ScanGel™
Monoclonal ABO/RH1/K

86495  48 Cards
86485  288 Cards

GELS FORMULATED WITH MONOCLONAL
REAGENTS OF MURINE OR HUMAN ORIGIN
ABO1, ABO2, RH1, KEL1 Ag determination

IVD

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 determination of ABO1 (A), ABO2 (B), RH1 (D) and KEL1 (K) antigens, the test combines the principles of agglutination and gel filtration. The reaction is obtained and read after centrifugation specially designed microtubes containing gel impregnated with the reagent specific to the erythrocyte antigen to be determined. 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.

II - CHARACTERISTICS OF THE REAGENTS

The first two microtubes of the ScanGel Monoclonal ABO/RH1/K card contain gel impregnated with murine monoclonal reagent specific to anti-ABO1 (A) and anti-ABO2 (B), respectively. The antibodies are produced by the following clones:
- anti-ABO1 (A): 15750F7
- anti-ABO2 (B): X9
The third and fourth microtubes each contain a gel impregnated with human monoclonal reagent specific to anti-RH1 (D):
- The antibody contained in the 3rd microtube is an IgM produced by clone B9A4-B2A6A6A1A1
- The antibody contained in the 4th microtube is an IgG produced by clone H2D5D2F5
The two anti-D reagents do not enable detection of phenotype RH1 partial category VI (D)
The fifth microtube contains a gel impregnated with human monoclonal reagent specific to anti-KEL1 (K). The antibody is an IgM produced by clone MS 56.
The sixth microtube contains an antibody-free gel and is the control (Ctl). The reagents 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 observance of 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 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°Cl 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 analyzed 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

Material supplied
• ScanGel Monoclonal ABO/RH1/K cards

Material required but not provided
• Red blood cell suspension mediums
  86441 ScanLiss 100 ml
  86442 ScanLiss 500 ml
  86448 ScanSol 100 ml
  86449 ScanSol 500 ml
• IH QC : Blood group serology control
  86745 IH QC 4 x 6 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 and negative controls: red blood cells known to be positive and negative for each antigen are tested together with the sample to validate reagent activity. 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 centrifugation.

VI.1 - Suspension in ScanLiss
a) Immediately prior to use prepare a suspension of 1% red blood cells to be tested in ScanLiss
• Transfer 1 ml of ScanLiss to a labelled disposable tube.
• Add 10 μl of red blood cell pellet.
• Mix.
• The red blood cell suspension is ready for use.
b) 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. Distribute 50 μl of red blood cell suspension into the well of each card's microtube.
3. Centrifuge 10 minutes in ScanGel Centrifuge.
4. Read the reactions.

VI.2 - Suspension in ScanSol
a) Immediately prior to use prepare a suspension of 5% red blood cells in ScanSol
   • Transfer 0.5 ml of ScanSol to a labelled disposable tube.
   • Add 25 μl of red blood cell pellet.
   • Mix.
   • The red blood cell suspension is ready for use.

b) 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. Distribute 10 μl of red blood cell suspension into the well of each card’s microtube.
3. Centrifuge immediately 10 minutes in ScanGel Centrifuge. Under no circumstance must the interval between the end of the distribution and the start of the centrifugation exceed 10 minutes.
4. Read the reactions.

VII - RESULTS AND INTERPRETATION
• Agglutinates on the surface of, or dispersed through, the gel constitutes a positive result indicating the presence of the corresponding erythrocyte antigen.
• A compact red blood cell button at the bottom of the microtube constitutes a negative result indicating that the corresponding erythrocyte antigen has not been detected.
• 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)
   Resume the procedure as indicated in VI.1 or VI.2.
If the Ctl microtube still shows a positive result, the reactions obtained with the ScanGel Monoclonal ABO/RH1/K card can not be interpreted. Rerun the test in a different method than the gel filtration method. If the Ctl microtube is negative, the interpretation for each of the other microtubes is as follows:

Positive result Weak positive result Negative result
++++ + to +++ -

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

a) Interpretation of microtubes ABO1 (A) and ABO2 (B)
A positive result in microtube ABO1 (A) indicates the presence of antigen ABO1 (A) on the surface of the red blood cells.
A positive result in microtube ABO2 (B) indicates the presence of antigen ABO2 (B) on the surface of the red blood cells.
Complete ABO grouping requires 2 complementary tests: the forward test conducted with anti-ABO1 (A), anti-ABO2 (B) reagents and if necessary anti-ABO3 (AB) reagent, and the reverse test conducted with the reagent red blood cells.
The forward and reverse test results must concord. Any discrepancy between those two tests must be resolved before any ABO result can be given.
Whenever the forward and reverse test results conflict, complementary tests with appropriate controls are to be conducted.

b) Interpretation of microtube RH1 (D)
A positive result in at least one of the microtubes RH1 (D) indicates the presence of antigen RH1 (D) on the surface of the red blood cells.
A negative result in one of the microtubes RH1(D) and a positive result in the other may be related to the presence of antigen RHW1 (weak D) or a variant antigen RH1(D). A complementary test is to be conducted with ScanGel Monoclonal Anti-RH1(D)/RHW1 liquid reagent together with the ScanGel COOMBS Anti-IgG, -C₃d card.

c) Interpretation of microtube KEL1 (K)
A positive result in microtube KEL1 (K) indicates the presence of antigen KEL1 (K) on the surface of red blood cells.
VIII - PERFORMANCE

The performance of ScanGel Monoclonal ABO/RH1/K card has been evaluated on a panel of unselected samples (donors, patients, and newborn) and a panel of selected samples. Each result has been compared with the one obtained in slide, tube, microplate or gel filtration techniques.

a) Specific performance of reagents anti-ABO1 (A) and anti-ABO2 (B)

Anti-ABO1 (A) and anti-ABO2 (B) reagents were evaluated using a panel of 1641 unselected samples (1150 donors, 332 patients, and 159 newborn samples) completed by a panel of selected samples (weak antigens).

The 1641 samples all gave compliant results with expected ones. A panel of 17 selected samples (Ax, B3, AxB, Bh, CisAB, A3B, Abf) were tested. All samples were detected with a 1+ to 3+ reactivity. The tested acquired B antigens were not detected with the anti-ABO2(B) of the ScanGel Monoclonal ABO/RH1/K card.

Anti-ABO1 (A) and anti-ABO2 (B) reagents of the ScanGel Monoclonal ABO/RH1/K card showed good reproducibility in both intra and inter tests.

b) Specific performance of anti-RH1(D) reagents

Anti-RH1(D) reagent, B9A4 clone, was evaluated using a panel of 1641 unselected samples (1150 donors, 332 patients, and 159 newborn samples) completed with a panel of 24 selected samples (weak antigens, variants and particular phenotypes). The 1641 samples all gave compliant results with expected ones. 94% of RHW1 (weak D) tested antigens were detected. All variants and particular phenotypes were also detected, except the phenotype RH1 partial category VI (DVI).

Anti-RH1(D) reagent, H2D5D2F5 clone, was evaluated on a panel of 1444 unselected samples (1121 donors, 292 patients, 26 newborns and 5 frozen samples) including 21 RHW1 (weak D) antigens and 5 RH1(D) variants including 3 phenotype RH1 partial category VI (D^a). The 1444 samples all gave compliant results with expected ones. The 3 tested samples of the phenotype RH1 partial category VI (D^a) have not been recognised.

Both Anti-RH1(D) reagents of the ScanGel Monoclonal ABO/RH1/K card showed good reproducibility in both intra and inter tests.
c) Specific performance of the anti-KEL1 (K) reagent

Anti-KEL1 (K) reagent was evaluated on 1519 unselected samples (1150 donors, 332 patients, and 37 new born) and a panel of 5 frozen red blood cells. All samples gave compliant results with expected ones. Anti-KEL1(K) reagent of the ScanGel Monoclonal ABO/RH1/K card showed good reproducibility 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.
• a red blood cell preparation different to that recommended.
• 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).
• use of a red blood cell suspension medium other than that recommended.
• 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)
- Marco do CE (Directiva europeia 98/79/CE sobre produtos sanitários 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 för in vitro-diagnostik)
- CE-mærkning (Europa-direktiv 98/79/EF om medicinsk udstyr til in vitro-diagnostik)

**IVD**
- 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-diaaose

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

**EC REP**
- Authorised Representative
- Représentant agréé
- Representante autorizado
- Bevollmächtigter
- Distributore autorizzato
- Representante Autorizado
- Auktorisieret representant
- Autoriseret repræsentant

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

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

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