Data-Cyte Plus
Reagent Red Blood Cells 3±1%

U.S. LICENSE NO. 1740

For use in the identification of unexpected antibodies. For *in vitro* diagnostic use. For professional use only.

INTENDED USE

Data-Cyte Plus 3% Reagent Red Blood Cells is used in tube technique for a careful and complete identification of unexpected antibodies in human blood samples in the diagnosis and treatment of Hemolytic Disease of the Newborn (HDN) and certain blood dyscrasias, 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]

SUMMARY AND EXPLANATION

Data-Cyte Plus 3% 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 antigenic constitution matrix accompanying the product. Data-Cyte Plus Reagent Red Blood Cells may be utilized in the commonly accepted antibody identification techniques.

PRINCIPLE OF THE TEST

Antibodies react with red blood cells possessing the corresponding antigenic determinants. These antibodies may agglutinate red blood cells in saline, Low Ionic Strength Solution (LISS), high protein media, or antiglobulin testing. Following this principle, an antibody may be identified by its pattern of reactivity with a panel of human red blood cells whose antigenic constitution is known.

REAGENT

Data-Cyte Plus Reagent Red Blood Cells: A panel of 11 individual group O human red blood cells suspensions.

Data-Cyte Plus Reagent Red Blood Cells panel is composed of 3±1% suspensions in isotonic medium with added buffers (bicarbonate and phosphate) and preservatives (0.03% (w/v) neomycin and 0.05% (w/v) chloramphenicol).

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. Meets other FDA requirements.

Storage and stability

- Store at 2-8 ºC.
- **Do not freeze.**
- If stored appropriately at 2-8 ºC the product is stable after the first opening until the indicated expiration date.
- Resuspend by gentle inversion immediately prior to use.
- **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 diminish during the dating period.

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. Once used, the product must be disposed in special containers for biological waste.

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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/plasma should be stored at 2-8 ºC no longer than 48 hours prior to testing; however, serum/plasma may be frozen at -20 to -80 ºC and tested at a later time if necessary. If the recipient has been pregnant or transfused within the previous three months samples stored at 2-8 ºC should be used within 72 hours after collection. 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

Material provided

Reagent is ready to use.

Code	Product Designation	Packaging
213231	Data-Cyte Plus 3±1% Reagent Red Blood Cells	11 x 4 mL

Materials required but not provided

- Disposable test tubes (12 x 75 mm or 10 x 75 mm).
- Pipette (drop size ~ 50 µL).
- Physiologic saline solution.
- Coombs Control cells (Code 213630).
- Timer.
- Anti-human globulin reagent.
- Potentiator.
- Calibrated centrifuge for tube (calibrated for 1000 rcf* or 150 rcf*).
- Waterbath or heating block at 37 ºC.
- Optical aid.[3]

* rcf = 0.00001118 x rotating radius (cm) x rpm^2.

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

PROCEDURE

The Data-Cyte Plus 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 Reagent Red Blood Cells of Data-Cyte Plus panel need be used to provide preliminary identification of the most common 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.

Note: If a potentiator is to be used, follow manufacturer’s instructions for preparation and testing of samples instead of the procedure suggested below.

1. Place 2 or more drops (≥ 100 µL) of the patient or donor serum in a tube for each Reagent Red Blood Cell to be tested.
2. Add 1 drop (~ 50 µL) of each Data-Cyte Plus Reagent Red Blood Cells suspension to the appropriate tube.
3. Shake all tubes to mix reagents.
4. If immediate spin testing is desired, centrifuge for 15-20 seconds at approximately 1000 rcf* (1 minute at approximately 150 rcf*) or time appropriate to the calibration of the centrifuge.
5. Gently resuspend red blood cells completely and examine immediately for agglutination or hemolysis.[3] Grade and record results.

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Indirect Antiglobulin Test

6. Incubate at 37 ºC for 15-60 minutes or according to directions for the potentiator used.
7. Immediately centrifuge, examine and interpret as in Steps 4 and 5. Record results 37 ºC testing.
8. Fill each tube with physiologic saline added in a forceful stream. Centrifuge to pack red blood cells. Carefully decant supernatant. Shake to resuspend red blood cells.
9. Repeat Step 8 twice for a total of 3 washings.
10. Add anti-human globulin to each tube according to manufacturer's instructions and shake to mix.
11. Centrifuge, examine and interpret as in Step 4 and 5. Grade and record results.
12. Negative reactions obtained with anti-human globulin should be tested by adding 1 drop of IgG-sensitized cells.

Note: The reactions should be interpreted immediately after centrifugation due to the possibility of dissociation of the antigen-antibody complex.

Saline Room Temperature - Low Temperature

6. Incubate at room temperature (20-25 ºC) for 15-30 minutes.
7. Centrifuge, examine and interpret as in Steps 4 and 5. Grade and record results.
8. If detection of cold agglutinins is desired, incubate tubes at 5 ºC for 5-15 minutes. Then centrifuge, examine and interpret as in Step 4 and 5. Grade and record results of low temperature testing.

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 autoantibody and further testing may be indicated.[2]

To ensure proper centrifugation, each individual centrifuge should be calibrated for the specific test procedure being performed. Red blood cells should be packed firmly, but negative control red blood cells should resuspend easily.[4]

RESULTS

Agglutination and/or hemolysis (positive reaction) in one or more Data-Cyte Plus Reagent Red Blood Cells tubes at any phase of the test procedure prior to the addition of Coombs Control 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 antigenic constitution 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.

Interpretation

Identification of the antibody(ies) present may be conveniently performed by the "crossing out" method using the antigenic constitution matrix accompanying the lot of Data-Cyte Plus Reagent Red Blood Cells.

1. Choose the first Reagent Red Blood Cell giving a negative reaction at all phases of testing. Cross out all antigenic determinants present on that Reagent Red Blood Cell.
2. Repeat Step 1 for all other negative Reagent Red Blood Cells.
3. Circle remaining antigens.
   a. If only one antigen is circled, check to see that all Reagent 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 one of those antigens is present on all the reacting Reagent Red Blood Cells. If so, additional Reagent Red Blood Cells lacking that antigen, but possessing the others circled, should be tested to determine if multiple antibodies are present.
   c. Antigen typing on patient/donor red blood cells may be useful to rule out antibodies.
   d. If antibodies against high incidence antigens or multiple antibodies are present, all Reagent 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]

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LIMITATIONS OF PROCEDURE

1. A 15-minute incubation at 37 ºC may not be adequate to detect some weak blood group antibodies if no potentiating medium is added to the test system.
2. Red blood cells having low frequency antigens, a double dose of antigen 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.
3. 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 allele.[5]
4. If antibodies directed against high incidence antigens or multiple antibodies are present, all Reagent Red Blood Cells may be agglutinated.
5. As in all serological tests, such factors as contaminated materials, improper incubation time or temperature, improper centrifugation or improper examination for agglutination may give rise to false test results.

False negative results may occur if:

1. Reagent Red Blood Cells are not properly washed, or human globulins are present as contaminants in glassware. These residual globulins will neutralize the globulin-reactive antibodies present in the anti-human globulin.
2. Antibody elutes from Reagent Red Blood Cells during incubation or washing.
3. Reagent Red Blood Cells and/or serum are stored improperly and lose reactivity.
4. Anti-human globulin is inadvertently omitted.
5. Reagent Red Blood Cells are improperly centrifuged.
6. Incubation times and/or temperatures are incorrect for proper red blood cells sensitization.
7. Resuspension technique is too vigorous to preserve agglutination of weakly sensitized red blood cells.

False positive results may occur if:

1. Reagent Red Blood Cells have microbial contamination.
2. Reagent Red Blood Cells are improperly centrifuged.
3. Antibodies to antibiotics or to other ingredients in the red blood cells suspending medium or in the potentiators used are present in the test serum.
4. Incomplete resuspension may counterfeit agglutination.
5. In rare cases, the test serum contains an antibody directed at one of the components of the reagent diluent.

SPECIFIC PERFORMANCE CHARACTERISTICS

Each lot of Data-Cyte Plus 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 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).

* Typed only if a source is available.

Unless otherwise indicated, the red blood cells of Data-Cyte Plus Reagent Red Blood Cells donors have been phenotyped as follows:

Positive: H, U, Kp^b, Js^b, Vel, Ge, Di^b.

Negative: V^w, 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.

The stability of the product is monitored throughout the dating period.

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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 can be expected to perform as described throughout its dating.

BIBLIOGRAPHY

1. Technical Manual, 20th edition, American Association of Blood Banks, Bethesda, Maryland, 2017, Chapter 13 and 15.
2. Mollison PL. Blood Transfusion in Clinical Medicine, 12th edition, Blackwell Scientific Publications, 2014.
3. Chapter 8. Ibidem: Chapter 15, p. 445.
4. Ibidem: Methods 8.5, p. 980.
5. Ibidem: Chapter 14, p. 421.

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SYMBOLS KEY

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

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