ScanGel™
DIRECT COOMBS
86439 12 cards

GEL FORMULATED WITH MONOSPECIFIC ANTI HUMAN GLOBULIN (POLYCLONAL OR MONOCLONAL MURINE ORIGINS)
Direct antiglobulin test

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. 
Design for the direct antiglobulin testing (Direct Coombs), this test used to demonstrate IgG antibodies and or C_{3d} bound to the red cells in vivo. 
It combines the principles of agglutination and gel filtration.
The ScanGel card DIRECT COOMBS allows to test 2 samples. For each sample, 3 microtubes should be used: IgG, C_{3d}, Ctl.
The reaction is obtained and read after centrifuging specially designed microtubes containing gel impregnated with antiglobulin reagent.
Red blood cell suspension is added to the well of each microtube then immediately centrifuged.
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.

![Reaction Intensity Symbols](image)

The ability of the gel to separate red blood cells from serum renders the washing phase, that is mandatory in direct antiglobulin test conventional methods, unnecessary.

II - CHARACTERISTICS OF THE REAGENTS
The first and the fourth microtubes each contain gel impregnated with Anti-IgG antiglobulin reagent. The anti-IgG fraction is prepared from sera from hyperimmunised goats.
The second and the fifth microtubes each contain gel impregnated with anti-C_{3d} antiglobulin reagent. The anti-C_{3d} fraction is a murine monoclonal antibody produced by clone 053A714.
The third and the sixth microtubes each contain gel without specific reagent. They correspond to the control (Ctl).
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.
• 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 withdrawal of the aluminium strip and during the distribution steps.
• Use a different tip for each sample.
• 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. Clotted blood samples must be tested before they are refrigerated.
Under no circumstance should haemolysis be visible.
Do not heat the samples.

VI - METHOD
Equipment supplied
• ScanGel DIRECT COOMBS cards

Material required but not provided
• ScanLiss: red blood cell suspension medium
  86441 ScanLiss 100 ml
  86442 ScanLiss 500 ml
• 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 (red blood cells sensitised by an antibody of known IgG nature and/or by the C₃d fraction of the complement) and negative control (not sensitised red blood cells).

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. Label the card with the sample name or number.
   Withdraw the entire aluminium strip from the card.
   Resuspend the red blood cells before use.
2. Transfer 50 µl of red blood cell suspension to be tested into the well of the appropriate microtubes.
3. Centrifuge immediately for 10 minutes in ScanGel Centrifuge. Under no circumstance must the interval between red blood cell transfer and the start of the centrifugation exceed 10 minutes.
4. Read the reactions. The reading must be carried out in the hour following the end of the centrifugation.
VII - RESULTS AND INTERPRETATION

- Agglutinates (on the surface of, or dispersed through, the gel) constitute a positive result.
- A compact red blood cell button at the bottom of the microtube constitutes a negative result.
- A positive reaction in one of the microtubes can only be validated if the Ctl microtube is negative.

If the Ctl microtube shows a positive reaction:
- Wash the red blood cells in normal saline solution (0.9% NaCl).
- Repeat the procedure as indicated in VI.a and VI.b.

If the microtube still shows a positive result, rerun the test in a different method from the gel filtration method.
- A positive result in the IgG microtube indicates the presence of IgG on the red blood cells.
- A positive result in the C_3d microtube indicates the presence of C_3d on the red blood cells.

**The results are validated only if the positive and negative controls give the expected results.**

VIII - PERFORMANCE

The specific performance was evaluated on 677 samples (108 patients, 346 donors and 223 new born samples).

Each result has been compared with the one obtained in tube or gel filtration techniques.

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.
- 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 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"
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)
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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)

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-diagnóstico
In vitro-diagnose

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

Expiry date YYYY/MM/DD
Date de péremption AAAA/MM/JJ
Estable hasta AAAA/MM/DD
Vervennigd bis YYYY/MM/TT
Da utilizzare prima del AAAA/MM/GG
Data de expiração AAAA/MM/DD
Utgångsdatum År/Månad/Dag
Anvendes før AAAA/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 brukanvisning
Instruktion Erstat med: bruksanvisningen

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

Manufacturer
Fabricant
Fabricante
Hersteller
Produttore
Fabricante
Tillverkad av
Fremstillet af

Batch code
Code du lot
Código de lote
Chargen-Bezeichnung
Codice del lotto
Código do lote
Batch nr.
Batchnummer

Storage temperature limitation
Limites de températures de stockage
Temperatura limite
Lagerungstemperatur
Limiti di temperatura di conservazione
Limites de temperatura de armazenamento
Temperaturbegrenzung
Temperaturbegrænsning