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HBS-PEG 8000

Polyethylene Glycol Solution

Intended Use:
HBS-PEG 8000 is intended for use as a potentiator in antibody detection, antibody identification and compatibility test procedures.

Summary and Explanation:
HBS-PEG 8000 is added to antibody detection tests to enhance the sensitivity of the procedure and creates a low-ionic-strength test environment that increases the rate of antibody uptake during incubation.

Principle of the Procedure:
The sensitivity of the indirect antiglobulin procedure for the detection and identification of clinically significant antibodies is enhanced by the addition of polyethylene glycol, a macromolecule. In addition, a substantial reduction in the incubation time for antigen/antibody mixtures can be achieved when the red cells and serum are suspended in a low ionic strength test environment. Polyethylene glycol can also be used as an additive when testing eluates with significantly improved sensitivity when compared to usual methods [3].

Reagent Description:
HBS-PEG 8000 is a solution of polyethylene glycol in a low ionic strength solution.

The format for the expiration date is expressed as YYYY-MM-DD (year-month-day). Lot number and expiration date information appears on the vial.

Precautions

1. This reagent contains 0.1% (w/v) sodium azide which is below the national and international regulatory thresholds and when used under normal condition is not chemically hazardous. If this reagent is discarded in the sink, flush with large volumes of water to prevent the buildup of azide.
2. Do not use if the reagent is turbid.
3. The packaging of this product contains dry natural rubber.
4. This reagent is for *in vitro* diagnostic use only.

Storage
This reagent should be stored at 2-8°C when not in use. Do not freeze or expose to elevated temperatures.

Specimen Collection:
Blood should be drawn by aseptic methods and the serum or plasma should be tested as soon as possible. If testing is delayed, the samples should be stored at 2-8°C**.**

Procedure:

Materials Provided
Hemo bioscience PEG-8000

Materials Required But Not Provided
Test tubes (12 x 75 or 10 x 75 mm)
Transfer pipettes
Centrifuge (1000 rcf)
Isotonic or phosphate buffered saline
Timer
Anti-Human Globulin reagent containing IgG
Antiglobulin Control Cells (cells sensitized with IgG)
37˚C incubator

Recommended Technique

1. Donor/Patient red cells should be washed once in isotonic or Phosphate Buffered Saline (PBS) making a final suspension of 2-4%.
   NOTE: Reagent red blood cells may be used directly from the vial or in accordance with manufacturer's directions.
2. Add two drops of serum, plasma or eluate to a test tube.
3. Add one drop of the red blood cell suspension.
4. Add two drops of HBS-PEG 8000.
5. Mix thoroughly.
6. Incubate for 10-15 minutes at 37°C in a water bath or heat block.
   NOTE: The test must not be centrifuged and examined for direct agglutination after the incubation phase. See Performance Limitations section for further information.
7. Perform AHG test as per manufacturer's instructions.
8. Following centrifugation, all tests should be read immediately and results should be interpreted without delay. Delays may result in disassociation of antigen-antibody complexes leading to falsely negative, or at most, weakly positive reactions.

Quality Control
To control the use of this product as a potentiator, a known weakly reacting IgG antibody may be tested.

Results:

Positive Test
Agglutination or hemolysis of the red blood cells.

Negative Test
No agglutination or no hemolysis of the red blood cells.

Limitations:

1. Following centrifugation, all tests should be read immediately and results should be interpreted without delay. Delays may result in disassociation of antigen-antibody complexes leading to falsely negative, or at most, weakly positive reactions.
2. Polyethylene glycol causes the red blood cells to aggregate, which makes examination for direct agglutination difficult. As a result, the test should **only** be read at the antiglobulin phase.
3. IgM antibodies may not be detected when using the polyethylene glycol procedure, care should be taken to ensure ABO compatibility when cross matching.
4. Polyethylene glycol may precipitate serum globulins. It is imperative that the red blood cells are resuspended thoroughly between washes. The anti-Human Globulin reagent may be neutralized if cells are not washed thoroughly, resulting in false negative results. It may also be necessary to wash the red blood cells more than four times to remove all unbound human protein.

Specific Performance Characteristics:
Each lot of HBS-PEG 8000 is tested to assure appropriate performance . For Technical support, contact Hemo bioscience at 1-866-332-2835.

Bibliography:

1. Nance SJ, Garratty G. Polyethylene glycol: A new potentiator of red blood cell antigen–antibody reactions.
   Am J Clin Pathol 1987; 87:633-5.

2. Löw B, Messeter L. Antiglobulin test in low ionic strength salt solution for rapid antibody screening and crossmatching. Vox Sang 1974; 26:53-61.
3. Combs MR, Telen MJ. Testing eluates in Polyethylene glycol (PEG): A sensitive technique for detecting early alloimmunization. [Abstract] Transfusion 1989; Supplement 58S.
4. Fung, MK (ed): Technical Manual, 18th ed. AABB, Bethesda MD, 2014.

Glossary of Symbols:

Symbol	Definition
	Batch code
	Manufacturer
	Temperature limitation
	Consult instructions for use.
	Use by YYYY-MM-DD
	For *in vitro* diagnostic use
	Caution, consult documents.