ScanGel™
Anti-IgG
86437  48 Cards
86438  1080 Cards

GEL FORMULATED WITH A POLYCLONAL
ANTI-IgG ANTI-HUMAN GLOBULIN
Irregular Ab screening, crossmatch, phenotyping

All the products manufactured and commercialised by Bio-Rad are under complete quality system starting from reception of raw material to the final commercialisation of the product. Each lot is submitted to a quality control and only is released on the market when conforming to the acceptance criteria. The records relating to production and control of each single lot are kept within our company.
I - USE AND PRINCIPLE OF THE TEST
This card is strictly reserved for professional and in vitro diagnostic use.
Designed for screening and identification of irregular anti-erythrocytic antibodies, crossmatch and phenotyping, the test combines the principles of agglutination and gel filtration.
The reaction is obtained and read after centrifuging specially designed microtubes containing gel impregnated with antiglobulin reagent.
The red blood cell suspension and plasma or serum are distributed into each well of the microtube. The microtube is centrifuged after an incubation period.
Non-agglutinated red blood cells are collected at the bottom of the microtube while the agglutinates are dispersed throughout the length of the gel, depending upon their size. Their position in the gel determines the intensity of the reaction.

II - CHARACTERISTICS OF THE REAGENTS
The microtubes of the ScanGel Anti-IgG card contain a gel impregnated with an anti-IgG antihumanglobulin reagent. This anti-IgG fraction is prepared from sera from hyperimmunised goats.
The reagent contains sodium azide (< 0.1%) as preservative.
The product code and number of cards per box are stated on the box label.

III - STORAGE - SHELF LIFE
The expiry date and storage conditions are stated on the box.
Store the cards at room temperature (+15°C - +25°C).
Store the cards vertically under protection from all sources of heat in a facility with a relatively constant temperature and relative humidity.

IV - WARNINGS AND PRECAUTIONS
The reliability of the results depends on correct adherence to the following Good Laboratory Practices:
• Do not use the reagents after the expiration date indicated on the label.
• Do not use cards showing signs of drying, bubbles, a damaged or partially removed seal strip.
• It is essential to take precautions in order not to provoke between-microtubes contamination, particularly during the distribution steps.

• Use a different tip for each sample, each reagent or reagent red blood cell.

• Check that the pipettes and other apparatus are working correctly and check their precision.

• Wear gloves and safety glasses when handling the reagents and samples.

• Never pipette directly by mouth.

• Avoid splashing. In the event of splashes, clean with 12°C1 bleach (Javel water) diluted 1:10 and wipe with absorbent paper. The materials used for cleaning are to be discarded in the contaminated waste container.

• Consumables and products which have been in contact with either samples or reagents which contain material of human origin, must be discarded after they have been decontaminated.

• The safety datasheets are available on request.

V - SAMPLING AND SAMPLE PROCESSING

Draw the blood aseptically into a tube without or with anticoagulant (EDTA, CPD). Conduct the test as soon as possible after sampling. Samples that cannot be analysed rapidly should be stored between +2°C and +8°C and tested within 48 hours. Under no circumstance should haemolysis be visible. Do not heat the samples.

VI - METHOD

Equipment supplied

• ScanGel Anti-IgG cards

Material required but not provided

• ScanLiss : red blood cell suspension medium
  86441 ScanLiss 100 ml
  86442 ScanLiss 500 ml

• IH QC : Blood group serology control
  86745 IH QC 4 x 6 ml

• Centrifuge : ScanGel Centrifuge

• Incubator : ScanGel Incubator

• Automatic or semi-automatic pipettes

• Pipette tips

• Disposable tubes

• Container for wastes associated with a biological risk

• Bleach (Javel water)

• Latex gloves

• Absorbent paper

• Safety glasses
1. Irregular antierythrocytic antibody screening and identification

Controls
- An autocontrol (plasma or serum and red blood cells of the patient) should preferably be conducted in parallel with each test.
- Positive control (known serum, containing at least one antibody detectable in indirect antiglobulin technique) and negative control (known serum, containing no antibody), IH QC : Blood group serology control.

Material required but not provided
- EryScan, ScanCell, ScanPanel : ready for use reagent red blood cells for the screening and the identification of irregular antierythrocytic antibodies (Indirect Antiglobulin Test)
  86597 EryScan 2 x 10 ml
  86595 ScanCell 3 x 10 ml
  86593 ScanPanel 10 x 3 ml

Procedure
Strictly comply with the procedure.

Allow all the reagents to reach room temperature before use.
Separate the serum or plasma from the red blood cells of the sample by centrifuging.
When the blood is drawn without anticoagulant, centrifuge the serum a second time at 1,500 g for 10 minutes.

a) Prepare a suspension of red blood cells when these are not ready for use

Autocontrol :
- Transfer 1 ml of ScanLiss to a labelled disposable tube.
- Add 10 µl of red blood cell pellet (autocontrol).
- Mix.

b) Method
1. Label each card or part of card (depending upon the number of reagent red blood cells used for the sample) with the sample name or number; label the reagent red blood cell to transfer for each microtube.
   Withdraw the entire aluminium strip from the card.
   Resuspend the red blood cells before use.
2. Transfer 50 µl of each Eryscan, ScanCell or ScanPanel suspension or the red blood cell suspension as prepared in 1- a) into the well of the appropriated microtubes.
3. **Immediately** add 25 µl of plasma or serum into the well of the microtubes corresponding to the tested sample. Under no circumstance must the interval between red blood cell transfer and plasma or serum transfer exceed 10 minutes.

4. Incubate at 37°C for 15 minutes in ScanGel Incubator.

5. Centrifuge 10 minutes in ScanGel Centrifuge.

6. Read the reactions.

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**2. Crossmatch test**

**Controls**

- Positive control (known serum, with at least, one antibody detectable in Coombs technique) and negative control (known serum, without any antibody), IH QC: Blood group serology control.

**Procedure**

**Strictly comply with the procedure.**

Allow all the reagents to reach room temperature before use.

Separate the serum or plasma from the red blood cells of the sample by centrifuging.

When the blood is drawn without anticoagulant, centrifuge the serum a second time at 1,500 g for 10 minutes.

**a) Prepare a suspension(s) of red blood cells (donor(s))**

For each donor:

- Transfer 1 ml of ScanLiss to a labelled disposable tube.
- Add 10 µl of red blood cell pellet (donor red blood cells).
- Mix.
- The red blood cell suspension is ready for use.

**b) Method**

1. Label the card or part of the card with the receiver name or number and with corresponding donor(s) number.
   
   Withdraw the entire aluminium strip from the card.
   
   Resuspend the red blood cells before use.

2. Transfer 50 µl of each red blood cell suspension into the well of the appropriate microtubes.

3. **Immediately** add 25 µl of receiver’s plasma or serum into the well of the appropriate microtubes. Under no circumstance must the interval between red blood cell transfer and plasma or serum transfer exceed 10 minutes.

4. Incubate at 37°C for 15 minutes in ScanGel Incubator.

5. Centrifuge 10 minutes in ScanGel Centrifuge.

6. Read the reactions.
3. **Phenotyping**

**Controls**
- Positive and negative controls: red blood cells known to be positive and negative for the antigen are tested together with the sample.
- IH QC: Blood group serology control
- Sample control (red blood cells of the sample only).

**Material required but not provided**
- Bio-Rad reagents corresponding to the studied antigen.

**Procedure**

**Strictly comply with the procedure.**
Allow all the reagents to reach room temperature before use.
Separate the serum or plasma from the red blood cells of the sample by centrifuging.

**a) Prepare a suspension of red blood cells**
For each sample:
- Transfer 1 ml of ScanLiss to a labelled disposable tube.
- Add 10 µl of red blood cell pellet of the sample.
- Mix.
- The red blood cell suspension is ready for use.

**b) Method**
1. For each sample, identify a microtube by the name or the number of corresponding sample and the identifier of the serum-test used and a microtube by the name or the number of sample (control sample).
   Withdraw the entire aluminium strip from the card.
   Resuspend the red blood cells before use.
2. Transfer 50 µl of each red blood cell suspension into the well of the appropriate microtubes.
3. **Immediately** add 25 µl of serum-test into the well of the appropriate microtubes (except in the microtubes being used as sample control). Under no circumstance must the interval between red blood cell transfer and serum-test transfer exceed 10 minutes.
4. Incubate at 37°C for 15 minutes in ScanGel Incubator.
5. Centrifuge 10 minutes in ScanGel Centrifuge.
6. Read the reactions.
VII - RESULTS AND INTERPRETATION

- Agglutinates (on the surface of, or dispersed through, the gel) or an haemolysis in the microtube constitutes a positive result.
- A compact red blood cell button at the bottom of the microtube and the absence of haemolysis constitutes a negative result.
- The results are validated only if the controls give the expected results.

1. Irregular antierythrocytic antibody screening and identification

A negative result (no agglutination and no haemolysis) in each microtube indicates that the serum or plasma tested does not contain antibodies corresponding to the antigens present on the reagent red blood cells, detectable by the method used.

In contrast, a positive result (agglutination and/or haemolysis) in at least one of the microtubes indicates the presence of one or more antibodies in the serum or plasma. The antibodies have then to be identified.

A positive reaction in the autocontrol microtube may indicate that an autoantibody is present.

If, in addition to the positive autocontrol, at least one reagent red blood cell is agglutinated, mixed autoantibody/alloantibody should be considered.

Only the antibodies that correspond to the antigens present on the reagent red blood cells can be detected.

During the identification, the compared analysis between the positive reactions and the negative reactions observed with each reagent red blood cells of the panel used, makes it possible to characterize, using the master-list joined to the panel, antibody’s specificity(ies) present in the tested serum (or plasma).

2. Crossmatch test

A positive result (agglutination and/or haemolysis) shows the existence of an incompatibility between the serum or plasma of the receiver and the red blood cells of the donor.

3. Phenotyping

Refer to the package insert of the serum-test used.

The results are valid only if the control sample is negative.

VIII - PERFORMANCE

1. Irregular antierythrocytic antibody screening and identification

The specific performance was evaluated on 1086 patients and demonstrated a good balance between sensitivity and specificity.

Each result has been compared with the one obtained in immunoadherence or gel filtration techniques.
The specificity in an unselected patient population was 99.6%.
The application makes it possible to detect a human anti-RH1(D)
concentration equalizes to 20 ng/ml.
The reproducibility of the application was tested and showed good
performance in both intra and inter tests.

2. Crossmatch test
The performance evaluation gave concordant results with the gel filtration
technique used as a reference.
The reproducibility of the application was tested and showed good
performance in both intra and inter tests.

3. Phenotyping
Refer to the package insert of the serum-test used.

LIMITS
Abnormal results may be caused by:
• bacterial or chemical contamination of the serum, plasma, red blood cells
  or equipment.
• patient medication or disease yielding a cross-reaction.
• use of a red blood cell suspension medium other than that recommended.
• a red blood cell preparation different to that recommended.
• incomplete resuspension of the red blood cells.
• sample or reagent red blood cell haemolysis.
• the presence of fibrin (compact cell button at the bottom of the microtube
together with a fine pink band at the top of the gel made up of red blood
cells retained by the fibrin residues).
• between-microtube contamination.
• use of other procedure than the one described above.
IX - LITERATURE

"Under license from DiaMed SA, 1785 Cressier-sur-Morat, Switzerland"
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| *In vitro-Diagnostikum* | *Bestellnummer*
| *Per uso diagnostico in vitro* | *Numero di catalogo*
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| *Storage temperature limitation* | *Consult Instruction for use* |
| *Limites de températures de stockage* | *Consulter le mode d'emploi* |
| *Temperatura limite* | *Consulte la instrucción para el uso* |
| *Lagerungstemperatur* | *Siehe Gebrauchsanweisung* |
| *Limiti di temperatura di conservazione* | *Consultare le istruzioni per uso* |
| *Limites de temperatura de armazenamento* | *Consulte o folheto Informativo* |
| *Temperaturbegränzung* | *Se bruksanvisning* |
| *Temperaturbegrænsning* | *Instruktion Erstat med: brugsanvisningen* |

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**CE**

CE marking (European directive 98/79/CE on in vitro diagnostic medical devices)

Marquage CE [Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro]

Marcado CE [Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro]

EG Markierung [Europäische Richtlinie 98/79/EG über In-vitro-Diagnostika]

Marchiatura CE [Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici in vitro]

Marcação CE [Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico in vitro]

CE-märkning [Europadirektiv 98/79/EG om medicintekniska produkter för in-vitro-diagnostik]

CE-mærkning [Europa-direktiv 98/79/EF om medicinsk udstyr til in-vitro-diagnostik]

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**06/2009**

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