Ortho Clinical Diagnostics

Because Every Test Is A Life™

Assuring ABO Compatibility Detection Using Full Automation

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Background

AABB Standards require testing to detect ABO incompatibility when a serological crossmatch test is performed. Although the immediate spin crossmatch (ISXM) is accepted as the choice serology test to meet this standard, previous studies using the claimed tube test as the gold standard has been proven to be imperfect in detecting all ABO incompatible situations. Although the electronic crossmatch using a validated laboratory information system has become more prevalent, interest remains in the performance of a serological approach to detect ABO incompatibility. As automation for immunohematology tests has expanded, the interest in maintaining a serological test on an automated system for the ISXM test has persisted. This study was undertaken to demonstrate that the ORTHO VISION® Analyzer platform would detect ABO incompatibility based on the expected result of crossmatch pairing.

Study Design

Testing was executed on the ORTHO VISION (OV) and ORTHO VISION Max (OVM) with the ID-MTS Buffered Gel Card for the ISXM and compared to the expected test result based on ABO of the paired recipient (R)/donor (D) samples. All samples were provided by a third party with a defined ABO grouping which was confirmed with a second ABO test to assure the validity of the provided ABO grouping. Samples were representative of a diverse population from various geographic areas. A total of 2058 on VISION and 2054 on VISION Max, individual unique crossmatch pairings were processed. **Table 1** and **Table 2** show the number of pairings utilized in the testing. Any discrepant result was investigated for causative. The acceptance criteria for concordance was set at 100% total agreement.

Table 1: ISXM Pairings Compatible

Compatible			
Recipient	**Donor**	**OV#**	**OVM#**
A	A	189	189
	O	198	197
B	B	60	60
	O	51	51
AB	AB	19	18
	A	12	12
	B	7	7
	O	12	12
O	O	407	418

Table 2: ISXM Pairings Incompatible

Incompatible			
Recipient	**Donor**	**OV#**	**OVM#**
A	B	379	377
	AB	28	28
B	A	158	118
	AB	20	20
O	A	317	343
	B	161	164
	AB	40	40

The test results were evaluated for concordance versus expected results. A statistical analysis of the testing results was applied using the lower bound 95% confidence interval (LB95CI). The LB95CI was calculated for each the positive % agreement, negative % agreement and total % agreement.

Results

Both analyzers achieved the acceptance criteria of 100% total agreement and a 99.9% LB95CI (**Table 3**). The positive % agreement for 1103 and negative % agreement for 955 ORTHO VISION tests was 100% with a 99.7% LB95CI for both. The positive % agreement for 1090 and negative % agreement for 964 ORTHO VISION Max tests was 100% with a 99.7% LB95CI for both. There were no false negative crossmatch tests across all tests on both analyzers, however there were ten false positive crossmatch tests.

Eight of the ten crossmatch tests were from the ORTHO VISION. Seven of these results occurred with one single recipient sample. After investigation, the cause was identified as significant rouleaux properties of the sample in both gel and tube tests. One additional crossmatch test in a single unit crossmatch demonstrated reactivity which identified rouleaux being the responsible factor for the incompatibility. These eight crossmatch tests were considered invalid and not included in the final concordance analysis. Two of the crossmatch tests on the Ortho VISION Max that produced false positive results were caused by sample quality issues. The cause specifically related to a low volume plasma on the sample and the presence of white cells in the plasma used in the test. After removal and centrifugation of the plasma the tests were repeated with the expected compatible results. These were resolved and deemed valid.

Table 3: Concordance of ISXM on ORTHO VISION and ORTHO VISION Max

	Total			Positive			Negative		
Test	**N**	**% Agreement**	**LB95CI**	**N**	**% Agreement**	**LB95CI**	**N**	**% Agreement**	**LB95CI**
OV-ISXM	2058	100.0%	99.9%	1103	100.0%	99.7%	955	100.0%	99.7%
OVM-ISXM	2054	100.0%	99.9%	1090	100.0%	99.7%	964	100.0%	99.7%

Discussion

Although the electronic crossmatch has become a mainstay for many transfusion services facilities with validated laboratory information systems, the common practice of testing for ABO incompatibility using a serological test that is regulatory approved continues. Many of those facilities have become automated and desire the benefits of automation to extend to the immediate spin crossmatch. This study on the ORTHO VISION platform of instruments demonstrated that the ISXM test could be effectively implemented and serologically validated on automation. Using barcoding of patient and donor samples for tracking and tracing along with the standardized process control through precision pipetting and monitoring of system test parameters, the key benefits of automation are achieved. The reliance on human interaction with the greatest risk for potential error from the testing process is removed. The capture of test result images further augments the confidence delivered by automation.

Conclusion

Eliminating the manual performance of the ISXM test by having the automated capability on the instrument used to process all other routine immunohematology tests is an important contributor to the safety and security that automation brings to the transfusion service.

Product availability in different countries may vary and be subject to local regulatory approval.

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