Quantitative residual WBC counter

ADAM-rWBC
Product name: ADAM-rWBC

Description: Residual Leukocyte Counter

Features:
- Attractive alternatives to either Nageotte or flow cytometry
- Portable image cytometry with disposable slide
- Accurate and reliable results (Scans sample for 203 images / Optimized image analysis)
- Auto-stage control and auto-focusing / High speed measurements
- Real-time live image viewing
- User-friendly interface
How to use

1. Preparation
   - Barcode Reading

2. Sample Loading
   - Sample Preparation
   - Sample Loading in r-Slide

3. ADAM Operation
   - ADAM Operation
   - Result

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# Comparison with existing residual counting technologies

<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nageotte</td>
<td>Simple &amp; inexpensive technology</td>
<td>Very labor intensive</td>
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<tr>
<td></td>
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<td>Variable results depending upon staff skill</td>
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<td></td>
<td></td>
<td>High coefficient of variation at low WBC concentration</td>
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<tr>
<td>Flow Cytometry</td>
<td>Rapid, once set up, allows higher throughput of specimens</td>
<td>Very expensive</td>
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<tr>
<td></td>
<td></td>
<td>Highly trained staff required</td>
</tr>
<tr>
<td>ADAM, rWBC</td>
<td>Rapid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consistent between users</td>
<td></td>
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<tr>
<td></td>
<td>High degree of correlation with reference methods</td>
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</table>
Current LR Standards

- Must be prepared by a method known to reduce the leukocyte number to \(< 5 \times 10^6\)
- Validation and quality control shall demonstrate that at least 95% of units sampled meet this criterion

Source: AABB standard 5.7.4.1 and FDA memorandum May 29, 1996; Recommendations and Licensing requirements for leukocyte-reduced blood products
Quantitatively quantitating residual WBC in leuko-reduced products

Validating a new device that uses fluorescence of pro-pidium iodide to identify nucleated cells

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Validation study

- Performed at Memorial Blood Centers and Mayo Transfusion Service
- Compared to Nageotte and BD LeucoCount
- Testing included:
  - Reproducibility/Precision
  - Linearity testing
  - Stability
  - IRB-Approved Clinical Study
# Reproducibility/Precision

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>WBC range/μl</th>
<th>Mean</th>
<th>SD</th>
<th>% CV</th>
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</thead>
<tbody>
<tr>
<td><strong>RBC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>~0-1</td>
<td>0.12</td>
<td>0.09</td>
<td>69.33</td>
<td></td>
</tr>
<tr>
<td>1~5</td>
<td>3.48</td>
<td>0.49</td>
<td>14.19</td>
<td></td>
</tr>
<tr>
<td>5~10</td>
<td>6.28</td>
<td>0.50</td>
<td>7.99</td>
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<tr>
<td>10~15</td>
<td>13.37</td>
<td>0.74</td>
<td>5.53</td>
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<tr>
<td>15~20</td>
<td>15.66</td>
<td>0.84</td>
<td>5.39</td>
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</tr>
<tr>
<td>20~300</td>
<td>168.20</td>
<td>3.93</td>
<td>2.34</td>
<td></td>
</tr>
<tr>
<td><strong>Platelet</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>~0-1</td>
<td>0.16</td>
<td>0.10</td>
<td>62.70</td>
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</tr>
<tr>
<td>1~5</td>
<td>3.51</td>
<td>0.41</td>
<td>11.64</td>
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<tr>
<td>5~10</td>
<td>7.41</td>
<td>0.55</td>
<td>7.47</td>
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<tr>
<td>10~15</td>
<td>11.30</td>
<td>0.71</td>
<td>6.24</td>
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<tr>
<td>15~20</td>
<td>17.75</td>
<td>0.84</td>
<td>4.76</td>
<td></td>
</tr>
<tr>
<td>20~300</td>
<td>104.10</td>
<td>2.22</td>
<td>2.13</td>
<td></td>
</tr>
</tbody>
</table>
Linearity

**RBC sample**

- Equation: \( y = a + b \cdot x \)
- Weight: No Weight
- Residual Sum of Squares: 578.43938
- Adj. R-Square: 0.9921
- Manual Intercepts: -0.9301, 1.64275
- Manual Slopes: 1.0913, 0.02362

**Platelet sample**

- Equation: \( y = a + b \cdot x \)
- Weight: No Weight
- Residual Sum of Squares: 51.25345
- Adj. R-Square: 0.9927
- FACS Intercepts: -0.059, 0.48899
- FACS Slopes: 1.0749, 0.00703

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**Manual sample**

- Equation: \( y = a + b \cdot x \)
- Weight: No Weight
- Residual Sum of Squares: 40.9047
- Adj. R-Square: 0.99546
- Manual Intercepts: -0.710, 1.12969
- Manual Slopes: 1.0701, 0.01752

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**ADAM**

- Equation: \( y = a + b \cdot x \)
- Weight: No Weight
- Residual Sum of Squares: 272.99566
- Adj. R-Square: 0.99921
- Manual Intercepts: -0.710, 1.12969
- Manual Slopes: 1.0701, 0.01752

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**FACS**

- Equation: \( y = a + b \cdot x \)
- Weight: No Weight
- Residual Sum of Squares: 40.9047
- Adj. R-Square: 0.99921
- FACS Intercepts: 0.6203, 0.43729
- FACS Slopes: 0.9890, 0.00678
RBC samples (n=20) and platelet samples (n=20) were tested within 1 minute of leukoreduction.

Retested (10 times each) after a one hour hold.

No statistically significant differences found.
Prestorage leukoreduced red cells (n=64) and apheresis platelets (n=86) were measured on all three platforms.

RBC Samples: Both the ADAM and FACS were significantly different (p=0.00 for both) when compared to the manual procedure.

Platelet Samples: No statistical differences between the ADAM, Manual or FACS (removing outlier)
Summary

- Adam is an attractive alternative to either Nageotte or Flow Cytometry.
- Approved by the Korea Food & Drug Administration on December 2, 2009.
- Data have been submitted to FDA for device approval and are currently in evaluation.