

AHG

REF No: RCAHG

CE 1434

IVD

INTENDED USE

This test allows Direct Coombs test (DAT), Indirect Coombs test (IAT), compatibility test, antibody screening and antibody identification in gel technique.

INTRODUCTION

Antibody screening is the most reliable and sensitive method of detecting a clinically significant antibody. This test contains antibodies to human IgG and a murine monoclonal antibody to C3 (class IgG). The antihuman globulin test is used in numerous ways in pretransfusion and compatibility testing.

The Direct Antiglobulin Test (DAT) is used to detect in-vivo sensitization and detects antibodies on a patient's red cells. The Indirect Antiglobulin Test (IAT) is used to detect in-vitro sensitization and detects anti-red cell antibodies in patient's serum.

PRINCIPLE OF TEST

The test contains 8 microtubes Polyspecific anti-human globulin (AHG) gel matrix. The red blood cells will agglutinate in the presence of antibody directed towards the antigen. Agglutinated cells forming a red button on the surface of the gel or agglutinates dispersed in the gel is a positive result and indicates the presence of the corresponding antibody.

KIT CONTENTS

48 AHG cards. 1 gel card contains 8x1 microtubes

AHG	AHG	AHG	AHG	AHG	AHG	AHG	AHG
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Ready to use. Contains Sodium azide < 0,1% as preservative.

Each microtube of the card contains Polyspecific anti-human globulin (AHG) gel medium.

MATERIAL REQUIRED BUT NOT PROVIDED

- 10 µl, 50 µl and 1 ml automatic pipettes.
- Disposable pipette tips.
- Test tubes.
- LISS Diluent
- Centrifuge for Blood Grouping Gel System.
- Incubator
- Test cells for antibody screening.

STORAGE CONDITIONS AND STABILITY

- Store the gel cards at 2-24 °C in upright position.
- Do not use reagents over the expiration date.
- **All the components of the kit are stable until the expiration date on the label when stored 2-24 °C.**
- **Do not remove foil seal until ready to use. Once opened, the gel may begin to dry out which could affect test results.**
- **Use the card within 2 hours after removing the aluminum foil. Otherwise, don't use the card.**
- **Stability of the opened gel card is 2 hours.**

PRECAUTIONS AND WARNINGS

- This reagent kit is for in vitro diagnosis only.
- This reagent kit is for professional use only.
- All human sourced material (monoclonal antibodies) are tested free from HBsAg, Anti-HCV and Anti-HIV. However, all materials of human origin should be considered as potentially infectious and it is recommended that all kit materials and test specimens to be handled using established good laboratory practice.
- All kit components and specimens should be regarded as potential hazards to health. It should be used and discarded according to your own laboratory's safety procedures.

SAMPLE COLLECTION

Fresh red blood cells are preferred for testing. Use the red blood cells collected with anticoagulants (EDTA, Citrate) for determination of the antigens. If necessary, samples stored at 2-8 °C can be used up to 48 hours.

Red blood cells collected in ACD, CPD, CPDA can also be used until the expiry date indicated on the label of the bag at 2-8 °C (9).

Serum samples must be cleared. Fibrin residues may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE

1 % red blood cell suspension :

Do not use haemolysed, cloudy or contaminated samples or those containing clots

- 1- Bring LISS Diluent to reach room temperature before use
- 2- Dispense 1 mL of LISS Diluent into a clean tube.
- 3- Add 20 µL of whole blood or 10 µL of packed cells to the diluent and mix gently

Serum :

If necessary, samples stored at 2-8 °C can be used up to 48 hours after their extraction; or frozen samples (from -20 °C to -70 °C) up to the time of performing the test.

TEST PROCEDURE

Allow the test card and cell reagent to reach room temperature before use.

Direct antiglobulin test (DAT)

- 1- Homogenize the reagent red blood cells.
- 2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
- 3- Pipette 50 µL of 1% patient's or donor's red cell suspension to the appropriate microtubes.
- 4- Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
- 5- Read the results.

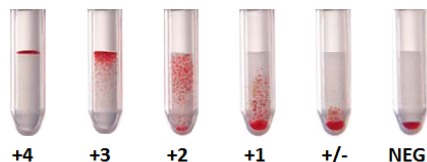
Antibody screening (IAT)

- 1- Homogenise the reagent red blood cells.
- 2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
- 3- Pipette 50 µL of test red cell suspension (Coombs control) to the appropriate microtubes.
- 5- Add 25 µL of the patient's or donor's serum to the microtubes.
- 6- Incubate the gel card for 15 minutes at 37 °C.
- 7- Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
- 8- Read the results.

Compatibility test

- 1- Homogenise the reagent red blood cells.
- 2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
- 3- Pipette 50 µL of 1% donor's red cell suspension to the appropriate microtubes.
- 4- Pipette 50 µL of the patient's red cell suspension to the appropriate microtube.
- 5- Add 25 µL of the patient's serum to the microtubes.
- 6- Incubate the gel card for 15 minutes at 37 °C.
- 7- Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
- 8- Read the results.

Negative	Band of red blood cells at the bottom of the column and no visible agglutinations in the rest of the column.
+/-	Scarce small-sized agglutinations in the lower half of the column
+1	Some small-sized agglutinations in the column
+2	Small or medium-sized agglutinations throughout the column
+3	Most agglutinated red blood cells remain in the upper half of the gel column
+4	Agglutinated red blood cells form a band at the top of the gel column



Stability of the results:

It is recommended an immediate reading of the results after centrifuging the cards. Do not leave processed cards in horizontal position. If necessary, a delayed reading can be made up until 24 hours after processing the cards if kept in vertical position, refrigerated (2-8°C) and sealed with parafilm or similar material to avoid evaporation of the supernatant.

Interpretation of the results:

Direct antiglobulin test (DAT)

- A negative reaction indicates absence of detectable IgG antibodies or C3d complement component on the red cells.
- A positive reaction (± to +++) indicates that the patient's red cells are sensitized (red cells coated with IgG antibodies and/or C3d).

Antibody Screening

- A negative reaction indicates the absence of detectable irregular antibodies in the patient's or donor's serum.
- A positive reaction indicates the presence of irregular antibodies.
- Following the reaction pattern and the antigen configuration, the type of antibody present may be indicated.
- A positive reaction with some test cells and a negative auto control suggest the presence of a specific antibody.
- A positive reaction with all test cells and a positive auto control may be due to an auto-antibody.
- A positive reaction with all test cells and a positive auto control but with one or more test cells showing a stronger positive reaction than the auto control, the patient sample should be submitted for further testing, to investigate the possibility of an underlying allo-antibody.

Compatibility test

- A negative reaction indicates compatibility of the donor blood with the recipient.
- A positive reaction indicates incompatibility of the donor blood with the recipient, due to presence of antibodies directed against antigens on the donor red cells. Further investigation to identify the antibody specificity should be performed

PERFORMANCE CHARACTERISTICS

Diagnostic sensitivity and specificity of AHG :

There is no described procedure or technique capable of detecting all the possible unexpected antibodies present in a sample. We conducted our own performance study. Antibody detection have been studied in 240 samples and obtained comparable results with other established products of equivalent intended use.

Precision:

Inter-assay and intra-assay reproducibility tests; no false positive or false negative results were obtained. Variability between agglutination views in positive samples were 1 agglutination rating or less in all assays.

LIMITATIONS

- The Aluminum foil on the matrix gel card should be removed carefully and gently.
- Do not use matrix gel cards, which show signs of drying.
- The gel cards which show air bubbles in the gel or drops in the upper part of the microtubes and/or the seal, must be centrifuged before use.
- Do not touch the pipet tip inside the gel card. Carryover problem may occur.
- Do not use hemolyzed, cloudy or contaminated samples or with clot presence.
- Use of suspension solutions other than REDCELL LISS Diluent may modify the reactions.

- Abnormal concentrations of serum proteins, the presence of macromolecular solutions in the serum may cause the non-specific agglutination of the red blood cells. It is recommended to wash the red blood cells before performing the test.

Label symbols

	Batch code
	Expiry date
	Storage temperature
	Consult instructions for use
	In vitro diagnostic medical device
	Product code
	Manufacturer

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Products: AHG

4x12 REF : RCAHG



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