# Data-Cyte® Plus
# Reagent Red Blood Cells 0.8±0.1%

**U.S. License No. 1740**

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

## INTENDED USE

Data-Cyte® Plus 0.8 % Reagent Red Blood Cells is for the identification of unexpected antibodies in gel techniques.

For use with the DG Gel 8 System.

## SUMMARY AND EXPLANATION

Careful and complete identification of an unexpected antibody is important in the diagnosis and treatment of hemolytic disease of the newborn (HDFN), as well as in the prevention of transfusion reactions due to infusion of incompatible red blood cells. Most clinically significant antibodies can be identified by agglutination in routine procedures using Reagent Red Blood Cells of known antigenic constitution.[1,2]

Data-Cyte® Plus 0.8% Reagent Red Blood Cells is a panel of suspensions of group O red blood cells from 11 individual donors. These donor red blood cells differ in antigenic configuration and are selected to enable identification of most single antibodies, as well as a majority of frequently found combinations of antibodies. The presence or absence of antigens of each of the major blood group systems is indicated for each of the 11 Reagent Red Blood Cells on the antigen matrix accompanying the product. Data-Cyte® Plus 0.8% Reagent Red Blood Cells are utilized in the gel technique for the identification of unexpected antibodies.

## PRINCIPLE OF THE TEST

Antibodies react with red blood cells possessing the corresponding antigenic determinants. These antibodies may agglutinate red blood cells in saline and/or antiglobulin testing. Following this principle, an antibody may be identified by its pattern of reactivity with a panel of human Reagent Red Blood Cells whose antigenic constitution is known.

## REAGENT

**Data-Cyte® Plus 0.8%** is a panel of 11 individual Reagent Red Blood Cells suspensions (0.8±0.1%) of group O in buffered isotonic solution with added preservatives (0.010% (w/v) neomycin and 0.017% (w/v) chloramphenicol). 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 an 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.

## PRECAUTIONS

- 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.

## MATERIALS

### Materials Provided

Data-Cyte® Plus 0.8% Reagent Red Blood Cells, 11x4ml, cat. no. 213654

### 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.**

The Data-Cyte® Plus 0.8% Reagent Red Blood Cells panel is uniquely designed so that it may be used either independently or in conjunction with reagent antibody screening cells. When combined with the results from screening cells and autocontrol, only the first four red blood cells of Data-Cyte® Plus 0.8% Reagent Red Blood Cells panel need to be used to provide preliminary identification of the most common anti-red blood cell antibodies. If the antibody cannot be clearly identified using this «mini-panel», the remaining Reagent Red Blood Cells of the panel and selected additional Reagent Red Blood Cells (if required) may be used to complete the identification.

Carefully resuspend Data-Cyte® Plus 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

Use of an autocontrol is recommended to help distinguish between autoantibodies and alloantibodies.[2]

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

## RESULTS

Agglutination and/or hemolysis (positive reaction) of one or more Data-Cyte® Plus 0.8% Reagent Red Blood Cells indicates the presence of unexpected antibodies. Such antibodies are usually directed against the known antigens present on the panel Reagent Red Blood Cells, but may be directed against an antigen not indicated on the antigen matrix.

The lack of both agglutination and hemolysis (negative reaction) in the test procedure indicates the absence of antibodies to antigens contained on the Reagent Red Blood Cells.[3]

### Interpretation

Identification of the antibody(ies) present may be conveniently performed by the «crossing out» method using the antigen matrix accompanying the lot of Data-Cyte® Plus 0.8% Reagent Red Blood Cells.

1. Choose the first red blood cell giving a negative reaction. Cross out all antigenic determinants present on that red blood cell.
2. Repeat Step 1 for all other negative red blood cells.
3. Circle remaining antigens.

a. If only one antigen is circled, check to see that all red blood cells which reacted possess the antigen. If so, the antibody is probably directed against that antigen and can be identified as such.
b. If several antigens are circled, check to see if any of those antigens are present on all the reacting red blood cells. If so, additional red blood cells lacking that antigen, but possessing the others circled, should be tested to determine if multiple antibodies are present.
c. Antigen typings on patient/donor red blood cells may be useful to rule out antibodies.
d. If high incidence antibodies or multiple antibodies are present, all red blood cells may be agglutinated. A reference laboratory should be consulted if rare red blood cells are not available for testing.

If the autocontrol is positive, the serum may contain autoantibody and further testing may be indicated.[2]

## LIMITATIONS OF PROCEDURE

1. If red blood cells have a low amount of an antigen, a homozygous cell may be required to detect very weakly reacting antibodies; therefore, negative reactions with panel red blood cells do not always indicate absence of unexpected antibodies in the serum under test.
2. Because of the high incidence of the *Fy4* gene in the black population, it cannot be assumed that the phenotypes Fy (a+b-) and Fy (a-b+) in black donors represent homozygous expressions of the $Fy^a$ or $Fy^b$ genes[3].

3. If antibodies to high incidence antigens or multiple antibodies are present, all Reagent Red Blood Cells may be agglutinated.
4. As in all serological tests, such factors as contaminated materials, improper incubation time or temperature, improper centrifugation, certain disease states or improper examination for agglutination may give rise to false test results.
5. 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.
6. Low-incidence antigens may not be represented in the Data-Cyte® Plus 0.8% Reagent Red Blood Cells, so negative reactions do not always indicate absence of an antibody in the sample under study.

**False negative results may occur under the following conditions:**

1. If red blood cells and/or serum are stored improperly and lose reactivity.
2. If plasma is used, as complement-dependent hemolytic reactions may not be detected.

**False positive results may occur under the following conditions:**

1. If test Reagent Red Blood Cells have microbial contamination.
2. If fibrin residues are present in the sample.
3. If centrifugation has been performed improperly.
4. In rare cases, the test serum contains an antibody directed to one of the components of the reagent diluent.
5. 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 Data-Cyte® Plus 0.8% Reagent Red Blood Cells is carefully prepared to permit identification of antibodies to the selected Reagent Red Blood Cells antigens.
All antigen typings listed on the antigen matrix are confirmed using two sources of antiserum except for the following which, due to the rarity of the antibodies, may be tested with only one source if a second source is unavailable: f, V, $Lu^a$, $Js^a$, $Jk^b$, $Xg^a$, Vel, Ge, $Yt^a$, $Di^a$, $Di^b$ and special typings (other antigens).

Unless otherwise indicated, the Reagent Red Blood Cells of Data-Cyte® Plus 0.8% donors have been phenotyped as follows:

Positive: H, I, U, $Kp^b$, $Js^b$, Vel, Ge, $Yt^a$, $Di^b$

Negative: $M^g$, Vw, $Wr^a$, $Di^a$

Identified low incidence antigens present are indicated on the antigenic constitution matrix. Direct antiglobulin tests are negative on all Reagent Red Blood Cells.

As with all Reagent 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 Red Blood Cells can be expected to perform as described throughout its dating.

## BIBLIOGRAPHY


1. Mollison, P.L. Blood Transfusion in Clinical Medicine. 11th ed.; Oxford: Blackwell Scientific Publication; 2005: Chapter 8.
2. Technical Manual of the American Association of Blood Banks. 17th ed.; 2011: Chapter 16 and 17.
3. Ibidem: Chapter 14, p. 421f.


Manufactured by:


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**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