PROCEDURE

Title: Quality Control Panel A Cells

Procedure #: 2015BLOODBANK71

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/12/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6/12/15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 5/3/2014

Review of procedure every two years

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Discontinued testing date: _____

Highlands Regional MEDICAL CENTER

719502

Policy Name: Resolve Panel A Quality Control **Department:** Blood Bank

Departmental Review: **Policy #:**

INITIATE DATE	DATE REVIEWED/REVISED	PAGE 1 of 2
05/03/2014	05/2015	

PURPOSE:
To ensure that the reagent is able to detect unexpected antibodies including the weak reacting antibodies.

POLICY:
For quality assurance Resolve Panel A should be tested with weak antibodies monthly, when new lot of reagent is received and on each day of use.

SPECIMEN:
Confidence antibody

REAGENTS:
MTS2 diluent
0.8 RESOLVE Panel A
IgG gel cards

PROCEDURE:
- Prepare a 1:20 dilution of Confidence Antibody by adding 50ul of Confidence antibody to 1ml of MTS2 diluent.
- Perform antibody identification as per manufacturer test procedure.
- Record reaction on the provided ANTIGRAM antigen profile list.

REPORTING RESULTS:
Positive reaction should be between 2+ and 3+. Negative reaction is not acceptable and should be repeated.

REFERENCES:
Ortho ID-Micro Typing System, Ortho RBC 0.8% Resolve Panel A Instruction Manual
QSA.05.06.01, Joint Commission E-edition effective 01-01-2015

HIGHLANDS REGIONAL MEDICAL CENTER
Sebring, FL
Laboratory

DOCUMENT CHANGE RECORD

Document Name: Routine Panel & Quality Control

Document Section: Blood Bank

Author: Mercedes Portuondo

Please circle one of the following: NEW (REVISION) ARCHIVE

Effective

Description of document, changes, and rationale: update of policy based on TJC BBP criteria (QC performance on each day of use)
Formal Training of staff required: None Attach email sent to staff about new procedures or changes to procedure if applicable
Method Validation required (attach documents): None
List any changes to the Lab Information system: None

Review and Approval	Signature	Date
Author	Mercedes Portuondo	5.28.15
Chief Technologist		
Admin. Lab Director		5/28/15
Laboratory Director		

Implementation occurs after signature by Laboratory Director.

Highlands Regional MEDICAL CENTER

Policy Name: Resolve Panel A Quality Control **Department:** Blood Bank

Departmental Review: **Policy #:**

INITIATE DATE **DATE REVIEWED/REVISED**
05/03/2014 **05/2015**

Reviewed by	Reviewed Date	Reviewed by	Reviewed Date

Initial Implementation Date: 05/03/2014

Reviewed by: _____ Date: 5.28.15
Department Supervisor

Reviewed by: _____ Date: 5/28/15
Department Adm. Director

Reviewed by: _____ Date: _____
Department Chief Technologist

Reviewed and Approved by: _____ Date: _____
Department Medical Director

Issued May 2006
e631202511_EN

Reagent Red Blood Cells
0.8% Resolve® Panel A

A Qualitative Test for the Identification of Unexpected Blood Group Antibodies Using the ID-Micro Typing System™ Gel Test Methods

REF
6902317

SUMMARY AND EXPLANATION

When an unexpected antibody has been detected in a sample, it must be identified to determine its clinical significance. Blood group antibodies are not all equally dangerous in transfusion therapy or in pregnancy. Once the identity of the antibody(ies) has been established, standard texts may be consulted for guidance in determination of clinical significance.

Antibody identification is accomplished by testing the serum/plasma against a panel of red cells having different antigen characteristics, observing the presence or absence of hemolysis or agglutination and comparing the pattern of reactivity with the antigen profile of the cells. 0.8% RESOLVE Panel A consists of human red blood cells from 11 individual donors and an ANTIGRAM® Antigen Profile. A separate product, 0.8% RESOLVE Panel B Reagent Red Blood Cells, is available should additional cells be required for the resolution of complex mixtures of antibodies.

PRINCIPLE OF PROCEDURE

Using the condition under which the antibody was originally detected, the serum/plasma is combined with each cell sample of the panel. Antibody identification is facilitated by recording the results of testing and grading the strength of reactivity.

REAGENT

0.8% RESOLVE Panel A is a series of human red blood cells in 0.8% suspensions from 11 group O individuals. The accompanying ANTIGRAM Antigen Profile lists the blood group factors determined to be present on (+) and absent from (0) each red blood cell.

One or more of the red blood cell donors used in 0.8% RESOLVE Panel A may have been held in frozen storage. The cells are suspended in a low ionic strength diluent, to which a purine and nucleoside have been added to maintain reactivity and/or retard hemolysis during the dating period. Trimethoprim (32 µg/mL) and sulfamethoxazole (160 µg/mL) have been added to retard bacterial contamination.

Use 0.8% RESOLVE Panel A directly from the vials. As with all reagent red blood cells, the reactivity of the cells may decrease during the dating period. The rate at which antigen reactivity (e.g., agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer. Do not use if marked hemolysis or evidence of contamination is observed.

FOR IN VITRO DIAGNOSTIC USE. No U.S. Standard of Potency. Do not freeze. Do not use beyond expiration date. The expiration date of each lot is no longer than 63 days, excluding the days in frozen storage, from the date of collection of red blood cells from any donor in the lot. Studies demonstrate consistent performance of this product from the time the vial is opened until the specified expiration date. Store at 2 to 8°C.

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

SPECIMEN COLLECTION AND PREPARATION

Either serum or plasma may be used. Specimen collection should be accomplished by accepted medical procedures. No special preparation of the patient is required prior to specimen collection. Bacterial contamination may interfere with the results and interpretation of the test. Specimen storage should be within applicable regulating agencies' requirements. If specimens are stored before testing, they should be stored at 2 to 8°C.

PROCEDURE

This product is to be used directly from the vial without further modification. Follow the Procedure section contained in the respective gel test package insert requiring a 0.8% red cell suspension in a low ionic strength diluent. Supplemental reagent red cells or autologous red cells may require modification to a 0.8% concentration according to the instructions in the relevant ID-Micro Typing System package inserts.

Material Provided

Reagent Red Blood Cells 0.8% RESOLVE Panel A

Materials Required But Not Provided

Please refer to the ID-Micro Typing System package insert for additional materials required for use.

RESULTS

Interpretation

1. Hemolysis or agglutination is a positive test result and reflects the presence of an antibody-antigen reaction.
2. No hemolysis or agglutination is a negative test result and indicates the absence of an antibody-antigen reaction.
3. Identification of the antibody present in the serum may be made by matching the reactions obtained with the ANTIGRAM Antigen Profile furnished with the reagent. If the antibody specificity is not evident, additional cells may be required. Such cells may be selected from 0.8% RESOLVE Panel B.
4. Due to the complexities associated with the Duffy blood group system in the black population, it cannot be assumed that cells which are labeled Fy(a+b-) or Fy(a-b+) are homozygous for the Fy^a or Fy^b antigen.

Stability of Final Reaction Mixture

All results should be read and recorded upon test completion.

CONTROL OF ERROR

1. A control consisting of the serum and autologous red blood cells prepared according to the ID-Micro Typing System package insert should be tested in parallel with 0.8% RESOLVE Panel A. A positive reaction indicates patient abnormality which must be resolved before the test results can be interpreted.
2. For quality assurance, 0.8% RESOLVE Panel A should be tested periodically with weak antibodies.

LIMITATIONS

1. Antibodies specific for low-incidence antigens not present on the test cells will not be detected.
2. Contaminated blood specimens may interfere with the test results.
3. Improper technique may invalidate the results obtained with this reagent.
4. False-positive test results may occur if antibodies to components of the preservative solution are present in the sample tested.
5. If multiple antibodies are present in the sample, additional cells may be required for identification.
6. These cells are contained in a low ionic strength diluent. The addition of other potentiators to the gel test card is not recommended and may affect the test results.
7. Complement-dependent antibodies may not be detected if a plasma specimen is used.
8. For antibody detection and identification, different serological methods are optimal for different antibodies. No single antibody screening or identification method optimally detects all antibodies. In some low ionic strength test systems, certain Anti-E and Anti-K antibodies have been reported to be nonreactive.

SPECIFIC PERFORMANCE CHARACTERISTICS

When properly stored and used for the identification of unexpected blood group antibodies, these reagent red blood cells will aid in the identification of antibodies directed against the antigens present on them within the limitations of the respective test system used. The complete antigen profile will vary with each individual lot. The presence or absence of each antigen listed on the accompanying ANTIGRAM Antigen Profile is demonstrated by testing in at least two independent laboratories. At least two sources of antiserum are used to test each antigen unless rarity of the antiserum precludes it. Each cell sample is shown to have a negative direct antiglobulin test, indicating that no human IgG or human complement components are detectable on the cell surface. Each lot of product is checked for compatibility with the ID-Micro Typing System gel test cards.

Meets requirements of the FDA.

Technical questions concerning this reagent should be directed in the U.S. to Customer Technical Services at 1-800-421-3311. Outside of the U.S., the company distributing this product should be contacted.

SUMMARY OF REVISIONS

Section	Revision
Title Section	Changed manufacturer's ID number from 631203663 to 631202511.
REAGENT	Changed concentrations for antibiotics to trimethoprim (32 µg/mL) and sulfamethoxazole (160 µg/mL).
	Added a new statement regarding open vial stability.
LIMITATIONS	Revised limitation #8 to include statement on antibody detection and identification.

BIBLIOGRAPHY / BIBLIOGRAPHIE / BIBLIOGRAFÍA

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Merry AH, Thomson EE, Lagar J, et al. Quantitation of antibody binding to erythrocytes in LISS. Vox Sang 1984;47:125-132.

Issitt PD. From kill to overkill: 100 years of (perhaps too much) progress. Immunohematology 2000;16:18-25.

KEY TO SYMBOLS / LÉGENDE DES SYMBOLES / CLAVE DE LOS SÍMBOLOS

The following symbols may have been used in the labeling of this product. / Les symboles suivants ont pu être utilisés sur l'étiquette de ce produit. / Los siguientes símbolos pueden haber sido empleados en el etiquetado de este producto.

Use by or Expiration Date (Year-Month-Day) /
À utiliser avant la date de péremption (année-mois-jour) /
Usar antes de o Fecha de caducidad (año-mes-día)

LOT

Lot Number / Numéro de lot / Número de lote

REF

Catalog Number or Product Code / Référence catalogue ou code produit / Referencia de catálogo o Código del producto

IVD

In vitro Diagnostic Medical Device / Pour diagnostic in vitro / Producto sanitario para diagnóstico in vitro

Temperature Limitation / Conserver à une température comprise entre / Limitación de temperatura

U.S. LICENSE 1236

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