



PEG

Polyethylene Glycol Additive Solution

INTENDED USE

American Red Cross (Red Cross) PEG is intended for use as a potentiator in antibody detection, antibody identification and compatibility testing.

SUMMARY AND EXPLANATION

Polyethylene glycol (PEG) is a water-soluble linear polymer which can be used as a potentiator for antigen-antibody reactions. ^(1,2,3,4)

PRINCIPLE OF PROCEDURE

The principle of the test is the antiglobulin technique which is based on antigen-antibody mediated agglutination. Red Cross PEG is added directly to antibody screens, antibody identification panels and crossmatches to enhance the sensitivity and shorten the incubation time for this reaction.

REAGENT

This reagent is a 20% solution of polyethylene glycol in a low ionic strength solution containing glycine and is designed to be added directly to the serologic test system. This reagent contains 0.1% (w/v) sodium azide as a preservative.

CAUTION

This product is for *in vitro* diagnostic use only.

This Product Contains Natural Rubber Latex (Dropper Bulbs) Which May Cause Allergic Reactions

Warning: Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into sinks, flush with a large volume of water to prevent azide build-up.

STORAGE

This reagent should be stored at 1-8 C when not in use. Do not freeze. Do not use if turbid. Do not dilute.

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

SPECIMEN COLLECTION AND PREPARATION

Specimens (plasma, serum or eluate) should be collected/prepared by standard techniques. Specimens should be tested as soon as possible after collection/preparation. If testing is delayed, specimens should be stored at 1-8 C.

MATERIALS

Materials provided: Red Cross PEG

Materials required but not provided:

1. Test tubes, 10 X 75 mm or 12 X 75 mm
2. Test tube racks
3. Pipettes
4. Calibrated serologic centrifuge
5. Isotonic saline or phosphate buffered saline (pH 6.0-7.5)
6. Heat block / water bath at 36-38 C
7. Patient, donor and/or reagent red blood cells
8. Anti-Human IgG Reagent
9. Antiglobulin control cells (IgG-sensitized red blood cells)
10. Timer

PROCEDURE

1. Prepare a 2-4% suspension of red blood cells washed at least once with isotonic saline or phosphate buffered saline.
NOTE: *Reagent red blood cells may be used directly from the vial or in accordance with the manufacturer's instructions.*
2. Add 2 drops of serum/plasma/eluate to be tested to an appropriately labeled test tube(s).
3. Add 1 drop of the previously prepared or reagent 2-4% red blood cell suspension.
NOTE: *Immediate spin may be performed prior to the addition of Red Cross PEG and the 36-38 C incubation.*
4. Add 2 drops of Red Cross PEG.
5. Mix well.
6. Incubate at 36-38 C for 15-30 minutes.
7. **DO NOT CENTRIFUGE AFTER 36-38 C INCUBATION.**
8. Wash the tests 3-4 times with isotonic saline or phosphate buffered saline.
9. Add Anti-Human IgG according to the manufacturer's directions.
10. Mix well and centrifuge for 15 seconds at 3400 rpm (900-1000 rcf*) or 1 minute at 1000 rpm (100-120 rcf*) or equivalent, as indicated by equipment calibration.
11. Resuspend the red blood cells by gentle agitation. Examine macroscopically for agglutination.
12. All tests should be read immediately and results recorded without delay.
13. Add antiglobulin control cells to all negative tests and centrifuge as above. Agglutination of the antiglobulin control cells confirms the presence of active anti-IgG. No agglutination of the antiglobulin control cells may indicate that the antiglobulin reagent has been neutralized or omitted and that tests should be repeated.

$$*rcf=0.00001118 \times \text{radius (cm)} \times (\text{rpm})^2$$

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STABILITY OF REACTION

Delays in reading antiglobulin tests may result in the disassociation of antigen-antibody complexes leading to false negative or weak positive results.

QUALITY CONTROL

All negative antiglobulin tests should be tested with antiglobulin control cells (IgG-sensitized cells). Agglutination after the addition of IgG-sensitized red blood cells ensures that the antiglobulin reagent was added, reactive and that washing was complete. A positive result indicates the presence of active anti-human globulin (anti-IgG) and removal of unbound proteins. A negative result should be considered invalid and the test repeated.

INTERPRETATION OF RESULTS

Positive result: Agglutination of the red blood cells.

Negative result: No agglutination of the red blood cells.

LIMITATIONS

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

Following centrifugation, all tests should be read immediately and the results recorded without delay.

Polyethylene glycol tests should only be read at the antiglobulin phase. IgM antibodies may not be detected using polyethylene glycol as a potentiator.

Polyethylene glycol may precipitate serum globulins. When testing samples with elevated globulins, more than three washes may be required. ⁽⁴⁾

False positive or false negative results may occur due to the contamination of the test materials, improper washing, improper incubation times and temperatures and omission of testing reagents.

The pH of the saline used for washing may affect the stability of the reaction. It is recommended that the pH be 6.0-7.5.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance of this reagent is predicated on the appropriate use of materials and methods.

Equilibrate all materials to room temperature for optimal test performance.

To assure optimal test performance, each lot is qualified serologically with known antibodies and inert samples. Additionally, pH is measured/standardized to maintain lot to lot consistency.

Non-concordance may be observed with similar reagents and/or alternate methodologies.

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

BIBLIOGRAPHY

1. Nance SJ, Garratty G. A New Potentiator of Red Blood Cell Antigen-Antibody Reactions. *Am J Clin Pathol* 1987; 87:633-635.
2. Wenz B, Apuzzo J. Polyethylene Glycol improves the indirect antiglobulin test. *Transfusion* 1989; 29:218-220.
3. Man AJM, Overbeeke, MAM. Evaluation of the Polyethylene Glycol Antiglobulin Test for Detection of Red Cell Antibodies. *Vox Sang* 1990; 58:207-210.
4. Issitt PD, Anstee DJ. *Applied Blood Group Serology*, Fourth Edition. Montgomery Scientific Publications, Durham, NC, USA 1998.

For Optional Use by User:

Lot Number: _____

Expiration: _____

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