Biopath Experience with the IH-1000 System: Integration Solutions and Performance Characteristics in a Large Laboratory Testing Center

Cyril Faucher, Anne Beauchamp-Nicoud, Guillaume Jeanne, Michèle Berdah, Fabrice Hayoun, Julie Jonte

Biopath • 6 avenue des Frères Lumière • 94360 Bry-sur-Marne, France

Background

In 2010, French Health policy introduced measures to rationalize laboratory provisions with a view to reducing the budgetary requirements. One of the measures proposed was to allow the regroupment of multi-site laboratories. With these changes in mind, Biopath established a sophisticated laboratory network and logistics infrastructure, handling more than 6,000 samples per day; its Immuno Hematology section carries out 60,000 ABO-RH1 + RH/KEL1 phenotypes and 50,000 antibody screening tests per year using two IH-1000 systems (Bio-Rad). Samples come from 34 sites including general hospitals, maternity hospitals, private laboratories and managed care organizations; Biopath operates 24/7 with an average of 300 samples/day for Blood Group serology including 15 % of emergency samples and 1 % of Newborn.

Objective

The objective is to demonstrate how the IH-1000 system, fully automated blood group serology instrument that uses gel card technology ID-System, could allow increased efficiency in the established procedures and improve the workflow of the laboratory routine in the environment of a demanding French Legislation with respect to immunohematology testing.

Process

Immunohematology testing in this facility was set up in 2011 to consolidate 3 laboratories which had previously been using 5 automates from other suppliers.

• The process includes the following steps: 34 client sites perform sample drawing, data is registered in a common LIS which was designed to replace the 3 previous host software.

• Tubes are collected and taken to Biopath where samples are continuously loaded into the two IH-1000 automates where blood group serology testing is performed (Graph 1).

• Each result is transferred to LIS after technical validation and finally each external site receives complete result data by means of electronic files.

Thanks to this process, biologists can carry out the biological validation with complete traceability, ie lot number, test pictures, before issuing final patient results.

Graph 1: Hospitals and Private Labs Tested Samples on IH-1000/Day

Validation Step

Risk assessment was conducted and validation criteria established to ensure the process would meet specifications. The two systems have to:

• ensure availability of ABO RH1, RH/KEL1 typing antibody screening and DAT results within 1 hour for emergency samples, 2 hours for others.

• integrate 2 activity peaks per day as well as continuous loading 24/7.

• answer to different requirements: pediatric samples.

• require minimum operator availability.

• comply with technical and biological regulations.

• provide a bidirectional communication interface to the LIS.

Phased validation was performed testing 628 patient files. Among them 173 samples were tested for ABO/RH KEL1 and antibody screening. This validation accounted for 30 % of the day to day activity. Overall performance was demonstrated before implementation of daily routine: patient/sample data flow, testing requests/results, loading capacity, continuous workflow, throughput, time to result, regulation compliance were assessed. Initially the daily routine was performed on 200 samples (21 client sites) but has now progressed to 400 (34 client sites).

Graph 2: Average time between arrival on the site and integration of results

Results

Tests Done July 2011-April 2012

June 2011-April 2012: Total Samples Tested

<table>
<thead>
<tr>
<th>Site</th>
<th>AB Screening</th>
<th>ABO Grouping</th>
<th>Phenotyping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals (including)</td>
<td>23,294</td>
<td>5,945</td>
<td>373</td>
</tr>
<tr>
<td>Emergencies</td>
<td>22,500</td>
<td>-</td>
<td>494</td>
</tr>
<tr>
<td>New born</td>
<td>15,384</td>
<td>13,052</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>38,848</td>
<td>35,554</td>
<td>484</td>
</tr>
</tbody>
</table>

Thanks to continuous sample loading we have the flexibility to load emergency and routine samples at any time. Testing can be achieved 24/7 with only one person per shift handling the 2 automates.

IH-1000 System allows highest priority, quick testing of emergency samples within 1 hour while being constantly available for other samples (Graph 2). Its data management system guarantees long-term storage of patient data and results for comparison of previous results and checking for discrepancies.

Conclusion

IH-1000 accomplished all the demands of a high workload laboratory for routine work particularly in terms of high capacity, throughput and turn around times. It ensures quality, traceability and safety thanks to the ID-System; improving efficiency and workflow, thus measuring cost reductions. It will allow Biopath to prepare the next step in order to get its accreditation (ISO 15189 compliance).