ScanGel™
COOMBS + NEUTRAL
86433  48 Cards
86434  1080 Cards

GEL FORMULATED WITH A POLYSPECIFIC ANTI
HUMAN GLOBULIN (POLYCLONAL AND MONOCLONAL
MURINE FRACTIONS) AND NEUTRAL GEL
Irregular Ab screening

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 the screening of irregular antierythrocytic antibodies, 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 for the Indirect Antiglobulin Technique (Indirect Coombs) and of neutral gel for the enzymatic technique. The reagent red blood cell suspension, treated or not with papain, depending on whether an enzymatic technique or an indirect antiglobulin test is being performed, and the serum or plasma to be tested, are distributed into the well of the microtubes and are 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.

The ability of the gel to separate red blood cells from serum or plasma renders the washing phase, that is mandatory in conventional Indirect Antiglobulin Techniques (Indirect Coombs), unnecessary.

II - CHARACTERISTICS OF THE REAGENTS
The first three microtubes of the Scangel COOMBS + NEUTRAL card contain a gel impregnated with polyspecific antihumanglobulin (AHG). The anti-IgG fraction is prepared from sera from hyperimmunised goats. The anticomplement fraction is prepared with a mixture of sera from hyperimmunised goats and a specific murine monoclonal anti-C₃d antibody produced by clone 053A714. The fourth, fifth and sixth microtubes contain a neutral gel (Neutr.). The reagent contain 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 or a damaged seal strip.
- The reagents contained in the microtubes are different so it is essential to take precautions in order not to provoke between-microtube contamination, particularly during the withdraw of the aluminium strip and during the distribution steps.
- Use a different tip for each sample and each 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°Ci 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). 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 circumstances should haemolysis be visible. Do not heat the samples.

VI - METHOD
Equipment supplied
- ScAngel COOMBS + NEUTRAL cards

Material required but not provided
- ScanCell : ready for use reagent red blood cells for the screening of irregular antierythrocytic antibodies (indirect antiglobulin test)
  86595 ScanCell 3 x 10 ml
- ScanCell P : ready for use reagent red blood cells for the screening of irregular antierythrocytic antibodies (enzymatic technique)
  86596 ScanCell P 3 x 10 ml
- IH QC : Blood group serology control
  86745 IH QC 4 x 6 ml
• Incubator : Scangel Incubator  
• Centrifuge : Scangel Centrifuge  
• 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

Controls
• Positive control (known serum, containing at least one antibody) and negative control (known serum, containing no antibody) and this, for each of the two techniques (indirect antiglobulin technique and enzymatic technique). 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 (2000 g x 2 minutes).
When the blood is drawn without anticoagulant, centrifuge the serum a second time at 1.500 g for 10 minutes.

Method

1. Label the card with the sample name or number.
   Withdraw the aluminium strip from the card, carefully to prevent between microtube contamination.
   Resuspend the red blood cells before use.
2. Transfer 50 μl of each ScanCell suspension into the well of the first three microtubes of the card (I in the 1st microtube, II in the 2nd microtube and III in the 3rd microtube) and 50 μl of each ScanCell P suspension into the well of the last three microtubes (IP in the 4th microtube, IIP in the 5th microtube and IIIP in the 6th microtube).
3. **Immediately** add 25 μl of plasma or serum into the well of each microtube. Under no circumstance must the interval between reagent 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.
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 positive and negative controls give the expected results.

a) Interpretation of the AHG microtubes
A negative result (no agglutination and no haemolysis) in each AHG microtube indicates that the sample under test does not contain antibody 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 AHG microtubes indicates the presence of one or more antibodies in the sample undertest. The antibodies have then to be identified.
Only the antibodies that correspond to the antigens present on the reagent red blood cells can be detected.

b) Interpretation of the Neutr. microtubes
A negative result (no agglutination and no haemolysis) in each Neutr. microtube indicates that the sample under test does not contain antibody 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 Neutr. microtubes indicates the presence of one or more antibodies in the serum or plasma. The antibodies have then to be identified.
Only the antibodies that correspond to the antigens present on the reagent red blood cells can be detected.

VIII - PERFORMANCE

a) Specific performance of the polyspecific antiglobulin reagent (AHG)
The specific performance was evaluated on 2,516 samples (1,782 patients and 734 donors) and demonstrated a good balance between sensitivity and specificity.
The application makes it possible to detect a human anti-RH1(D) concentration equalizes to 20 ng/ml.
The specificity in an unselected patient population was 99.8%.
The reproducibility of the application was tested and showed good performance in both intra and inter tests.
b) **Specific performance of the neutral reagent (Neutr.)**
The specific performance was evaluated on 2,517 samples (1,783 patients and 734 donors) and demonstrated a good balance between sensitivity and specificity.
The percentage of unselected samples found positive in irregular antibody screening (positive screens resulting in the identification of one or more allo- and/or autoantibodies) is 3.8%.
The specificity in an unselected patient population was 98.8%.
Some antigens, such as MNS1 (M), MNS2 (N), MNS3 (S), FY1 (Fya), FY2 (Fyb) and XG1 (Xga) being destroyed or being altered when red blood cells are treated with proteolytic enzymes thus, enzymatic technique can not be used as alone technique for screening of irregular antierythrocytic antibodies.
The reproducibility of the application was tested and showed good performance in both intra and inter tests.

**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.
- sample or reagent red blood cell haemolysis.
- incomplete resuspension of the red blood cells.
- 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


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 (Europa-direktiv 98/79/EG om medicintekniska produkter lär in vitro-diagnostik)
CE-mærkning (Europa-direktiv 98/79/EF om medicinsk udstyr til in vitro-diagnostik)

For in vitro diagnostic use
Pour diagnostic in vitro
Para diagnóstico in vitro
In vitro-Diagnostikum
Per uso diagnostico in vitro
Para uso em diagnóstico in vitro
In vitro-diagnostik
In vitro-diagnose

Catalogue number
Référence catalogue
Número de catálogo
Bestellnummer
Numero di catalogo
Número de catálogo
Katalognummer
Katalognummer

Authorised Representative
Représentant agréé
Representante autorizado
Bevollmächtigter
Distributore autorizzato
Representante Autorizado
Auktoriserad representant
Autoriseret repræsentant

Expiry date YYYY/MM/DD
Date de péremption AAAA/MM/JJ
Estable hasta AAAA/MM/DD
Vervenbar bis JJJJ/MM/TT
Da utilizzare prima del AAAA/MM/GG
Data de expiração AAAA/MM/DD
Utgångsdatum År/Månad/Dag
Anvendes før ÅÅÅÅ/MM/DD

Consult Instruction for use
Consulter le mode d’emploi
Consulte la instrucción para el uso
Siehe Gebrauchsanweisung
Consultare le istruzioni per uso
Consulte o folheto Informativo
Se bruksanvisning
Instruktion Erstat med: brugsanvisningen