The value of routine process controls in improving safety in immunohaematology testing – three years experience

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BACKGROUND

Immunohaematology laboratories perform tests that pose the most danger to patients when errors are made. Other pathology disciplines had readily available, stable commercial control products for decades but they have only recently been made available to immunohaematology laboratories. Home-made Quality Control (QC) materials are not satisfactory and are not compliant with modern quality systems, guidelines and directives. Published data demonstrates that the common dangerous system failures are due to human mistakes such as transposition and transcription errors. In recent years, externally validated commercial QC materials have become available that may be used for routine QC of testing processes and perhaps more importantly, regular competency assessment of staff.

METHODS

Securacell™ Quality Control system products have been commercially available in Australia for more than three years. These controls are formatted as whole blood samples and used for routine competency assessment of staff and to control the entire process of critical manual and automated immunohaematology tests. Securacell™ may be used for the following purposes:
1. ABO RhD blood grouping control
2. Antibody screening and identification control
3. Antibody titre standard
4. ABO analytical sensitivity control
5. Routine process control for manual and automated systems
6. Replicate testing control
7. Competency assessment control

We present a number of reported cases that demonstrate the utility of an external Quality Control system.

CASE REPORTS

Case 1 – Staff competency testing [1]
A large metropolitan hospital using a Column Agglutination Technology (CAT) based testing system implemented Securacell™ for routine staff competency assessment. Results from the first antibody screening assessment demonstrated one staff member reporting cell reaction scores on average of 2 points weaker than other staff. Detailed examination of that staff member’s sample loading technique revealed a consistent failure to maintain an air gap above the AHG liquid in the CAT column. This causes partial neutralisation of AHG in the column, loss of test sensitivity and presumably a long term inability to detect weak antibodies in antibody screening and crossmatching. Training and correction of the dispensing technique showed an improvement in scores to be consistent with other staff.

Result: Competency assessment to measure inter-staff variation demonstrated a significant technical error in a particular staff member that may have had serious ramifications for patient safety. This was easily rectified once detected.

Case 2 – Instrumentation cleaning and service
A large general hospital laboratory utilises an automated CAT system. The instrument daily cleaning and decontamination included system fluidics flushing with a hypochlorite bleach solution. Control result analysis showed failure to detect a control anti-S antibody. Investigation showed that the instrument was not thoroughly washed/rinsed, leaving residual bleach in the sample and reagent handling fluidics. Hypochlorite bleach has been shown to reduce or destroy S antigens on red cells.

Result: Securacell™ demonstrated inadequate flushing of the system and potential loss of sensitivity of antibody screening and crossmatching.

Case 3 – Ab Screening failure
A laboratory reported an inability to detect a control anti-D antibody in a tube LISS additive method. The laboratory had previously modified their tube based method to delete the spin and read step after the 37°C incubation in an attempt to reduce the incidence of detecting clinically irrelevant IgM antibodies on the assumption that clinically relevant IgM antibodies would still be detected in the Indirect Antiglobulin Test (IAT) phase of the test. The anti-D in the control product was an IgM class antibody and the failure to detect this clinically relevant, but IgM antibody caused the laboratory to rethink their testing process and reintroduce the full tube 37°C and IAT testing procedure.

Result: A planned but poorly characterised modification to routine laboratory testing procedures caused poor test performance and a significant test deficiency. Routine use of a test process control demonstrated this deficiency, the procedure was improved and the test failure corrected.

Case 4 – Laboratory conditions affecting grouping
A laboratory in a tropical region reported repeatable out of specification results for Anti-B in a column based testing system when testing the ABO sensitivity testing cell. Tube grouping showed acceptable reactions. It was noted that the CAT system grouping failure happened at the same time as the laboratory air conditioning failed. Investigation showed that a temperature change from 22°C to 29°C caused negative reactions with the A+B cell in the CAT anti-B column. Reactions returned to in specification levels after the air conditioning was repaired.

Result: Routine use of an ABO sensitivity control identified a grouping reagent/ system that appears to be very sensitive to temperature and shows test sensitivity loss with a temperature change of only a few degrees. The laboratory is now conscious of this issue and maintain laboratory temperature carefully and also maintain a backup grouping method if it is needed.
Anti-Fya and anti-K control antibodies were detected in a tube LISS additive testing system but at scores significantly weaker than published. Expected results were 2 (on a 4 scale) and the laboratory was seeing 0.5 lower volume than recommended. Inadequate volume had been incorrectly set to dispense a lower volume rather than cell group reactions that appeared to be group AB and the blood group should be considered uninterpretable (see Table 1 above).

**Table 1:** Example of reported reactions and group interpretation

<table>
<thead>
<tr>
<th>Securacell™ sample #</th>
<th>Cell group</th>
<th>Serum group</th>
<th>Result interpretation</th>
<th>Control result</th>
<th>Result acceptable Y/N</th>
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<tr>
<td></td>
<td>Anti-A</td>
<td>Anti-B</td>
<td>Anti-A/B</td>
<td>Anti-D</td>
<td>A cells</td>
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</table>

**Case 5 – Blood grouping sensitivity and reaction interpretation**

A multi-laboratory pathology practice reported two grouping issues. Some staff failed to detect the A-Bw ABO sensitivity testing cell in both tube and CAT grouping systems. This was identified as being caused by poor testing and reaction reading techniques in tube and some CAT card grouping insensitivity that was batch related. Perhaps more importantly, a number of staff would report a group interpretation of O when cell (forward) group reactions appeared to be group O with serum (reverse) group reactions that appeared to be group AB and the blood group should be considered uninterpretable (see Table 1 above).

**Result:** The A-Bw grouping sensitivity cell included in the QC system revealed poor reaction reading, an insensitive batch of gel cards and a dangerous lack of staff skills in ABO interpretation. QC materials are now regularly used as a training and competency checking tool in these laboratories.

**Case 6 – Instrumentation**

Anti-Fya™ and anti-K control antibodies were detected in a tube LISS additive testing system but at scores significantly weaker than published. Expected results were 2 (on a 4 scale) and the laboratory was seeing 0.5 scores. Investigations found that the routinely used automated cell washer fluid dispensing volume had been incorrectly set to dispense a lower volume than recommended. Inadequate washing resulted in a loss of antibody screening and crossmatch sensitivity.

**Result:** QC material out of specification results demonstrated incorrect instrument adjustment. Correction of wash volumes returned reaction grading to within specification.

**Case 7 – Staff competency testing [2]**

A metropolitan multi-laboratory hospital utilise Securacell™ samples that are labeled with a simulated patient sample labels and are introduced into laboratory samples batches. Staff were unaware of control samples when testing. Result review revealed failure to detect a control anti-Fy™ antibody in an antibody screen performed by a part-time staff member on a weekend. Investigation revealed a positive antibody screen reported in a real patient sample adjacent to the control sample in the testing batch. The same staff member had also performed an antibody identification panel and identified the antibody as an anti-Fy™. Repeat testing was performed on the patient sample and it was found to be antibody screen negative.

**Result:** Routine control use detected two serious technical errors of transposition and antibody misidentification. The staff member was removed from the laboratory, retrained and was prevented from performing immunohaematology testing until proven competent and safe.

**SUMMARY**

The use of a high quality routine process control and reaction interpretation in laboratory performs immunohaematology laboratories to implement Quality Control and Quality Assurance systems that have been available to other diagnostic disciplines such as biochemistry for decades. The use of a high quality externally produced QC product as biochemistry for decades. The use of a high quality externally produced QC product as shown to identify systematic errors such as transcription, transposition and poor scoring thus enabling system improvements. Test, staff and instrument performance may be constantly monitored, errors and poor performance detected and laboratory safety continuously improved.

**REFERENCES**