, if cards are not properly seated in the card holders and not allowed to spin at a 90 degree angle during centrifugation, a line of red blood cells may stream down one side forming a “J” appearance. See Illustrations 15 and 16. These tests should be repeated.

In these situations, do not recentrifuge these gel cards under any circumstances. The recentrifugation of gel cards may dissipate weak reactions producing false negative results.

NOTE: If a J like reaction is obtained with ORTHO Sera in ID-MTS Gel cards, refer to the ORTHO Sera IFU for additional information.

Chapter 5: Suggested Reading

Malyska H, Weiland D. The Gel Test. Laboratory Medicine, 1994; 25:81-5.

Lapierre Y. et al. The gel test: a new way to detect red cell antigen-antibody reactions. Transfusion, 1990;30:109-113.

Fung, Mark K., et al. (ed) Technical Manual, 19th Ed. Bethesda, MD: American Association of Blood Banks, 2017.

Instructions for Use: Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Card (current version). Pompano Beach, FL: Micro Typing Systems, Inc.

Instructions for Use: Blood Grouping Reagent MTS™ A/B/D Monoclonal Grouping Card, (current version). Pompano Beach, FL: Micro Typing Systems, Inc

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Revision History

Publication Lot Date	Section	Description
2022-05-01	Entire guide	• Updated layout and format to align with Ortho's bloodline branding. • All images edited to provide higher quality and cohesive look. • Separated guide into five chapters to help improve readability. • Edited content for formating within new chapters and sections. • Reviewed all content, clarified and simplified as appropriate. • Clarified references of serum and plasma from a usability perspective to serum/plasma.
	Front Cover	• Front and back covers changed as per the approved bloodline branding.
	Front Matter	• Replaced the outdated Proprietary Notice with Ortho's established Important notice. • Updated copyright information to reflect 2022.
	Introduction	• Added NOTE about illustrations and images used throughout guide. • Changed www.orthoclinical.com to www.orthoclinicaldiagnostics.com. • Removed the obsolete Ortho Fax on Demand option reference. • Gel Card with 6 Microtubes: - Replaced image. - Added call outs to identify sections of the card. • Microtube Enlarged: - Replaced microtube image. - Replaced dextran acrylamide gel particles with agglutinated cells image. - Identified sections within the image for clarity.

Publication Lot Date	Section	Description
2022-05-01	Visual Inspection of Gel Cards Prior to Use	• Content arranged based on Acceptable and Unacceptable Microtubes, followed by an acceptability table and additional topics for manual users. • Introduction paragraph updated to match the product(s) Instructions For Use (IFU). • Added Caution statement about acceptable and unacceptable microtubes impact on product performance. • Acceptable Microtubes- Microtube Levels: - Added a new sub-section under Acceptable Microtubes, *Microtube Levels*. • Acceptable Microtubes- Residue: - Changed section title from *Other Cards Acceptable for Use* to *Residue*. - Removed information redundant with *Liquid Drops Above the Liquid Layer*. • Acceptable Microtubes- Liquid Drops Above the Liquid Layer: - Changed section title from *Gel Cards with Splashing in Upper Reaction Chamber* to *Liquid Drops Above the Liquid Layer*. - Replaced “splash” references to “liquid drops”. - Content updated to reflect acceptability for use. - Replaced images. • Unacceptable Microtubes- No Liquid Layer: - Changed section title from *Gel Cards with No Liquid Layer above the Gel* to *No Liquid Layer.* - New images added. - Content updated to align with IFU. • Unacceptable Microtubes- Low Gel Level: - Changed title from *Gel Cards with Microtubes Containing Low Gel Levels* to *Low Gel Level.* - Clarified section describing microtube levels. - Replaced Images.

Publication Lot Date	Section	Description
2022-05-01	Visual Inspection of Gel Cards Prior to Use (continued)	• Unacceptable Microtubes- Bubbles in the Microtubes: - Changed section title from *Gel Cards with Bubbles in the Microtubes* to *Bubbles in the Microtubes*. - Added information about air entrapped in gel and/or liquid. - Information about bubbles and the migration of red blood cells added. • Unacceptable Microtubes- Signs of Drying in the Gel Matrix: - Changed section title from *Gel Cards Showing Signs of Drying* to *Signs of Drying in the Gel Matrix*. - Added content about drying gel, with or without liquid present. - Replaced images. • Acceptability of Gel Cards: Added new section. • Debris: Added new section. • Inspection of Gel Cards after Removal of Foil: Added information about foil seal removal and drying after removal.
	Test Reactions	• Interpreting Gel Test Reactions: - Added NOTE about patient history when interpreting reactions. - Removed page number references. • Range of Reactions in the ID-MTS™ Gel Test: - Moved reaction grades to bottom of card. • To improve the content flow, removed all sections titles: *Definition* and *Discussion*. • Negative Reactions: - Reduced the number of negative reaction images. • Strongly Positive Result with a Few Nonreactive Red Blood Cells: - Moved section from *Troubleshooting* section to *Reactions* chapter, to follow *4+ Reactions*.

Publication Lot Date	Section	Description
2022-05-01	Test Reactions (continued)	• Mixed-Field Reactions: - Removed sentence about mixed-field reactions when testing reagent red blood cells in an antibody screening or identification procedure. - For emphasis, added asterisks to two Mixed-Field Reaction images and the last sentence about sufficient minor population. - Added sub-section on Fibrin. • Hemolysis, Weak Reactions, Abnormal Position of Agglutinated Cells: - Moved content to precede *ABO and Rh Card Interpretations* to improve content flow. • MTS™ A/B/D Monoclonal Grouping Card: - Removed information about ideal use of card. • MTS™ A/B Monoclonal Grouping Card: - Removed information about ideal use of card. - Labeled last paragraph as a NOTE.
	Troubleshooting	• Renumbered illustrations. • Reactions Associated with Sample Quality Issues: - Added information about fibrin and interpreting as mixed field. • Reactions Associated with Recently Transfused Patients: - Placed content into a separate section. - Updated document version and reference for Fung, Mark K., et al. (ed) Technical Manual. • Too Many or Too Few Red Blood Cells in a Negative Reaction: - Changed “Normal Red Blood Cell Button” to “Typical Red Blood Cell Button” for consistency with other sections.

Publication Lot Date	Section	Description
2022-05-01	Troubleshooting (continued)	• Pipetting Error: - Removed pipetting example. - Clarified the size of the red blood cell button may be incorrect, and not reduced as previously stated. - Removed the irrelevant reaction results from example. - Removed illustration numbers from microtube images to improve clarity and connect to illustration 10. - Removed redundant content in the paragraph under the microtube illustrations. • Strongly Positive Result with a Few Nonreactive Red Blood Cells: - Moved to Chapter 3 *Test Reactions*. • Hemolyzed Sample vs. Red Blood Cells in the Upper Chamber: - Added caution statement to use hemolyzed results with caution. • Haze or Pink Color in Gel: - *Rouleaux* section merged with *Haze or Pink Color in Gel* section. - Content reorganized and condensed. - New content regarding patient diagnosis and total serum protein added. • Direct Agglutinating Antibody: - Removed references regarding reactions from a single donor source. • Improper Centrifugation: - Removed centrifuge image. - Added content to aid in identifying a mechanical issue and sample related issue. - Added NOTE about J like reactions.
	Suggested Reading	• Updated document version and reference for Fung, Mark K., et al. (ed) Technical Manual.

Publication Lot Date	Section	Description
2017-05-16	Front Cover	• Updated Revision date
	Front Matter	• Added copyright date 2017. • Updated Global Changes - - “Customer Technical Services” to “Ortho Care™ Technical Solutions Center” - “OCD Customer Technical Services (CTS)” to “Ortho Care™ Technical Solutions Center”
	Introduction	• Updated Global Changes - - “OCD” to “Ortho” - “Customer Technical Services” to “Ortho Care™ Technical Solutions Center” - “OCD Customer Technical Services” to “Ortho Care™ Technical Solutions Center”
	Troubleshooting	• Added CAUTION note • Added information related to pipetting error
	Back Cover	• Added copyright date 2017.
2016-03-15	Front Cover	• Updated company logo. • Placed “Rx ONLY” symbol on US Licensed prescription drug product labeling per the FDA Modernization Act of 1997 (FDAMA).
	Mixed Field Reactions	• Discussion: Inserted “(see section Troubleshooting: Reactions Associated with Recently Transfused Patients for information about recently transfused patients)” at the end of the second sentence.
	Troubleshooting	• Added section entitled “Reactions Associated with Recently Transfused Patients.”
	Suggested Reading	• Updated the reference to the AABB Technical Manual
	Back Cover	• Updated company logo.

Publication Lot Date	Section	Description
2010-06-04	Entire guide	• Updated trademarks.
	Introduction	• Replaced “package insert” with “Instructions for Use,” and described how to obtain IFUs. • Removed statement claiming improved sensitivity, specificity and reliability for gel test.
	Reading Gel Test Reactions	• Added statement that if hemolysis is observed, facility procedures should be consulted.
	Interpreting Gel Test Reactions	• Added page references; arranged following pages in corresponding order. • Added caution regarding clots, particulates and other artifacts.
	2+ Reactions	• Clarified Discussion of 2+ reactions.
	Other Reactions	• Changed heading from “Hemolysis\Weak Reactions\Other” to “Hemolysis, Weak Reactions, Abnormal Position of Agglutinated Cells.”
	Visual Inspection of Gel Cards Before Use	• Added instruction to inspect cards for residual film after removing foil. Added photos showing acceptable and unacceptable gel cards.
	Troubleshooting: Pipetting Errors	• Specified which microtubes exhibit pipetting error in Illustration 16.
	Troubleshooting: Rouleaux	• Specified which microtubes exhibit rouleaux in graphic. • Clarified definition and discussion of rouleaux; using verbiage from MTS™ Instructions for Use.

Publication Lot Date	Section	Description
2008-12-09	Introduction: Gel Test Principle	• Expanded history of gel test; rephrased description of centrifugation. • Updated photograph of gel card. • Added photograph of dextran acrylamide gel particles with agglutinated red blood cells.
	Introduction: Interpreting Gel Test Reactions	• Corrected description of 2+ reaction by changing “A few agglutinates may be observed in the bottom of the microtube” to “A few unagglutinated red blood cells may be observed in the bottom of the microtube.” • Re-ordered list of reaction levels and rearranged following pages to correspond. • Replaced photograph illustrating range of reactions.
	ABO and Rh Card Interpretations	• Added “monoclonal” to occurrences of • Anti-A, Anti-B and Anti-D. • Added photo of MTS™ A/B Monoclonal Grouping Card
	Troubleshooting: Pipetting Errors	• Adjusted images to more accurately depict the pipetting errors described.
	Troubleshooting: Rouleaux	• Expanded discussion to include guidance for dealing with rouleaux, reflecting the MTS™ Instructions for Use.
	Troubleshooting: Haze or Pink Color in Gel	• Added cross reference to Rouleaux section for additional information and instructions.
	Suggested Reading	• Updated edition of AABB Technical Manual.

Publication Lot Date	Section	Description
2006-04-27	Front Matter	• Added copyright date 2006.
	Table of Contents	• Regenerated for this revision.
	Introduction	• Provided additional information to consult the package insert for specific instructions for use. • Edited, “Reading Gel Test™ Reactions” title.
	Interpreting Gel Test Reactions	• Updated Mixed Field Note. Removed the second sentence. Added, “Additional patient history and testing will be necessary for resolution.”
	Negative Reactions	• Clarified Definition section.
	Mixed-Field Reactions	• Provided instruction to gather additional patient history and testing before interpreting reactions as mixed field.
	ABO and Rh Card Interpretations	• Added, “...and Rh”
	Visual Inspection of Gel Cards Before Use	• Added section on, “Other Cards Acceptable for Use.”
	Troubleshooting: Reactions Associated with Sample Quality Issues	• Removed, “...which can be minimized by the use of samples collected in EDTA.”
	Troubleshooting: Cold, Agglutinating Antibody	• Changed the title to, “Direct Agglutinating Antibody.” • Replaced “cold-reactive” with “direct” agglutinating. • Clarified the Discussion section.
	Trouble Shooting: Improper Centrifugation	• Clarified the Discussion section.
	Suggested Reading	• Updated the reference information.
	Revision History	• Revised to include listing of current revisions.

Publication Lot Date	Section	Description
2004-10-21	Entire guide	• Dated all pages YYYY-DD-MM. • Changed the page layout using the OCD template. • Edited wording for clarity. • Changed the term *mixed-cell* to *mixed-field.* • Used the term *red blood cells* consistently • When appropriate, numbered the illustrations.
	Front Matter	• Added this page.
	Table of Contents	• Added the Table of Contents.
	Introduction	• Added Gel Test Principle section.
	Introduction	• Added Reading Gel Test Reactions section.
	Introduction	• Added Interpreting Gel Test Reactions section.
	ABO Card Interpretations	• Added MTS™ AB Monoclonal Grouping Card information.
	Visual Inspection of Gel Cards Before Use	• Added this section.
	Troubleshooting Reactions Associated with Sample Quality Issues	• Renamed this section and added information.
	Troubleshooting Pipetting Errors	• Added to the explanation.
	Troubleshooting Haze or Pink Color in Gel	• Reworded the Discussion section.
	Troubleshooting Improper Centrifugation	• Added to the explanation.
	Suggested Reading	• Added this section.
	Revision History	• Added this section.

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