**INTENDED USE**

The IH-Basic QC is intended for daily quality control of blood bank reagents including Blood Grouping Reagents for ABO/Rh, Rh Phenotyping, K, Reagent Red Blood Cells and reagents for antibody detection. The IH-Basic QC is “Rx only”

**SUMMARY**

Transfusion guidelines recommend regular checking of test materials, test methods, personnel working procedures and automated equipment/instruments used. The control samples should always have the same characteristics as a patient sample and therefore be treated identically. These activities are intended to ensure the accuracy and safety of the blood group serology results.

**PRINCIPLES OF THE TEST**

Refer to the instructions for use for the specific IH-Card being controlled.

**REAGENTS**

**IVD**

**OBSERVABLE INDICATIONS**

Do not use if markedly hemolyzed (dark red appearance of serum) or discolored.

**NOTE:** INSPECT THE CONDITION OF THE CARDS BEFORE USE (SEE PRECAUTIONS AND LIMITATIONS).

The 8 vials of 2 human blood from donors are in a 15.0±2.0% red blood cell suspension in a buffered medium. The liquid portion of the samples contains serum with antibodies of human origin directed against red blood cell antigens. The reagents contain bovine albumin.

Once opened, each sample tube may be used for two hours per day over a maximum period of 7 days on the IH-1000 Analyzer.

Each kit contains the following quality control samples:

- **IH-Basic QC Sample 1**  
  A, RhD negative, ccee, K positive, and containing Anti-B and Anti-D (0.05 IU/mL)
- **IH-Basic QC Sample 2**  
  B, RhD positive, CcEe, K negative, and containing Anti-A and Anti-Fy^a^

Preservatives: 0.01 mM Trimethoprim (2.5 mg/L) and 0.19 mM Sulfamethoxazol (47.5 mg/L).

The bovine albumin used for the production of this reagent is purchased from BSE-free sources.

These reagents are supplied in liquid form and ready for use.

**STORAGE REQUIREMENTS**

- Store at 2 to 8°C.
- Do not use beyond expiration date which is expressed as YYYY-MM-DD (Year-Month-Day).
- Store in an upright position.
- Do not freeze or expose cards to excessive heat.
- Do not store near any heat, air-conditioning sources or ventilation outlets.

**PRECAUTIONS**

- All reagents and test samples must be brought to room temperature (18 to 25 °C) prior to use.
- Use reagents as furnished.
- Once the reagent has been used for testing, it may contain infectious material and should therefore be handled and disposed of as biohazardous waste in accordance with local, state, and national regulations.
- Caution: The packaging of this product contains natural rubber latex which may cause allergic reactions.
- Caution: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED WITH FDA LICENSED ELISA TESTS. NAT TESTING WAS NOT PERFORMED. NO KNOWN TEST METHOD CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
- The reactivity of the IH-Basic QC samples containing red blood cells may decrease during the dating period.

**SPECIMEN COLLECTION AND PREPARATION**

Preparation of Quality Control Samples:
Allow the test material to reach room temperature before use. The tubes of red blood cells should be centrifuged as with regular test samples.

Please refer to the instructions for use for the IH-Card used for testing and the appropriate instrument operator's manual for card and instrument specific sample handling requirements.

TEST PROCEDURE FOR AUTOMATED SYSTEMS

Material provided
- IH-Basic QC

Materials required but not provided
Please refer to the instructions for use for the specific IH-Card.
- IH-1000

Method
Use the quality control samples the same way as test samples in routine work. Please refer to the IH-1000 User Manual NA for testing and reagent handling instructions.

INTERPRETATION OF RESULTS

Please refer to the instructions for use for the IH-Card that was used for testing.

LIMITATIONS

Erroneous and abnormal results may be caused by:
- Bacterial or chemical contamination of the serum, plasma, red blood cells or equipment.
- A red blood cell concentration or suspension medium different from that recommended.
- Incomplete resuspension of the red blood cells.
- Sample or Reagent Red Blood Cell hemolysis. Potential occurrence of hemolysis can be observed and could influence the result for certain tests.
- Contamination between microtubes through pipetting errors.
- Use of cards showing signs of drying.
- Use of cards with bubbles.
- Use of cards with damaged foil strips.
- Fibrin, clots, particulates or other artifacts may cause some red blood cells to be trapped at the top of the gel that may cause an anomalous result.
- The reactivity of the product may decrease during the dating period and therefore it should not be used after the expiration date. The rate of decrease in reactivity is partially dependent on individual donor characteristics that are neither controlled nor predicted by the manufacturer.
- Due to the variation in the number of D antigen sites from donor to donor, variations in reaction strength may be observed with D positive quality control samples.

SPECIFIC PERFORMANCE CHARACTERISTICS

The final release testing is performed according to product specific Standard Operating Procedures. As part of the lot release process, each lot of Bio-Rad IH QC products is tested against appropriate reagents (antibodies) to ensure suitable reactivity and specificity. The performance of the Bio-Rad IH products was confirmed in a multi-center clinical trial.

For technical support or further product information, contact Bio-Rad Laboratories, Inc at 800-224-6723.

GLOSSARY OF SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch code</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>⚠️</td>
<td>Caution, consult accompanying documents</td>
<td>📄</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>🛡️</td>
<td>Manufacturer</td>
<td>⚗️</td>
<td>use by (YYYY-MM-DD)</td>
</tr>
<tr>
<td>🛠️</td>
<td>Contains sufficient quantity for &lt;n&gt; test.</td>
<td>REF</td>
<td>Catalog number</td>
</tr>
<tr>
<td>🚨</td>
<td>Temperature limitation</td>
<td>VOL</td>
<td>Volume</td>
</tr>
</tbody>
</table>

BIBLIOGRAPHY


