

# Competency Training Kit

**REF** Z275U

## INTRODUCTION

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

## INTERPRETATION OF LABEL SYMBOLS



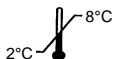
Batch code



Use by (YYYY-MM-DD)



Product code



Storage temperature limitation (2°C– 8°C)



Consult instructions for use



Harmful



Manufacturer

## INTENDED PURPOSE

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

## REAGENT DESCRIPTION

Competency Training Kit has been prepared from plasma donations collected from blood donors. Conversion to serum was achieved by the addition of calcium chloride and, when necessary, thrombin. Excess calcium was removed by the addition of sodium oxalate. The formulation also contains 1g/L sodium azide.

Each individual donation contains the appropriate blood group antibody(ies) and has been formulated to give weak reactions in the indirect antiglobulin test. Each kit comprises 20 randomly numbered and randomly selected samples.

## STORAGE CONDITIONS

The reagent should be stored at 2°C - 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.

**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) 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) system validated for use in the laboratory.

### Manual Tube Test Procedure

#### Additional Materials and Reagents Required

- Isotonic saline
- Antibody screening panel
- Polyspecific Anti-Human Globulin / Monospecific Anti-Human IgG
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath @ 37°C
- Timer

### 37°C Indirect Antiglobulin

- Add 2 drops of reagent to a test tube.
- Add 1 drop of red blood cells suspended to 2-4% in isotonic saline.
- Mix the contents of the test tube well and incubate for 45 minutes at 37°C ± 1°C.
- Wash the test 4 times with a large excess of isotonic saline.

(eg 4ml of saline per 12 (or 10) x 75mm glass tube)

- NOTE:** (i) allow adequate spin time to sediment the red cells.
- (ii) make sure that most of the residual saline is removed at the end of each wash.
- Add two drops of anti-human globulin reagent to each tube.
  - Mix the contents of the test tube well and centrifuge.

Suggested centrifugation: 1000g 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 resuspension of antigen-negative red blood cells.

• After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

## INTERPRETATION OF RESULTS

Agglutination = positive test result  
No agglutination = negative test result

## VERIFICATION OF RESULTS

Sample identification and corresponding antibody specificity can be found in the files contained within the USB Mass Storage Device supplied with the kit.

## 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.

## DATE OF ISSUE

03 March 2010

## US Distributor

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