Micro Typing Systems, Inc.

# INSTRUCTIONS FOR USE

## Red Blood Cell Diluent
## MTS™ Diluent 2

REF MTS9230

## Intended Use

MTS™ Diluent 2 is a red blood cell diluent for exclusive use with tests performed in the ID-Micro Typing System™.[1]
For *in vitro* diagnostic use only.

## Observable Indications

Do not use if product shows signs of discoloration, turbidity, or other signs of microbial growth.

## Summary and Explanation

It has been well established that chromatography gels are very sensitive to physical and chemical parameters such as pH and ionic strength.[2] Therefore, all red blood cells must be diluted in the recommended diluents such as MTS™ Diluent 2 prior to use in the ID-MTS™ Gel Test.[3]

## Reagents

MTS™ Diluent 2 is a hypotonic buffered saline solution specially formulated to give the appropriate pH and ionic strength levels compatible with dextran acrylamide gel.
Preservatives: Trimethoprim and Sulfamethoxazole
No FDA Standard of Potency requirement.

## Storage Requirements

Store MTS™ Diluent 2 at 2–8 °C.

## Precautions

- For *in vitro* diagnostic use only.
- Do not use beyond expiration date.
- Do not freeze or expose MTS™ Diluent 2 to excessive heat.
- Use reagents as furnished. Do not dilute.
- Do not use if product shows discoloration, turbidity, or other signs of microbial growth.
- Remove plastic insert before use.

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| **Caution:** | **If using an MTS™ Dispenser, it is important to follow cleaning and maintenance procedures to reduce risk of contamination.**<br><br>**Not suitable for use as a red blood cell diluent in other immunohematology blood bank systems.** |

## Specimen Collection and Preparation

Instructions and precautions for the collection and storage of blood specimens are the same as those contained in the specific package insert for the ID-Micro Typing System™ Gel card(s) being used.

## Reagent Preparation

MTS™ Diluent 2 is provided ready to use.

## *Procedure*

Refer to the appropriate package insert for the ID-Micro Typing System™ test being used for the Red Blood Cell Dilution Method.

The procedures identified in the ID-Micro Typing System™ package inserts 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.

### Materials Provided

MTS9230 (5 x 100 mL bottles)

### Materials Required but not Provided

Refer to the appropriate package insert for the ID-Micro Typing System™ test being used.

### Test Procedure

Refer to the appropriate package insert for the ID-Micro Typing System™ test being used.

## Interpretation of Results

Refer to the appropriate package insert for the ID-Micro Typing System™ test being used.

## Stability of the Dilution

For best results it is recommended that red blood cells be used on the day of dilution. When diluted red blood cells are not being used they should be stored at 2–8 °C.

## Quality Control

Proper controls are essential in the performance of all laboratory procedures. MTS™ Diluent 2 should be visually checked on each day of use to ensure it has not become discolored, turbid, or show any other signs of bacterial contamination. Daily Quality Control should consist of known positive and negative red blood cells diluted with each lot of MTS™ Diluent 2 and tested with the ID-Micro Typing System™ test being used.

## Stability of Reaction

Refer to the appropriate package insert for the ID-Micro Typing System™ test being used.

## Limitations of the Procedure

1. Strict adherence to the procedures and recommended equipment is essential.
2. MTS™ Diluent 2 is a red blood cell diluent for exclusive use with the ID-Micro Typing System™.
3. Variations in red blood cell concentration can markedly affect the sensitivity of test results.[4] If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in the antigen/antibody ratio. In addition, red blood cells may fail to completely migrate to the bottom of the microtube and could cause a false positive interpretation. When red blood cells are too low in concentration, they become difficult to visualize, and, in extreme cases, a weak positive can fail to be detected.
4. 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.
5. Should extended delays in testing occur, red blood cells may lose antigenicity, hemolyze and may have an elution of antibodies from *in vivo* coated cells.
6. Anomalous results may be caused by fibrin or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube. Anomalous results (i.e. a line of red blood cells on the top of the gel) may be observed with serum samples and can be minimized with the use of EDTA plasma.
7. False-positive results may occur if a gel card that shows signs of drying is used in the ID-Micro Typing System™ test.
8. Refer to the appropriate package insert for the ID-Micro Typing System™ test being used.

## Bibliography

1. 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.
2. Heftmann E. ed. Chromatography, A Laboratory Handbook of Chromatographic and Electrophotetic Methods. 3rd. ed. VanNostrand Reinhold Company, 1975.
3. Malyska H, Weiland D. The gel test. Laboratory Medicine 1994; 25:81-85.
4. Brecher M. (ed) Technical Manual, 15th Ed. Bethesda, MD: American Association of Blood Banks, 2005.

## Glossary of Symbols

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

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|---|---|---|
|  Use by or Expiration Date (Day-Month-Year) |  Manufacturer |  Store at |
| LOT Lot Number | IVD *In vitro* Diagnostic Medical Device |  Consult Instructions for Use |
| REF Catalog Number or Product Code | | |

## Summary of Revisions

| Date of Revision | Version | Section | Description of Technical Changes* |
|---|---|---|---|
| 2014-11-24 | 3.0 | Specimen Collection and Preparation | Replaced section with a reference for the user/customer to refer to the Specimen Collection and Preparation section described in the package insert for the ID-Micro Typing System™ Gel card(s) in use. |
| 2010-12-30 | 2.0 | Summary of Revisions | Correction to version 1.0 description – technically equivalent to document 631207011 (February 2008). |
| 2010-01-14 | 1.0 | | New format; technically equivalent to document 631207021 (February 2008), with changes listed below. |
| | | All | • Minor format changes without affect on technical content. |
| | | All | • Updated Trademarks |
| | | Intended Use | • Moved the following statement from Summary and Explanation section to Intended Use section: "MTS™ Diluent 2 is a red blood cell diluent for exclusive use with tests performed in the ID-Micro Typing System™." |
| | | Summary and Explanation | • Moved the following statement to Reagents section "MTS™ Diluent 2 is a hypotonic buffered saline solution specially formulated to give the appropriate pH and ionic strength levels compatible with dextran acrylamide gel." |
| | | Reagents | • New section<br>• Moved preservatives to this section.<br>• Moved following statement to this section: "No FDA Standard of Potency requirement." |
| | | Precautions | • Cautions statements moved to this section. |
| | | Specific Performance Characteristics | • Removed section |
| | | Limitations of the Procedure | • Revised step 8 for documentation consistency. |
| | | Glossary of Symbols | • Updated Glossary of Symbols to be consistent with Glossary of Symbols used in the MTS™ Gel Card Instructions for Use. Definitions in the Glossary of Symbols have also been updated. |
| | | Copyright | • Consolidated text |

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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