IMPLEMENTATION OF A FULLY AUTOMATED ANALYZER USING GEL TECHNOLOGY AT A BLOOD BANK IN A REGIONAL TRAUMA CENTER

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INTRODUCTION/ABSTRACT

High throughput and high efficiency automation of serologic tests is crucial in the workflow of a blood bank contracted by a 650-bed level I trauma hospital that tests one hundred (100) type and screen samples per day on average. The Erytra® (Grifols) is a fully-automated walkaway analyzer utilizing 8-column DG Gel® cards for ABO/D typing, antibody screening, antibody identification, antigen typing (C,E,e,K), direct antiglobulin test, and crossmatching. The blood bank validated and implemented the use of Erytra® only for ABO/D typing, antibody screening, and identification of adult patient samples: same tests that were automated using the incumbent solid-phase testing platform by the ECHO® (Immucor). Additionally, this blood bank validated the use of Erytra® for automated RBC donor unit ABO/D retypes. The Erytra® has bidirectional interface to the blood bank information system, HCLL™ (Hemocare Life Line, Mediware). The Erytra® instrument validation and implementation were done in conjunction with the software version upgrade of HCLL™ from version 2013 to 2015 SP1, and an interface system change to Maestro® (Mediware).

OBJECTIVES

• To replace the incumbent analyzer with an instrument that has improved efficiencies and performance.
• To select and implement an analyzer utilizing a technology that has the “truest” STAT function, random access.
• To maintain a bidirectional interface system between the blood bank automated analyzer and the upgraded version of the blood bank computer system.
• To automate other blood bank tests – donor retyping was validated to become an automated test.
• To implement an analyzer with the highest throughput for the Blood Bank at Westchester Medical Center—a level I trauma center—performs 100 to 150 type and screen samples daily.

MATERIALS AND METHODS

Correlation testing of the Erytra® with the manual tube testing as the reference method was performed. Tube method was used as a reference method because it is one of the standard methods of testing currently in use and will remain in use in conjunction with automation. Testing was performed on a total of one hundred (100) adult patient EDTA samples for ABO/D typing and antibody screening; of which at least ten (10) had positive antibody screening results; and out of the ten (10) samples with positive antibody screening, five (5) had known antibody specificities. The tube antiglobulin method for antibody screening and identification used Gamma PeG™ (Immucor) as the potentiator. Forty-two (42) RBC units were also tested for ABO/D confirmation; of which seventeen (17) were D(−) and twenty-five (25) were D(+) . Calculations of concordance, sensitivity, and specificity were performed to validate the performance of the Erytra® against the reference method. Precision studies were also performed. Interface of Erytra® results with HCLL was validated parallel with the upgrade of HCLL from version 2013 to 2015 SP1 and changing the interface system to Maestro.

RESULTS

Concordant results between the Erytra® and the reference method (tube method) were obtained in all of the one hundred (100) patient samples and forty-two (42) donor samples tested; translating to one hundred percent (100%) correlation. Erytra® yield positive antibody screens to the ten (10) samples with positive antibody screening by PeG™ antiglobulin testing. Erytra® detected all clinically significant antibodies identified by PeG™ antiglobulin testing; anti-D, anti-c, anti-E, and anti-K.

ERYTRA VALIDATION WITH REFERENCE METHOD:

<table>
<thead>
<tr>
<th>Correlation Points</th>
<th>Description</th>
<th>Acceptance Criteria</th>
<th>Results Obtained</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>SENSITIVITY</td>
<td>TP</td>
<td>≤100</td>
<td>% of samples that test positive when in condition in which you are testing actually exists</td>
<td>&gt;95%</td>
</tr>
<tr>
<td>SPECIFICITY</td>
<td>TN</td>
<td>≥1200</td>
<td>% of samples that test negative when in condition you are testing for is not present</td>
<td>&gt;95%</td>
</tr>
<tr>
<td>CONCORDANCE STUDIES</td>
<td># of samples with correct result compared to reference method</td>
<td>&gt;1000</td>
<td>Testing samples multiple times and obtaining the same results for all events</td>
<td>&gt;95%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• The Erytra® was validated showing 100% correlation with the results of the tube testing of patient specimens and donor units.
• All antibody specificities identified by PeG IAT were also detected by Erytra®.
• The transition of the automated test platform from ECHO® (solid phase) to Erytra® (gel) was smooth. This blood bank found the Erytra® to be user-friendly making training of the staff on the analyzer easy and straightforward.
• The random access functionality of the Erytra® for STAT samples is an important feature; although, it is evident that the function is under-utilized. The staff at our blood bank still relies on tube method for their STAT T&S and ABO/D.
• Establishing bidirectional interface of Erytra-HCLL for donor retypes has not been done before and was a lengthy laborious aspect of this implementation; but a successful one.
• The Erytra® is better capable of handling the volume of T&S samples performed at Westchester Medical Center (Valhalla) than the previous analyzer.
• Validation of the new Erytra® concurrent with an LIS upgrade was challenging but found to be the most practical approach.

CREDITS

• Photo of the Erytra® analyzer courtesy of Diagnostic Grifols, S.A.
• Photographed with the Erytra® in Westchester Medical Center, Valhalla, NY.

ACKNOWLEDGEMENTS

Dr. Beth Shaz, M.D.–NYBC SVP and CMO–support of this implementation project NYBC IT and QA Departments–support during interface, validation, implementation.

PATIENT SAMPLE SOURCE

| WESTCHESTER MEDICAL CENTER |
| VALHALLA, NY |

TYPE OF PATIENT (ADULT) SAMPLES | EDTA, 47 DAYS CLD |
REFERENCE METHOD TO ERYTRA TESTING | MANUAL TUBE METHOD |
IMMUCOR PeG™ IAT for ABS OR ABD |
LIS (Lab/Interface Systems) | HCLL/MAESTRO (Mediware) |

<table>
<thead>
<tr>
<th>TYPE OF TEST</th>
<th># OF SAMPLES TESTED</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT ABO/D</td>
<td>100</td>
<td></td>
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<tr>
<td>ANTIBODY SCREENING</td>
<td>100</td>
<td>10 samples had (+) screens</td>
</tr>
<tr>
<td>DONOR RETYPE (D+)</td>
<td>25</td>
<td>AntiD (&lt; 4 KU/L)</td>
</tr>
<tr>
<td>DONOR RETYPE (D-)</td>
<td>17</td>
<td></td>
</tr>
</tbody>
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