







# Competency Testing Kit

REF Z276

## INTERPRETATION OF LABEL SYMBOLS

	Batch code
	Use by (YYYY-MM-DD)
	Product code
	Storage temperature limitation (2-8 °C)
	Consult instructions for use
	Manufacturer

## INTRODUCTION

Competency Testing Kit is for self-assessment of blood banking techniques and test systems.

## INTENDED PURPOSE

Competency Testing Kit is intended for use as an internal, self assessment of both individual operators and of antibody screening testing platforms.

## REAGENT DESCRIPTION

Competency Testing Kit has been prepared from plasma donations collected from blood donors or monoclonal antibodies. For human derived components conversion to serum was achieved by the addition of calcium chloride. Excess calcium was removed by the addition of sodium oxalate.

Each individual kit component may contain irregular blood group antibody(ies) and has been formulated to give weak reactions in the indirect antiglobulin test. Each kit comprises 10 randomly numbered and randomly selected samples.

## STORAGE CONDITIONS

The reagent should be stored at 2-8 °C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

## PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper

plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide buildup.

In the EU harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

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.

This reagent is for *in vitro* use only.

## TEST PROCEDURES

This reagent has been validated for use by column agglutination technology/manual tube test method and therefore its suitability for use by other methods cannot be guaranteed. Users are advised to carefully confirm reagent suitability before using alternative techniques.

## RECOMMENDED TECHNIQUES

### Column Agglutination Technology (CAT)

Strictly follow the test procedures described in the manufacturer's specific Instructions for Use for the CAT (gel/bead) system validated for use in the laboratory.

### Additional Materials and Reagents Required

Refer to the manufacturer's specific Instructions for Use for the CAT (gel/bead) system validated for use in the laboratory.

### Manual Tube Test Procedure

#### Additional Materials and Reagents Required

- Isotonic saline
- Antibody screening/identification panel
- ALBAhance™ LISS Additive Solution Z333U (optional)
- ALBAhance™ PEG Z312U (optional)
- 22% Bovine Serum Albumin Z305U (optional)
- Polyspecific Anti-Human Globulin/Monospecific Anti-Human IgG
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath
- Timer
- ALBAcyte® IgG-sensitized red blood cells Z441/Z441U

### 37 °C Indirect Antiglobulin Test

- Prepare a 2-3% suspension of red blood cells in isotonic saline solution. Note that red cell samples may be used as provided by the reagent manufacturer, i.e. as preservative-suspended red cells.
- Add 1 drop of red blood cell suspension to an appropriately labeled test tube.
- Add 2 drops of the serum or plasma to be tested.

- Mix the test well and incubate for 45 minutes at 37 ± 1 °C.
- Wash the test at least 3 times with a large excess isotonic saline, e.g. 4 mL of saline per 12 (or 10) x 75 mm glass tube).

**NOTE:** (i) allow adequate spin time to sediment the red blood cells.  
(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add Anti-Human Globulin to each test tube in the amount specified in the manufacturer's product insert.
- Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
- Record results.
- Add IgG-sensitized red blood cells to confirm the validity of negative test results.

### 37 °C Indirect Antiglobulin Test - PEG

- Prepare a 2-3% suspension of red blood cells in isotonic saline solution. Note that red cell samples may be used as provided by the reagent manufacturer, i.e. as preservative-suspended red cells.
- Add 1 drop of red blood cell suspension to an appropriately labeled test tube.
- Add 2 drops of the serum or plasma to be tested.
- Add 2 or 4 drops of ALBAhance™ PEG. If another manufacturer's PEG is used, follow manufacturer's instructions.
- Mix the test well and incubate for 15-20 minutes at 37 ± 1 °C.
- Re-suspend the contents of the test tube completely.
- Wash the test four times with a large excess of isotonic saline. However, when two drops of ALBAhance™ PEG are used in testing, three washes may be adequate. When using an automated cell washer the laboratory should determine the adequate number of washes needed during the validation process.
- Centrifuge the test tube. Suggested centrifugation: 1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy re-suspension of antigen-negative red blood cells.
- Add 2 drops of Anti-Human Globulin Anti-IgG.
- Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.
- Record results.

- Add IgG-sensitized red blood cells to confirm the validity of negative test results.

### 37 °C Indirect Antiglobulin Test – LISS Additive

- Add 2 drops of sera to a test tube.
- Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Note that reagent red blood cells may be used as provided by the manufacturer, i.e. as preservative-suspended red cells.
- Add 2 drops of ALBAhance™ LISS Additive Reagent. If another manufacturer's LISS is used, follow manufacturer's instructions.
- Mix the test well and incubate for 15-20 minutes at  $37 \pm 1$  °C. (Opt) Following incubation at 37 °C, the test may be examined macroscopically for evidence of agglutination.
- Mix the contents of the test tube and centrifuge. Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells. Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.
- Wash the test at least 3 times with a large excess of isotonic saline, e.g. 4 mL of saline per 12 (or 10) x 75 mm glass tube.

**NOTE:** (i) allow adequate spin time to sediment the red blood cells.  
(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add Anti-Human Globulin Reagent to each test tube in the amount specified in the manufacturer's product insert.
- Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
- Record results.
- Add IgG-sensitized red blood cells to confirm the validity of negative test results.

### 37 °C Indirect Antiglobulin Test – Albumin Addition

- Add 2 drops of sera to a test tube.
- Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Note that reagent red blood cells may be used as provided by the manufacturer, i.e. as preservative-suspended red cells.
- Add 2 drops of 22% BSA.
- Mix the test well and incubate for 30 minutes at  $37 \pm 1$  °C.
- Mix the contents of the test tube and centrifuge. Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells. Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

- Wash the test at least 3 times with a large excess of isotonic saline, e.g. 4 mL of saline per 12 (or 10) x 75 mm glass tube.

**NOTE:** (i) allow adequate spin time to sediment the red blood cells.  
(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add Anti-Human Globulin Reagent to each test tube in the amount specified in the manufacturer's product insert.
- Mix the contents of the test tube well and centrifuge.
- Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
- Record results.
- Add IgG-sensitized red blood cells to confirm the validity of negative test results.

### INTERPRETATION OF RESULTS

Agglutination = positive test result  
No agglutination = negative test result

### VERIFICATION OF RESULTS

**EU (and rest of world) Customers:** Sample identification and corresponding antibody specificity can be found in a password-protected area of the AliveDx EU website: [www.eu.quotientbd.com](http://www.eu.quotientbd.com).

To obtain a password, please contact: [customer.serviceEU@alivedx.com](mailto:customer.serviceEU@alivedx.com).

**US Customers:** Sample identification and corresponding antibody specificity can be found in password-protected area of the AliveDx US website: <http://us.quotientbd.com>.

To obtain a password, please contact: AliveDx US Technical Service at 1-888-228-1990 or [technical.serviceUS@alivedx.com](mailto:technical.serviceUS@alivedx.com).

### QUALITY CONTROL

This is a quality control reagent and its satisfactory performance when used by the recommended techniques represents an adequate level of control.

### PERFORMANCE LIMITATIONS

Improper techniques may invalidate the results obtained with this product.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials and omission of test reagents.

Variability in reactivity would be expected when testing is performed using different enhancement solutions. For instance, the strength of antibody reactivity may be less when testing is performed using LISS enhancement or PEG

enhancement technique than by Column Agglutination Technique (Gel).

In some instances the contrary may be experienced.

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