Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

3036856/116
(09/2021)

Data-Cyte® Plus
Data-Cyte® Plus 2
Data-Cyte® Extend
Reagent Red Blood Cells 0.8±0.1%

U.S. License No. 1740

For use in the identification of unexpected antibodies in gel techniques

For *in vitro* diagnostic use

INTENDED USE

Data-Cyte® Plus, Data-Cyte® Plus 2 and Data-Cyte® Extend 0.8% Reagent Red Blood Cells are for the identification of unexpected antibodies in gel techniques. Data-Cyte® Extend 0.8% cannot detect anti-D.

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 fetus and 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 and Data-Cyte® Plus 2 0.8% Reagent Red Blood Cells are panels 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.

Data-Cyte® Extend 0.8% Reagent Red Blood Cells is a panel of suspensions of group O RhD Negative red blood cells from 4 individual donors in order to complement Data-Cyte® Plus panels.

The presence or absence of antigens of each of the major blood group systems is indicated for each Reagent Red Blood Cells on the antigen matrix accompanying the products. Data-Cyte® 0.8% Reagent Red Blood Cells panels 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% and Data-Cyte® Plus 2 0.8% are two different panels of 11 individual Reagent Red Blood Cell suspensions (0.8±0.1%) of group O.

Data-Cyte® Extend 0.8% is a panel of 4 individual RhD Negative Reagent Red Blood Cell suspensions (0.8±0.1%) of group O.

All Reagent Red Blood Cells are 0.8±0.1% suspensions 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 these products. 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.
- Once a vial has been used, it must be stored at the indicated storage temperature.
- To avoid contamination, close the caps on the vials when they are not in use. Ensure that the caps on the Reagent Red Blood Cell vials have not been swapped.
- If handled and stored appropriately, this product is stable from the time it is first opened until the indicated expiration date.
- **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 shelf-life.

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 shelf-life.
- 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

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

Data-Cyte® Plus 2 0.8% Reagent Red Blood Cells, 11x4ml, cat. no. 213641

Data-Cyte® Extend 0.8% Reagent Red Blood Cells, 4x4ml, cat. no. 213684

Materials Required but Not Provided

Please refer to the Instruction for Use of DG Gel 8 cards.

Associated Instruments:

For Manual Method

- DG SPIN centrifuge
- DG Therm
- DG Reader Net or DG Reader (optional)

For fully automated Methods

- Erytra Eflexis, Erytra or WADiana Compact

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%, Data-Cyte® Plus 2 0.8% and Data-Cyte® Extend 0.8% Reagent Red Blood Cells panels are uniquely designed so that they may be used either independently, combined or in conjunction with reagent antibody screening cells (Data-Cyte® Extend 0.8% can be used independently only for known anti-D-positive samples). When combined with the results from screening cells and autocontrol, only the first four red blood cells of Data-Cyte® Plus 0.8% and Data-Cyte® Plus 2 0.8% Reagent Red Blood Cells panel or Data-Cyte® Extend 0.8% 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. Selected red cells with different antigen combinations can be used to confirm or rule out the presence of antibodies.

Carefully resuspend 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 periodically.

RESULTS

Agglutination and/or hemolysis (positive reaction) of one or more 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].

Panel interpretation

Identification of the antibody(ies) present may be conveniently performed by the «crossing out» method using the antigen matrix accompanying the lot of 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 poorly 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 Reagent Red Blood Cells, so negative reactions do not always indicate absence of an antibody in the sample under study.
7. Data-Cyte® Extend 0.8% cannot detect anti-D.

False negative results may occur if

1. Red blood cells and/or serum are stored improperly and lose reactivity.
2. Plasma is used, as complement-dependent hemolytic reactions may not be detected.
3. The antibody is directed against a low incidence antigen which is not present in the Reagent Red Blood Cells.

False positive results may occur if

1. Test Reagent Red Blood Cells have microbial contamination.
2. Fibrin residues are present in the sample.
3. 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%, Data-Cyte® Plus 2 0.8% and Data-Cyte® Extend 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® 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, 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.
- As with all Reagent Red Blood Cells, the reactivity of the product may decrease during the shelf-life. 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 shelf-life.

For manual method, the performance of the Data-Cyte Plus 0.8% reagent was confirmed against FDA-licensed reagents in a comparison study where reagents were tested in parallel at different clinical sites. The estimated percent agreements and their lower limits of 95% one-side confidence interval for all sites combined are indicated on the table below.

Overall Statistical Analysis Results of the comparison study				
	Negative Agreement		Positive Agreement	
	Nº of samples	Percent Agreement (lower 95% CI)	Nº of samples	Percent Agreement (lower 95% CI)
Ab. Identification	613	99.67% (98.98%)	553	94.03% (92.10%)

- Percent of Agreement only indicates agreement between reagents and does not indicate which reagent gave the correct result(s).
- For further information about the performance data for manual method using DG Reader or DG Reader Net and for automated method, please refer to the Instruction for Use of the related instrument.

BIBLIOGRAPHY

1. Mollison P.L., Blood Transfusion in Clinical Medicine. 11th ed. Blackwell Scientific Publications, 2005, Chapter 4.
2. Technical Manual of the American Association of Blood Banks. 17th ed. 2011, Chapter 12.
3. Ibidem: Chapter 14, p. 421f.

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

Technical Service:
Emeryville, CA 94608 USA
Telephone (in U.S.): (800) 452-6877
Or: (510) 923-3757
Fax: (800) 462-3938
Email: service.americas@grifols.com

Date of last version: May, 2021

SYMBOLS KEY

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

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