PROCEDURE

Title: Immediate Spin Crossmatch Using MTS Buffered Gel Card

Procedure #: 2015BLOODBANK12

Institution: Highlands Regional Medical Center

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Accepted by: _____ Date: 5-27-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 5/27/2015 - 3/1/1999

Review of procedure every two years

Reviewed by: _____ Date: _____

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Discontinued testing date: _____

PROCEDURE 12

Buffered Gel

Immediate Spin Crossmatch Using MTS™ Buffered Gel Card

Principle

The crossmatch compatibility test is used to detect the presence of blood group antibodies in an intended recipient's serum/plasma directed towards antigens present on donor red blood cells. An immediate spin crossmatch can be performed using the MTS™ Buffered Gel Card. In the gel test, the donor red blood cells are combined with recipient serum/plasma in the upper reaction chamber of the microtube of an MTS™ Buffered Gel Card. The gel cards are centrifuged and examined for agglutination. Agglutination indicates the presence of an antigen/antibody reaction while lack of agglutination indicates the absence of an antigen/antibody reaction. Agglutinated red blood cells become trapped in the gel at various levels within the microtube, depending on the size of the agglutinates. Free nonagglutinated red blood cells pass through the gel and form a button of red blood cells on the bottom of the microtube.

Specimen

No special preparation of the patient is required prior to specimen collection. Blood should be collected by approved techniques.

Fresh serum or plasma collected with or without anticoagulants may be used for antibody detection and identification. Testing should be performed as soon as possible. Samples that cannot be tested immediately should be stored at 2-8°C or frozen. In the case of potential recipients of blood transfusion, an FDA requirement states that the specimen should not be stored for longer than 3 days before testing. Antibodies dependent for their detection upon the binding of complement may not be detected if aged serum or plasma from an anticoagulated sample is used for antibody detection tests. Serum should be separated from the red blood cells when stored or shipped.

Hemolyzed and grossly icteric blood samples may be difficult to interpret in the ID-Micro Typing System™™. Test results should not be used. Grossly lipemic samples containing particulates that clog the gel as indicated by diffuse blotches of red blood cells may be clarified by centrifugation or filtration and retested.

Donor red blood cells collected in CPDA-1 or CPD may be tested up to the expiration date of the unit.

Reagents

- MTS™ Buffered Gel Card (buffered gel suspension)
- MTS™ Diluent 2 *PLUS* (a hypotonic buffered saline solution containing EDTA for red blood cell preparation only)

Do not use reagents beyond the expiration date.
Do not use gel cards that have not been shipped in an upright position.
Store gel cards upright at 2°C to 25°C.
Store diluent and red cells at 2°C to 8°C.
Bring reagents to room temperature (18°C to 25°C) prior to use.
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 ID-Micro Typing System™ Interpretation Guide for additional information related to the visual inspection of gel cards before use.

Quality Control

Gel Card

To confirm the reactivity of the MTS™ Buffered Gel Card, it is recommended that each lot be tested on each day of use with known positive and negative antibody samples with the appropriate red blood cells. Reactivity must be present with the positive sample only.

Diluent

MTS™ Diluent 2 *PLUS* should be visually checked to ensure that the liquid is not discolored, turbid, or showing any signs of bacterial contamination.

Procedure

Donor Unit 0.8% Cell Preparation, using packed red blood cells from donor unit segments or pilot tubes

1. Label a test tube for each donor to be tested.
2. Dispense 1.0 mL of MTS™ Diluent 2 *PLUS* into the labeled tube(s). Add 10 µL of the donor packed red blood cells.
3. Mix gently to resuspend. The final red blood cell suspensions should be approximately 0.8%.

Immediate Spin Crossmatch Test Procedure

1. Visually inspect each gel card 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 if 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 centrifuge cards that have failed the visual inspection. The use of these cards may lead to erroneous test results. Do not use cards if foil seals appear damaged or opened.**

Note: Refer to the ID-Micro Typing System™ Interpretation Guide for additional information related to the visual inspection of gel cards before use.

2. Label the MTS™ Buffered Gel Card with the appropriate identification.
3. Remove the foil seal from the gel card or from the individual microtubes used for testing.

Note: Foil should be removed immediately before testing or within one hour of testing. Once opened, the gel may begin to dry out which could affect test results. Ensure that residual foil does not block the opening of any microtube after removal of the foil.

4. Add 50 µL of the 0.8% donor red blood cell suspension to the appropriate microtube.

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

5. Add 50µL of recipient serum or plasma to the microtubes.

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

6. Centrifuge the gel card(s) in the MTS™ Centrifuge at the preset conditions.
7. For manual readings, observe the front and the back of each microtube macroscopically and record reactions as described in the interpretation section of the corresponding MTS™ Gel Card Instructions for Use.
   When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

Interpretation of Results (Refer to the Instructions for Use and the ID-Micro Typing System™ Interpretation Guide for detailed interpretation information)

- Negative Result (Compatible Crossmatch) – No agglutination and no hemolysis of the red blood cells is a negative test result.
- Positive Result (Incompatible Crossmatch) – Agglutination and/or hemolysis of the red blood cells is a positive test result. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few red blood cells may form a button in the bottom of the microtube in some positive reactions.

Comments

Interpretation of mixed-field reactions must be done with caution. The presence of fibrin, clots, or particulates may cause some cells to be trapped at the top of the gel. Mixed-field reactions are generally only be observed in tests containing a dual population of red blood cells, such as a transfused patient, bone marrow recipient, or when a pooled cell sample is used for testing. However, not all mixed cell situations have a sufficient minor population to be detected.

Limitations of the Procedure (Refer to the Instructions for Use and the ID-Micro Typing System™ Interpretation Guide for detailed product limitation)

CAUTION: **Adherence to the manufacturer's Instructions for Use is critical to test performance.**

- Proper centrifuge calibration is particularly important to the performance of the MTS™ Buffered Gel Card. The MTS™ Centrifuge has been exclusively designed to provide the correct time, speed, and angle.
- False positive or false negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples.
- Anomalous results may be caused by fresh serum, fibrin, or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube. Anomalous results (i.e., a line of red blood cells on the top of the gel) may be observed with serum samples and can be minimized by the use of EDTA plasma.
- Rouleaux caused by serum or plasma with abnormally high concentrations of protein (such as in patients with multiple myeloma or Waldenstrom's macroglobulinemia or from patients who have received plasma expanders of high molecular weight) may infrequently cause difficulties in Gel Test interpretation. 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. If the control test again gives a positive reaction, a valid interpretation of the results obtained cannot be made.
- Red blood cells must be diluted in the appropriate MTS™ Diluent at the proper concentration before the addition to the MTS™ Buffered Gel Card.
- Cold agglutinin testing may be done by pre-chilling and incubating cards at 2-8 °C. However, these reactions will be warmed during the centrifugation, which may result in the weakening of cold agglutination reactions.
- Antibodies to preservatives, medication, disease states, Wharton's jelly, and/or cross-contamination of reaction tubes may cause false positive reactions.
- False positive results may occur if a card that shows signs of drying is used in testing.

References

1. Roback, J. (ed) Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008.
2. Instructions for Use: MTS™ Buffered Gel Card (J32853), current revision. Pompano Beach, FL: Micro Typing Systems, Inc.
3. Instructions for Use: MTS™ Diluent 2 *PLUS* Red Blood Cell Diluent, current revision. Pompano Beach, FL: Micro Typing Systems, Inc.
4. Malyska H, Weiland D. The Gel Test. Laboratory Medicine, 1994; 25:81-5.
5. ID-Micro Typing System™ Interpretation Guide (6902201), Ortho Clinical Diagnostics

Authorization

Supervisor: _____ Date Instituted: 5/27/15

Pathologist: See Cover Sheet Date Reviewed: _____

Note: It may be necessary and is acceptable to modify any or all of these procedures to meet individual facility requirements. A facility may choose to use only those procedures it deems appropriate; however, consideration must be given to the particular product in use and its Instructions for Use, reference manual, and user's guide prior to altering any portion of this information. It is the responsibility of the end user to ensure that the procedures, as they are currently written or modified by the end user to meet needs, comply with regulations of local, state, and federal agencies and that appropriate documentation is available upon request to demonstrate changes to original documents and effective dates when changes were implemented.

Revision History

Date of Revision	Version	Description of Technical Changes
2010-05-31	5.0	• Aligned content with Instructions for Use (MTS™ Buffered Gel Card J32853) • Updated product references and trademarks. • Added reference to ID-Micro Typing System™ Interpretation Guide • Expanded limitations of the procedure to include guidance for resolving rouleaux test interference in agreement with Instructions for Use. • Added caution against the pre-centrifugation of cards that have failed visual inspection. • Replaced "package insert" with "Instructions for Use". • Updated References section.
2005-05-02	4.0	• Changed the format of document. • Changed the date format to YYYY-MM-DD. • Used the term **red blood cells** consistently. • Added step 1 to visually inspect gel cards and the Caution statement. • Added **or within one hour of testing** to the Note about the foil on the gel cards. • Added the sentence **Erroneous results due to carryover may occur.** to the Note stating the pipette tip must not touch the gel card. • Included the Note about the pipette tip not touching the gel card after each Add step. • Changed the wording of the title for preparing 0.8% suspension of antibody screen cell. • In Interpretation of Results, changed the first sentence in Negative Result to **No agglutination and no hemolysis**... and changed the first sentence in Positive Reaction to **Agglutination and/or hemolysis**... . • Changed the technical manual reference. • Changed the revision dates for the package inserts to **Current Revision.** • Added Revision History.