ScanGel™

ABO Complete/RH/K Duo

86719  2 x 24 cards
86709  2 x 144 cards

ScanGel ABO Complete/RH1 Duo and ScanGel Monoclonal RH/K Phenotypes Duo cards

GELS FORMULATED WITH MONOCLONAL REAGENTS OF MURINE OR HUMAN ORIGIN OR NEUTRAL GEL

ABO grouping. RH1, RH2, RH3, RH4, RH5 and KEL1 Ag determination

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 REAGENT
These cards are strictly reserved for professional and *in vitro* diagnostic use. Designed for ABO grouping and the determination of RH1, RH2, RH3, RH4, RH5 and KEL1 antigens, 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 the reagent specific to the erythrocyte antigen to be determined (forward grouping and determination of the RH1 antigen) and neutral gel for the reverse grouping. Red blood cell suspension and the plasma or serum (for the reverse grouping) are 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 REAGENT
IMPORTANT NOTICE: The ScanGel ABO Complete/RH1 Duo card must be used together with the ScanGel Monoclonal RH/K Phenotypes Duo card.

1. ScanGel ABO Complete/RH1 Duo card
The first three microtubes of the ScanGel ABO Complete/RH1 Duo card each contain gel impregnated with murine monoclonal reagent specific to anti-ABO1 (A), anti-ABO2(B) and anti-ABO3(AB), respectively. The antibodies are produced by the following clones:
   - anti-ABO1 (A) : 15750F7
   - anti-ABO2 (B) : X9
   - anti-ABO3 (AB) : AB5-63A5A2/X9
The fourth microtube contains a gel impregnated with human monoclonal reagent specific to anti-RH1 (D). The antibody is an IgM produced by clone B9A4-B2A6A6A1A1. This anti-RH1 (D) reagent does not enable the detection of phenotype RH1 partial category VI (DVI). The fifth and the sixth microtubes each contain a neutral gel.

The reagents contain sodium azide (< 0.1%) as preservative. The product code and number of cards per box are stated on the box label.
2. ScanGel Monoclonal RH/K Phenotypes Duo card
The first five microtubes of the ScanGel Monoclonal RH/K Phenotypes Duo card contain gel impregnated with human monoclonal reagent specific to anti-RH2 (C), anti-RH3 (E), anti-RH4 (c), anti-RH5 (e) and anti-KEL1 (K), respectively. The antibodies are produced by the following clones:
• Anti-RH2 (C) : MS-24
• Anti-RH3 (E) : MS-260/MS-258
• Anti-RH4 (c) : MS-33
• Anti-RH5 (e) : MS-63/MS-21/MS-16
• Anti-KEL1 (K) : MS-56
The sixth microtube contains an antibody-free gel and is the control (Ctl), validated for both ScanGel ABO Complete/RH1 Duo and ScanGel Monoclonal RH/K Phenotypes Duo cards.
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 withdraw 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°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 circumstances should haemolysis be visible. Do not heat the samples.

VI - METHOD
Material supplied
**ABO Complete/RH/K Duo 2 x 24 cards including**
- ScanGel ABO Complete/RH1 Duo 24 cards
- ScanGel Monoclonal RH/K Phenotypes Duo 24 cards

**ABO Complete/RH/K Duo 2 x 144 cards including**
- ScanGel ABO Complete/RH1 Duo 144 cards
- ScanGel Monoclonal RH/K Phenotypes Duo 144 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
- ReverScan A1 and B : reagent red blood cells for reverse grouping test
  86790 ReverScan A1, B, 2 x 5 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
- **ABO forward grouping and RH1, RH2, RH3, RH4, RH5, KEL1 Ag determination**
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.
• **ABO reverse test**
  Positive control (known plasma or serum containing at least a specific antibody), negative control (known plasma or serum not containing antibody). IH QC : Blood group serology control.

**Procedure**

**Strictly comply with the procedure.**

It is compulsory to use the ScanGel ABO Complete/RH1 Duo card together with ScanGel Monoclonal RH/K Phenotypes Duo card, with the same red blood cell suspension to be tested.

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.

**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 each ScanGel ABO Complete/RH1 Duo and ScanGel Monoclonal RH/K Phenotypes Duo 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 ReverScan A1 into the well of microtube 5 of ScanGel ABO Complete/RH1 Duo card.
3. Distribute 50 μl of ReverScan B into the well of microtube 6 of ScanGel ABO Complete/RH1 Duo card.
4. Add 50 μl of serum or plasma to be tested in the wells of microtubes 5 and 6 of ScanGel ABO Complete/RH1 Duo card.
5. Distribute 50 μl of red blood cell suspension to be tested into the wells of microtubes 1, 2, 3, 4 of ScanGel ABO Complete/RH1 Duo card and in into each microtube of the ScanGel Monoclonal RH/K Phenotypes Duo card.
6. Centrifuge 10 minutes in ScanGel Centrifuge.
7. 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 each ScanGel ABO Complete/RH1 Duo and ScanGel Monoclonal RH/K Phenotypes Duo 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 ReverScan A1 into the well of microtube 5 of ScanGel ABO Complete/RH1 Duo card.
3. Distribute 50 μl of ReverScan B into the well of microtube 6 of ScanGel ABO Complete/RH1 Duo card.
4. Add 50 μl of serum or plasma to be tested in the wells of microtubes 5 and 6 of ScanGel ABO Complete/RH1 Duo card.
5. Distribute 10 μl of red blood cell suspension to be tested into the wells of microtubes 1, 2, 3, 4 of ScanGel ABO Complete/RH1 Duo card and into each microtube of the ScanGel Monoclonal RH/K Phenotypes Duo card.
6. 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.
7. Read the reactions.

VII - RESULTS AND INTERPRETATION

- Agglutinates on the surface of, or dispersed through, the gel constitutes 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 1 to 4 of the ScanGel ABO Complete/RH1 Duo card or in microtubes 1 to 5 of the ScanGel Monoclonal RH/K Phenotypes Duo card can only be validated if the Ctl microtube of the ScanGel Monoclonal RH/K Phenotypes Duo card 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.1 or VI.2.
If the Ctl microtube is negative, the interpretation for microtubes 1 to 4 of ScanGel ABO Complete/RH1 Duo card is as follows:

<table>
<thead>
<tr>
<th>Positive result</th>
<th>Weak positive result</th>
<th>Negative result</th>
</tr>
</thead>
<tbody>
<tr>
<td>++++</td>
<td>+ to +++</td>
<td>-</td>
</tr>
</tbody>
</table>

If the Ctl microtube is negative, the interpretation for each microtube of ScanGel Monoclonal RH/K Phenotypes Duo card is as follows:

<table>
<thead>
<tr>
<th>Positive result</th>
<th>Weak positive result</th>
<th>Negative result</th>
</tr>
</thead>
<tbody>
<tr>
<td>+++ to ++++</td>
<td>+ to ++</td>
<td>-</td>
</tr>
</tbody>
</table>

If the microtube still shows a positive result, rerun the test in a different method than the gel filtration method.

- The interpretation for microtubes 5 and 6 of ScanGel ABO Complete/RH1 Duo card is as follow:

<table>
<thead>
<tr>
<th>Positive result</th>
<th>Negative result</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ to +++</td>
<td>-</td>
</tr>
</tbody>
</table>

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

**a) Interpretation of ABO grouping**

Complete ABO grouping requires 2 complementary tests: the forward test conducted with anti-ABO1 (A), anti-ABO2 (B) reagents and anti-ABO3 (AB) reagent, and the reverse test conducted with the A1, B reagent red blood cells. The profiles of the expected results with anti-ABO1 (A), anti-ABO2 (B), anti-ABO3 (AB) reagents and A1 and B reagent red blood cells and their interpretation are presented in the following table:

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>ABO FORWARD TEST</th>
<th>ABO REVERSE TEST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anti-ABO1 (A)</td>
<td>Anti-ABO2 (B)</td>
</tr>
<tr>
<td>A</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>B</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>AB</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>O</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
The forward and the 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 microtube RH1 (D) indicates the presence of antigen RH1 (D) on the surface of red blood cells.
In spite of its performance, ScanGel ABO Complete/RH1 Duo card does not allow neither the detection of all D weak antigens neither the detection of the phenotype RH1 partial category VI (DVI). If the detection of those particular antigens is required, a complementary test is to be conducted with ScanGel Monoclonal Anti-RH1 (D)/RHW1 reagent together with the ScanGel COOMBS Anti-IgG,-C3d card.

c) Interpretation of microtubes RH2 (C), RH3 (E), RH4 (c), RH5 (e)
A positive result in one of the microtubes RH2 (C), RH3 (E), RH4 (c) or RH5 (e) indicates the presence of the corresponding antigen on the surface of red blood cells.

d) Interpretation of the microtube KEL1 (K)
A positive result in one of the microtube KEL1 (K) indicates the presence of antigen KEL1 (K) on the surface of red blood cells.

VIII - PERFORMANCE
a) Specific performance of anti-ABO1 (A), anti-ABO2 (B) and anti-ABO3 (AB) reagents
The performance of ScanGel ABO Complete/RH1 Duo card has been evaluated on a panel of 1641 unselected samples (1150 donors, 332 patients and 159 new born samples) completed with a panel of selected samples (weak or variant antigens).
Each result has been compared with the one obtained in slide, tube, microplate or gel filtration techniques.
The 1641 samples gave compliant results with the expected ones.
A panel of 17 selected samples (Ax, B3, AxB, Bh, CisAB, A3B, ABf) were tested. All were detected with a 1+ to 3+ reactivity.
The tested acquired B antigens were not detected with the anti-ABO2 (B) of the ScanGel ABO Complete/RH1 Duo card.
Anti-ABO1 (A), anti-ABO2 (B) and anti-ABO3 (AB) reagents of the ScanGel ABO Complete/RH1Duo card showed good reproducibility in both intra and inter tests.
b) Specific performance of anti-RH1 (D) reagent
Anti-RH1 (D) reagent has been evaluated on a panel of 1641 unselected samples (1150 donors, 332 patients and 159 new born samples) completed with a panel of selected samples (weak antigens).
Each result has been compared with the one obtained in slide, tube, microplate or gel filtration techniques.
The 1641 samples gave compliant results with the expected ones.
A panel of 24 selected samples (weak antigens, variants and particular phenotypes) were tested.
All variants and particular phenotypes were detected, except one sample of the phenotype RH1 partial category VI (DVI). 94% of RHW1 (weak D) tested antigens were detected.
Anti-RH1 (D) reagent of the ScanGel ABO Complete/RH1 Duo card showed good reproducibility in both intra and inter tests.

c) Specific performance of neutral reagent (microtubes A1 and B, fifth and sixth microtubes of the ScanGel ABO Complete/RH1 Duo card)
ReverScan A1 and B red blood cells have been evaluated on a panel of 1132 samples.
Each result has been compared with the expected one obtained in slide, microplate or gel filtration techniques.
On all samples tested, 1130 gave expected results whilst 2 were discordant, with one of the methods used in parallel, which were able to be raised after confrontation with the ABO forward test.
Whatever the tested sample is, ReverScan red blood cells used with ScanGel ABO Complete/RH1 Duo card show good reproducibility in both intra and inter tests.

d) Specific performance of the ScanGel Monoclonal RH/K Phenotypes Duo card
The performance of ScanGel Monoclonal RH/K Phenotypes Duo card has been evaluated on a panel of 1518 unselected samples (1149 donors, 332 patients and 37 new born samples) completed with a panel of selected samples (weak antigens).
Each result has been compared with the one obtained in slide, tube, microplate or gel filtration techniques.
The 1518 samples gave compliant results with the expected ones.
A panel of 13 week samples and rare phenotypes were tested. All samples were detected with a 2+ to 4+ reactivity.
The reagents of the ScanGel Monoclonal RH/K Phenotypes Duo 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.
• use of a red blood cell suspension medium other than that recommended.
• a red blood cell preparation different to that recommended.
• hemolysis of the tested red blood cell suspension.
• 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 ln 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 (Europap-direktiv 98/79/EF om medicintechniska 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 diagnostic in vitro
• Para uso em diagnóstico in vitro
• In vitro-diaagnostik
• 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
• Autorsrat 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

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