Ortho Clinical Diagnostics

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A Semiautomated Reader Solution Designed to Deliver Equivalence in Results

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Background/Case Studies

Automation of immunohematology testing has developed a stronger foothold in many transfusion services as instrument capability and software resourcefulness have expanded the safety and security of testing. Automation does not necessarily meet all laboratories needs due to economic feasibility and operational volumes. However, it has been shown that full automation can minimize risks, therefore, solutions for transfusion services that do not use fully automated systems need to be designed to reduce risks. In laboratories reliant on manual methods, a semiautomated solution would address this need. Using elements of a full automation instrument imaging system and software, a new reader system, ORTHO OPTIX™ Reader (OPTIX) was developed. This study validated the performance of the reader compared to the ORTHO VISION® Analyzer (VISION) for concordance.

Study Design

Three sites participated in the study using samples out of their normal donor/patient population or acquired through a third-party source. Minimal sample sizes were determined to meet criteria to produce valid statistical relevance and allow statistical analysis using a one-sided lower bound 95% confidence interval (95%LBCI) to be calculated. In some circumstances, due to low frequency of the antigen positive or negatives or DAT positive samples minimal volumes were not achieved. DAT positive samples were supplemented with laboratory prepared samples. Direct agglutination tests and antiglobulin (AHG) tests using the ID-MTS® Gel cards were processed and read on the VISION and then immediately read on the OPTIX reader. Direct agglutination tests included ABO forward and reverse grouping, RhD, and Rh phenotype tests. A microtube to microtube comparison for positive % agreement, negative % agreement and total % agreement was made between the two devices. For the direct agglutination tests and the AHG crossmatch (AXM), the acceptance criteria was set at ≥99.0% at 95%LBCI. The indirect antibody detection (AbSC) and antibody identification (AbID) and direct antiglobulin test (DAT), test acceptance criteria was set at ≥98.0% at 95%LBC. Discordant results were retested manually using the ID-MTS Workstation, read manually and immediately read on the reader device. When sufficient discordant sample was available the test was repeated on the automated instrument, then reread on the OPTIX reader.

Results

Table 1 demonstrates that the acceptance criteria of ≥99.0% was met or exceeded for direct agglutination tests.

Table 1: Total Concordance of Direct Agglutination Tests

Test	# Microtubes Tested	# Microtubes Agreement	Percent Agreement	Lower Bound of 95% CI
Anti-A	3637	3637	100%	99.9%
Anti-B	3637	3637	100%	99.9%
Anti-A,B	1105	1105	100%	99.7%
Anti-D	5093	5093	100%	99.9%
Anti-C	1456	1456	100%	99.8%
Anti-E	1456	1456	100%	99.8%
Anti-c	1456	1456	100%	99.8%
Anti-e	1456	1456	100%	99.8%
A1 Cells	3637	3637	100%	99.9%
B Cells	3637	3637	100%	99.9%

Table 2 demonstrates that the acceptance criteria of ≥98.0% was exceeded for antibody detection, antibody identification, and DAT tests.

Table 2: Total Concordance of AHG Tests

Test	# Microtubes Tested	# Microtubes Agreement	Percent Agreement	Lower Bound of 95% CI
AbSC	5084	5083	99.98%	99.9%
AbID	1023	1023	100%	99.7%
DAT	1007	1007	100%	99.7%

Table 3 demonstrates that the acceptance criteria of ≥99.0% was exceeded for the antiglobulin crossmatch tests

Table 3: Total Concordance of AHG Crossmatch Tests

Test	# Microtubes Tested	# Microtubes Agreement	Percent Agreement	Lower Bound of 95% CI
AXM	1553	1553	100%	99.8%

Table 4 demonstrates that positive/negative concordance for the direct agglutination tests set at ≥99% LBCI was achieved in the comparison testing. The one exception was anti-e for the antigen negative population at 97.5% at the 95%LBCI which related to the low frequency of the antigen negatives in the sample population tested. There was 100% agreement on all negative samples tested with the anti-e.

Table 4: Positive and Negative Microtube Concordance ABO and Rh phenotype

		Positive			Negative		
Direct Agglutination	**Test**	**# Microtubes Tested**	**Percent Agreement**	**Lower Bound of 95% CI**	**# Microtubes Tested**	**Percent Agreement**	**Lower Bound of 95% CI**
Antigen	**Anti-A**	1584	100.0%	99.8%	2053	100.0%	99.9%
	Anti-B	541	100.0%	99.4%	3096	100.0%	99.9%
	Anti-A,B	441	100.0%	99.3%	664	100.0%	99.5%
	Anti-C	945	100.0%	99.7%	511	100.0%	99.4%
	Anti-D	4358	100.0%	99.9%	735	100.0%	99.6%
	Anti-E	434	100.0%	99.3%	1022	100.0%	99.7%
	Anti-c	1090	100.0%	99.7%	366	100.0%	99.2%
	Anti-e	1338	100.0%	99.8%	118	100.0%	97.5%
Reverse Grouping	**A1 Cells**	2055	100.0%	99.9%	1582	100.0%	99.8%
	B Cells	3094	100.0%	99.9%	543	100.0%	99.4%

Table 5 demonstrates the positive and negative concordance for the antibody screen, antibody identification and DAT tests with acceptance set at greater than or equal to 95% LBCI. Each test achieved greater than 98% concordance at a 95% LBCI. Of the 4909 microtubes in the antibody detection tests performed, there was 1 non-agreement between the predicate device and OPTIX. The one discrepant result was initially weakly positive on the OPTIX reader and negative on the VISION. Repeat testing demonstrated a negative test. No root cause for the discrepancy was identified. The antiglobulin crossmatch achieved the ≥99% criteria at the 95% LBCI for both positive and negative agreement.

Table 5: Positive and Negative Microtube Concordance for AHG Tests

	Positive			Negative		
Anti-Human Globulin Tests	**# Microtubes Tested**	**Percent Agreement**	**Lower Bound of 95% CI**	**# Microtubes Tested**	**Percent Agreement**	**Lower Bound of 95% CI**
Antibody Screen	175	100.0%	98.3%	4909	99.98%	99.9%
Antibody ID	227	100.0%	98.7%	796	100.0%	99.6%
IAT Crossmatch	708	100.0%	99.6%	845	100.0%	99.6%
DAT (Anti-IgG, -C3d)	364	100.0%	99.2%	643	100.0%	99.5%

Discussion

Automating immunohematology has gained significant support in the transfusion medicine testing laboratory as focus on improving safety and security has become paramount. Fully automating the process is the ideal as comprehensive process control can be achieved. However full automation may not be the right solution for all circumstances. In some instances, economic feasibility to fully automate may not be attainable but there remains the desire to minimize many of the more potential common errors that occur with a fully manual testing process. Effectively designed semi-automated solutions can address this need by employing as many as possible process steps that are achieved on full automation into the system design. Linkage of the patient sample to the reagent tested is the critical first step. Consequential to the final steps in the process is the reading of agglutination reactions and interpretation of test results and associating those to the appropriate patient, all of which can be automated and software driven. The intent of a reader is to deliver reaction grading and interpretation consistent with reactivity seen on a fully automated system. This study was designed to demonstrate that consistency in reaction grading.

Conclusion

Concordance testing comparing the results of cards processed and read on the fully automated system and then reread on the standalone reader device demonstrated that the OPTIX Reader produces results equivalent to the VISION analyzer. Additionally, the software assures trackability and traceability of samples linked to reagents along with image capture and storage. The use of common componentry and software elements of the fully automated system provides confidence that a standalone reader system can deliver safe and secure results.

Presented at 2021 AABB Virtual Annual Meeting, Oct. 17 -19, 2021 | PR-11806
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