



## Control Cells IgG Coated Human Red Blood Cells

### INTENDED USE

American Red Cross (Red Cross) Control Cells are used for control of the antiglobulin test performed with Anti-Human Globulin containing anti-IgG.

### SUMMARY AND EXPLANATION

The direct antiglobulin test (DAT) is typically used to detect immunoglobulins bound to red blood cells *in vivo*. The indirect antiglobulin test (IAT) is a two phase test used to detect the presence of serum immunoglobulins (antibodies). Both tests involve thorough washing of red blood cells to remove unbound antibodies/protein and then the addition of an antiglobulin reagent (Anti-IgG). IgG coated red blood cells are added to all negative tests to verify the washing process was sufficient and antiglobulin reagent was added.<sup>1,2</sup>

### PRINCIPLE OF PROCEDURE

Under appropriate test conditions Anti-Human Globulin reagents agglutinate red blood cells sensitized with immunoglobulin. Red Cross Control Cells are added to negative tests, centrifuged and read. Agglutination of the Control Cells indicates that active antiglobulin reagent is still present, the washing process was successful and antiglobulin reagent was added. A negative result after the addition of Red Cross Control Cells indicates either insufficient antiglobulin reagent was added or the antiglobulin reagent may have been neutralized.

### REAGENT

Each lot of Red Cross Control Cells is prepared from human group O red blood cells sensitized with human IgG. These red blood cells are supplied as a 2-4% suspension in a diluent solution. Chloramphenicol (0.05%) and neomycin sulfate (0.03%) have been added as preservatives.

Red Cross Control Cells are for *in vitro* diagnostic use and are supplied ready for use, no dilution or modification is required.

**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.

**Caution: This Product Contains Natural Rubber Latex (Dropper Bulbs) Which May Cause Allergic Reactions.**

### STORAGE

Re-suspend each vial of Red Cross Control Cells prior to use by gentle inversion.

Store at 1-8 C when not in use. Do not freeze. Improper storage may cause loss of reactivity.

Do not use if grossly hemolyzed. Avoid contamination during use.

Do not use beyond expiration date. The format for the expiration date is expressed as YYYY-MM-DD (year month day).

### MATERIALS

#### Materials provided:

1. American Red Cross Control Cells

#### Materials required but not supplied:

1. Test tubes, 10 x 75 mm or 12 x 75 mm
2. Test tube racks
3. Centrifuge
4. Anti-Human Globulin containing anti-IgG

### PROCEDURE

1. Perform the direct or indirect antiglobulin test and record results.
2. Add 1 drop of re-suspended Red Cross Control Cells to each negative antiglobulin test.
3. Mix well and centrifuge the tube for 15 seconds at 3400 rpm (900-1000 rcf\*) or 1 minute at 1000 rpm (100-120 rcf\*) or equivalent, as indicated by equipment quality control calibration.
4. Re-suspend the red blood cells by gentle agitation.
5. Immediately read macroscopically for agglutination and record results.

\*rcf=0.00001118 x radius (cm) x (rpm)<sup>2</sup>

### STABILITY OF REACTION

Tests should be read and results recorded immediately following centrifugation. Delays greater than five minutes may result in weaker or, in some cases, false negative results.

Consideration must be given to the time it takes to process, read and record each group of tests. It is the responsibility of the user to determine the most practical number of samples that can be tested at one time that provides for a consistent test process and keeps delays at a minimum.

### QUALITY CONTROL

A positive control should be run each day of use to verify the reactivity of Red Cross Control Cells. Red Cross Control Cells should only be used if the control performs as expected.

Positive control: 1 drop of Red Cross Control Cells plus Anti-IgG (according to manufacturer's package insert). Mix well, centrifuge (see Procedure) and read results.

### INTERPRETATION OF RESULTS

Agglutination of Red Cross Control Cells 1+ or greater in a negative antiglobulin test is a positive (+) test result and indicates that the original negative antiglobulin test result is valid.

Absence of agglutination of Red Cross Control Cells is a negative (-) test result and indicates the original negative antiglobulin test result is invalid. All implicated tests should be repeated.

Weaker than expected reactions with Red Cross Control Cells may be due to inadequate washing – see Limitations. All implicated tests should be repeated.

### LIMITATIONS

All serological tests have limitations. To maximize success in obtaining valid results, follow the directions for use carefully. Deviations from manufacturers' instructions without appropriate validation and controls may produce erroneous results.

Negative or weaker than expected results using Red Cross Control Cells in negative antiglobulin tests may be caused by:

- Inadequate washing (failure to remove all unbound serum proteins)
- Failure to add antiglobulin reagent
- Improper re-suspension technique
- Improper centrifugation

False positive results using Red Cross Control Cells in negative antiglobulin tests may be caused by:

- Bacterial or fungal contamination
- Improper centrifugation

### SPECIFIC PERFORMANCE CHARACTERISTICS

Red Cross Control Cells have been manufactured to provide a standardized control for the antiglobulin test. Each lot is tested to assure appropriate reactivity when used by the recommended test procedure.

For technical questions, contact the American Red Cross Diagnostic Manufacturing Division at 1-800-882-3737.

### BIBLIOGRAPHY

1. Issitt PD, Anstee DJ. *Applied Blood Group Serology*, 4th ed. Durham, NC; Montgomery Scientific Publications, 1998.
2. Fung, Mark K., ed. *Technical Manual*, 18<sup>th</sup> ed. Bethesda, MD; AABB, 2014.

For Optional Use by User:

Lot Number: \_\_\_\_\_

Expiration: \_\_\_\_\_

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