ODAK Blood Grouping Gel System

**OBG A Subgroup**

**REF No:** OBGAS-12, OBGAS-48

**INTENDED USE**

This test allows the detection of A1 in gel technique.

**INTRODUCTION**

The two main subgroups of A are A1 and A2. Red cells of both react strongly with anti A reagents. The serologic distinction between A1 and A2 is based on results obtained in tests with reagent anti-A1, the lectin of Dolichos biflorus seeds. Anti-A1 reagents agglutinate A1 but not A2 red cells.

**PRINCIPLE OF TEST**

OBG A Subgroups test allows the detection of A1 on a gel card. The microtubes contain gel matrix. Each microtube contains Anti-A lectin in the gel. The red blood cells will agglutinate in the presence of antibody directed towards the antigen. Agglutinated cells forming a red button on the surface of the gel or agglutinates dispersed in the gel is a positive result and indicates the presence of the corresponding antibody.

**KIT CONTENTS**

12 or 48 OBG A Subgroup gel cards. 1 gel card contains 8x1 microtubes

Ready to use. Contains Sodium azide as preservative. Each microtube of the card contains buffered gel medium with preservative and mixed different reagent.

- microtubes A1: Anti-A1 Lectin

**MATERIAL REQUIRED BUT NOT PROVIDED**

- 10 μL, 50 μL and 1 mL automatic pipettes.
- Disposable pipette tips.
- Test tubes.
- OBG Liss Diluent
- Centrifuge for Blood Grouping Gel System.

**STORAGE CONDITIONS AND STABILITY**

- Store the gel cards at 2-8 °C in upright position.
- Do not freeze.
- Avoid exposure of the cards to any heat source, direct air-conditioning sources or direct sunlight.
- Do not use reagents over the expiration date.
- All the components of the kit are stable until the expiration date on the label when stored 2-8 °C.
- Do not remove foil seal until ready to use. Once opened, the gel may begin to dry out which could affect test results.
- Use the card within 2 hours after removing the aluminum foil. Otherwise, don’t use the card.
- Stability of the opened gel card is 2 hours.

**PRECAUTIONS AND WARNINGS**

- This reagent kit is for in vitro diagnosis only.
- This reagent kit is for professional use only.
- All human sourced material (monoclonal antibodies) are tested free from HBsAg, Anti-HCV and Anti-HIV. However, all materials of human origin should be considered as potentially infectious and it is recommended that all kit materials and test specimens to be handled using established good laboratory practice.
- All kit components and specimens should be regarded as potential hazards to health. It should be used and discarded according to your own laboratory’s safety procedures.

**SAMPLE COLLECTION**

Fresh red blood cells are preferred for testing. Use the red blood cells collected with anticoagulants for determination of the antigens of the ABO/Rh system. If necessary, samples stored at 2-8 °C can be used up to 48 hours. Red blood cells collected in ACD, CPD, SAGM and PAGGSM can also be used until the expiry date indicated on the label of the bag at 2-8 °C. Plasma or serum can be used for reverse grouping. Plasma and serum must be cleared. Fibrin residues may interfere with the reaction pattern.

**PREPARATION OF BLOOD SAMPLE**

5 % red blood cell suspension:
Do not use haemolysed, cloudy or contaminated samples or those containing clots.

1- Bring OBG Liss Diluent to reach room temperature before use
2- Dispense 0.5 mL of OBG Liss Diluent into a clean tube.
3- Add 50 μL of whole blood or 25 μL of packed cells to the diluent and mix gently.

**TEST PROCEDURE**

Allow the test card and cell reagent to reach room temperature before use.

<table>
<thead>
<tr>
<th>A1</th>
<th>A1</th>
<th>A1</th>
<th>A1</th>
</tr>
</thead>
<tbody>
<tr>
<td>+/</td>
<td>-/</td>
<td>+/</td>
<td>-/</td>
</tr>
</tbody>
</table>

**Stability of the results:**

It is recommended an immediate reading of the results after centrifuging the cards. Do not leave processed cards in horizontal position. If necessary, a delayed reading can be made up until 24 hours after processing the cards if kept in vertical position, refrigerated (2-8°C) and sealed with parafilm or similar material to avoid evaporation of the supernatant.

**Interpretation of the results:**

**Reactions for A subgroups antigens**

<table>
<thead>
<tr>
<th>Antigen</th>
<th>A1</th>
<th>A1</th>
<th>A1</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>+4</td>
<td>+4</td>
<td>+2 to +4</td>
</tr>
<tr>
<td>A2</td>
<td>+3 or +4</td>
<td>+4</td>
<td>Neg. to +1</td>
</tr>
<tr>
<td>A1</td>
<td>+1 to +3</td>
<td>+2 to +4</td>
<td>Neg.</td>
</tr>
<tr>
<td>A2</td>
<td>Neg. to +1</td>
<td>+1 to +3</td>
<td>Neg.</td>
</tr>
<tr>
<td>A1B</td>
<td>+4</td>
<td>+4</td>
<td>+2 to +4</td>
</tr>
<tr>
<td>A2B</td>
<td>+3 to +4</td>
<td>+4</td>
<td>Neg. to +1</td>
</tr>
<tr>
<td>A1B</td>
<td>+2 to +4</td>
<td>+4</td>
<td>Neg.</td>
</tr>
<tr>
<td>A2B</td>
<td>Neg. to +1</td>
<td>+4</td>
<td>Neg.</td>
</tr>
</tbody>
</table>
LIMITATIONS
- The Aluminum foil on the matrix gel card should be removed carefully and gently.
- Do not use matrix gel cards, which show signs of drying.
- The gel cards which show air bubbles in the gel or drops in the upper part of the microtubes and/or the seal, must be centrifuged before use.
- Do not touch the pipet tip inside the gel card. Carryover problem may occur.
- Do not use hemolysed, cloudy or contaminated samples or with clot presence.
- Use of suspension solutions other than OBG Diluent1 may modify the reactions.
- Red blood cells from individuals with A or B variants may present a weak expression of the antigens.
- Abnormal concentrations of serum proteins, the presence of macromolecular solutions in the serum may cause the non-specific agglutination of the red blood cells. It is recommended to wash the red blood cells before performing the test.
- Transfused patients or those subjected to bone marrow transplant may present images of double Population.
- Patients with high-potency cold antibodies may coat the red blood cells completely so spontaneous agglutination may occur.

PERFORMANCE CHARACTERISTICS

Diagnostic sensitivity and specificity of A subgroups:
The diagnostic sensitivity and specificity of the antibodies present in OBG A Subgroup test for the determination of the antigens of the A1 have been studied in a representative number of positive and negative samples. In the study using 618 blood samples, the sensitivity and specificity of ODAK Blood Grouping Gel System was as follows.

<table>
<thead>
<tr>
<th></th>
<th>Number of samples</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-A1</td>
<td>353</td>
<td>% 100</td>
<td>% 100</td>
</tr>
</tbody>
</table>

Precision:
Inter-assay and intra-assay reproducibility tests; no false positive or false negative results were obtained. Variability between agglutination views in positive samples were 1 agglutination rating or less in all assays.

Label Symbols
- **LOT**: Batch code
- **Expiry date**
- **Storage temperature**
- **Consult instructions for use**
- **In vitro diagnostic medical device**
- **REF**: Product code
- **Manufacturer**
- **Harmful**

BIBLIOGRAPHY
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3-Harvey G. Klein MD, David J. Anstee ,Mollison’s Blood Transfusion in Clinical Medicine 11TH EDITION Blackwell Publishing Ltd
4-Michael F. Murphy , Derwood H. Pamphilon , Practical Transfusion Medicine Third Edition 2009 Blackwell Publishing Ltd
6- Christopher D. Hillyer ... BLOOD BANKING AND TRANSFUSION MEDICINE, Second Edition, Churchill Livingstone 2007

Products : OBG A Subgroup
1x12 REF OBGAS-12
4x12 REF OBGAS-48

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ODAK Blood Grouping Gel System
OBG A Subgroup
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