BLOOD GROUPING REAGENTS

- Anti-A (Monoclonal)
- Anti-B (Monoclonal)
- Anti-A, B (Monoclonal)
- Anti-AB (Monoclonal)
- Anti-D (Monoclonal)
- Anti-D (Polyvalent)
- Anti-E (Polyvalent)
- Anti-K (Polyvalent)

BECKMAN COUNTER CONTROLS

Manufactured by:
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BREA, CA 92622 USA

U.S. License No: 1764

INTENDED USE

The BECKMAN COUNTER PK SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS are intended for the determination of blood ABO group and Rh type and the phenotypes in blood donors using the BECKMAN COUNTER PK200 and the BECKMAN COUNTER PK700i Automated Microplate System.

The Anti-A, Anti-B, and Anti-AB reagents are used in the red blood cell determinations of the ABO blood group.

The Anti-D reagent is used to detect the presence of the D antigen.

The Anti-E reagent is used to detect the presence of the E antigen.

The Anti-K reagent is used to detect the presence of the K antigen.

SUMMARY OF TEST

The determination of an ABO blood group is done by mixing the plasma of the unknown sample with the ABO reagents. A positive test indicates the presence of the A antigen and a negative test indicates the absence of the A antigen.

The determination of the Rh type is done by mixing the red blood cells with the anti-D reagent and the anti-K reagent. A positive test indicates the presence of the D antigen and a negative test indicates the absence of the D antigen.

The determination of the K antigen is done by mixing the red blood cells with the anti-K reagent and the anti-E reagent. A positive test indicates the presence of the K antigen and a negative test indicates the absence of the K antigen.

PRINCIPLE OF PROCEDURE

The test is based on the principles of agglutination and pattern recognition. When red blood cells bearing antigens are preincubated with BECKMAN COUNTER PK SYSTEM PHENOTYPING REAGENTS, agglutination will occur with the reagent carrying the corresponding antibody. Agglutination with a particular antibody indicates the presence of the specific antigen.

The PK200 and PK700i analyzers will read the settling patterns of the red blood cells in each well of the microplate and make a determination based on the threshold setting chosen for each reagent. For complete details on the setup and operation of the BECKMAN COUNTER PK200 please refer to the Operator's Manual, and for the PK700i refer to the User's Guide.

PRINCIPLES OF REAGENTS

- Anti-A, Anti-B, Anti-AB
- Anti-D (Monoclonal)
- Anti-E (Polyvalent)
- Anti-K (Polyvalent)

The anti-A reagent is used to detect the presence of the A antigen. The anti-B reagent is used to detect the presence of the B antigen. The anti-AB reagent is used to detect the presence of both the A and B antigens. The anti-D reagent is used to detect the presence of the D antigen. The anti-E reagent is used to detect the presence of the E antigen. The anti-K reagent is used to detect the presence of the K antigen.

Table 1: Fishnet-Base

<table>
<thead>
<tr>
<th>Fishnet-Base</th>
<th>Winer</th>
<th>Classical %</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>Rh-</td>
<td>05</td>
</tr>
<tr>
<td>C</td>
<td>Rh+</td>
<td>70</td>
</tr>
<tr>
<td>E</td>
<td>Rh+</td>
<td>30</td>
</tr>
<tr>
<td>c</td>
<td>Rh+</td>
<td>60</td>
</tr>
<tr>
<td>e</td>
<td>Rh+</td>
<td>08</td>
</tr>
</tbody>
</table>

Table 2: Anti-E

<table>
<thead>
<tr>
<th>Anti-E</th>
<th>Probable Genotypes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anti-D</th>
<th>Anti-E</th>
<th>Anti-K</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This is the most frequently encountered antibody in the Kell system in anti-K. The Kell antibody is strongly immunogenic and anti-K is frequently found in the sera of transfusion patients. A positive test indicates the presence of the K antigen, while a negative test indicates the absence of the K antigen.

The anti-D reagent is used to detect the presence of the D antigen. The anti-E reagent is used to detect the presence of the E antigen. The anti-K reagent is used to detect the presence of the K antigen.

Table 3: Anti-A, Anti-B, Anti-AB

<table>
<thead>
<tr>
<th>Anti-A, Anti-B, Anti-AB</th>
<th>Anti-AB</th>
<th>Anti-AB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*These reagents are supplied in 50 ml glass and 20ml plastic vials. Be sure to use reagents from the PK200 or PK700i MICROPLATE GROUPING REAGENTS, PHENOTYPING REAGENTS and/or BECKMAN COUNTER CONTROLS should be used within 20 days of disinfection.

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### VI. REAGENT PREPARATION
1. The reagents are supplied for use as supplied. No prior preparation or dilution of the reagents is required or permitted.
2. All reagents should be brought to room temperature (+18°C to +30°C) before use or for analysis.
3. Effort should be made to minimize contamination during use of the product.
4. The date on which each reagent container is opened should be recorded on the container.
5. Do not transfer reagents back into the original container or between containers once dispensed or placed into use.

### VII. STORAGE
1. Store reagents at 2 to 8°C when not in use. Do not freeze.
2. Do not use beyond the expiration date.

### VIII. SPECIMEN COLLECTION AND PREPARATION
1. A special preparation of the device is required prior to specimen collection. Blood samples must be collected in 6.0 mL anticoagulant in either glass or plastic tubes. Clarified samples should not be used when red blood cells are being counted.
2. Synchrony from donors with previous interventions may give erroneous results for the PK200 and/or PK200 Automated Centrifuge. Clarified samples containing platelets may also give erroneous results in ASSO cell testing.
3. If testing must be performed for longer than 24 hours after collection, the specimen should be stored at 2 to 8°C. Samples must be returned to room temperature (18°C to 30°C) prior to analysis. Testing should not be carried out within the 60 days of storage for the PK200 and PK200 Automated Centrifuge.
4. Residual cell material of the specimen may cause erroneous test results.

### IX. INSTRUCTIONS FOR USE

#### A. PRECAUTIONS
- **REMEMBER: PK SYSTEM TESTS ARE Semiquantitative.**
- **REMEMBER**:
- **NEVER**:
- **ALWAYS**:

#### B. REAGENT PREPARATION
- **REMEMBER**:
- **NEVER**:
- **ALWAYS**:

#### C. CALIBRATION AND DILUTION
- **REMEMBER**:
- **NEVER**:
- **ALWAYS**:

#### D. TESTING PROCEDURE
- **REMEMBER**:
- **NEVER**:
- **ALWAYS**:

#### E. RESULTS INTERPRETATION
- **REMEMBER**:
- **NEVER**:
- **ALWAYS**:

### TYPICAL RESULTS

#### A. PK200 RECOMMENDED PARAMETERS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Volume</td>
<td>20 µL</td>
</tr>
<tr>
<td>Diluted Volume</td>
<td>1000 µL</td>
</tr>
<tr>
<td>Diluted Sample</td>
<td>20/1000</td>
</tr>
<tr>
<td>Residual Volume</td>
<td>25 µL</td>
</tr>
<tr>
<td>Residual Volume</td>
<td>25 µL</td>
</tr>
<tr>
<td>Chilled Name</td>
<td>Variable</td>
</tr>
<tr>
<td>Diluent (µL)</td>
<td>25 µL</td>
</tr>
<tr>
<td>Temperature Setting</td>
<td>20°C</td>
</tr>
<tr>
<td>Residual Volume</td>
<td>50 µL</td>
</tr>
<tr>
<td>Residual Volume</td>
<td>10 µL</td>
</tr>
</tbody>
</table>

The PK200 and PK200 Automated Centrifuge are programmed analyzers, the operation of which is controlled by user defined control units. A list of recommended preparation and batch setting for PK200 and PK200 Automated Centrifuge is shown below. Each laboratory must ensure that each laboratory validates the operating protocols. For further information, please consult Section A11 of the PK200 Operator's Manual. Section 11 of the PK200 User's Guide.
XIV. EXPECTED VALUES

<table>
<thead>
<tr>
<th>Rh D</th>
<th>Blood Group</th>
<th>Frequency %</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A-negative</td>
<td>65</td>
</tr>
<tr>
<td>B</td>
<td>B-negative</td>
<td>65</td>
</tr>
<tr>
<td>AB</td>
<td>AB-negative</td>
<td>15</td>
</tr>
</tbody>
</table>

XIV. SPECIFIC PERFORMANCE CHARACTERISTICS

- **Rh Inhibitor Blood Grouping Reagents**
  - A-, B-, and D-negative
  - A-positive
  - B-positive
  - AB-positive

- **Blood Grouping Reagents**
  - A-positive
  - B-positive
  - AB-positive

- **Rh and D-positive**
  - A-positive
  - B-positive
  - AB-positive

- **Rh and D-negative**
  - A-negative
  - B-negative
  - AB-negative

**BIBLIOGRAPHY**

1. Standards for Blood Banks and Transfusion Services, 24th ed., 2006; American Association of Blood Banks: E.0.12; and, 21 CFR 800.121(c)(17)

Glossary of Symbols: [Details of symbols provided in the document]