Validating Normal Saline as the Diluent in the Grifols System for Instructional Use

Katherine Guise
Faculty Mentor: Dr. Kyle Riding MLS(ASCP)

Abstract
The purpose of this project was to evaluate the suitability of normal saline (0.9% NaCl) as the diluent in the Grifols gel-based ABO/D typing system for instructional blood typing exercises in a university-based MLS program’s immunohematology course. Grifols recommends that users of the gel-based ABO/D typing system prepare red blood cells suspensions using a proprietary diluent from the manufacturer. However, such a proprietary diluent adds additional cost to a university-based program – thus the desire to determine if normal saline can be validated for instructional use. To validate normal saline, a total of 40 patient blood samples collected in EDTA tubes were donated from a local affiliate. 13 O, 13 A, 10 B, and 4 AB ABO types with a mix of D-positive and D-negative samples were used for this small validation. ABO forward and D typing was rechecked via a standard tube-based hemagglutination procedure that used normal saline. The results of the tube hemagglutination were considered the reference method results. The Grifols gel-based A/B/D system was then used with red blood cell suspensions made using normal saline – not the proprietary diluent – and those results were compared to the results of the tube hemagglutination procedure. This results validated that normal saline served as an appropriate replacement for Grifols’ proprietary diluent for instructional use only.

Methods
• EDTA blood bank samples (n=40) were from a local partner hospital were used for this validation of normal saline
• A 5% suspension of RBC’s were made for each sample.
• All sample suspensions were forward typed and had Rh(D) testing completed using tube method as the reference.
• All samples were re-typed using Grifols’ A/B/D gel typing cards
• Results were collected and compared to assure normal saline produced expected results

Data

<table>
<thead>
<tr>
<th>ABO Type</th>
<th>Number of Samples</th>
<th>% Agreement to Reference Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>13</td>
<td>100%</td>
</tr>
<tr>
<td>Type B</td>
<td>10</td>
<td>100%</td>
</tr>
<tr>
<td>Type AB</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>Type O</td>
<td>13</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rh(D) Type</th>
<th>Number of Samples</th>
<th>% Agreement to Reference Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rh(D) Pos.</td>
<td>38</td>
<td>100%</td>
</tr>
<tr>
<td>Rh(D) Neg.</td>
<td>2</td>
<td>100%</td>
</tr>
</tbody>
</table>

Discussion
• ABO & Rh(D) typing resulted with 100% agreement between methods.
• This validation confirmed using normal saline in place of Grifols’ proprietary diluent yielded the same ABO results as tube typing in our instructional laboratory.
• This project only looked at using normal saline for teaching purposes and does not imply equivalency for a clinical setting.
• Further data will be collected to make up for gaps in the planned for number of Type AB and Rh(D) negative samples.

Acknowledgments
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For inquiries, please contact: katherineguise@knights.ucf.edu

Background
• Grifols, an immunohematology product company, released blood-typing cards in 1996 based on a then novel gel technology.
• Grifols recommends a proprietary diluent for manual A/B/D testing.
• The use of normal saline readily available in the MLS teaching lab was preferable for educational use.
• This validation project was conducted to assure that normal saline already in use was appropriate for educational activities using the Grifols Gel Platform.