

# Reagent Red Blood Cells

## 0.8% Surgiscreen®

For the Detection of Unexpected Blood Group Antibodies Using the ID-Micro Typing System™ Gel Test Methods

**REF**

6902316

**Rx ONLY**

### SUMMARY AND EXPLANATION

0.8% SURGISCREEN is used to detect unexpected antibodies in patient or donor samples. The detection of unexpected blood group antibodies depends on the method and/or medium and the temperature of reactivity of the antibody involved.

The likelihood of detecting a weak antibody or one that shows dosage can be increased by using screening cells from individuals with especially strong antigens. The strength of some antigens is greatest in homozygous individuals while D, C, E,  $\bar{c}$  and e antigen strength depends on the person's Rh genotype. 0.8% SURGISCREEN is a set of human group O red blood cells from three individual donors, each selected on the basis of expected antigen strength.

### PRINCIPLE OF PROCEDURE

Hemolysis or agglutination of 0.8% SURGISCREEN in the presence of serum/plasma may indicate the presence of an antibody directed against a corresponding antigen which is present on 0.8% SURGISCREEN. The specificity of the antibody can be determined through the use of 0.8% RESOLVE® Panel A Reagent Red Blood Cells.

### REAGENT

0.8% SURGISCREEN is composed of three vials containing 0.8% suspensions of human group O red blood cells which are labeled 0.8% SURGISCREEN 1, 0.8% SURGISCREEN 2 and 0.8% SURGISCREEN 3. 0.8% SURGISCREEN 1 is derived from the blood of an individual donor having the Rh phenotype  $R_1R_1$  (DCe/DCe) or  $R_1^wR_1$  (DC<sup>w</sup>e/DCe). 0.8% SURGISCREEN 2 is derived from the blood of an individual donor with the Rh phenotype  $R_2R_2$  (D $\bar{c}$ E/D $\bar{c}$ E). 0.8% SURGISCREEN 3 is derived from the blood of an individual donor with the Rh phenotype rr (d $\bar{c}$ e/d $\bar{c}$ e).

The accompanying ANTIGRAM® Antigen Profile lists the blood group antigens 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% SURGISCREEN 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% SURGISCREEN 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 Instructions for Use 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 Instructions for Use.

### Material Provided

Reagent Red Blood Cells 0.8% SURGISCREEN 1, 0.8% SURGISCREEN 2 and 0.8% SURGISCREEN 3

### Materials Required But Not Provided

Please refer to the ID-Micro Typing System Instructions for Use 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. 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<sup>a</sup> or Fy<sup>b</sup> antigen.

### Stability of Final Reaction Mixture

All results should be read and recorded upon test completion.

### CONTROL OF ERROR

1. 0.8% SURGISCREEN should be tested on day of use with weak antibodies following the procedure for the respective test method.
2. A control consisting of the serum and autologous red blood cells prepared according to the ID-Micro Typing System Instructions for Use may be tested in parallel with 0.8% SURGISCREEN. A positive reaction indicates patient abnormality which should be resolved before the test results can be interpreted.

### LIMITATIONS OF THE PROCEDURE

1. For optimal sensitivity, the sample under study should be tested with 0.8% SURGISCREEN 1, 0.8% SURGISCREEN 2 and 0.8% SURGISCREEN 3 individually.
2. Antibodies specific for low-incidence antigens not present on the test cells will not be detected.
3. Contaminated blood specimens may interfere with the test results.
4. Improper technique may invalidate the results obtained with this reagent.
5. False-positive test results may occur if antibodies to components of the preservative solution are present in the sample tested.
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 detection of unexpected blood group antibodies, these reagent red blood cells will detect 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. All vials of 0.8% SURGISCREEN contain red blood cells which are positive for the following high-incidence blood antigens: Lu<sup>b</sup>, Js<sup>b</sup>, Kp<sup>b</sup> and Yt<sup>a</sup> unless otherwise noted on the accompanying ANTIGRAM Antigen Profile. All vials of 0.8% SURGISCREEN contain red blood cells which are negative for the following low-incidence blood antigens: Js<sup>a</sup>, Kp<sup>a</sup>, Wr<sup>a</sup>, Di<sup>a</sup>, Vw, V, Lu<sup>a</sup> and C<sup>w</sup> unless otherwise noted on the accompanying ANTIGRAM Antigen Profile. The presence or absence of each antigen listed on the accompanying ANTIGRAM Antigen Profile has been demonstrated by testing with at least two sources of antiserum unless rarity of the antiserum precludes it. Each of these tests have been conducted and interpreted independently. 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 Ortho Care™ Technical Solutions Center at 1-800-421-3311. Outside of the U.S., the company distributing this product should be contacted.

ID-Micro Typing System is a trademark of Micro Typing Systems, Inc.

#### SUMMARY OF REVISIONS

Section	Revision
All	Changed package insert to Instructions for Use.
SPECIFIC PERFORMANCE CHARACTERISTICS	Changed Customer Technical Support to Ortho Care™ Technical Solutions Center.
Back Page	Updated copyright information.

## BIBLIOGRAPHY

1. Löw B, Messeter L. Antiglobulin test in low-ionic strength salt solution for rapid antibody screening and cross-matching. *Vox Sang* 1974;26:53-61.
2. Boral LI, Henry JB. The type and screen: a safe alternative and supplement in selected surgical procedures. *Transfusion* 1977;17:163-168.
3. Beattie KM. Control of the antigen-antibody ratio in antibody detection/compatibility tests. *Transfusion* 1980;20:277-284.
4. Allan JC, Bruce M, Mitchell R. The preservation of red cell antigens at low ionic strength. *Transfusion* 1990;30:423-426.
5. Lapierre Y, Rigal D, Adam J, Josef D, Meyer F, Greber S, Drot C. The gel test: a new way to detect red cell antigen-antibody reactions. *Transfusion* 1990;30:109-113.
6. Malyska H, Weiland D. The gel test. *Laboratory Medicine* 1994;25:81.
7. Technical manual. 14th ed. Bethesda, MD: American Association of Blood Banks, 2002.
8. Yaskanin DD, Jakway JL, Ciavarella DJ. Red blood cell diluent composition is important for detection of some anti-E. *Immunohematology* 2000;16:142-146.
9. Merry AH, Thomson EE, Lagar J, et al. Quantitation of antibody binding to erythrocytes in LISS. *Vox Sang* 1984;47:125-132.
10. 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*

US LICENSE 1236

Ortho Clinical Diagnostics

1001 US Highway 202, Raritan, NJ 08869 USA

© Ortho Clinical Diagnostics 1999-2017