Search-Cyte®
Search-Cyte® Plus
Search-Cyte® TCS
Reagent Red Blood Cells 0.8±0.1%

U.S. License No. 1740

For use in the detection of unexpected antibodies in gel techniquesFor *in vitro* diagnostic use

INTENDED USE

Search-Cyte®, Search-Cyte® Plus and Search-Cyte® TCS 0.8% Reagent Red Blood Cells are for the detection of unexpected antibodies in gel techniques.

For use with the DG Gel 8 System.

SUMMARY AND EXPLANATION

Search-Cyte®, Search-Cyte® Plus and Search-Cyte® TCS are suspensions of group O Reagent Red Blood Cells differing in antigenic configuration for use in antibody screening, and are selected to enable detection of most clinically significant blood group antibodies.

The antigen typings of each donor are provided on the antigenic constitution matrix that accompanies each product.

PRINCIPLE OF THE TEST

Antibodies react with red blood cells possessing the corresponding antigenic determinants. Search-Cyte® 0.8% Reagent Red Blood Cells products are utilized in the gel technique for the detection of unexpected blood group antibodies.

REAGENT

Search-Cyte® Reagent Red Blood Cells I and II are individual suspensions of group O red blood cells from two donors: one rr (cde/cde) and one R_1R_2 (CDe/cDE).

Search-Cyte® Plus Reagent Red Blood Cells I and II are individual suspensions of group O red blood cells from two donors: one R_1R_1 (CDe/CDe) and one R_2R_2 (cDE/cDE).

Search-Cyte® TCS Reagent Red Blood Cells I, II and III are individual suspensions of group O red blood cells from three donors: one R_1R_1 (CDe/CDe), one R_2R_2 (cDE/cDE) and one rr (cde/cde).

All red blood cells are 0.8±0.1 % suspensions in isotonic medium with added buffers (bicarbonate and phosphate) and preservatives (0.010 % neomycin (w/v) and 0.017 % chloramphenicol (w/v)). The suspending medium contains no ingredients to inhibit complement mediated hemolysis. Frozen/thawed red blood cells may have been used in this product. No U.S. standard of potency.

STORAGE AND STABILITY

- The expiration date of each lot is no longer than 61 days from the collection date of red blood cells from any donor in the lot.
- Store at 2-8 ˚C.
- **Do not freeze.**

Indication of deterioration: Notable hemolysis (which may be caused by microbial contamination or improper handling), darkening of Reagent Red Blood Cells or spontaneous clumping. The reactivity of the product may decrease slightly during the dating period.

PRECAUTION

- For *in vitro* diagnostic use.
- Use of plasma may result in failure to detect complement dependent antibodies due to its low complement activity.
- Do not use beyond expiration date. Reactivity of the product may decrease slightly during the dating period.
- 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.
- The pipette of the vial contains natural rubber latex, which may cause allergic reactions.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection. Serum from freshly clotted blood is preferred. For optimum test results, serum should be stored at 2-8 °C no longer than 72 hours prior to testing; however, serum may be frozen and stored up to 5 years at -20 °C or colder and tested at a later time if necessary. Plasma samples may be used; however, use of plasma may result in failure to detect complement dependent antibodies due to its low complement activity.[1,2]

MATERIALS

Materials Provided

Search-Cyte® 0.8% Reagent Red Blood Cells I and II , 2x10 ml, cat. no. 213657
Search-Cyte® Plus 0.8% Reagent Red Blood Cells I and II, 2x10 ml, cat. no. 213656
Search-Cyte® TCS 0.8% Reagent Red Blood Cells I, II and III, 3x10 ml, cat. no. 213655

Materials Required but Not Provided

DG Gel® 8 Anti-IgG cards (Diagnostic Grifols, S.A.)
Centrifuge for DG Gel cards (DG Spin, Diagnostic Grifols, S.A.)
Incubator DG Therm (Diagnostic Grifols, S.A.)

PROCEDURE

Both the reagent and the samples to be tested must be brought to room temperature (20-25 °C) prior to testing.

Carefully resuspend Search-Cyte® 0.8% Reagent Red Blood Cells by gentle inversion immediately prior to use. Reagent Red Blood Cells are ready-to-use.

Follow the procedure outlined in the DG Gel 8 System's instructions for use.

QUALITY CONTROL

A known negative and a known positive control with weak reacting antibodies should be run in parallel on each day of use.

Use of an autocontrol may be helpful in distinguishing autoantibodies and alloantibodies. If the autocontrol is positive, the serum may contain auto-antibody and further testing may be indicated.[2]

RESULTS

Interpretation

Agglutination and/or hemolysis (positive reaction) with any of the Search-Cyte® cells indicate the presence of unexpected antibodies. Such antibodies are usually directed against the known antigens present on the screening red blood cells, but may be directed against an antigen not indicated on the antigenic constitution matrix. The lack of both agglutination and hemolysis (negative reaction) in the test procedure indicates the absence of antibodies to antigens contained in the reagent. Agglutination or hemolysis in the autocontrol well indicates further studies are necessary.[1]

LIMITATIONS OF PROCEDURE

1. False positive or false negative results can occur due to contamination of test material, improper reaction temperature, improper storage of materials, improper centrifugation, omission of test reagents, or certain disease states.
2. Any modifications of the test procedures described in this instruction for use require validation by the user.
3. If poor anti-coagulated plasma or incompletely clotted serum is used, fibrin residues may trap non-agglutinated red blood cells at the top of the gel, appearing as a pinkish or reddish layer, but the negative reaction can be interpreted as such. It is recommended to reclot the serum and repeat the test.[2]
4. Low-incidence antigens may not be represented in the Search-Cyte® 0.8%Reagent Red Blood Cells, so negative reactions with them do not always indicate absence of an antibody in the sample under study.
5. Because of the high incidence of the *Fy4* gene in the Black population, it cannot be assumed that the phenoptypes Fy(a+b-) and Fy(a-b+) in Black donors represent homozygous expressions of the Fy^a or Fy^b genes. Use of an autocontrol may be helpful in distinguishing between autoantibodies and alloantibodies.[3]

False negative results may occur under the following conditions:

1. If antibody elutes from red blood cells during incubation.
2. If red blood cells and/or serum are stored improperly and lose reactivity.
3. If incubation times and/or temperatures are incorrect for proper red blood cells sensitization.

4. If plasma is used, complement-dependent hemolytic reactions may not be detected.

False positive results may occur under the following conditions:

1. If antibodies to antibiotics or to other ingredients in the red blood cells suspending medium used are present in the test serum.
2. In rare cases, the test serum contains an antibody directed at one of the components of the reagent diluent.
3. The formation of "rouleaux", caused by an excess of protein in the serum, the presence of abnormal proteins, drugs, plasma expanders, etc., may cause false positive reactions.[2]

SPECIFIC PERFORMANCE CHARACTERISTICS

Each lot of Search-Cyte® 0.8% Reagent Red Blood Cells is carefully prepared to permit detection of antibodies to the selected red blood cells antigens when used as outlined in these procedures.

All antigen typings listed on the antigenic constitution matrix are confirmed using two sources of antiserum except for those indicated on the antigenic constitution matrix enclosed with each lot.

Identified low incidence antigens present are indicated on the antigenic constitution matrix. Direct antiglobulin tests are negative on all red blood cells.

As with all red blood cells, the reactivity of the product may decrease during the dating period. The rate at which antigen reactivity is lost is partially dependent upon individual donor characteristics that are neither controlled nor predictable by the manufacturer. However, if properly stored when not in use, the reagent can be expected to perform as described throughout its dating.

BIBLIOGRAPHY

1. Mollison P.L., Blood Transfusion in Clinical Medicine. 11th ed. Blackwell Scientific Publication; 2005: Chapter 8.
2. Technical Manual of the American Association of Blood Banks. 17th ed. 2011: Chapter 15 and 17.
3. Ibidem: Chapter 14, p. 421f.

Manufactured by:

Medion Grifols Diagnostics AG
Bonnstrasse 9, CH-3186 Düdingen / Switzerland

Distributed by:

Novartis Vaccines and Diagnostics, Inc.
Emeryville, CA 94608 USA
Telephone (in U.S.): (800) 452-6877
Or: (510) 923-3757
Fax: (800) 462-3938
E-mail: emv.cts@novartis.com

Date of last version: May, 2013.

SYMBOLS KEY

One or more of these symbols may have been used in the labeling/packaging of this product.

"symbol" *In vitro* diagnostic medical device
"symbol" Batch code
"symbol" Use by YYYY-MM-DD or YYYY-MM
"symbol" Temperature limitation
"symbol" Consult instructions for use
"symbol" Catalog number
"symbol" This way up
"symbol" Fragile, handle with care
"symbol" Keep dry