



### Intended use :

To use multivalent cationic polymers in polybrene reagent in low ionic solution to enhancing antibodies of patient's plasma and red blood cell antigen agglutination .

### Test Principle

The manual polybrene reagent is mainly used to enhance the agglutination of antibodies and red blood cell antigens in plasma. Firrst a low ionic solution is to promote the binding of antibodies in plasma to red blood cell antigens.Then use polybrene (positive electricity) to neutralize red blood cells (negative electricity) to shorten the distance between the cells, forming a reversible nonspecific agglutination, or irreversible specific agglutination.Non-specific agglutination caused by polybrene can be neutralized and dispersed by the addition of resuspension solution.If there is a specific antibody-antigen reaction, the agglutination will not spread out, which is a positive reaction; if there is no specific antibody-antigen reaction, the agglutination will spread out, which is a negative reaction.

### Reagents and Materials

Product number	C0216	C0218	C0225
Specification	Manual polybrene reagent 300T	Manual polybrene reagent 500T	Manual polybrene reagent 2000T
1. LIM	200mlx1	300mlx1	300mlx4
2. Polybrene reagent	17mlx2	17mlx3	17mlx12
3. Re-suspending reagent	17mlx2	17mlx3	17mlx12

### Storage, Shelf life

The polybrene reagent should be stored at 2-8°C. DO NOT FREEZE. Expiration date is specified on the kit label and on each vial. Do not use the reagent after the expiry date.

### Material Supplied

1. Low Ionic Strength Medium Reagent(LIM)
2. Polybrene Reagent.
3. Re-suspending Reagents.

### Material & Equipment Not Supplied

Test Tubes(12x75mm or 10x75mm), Dropper, Glass Slides, Normal Saline(0.9% NaCl), 37 ° C incubator, Timer, Microscope,Centrifuge and control material.

### Specimen Collection and Preparation

Use sterile blood collection to collect blood into EDTA tubes, and use centrifugation to separate plasma.Fresh and uncontaminated plasma specimens can be stored at 2~8°C for 48 hours. If the specimen cannot be analyzed within 48 hours, it is recommended to freeze the plasma at -20°C or lower.

### Preparation for Test Procedure

1. EDTA plasma specimen should be used in the test.
2. Wash the donor's red blood cells three times with normal saline (0.9% NaCl).
3. Prepare 3-5% blood cell suspension.

### PROCEDURE

1. Place 2 drops of patient's EDTA plasma in a labeled tube.
2. Add 1 drop of the 3~ 5% cell suspensions to the labeled tube and mix.
3. Add 0.6ml of LIM solution, to the labeled tube,mix and let stand at room temperature(19~25 ° C) for 1 minute.
4. Add 2 drops of polybrene solution, to the labeled tube, mix and let stand at room temperature for 15 seconds.
5. Centrifuge for 15 seconds at 900-1000 g and then decant the supernatant.
6. Visually check whether there is agglutination reaction in the test tube (Retest if there is no agglutination reaction).
7. Add 2 drops of the resuspension solution and mix gently for 10 seconds to remove the non-specific resuspension generated by the polybrene.And use visual inspection or microscope to interpret the results.

### Interpretation of The Results

#### Negative Result

No agglutination reaction is a negative result (there is no agglutination reaction caused by the binding of the corresponding antibody to the antigen).

#### Positive Result

Agglutination reaction is a positive result,means that the test subject's plasma contains antibodies corresponding to the red blood cell antigens. Positive results need to be observed on a glass slide with a microsope.Weak positive needs to be observed with a microscope and compared with the negative control .

### Precaution /Notes

1. All reagents of this kit are strictly intended for professional in vitro diagnostic use only.
2. Orientals rarely have Anti-K antibodies, but the proportion of other ethnic groups is higher. If the patient is other ethnic groups it is recommended to do an auxiliary anti-globulin test.
3. Do not wait more than 3 minutes to interpret the results in step 7, as it may cause false negative results.
4. The operator must be familiar with the inspection techniques, otherwise it may lead to erroneous results and interpretations.
5. If the specimen contains heparin anticoagulant or other interfering factors, 1-2 more drops must be added when adding polybrene reagent to neutralize these interfering factors, please follow the instructions for the amount of low-ion solution added.After testing, even if the low-ion solution is increased to 1 ml, only a few samples will have a difference in agglutination titer.
6. Do not cross-use reagents from different lot.
7. Some patients may have cold agglutinin factors in plasma that may cause false positive. If there is any doubt, add the resuspension solution, place the tubes in a 37°C water bath and mix gently.Observe the result within one minute.

### BIBLIOGRAHY

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