ODAK Blood Grouping Systems

**OBG Red blood cells for antibody screening and identification**

**INTENDED USE**
These test cells are used for antibody screening and identification.

**INTRODUCTION**
Patient and donor plasma is screened for atypical antibodies using cells are prepared in advance. They are group O cells that have been tested for the presence of the most commonly encountered antigens. The reliability of antibody detection is largely dependent on the availability of test cells with appropriate antigens and on the sensitivity of the test methods used.

**REAGENT**
All test cell reagents are of human origin, in a buffered suspension medium at 0, 8%. Contains Gentamycin as preservative.

<table>
<thead>
<tr>
<th>Test Kit Code</th>
<th>Test Cells/Specimens</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBGRBCAS2</td>
<td>OBG Cell Screen 1-2</td>
<td>(2 x 5 ml) R1-R2</td>
</tr>
<tr>
<td>OBGRBCAS2P</td>
<td>OBG Cell Screen 1-2 Pap</td>
<td>(2 x 5 ml) R1-R2 Papainized</td>
</tr>
<tr>
<td>OBGRBCAS3</td>
<td>OBG Cell Screen 1-2-3</td>
<td>(3 x 5 ml) R1-R2 (rr)</td>
</tr>
<tr>
<td>OBGRBCAS3P</td>
<td>OBG Cell Screen 1-2-3 Pap</td>
<td>(3 x 5 ml) R1-R2 Papainized</td>
</tr>
<tr>
<td>OBGRBCAS11</td>
<td>OBG Cell ID 11</td>
<td>(11 x 3 ml) Identification Panel 11 test cells</td>
</tr>
<tr>
<td>OBGRBCAS11P</td>
<td>OBG Cell ID 11 Pap</td>
<td>(11 x 3 ml) Identification Panel 11 test cells papainized</td>
</tr>
<tr>
<td>OBGRBCCC</td>
<td>OBG Cell Coombs control</td>
<td>(1 x 5 ml)</td>
</tr>
</tbody>
</table>

**MATERIAL REQUIRED BUT NOT PROVIDED**
- Dispenser
- 10 µl, 50 µl ml automatic pipettes.
- Disposable pipette tips.
- Test tubes.
- OBG LSIS Diluent
- Appropriate gel cards and reagents for antibody detection
- Centrifuge for Blood Grouping Gel System.

**STORAGE CONDITIONS AND STABILITY**
The reagent should be stored at 2°C - 8°C. The reagent is stable until the expiry date stated on the product label.

Once opened the shelf life of the reagent vial is as described on the reagent vial label if stored 2-8°C

Do not freeze or expose the reagent to elevated temperatures. After usage immediately replace the reagent vial back to 2-8°C. The antigenicity of the cells may decrease during the shelf life due to the physiological ageing process.

**PRECAUTIONS AND WARNINGS**
- This reagent kit is for in vitro diagnosis only.
- This reagent kit is for professional use only.
- All human sourced material 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.

**TEST PROCEDURE**
- All test cell reagents are for use with the ODAK Blood Grouping Gel System.
- Follow the test procedures as described in the specific package inserts to be used.
- Bring the test cells to reach room temperature (18-25 °C) before use.
- Mix gently the bottles of red cells by inverting a few times before use.
- During operation, check that the test cell reagents remain in suspension. If there is settling of the cells, resuspend again.
- Avoid contamination of the test cell reagents.
- After use, close the bottles and replace them in the refrigerator.
INTERPRETATION OF THE RESULTS

- Agglutination indicate the presence of the agglutinins.
- No agglutination indicate the absence of agglutinins.

LIMITATIONS
- 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.
- Bacterial or other contamination of materials used can cause false positive or false negative results.
- Hemolysed samples may interfere the final interpretation of results.

PERFORMANCE CHARACTERISTICS
Diagnostic sensitivity and specificity:
There is no described procedure or technique capable of detecting all the possible unexpected antibodies present in a sample. We conducted our own performance study. Coombs, saline and enzymatic technique have been studied in 40 samples and obtained comparable results with other established products of equivalent intended use.

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
5-Neil D. Avent and Marion E. Reid , The Rh blood group system;BLOOD 2000 95: 375-387
6- Christopher D. Hillyer ... BLOOD BANKING AND TRANSFUSION MEDICINE, Second Edition, Churchill Livingstone 2007

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

Products:
- OBG Cell Screen 1-2: Set of 2 vials 2 x 5 ml REF: OBGRBCAS2
- OBG Cell Screen 1-2 Pap: Set of 2 vials 2 x 5 ml REF: OBGRBCAS2P
- OBG Cell Screen 1-2-3: Set of 3 vials 3 x 5 ml REF: OBGRBCAS3
- OBG Cell Screen 1-2-3 Pap: Set of 3 vials 3 x 5 ml REF: OBGRBCAS3P
- OBG Cell ID 11: Set of 11 vials 11 x 3 ml REF: OBGRBCAS11
- OBG Cell ID 11 Pap: Set of 11 vials 11 x 3 ml REF: OBGRBCAS11P
- OBG Cell Coombs control: Set of 1 vial 1 x 5 ml REF: OBGRBCCC

Manufacturer:
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