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DEVELOPMENT OF AN INDEPENDENT READER SYSTEM THAT PARALLELS SIGNIFICANT STEPS OF FULL AUTOMATION CAPABILITY FOR IMMUNOHEMATOLOGY TESTING

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Conflict of Interest

Tony S. Casina is a Consultant for Ortho Clinical Diagnostics

Amy Wilson-Colley and Joe Wycallis are employees of Ortho Clinical Diagnostics

Katherine Lucarelli is a former employee of Ortho Clinical Diagnostics

Background

The recognition that elimination of manual interaction in the processing of immunohematology (IH) tests is well established as a substantial way to mitigate the potential for error and establish improved safety and security of test results. Using a fully automated instrument is the ideal solution to achieve the highest level of mitigation. However, fully automated instruments are not economically feasible in all circumstances, therefore, a solution that addresses as many of the critical control points in the process to meet the needs of facilities endeavoring to enhance transfusion safety is essential. A reasonable alternative that would satisfy this expectation addresses linkage of patient sample to reagents tested with reader reaction grading/ interpretation, all captured through system software.

Background

Critical Control Points (CCP) in Test Execution

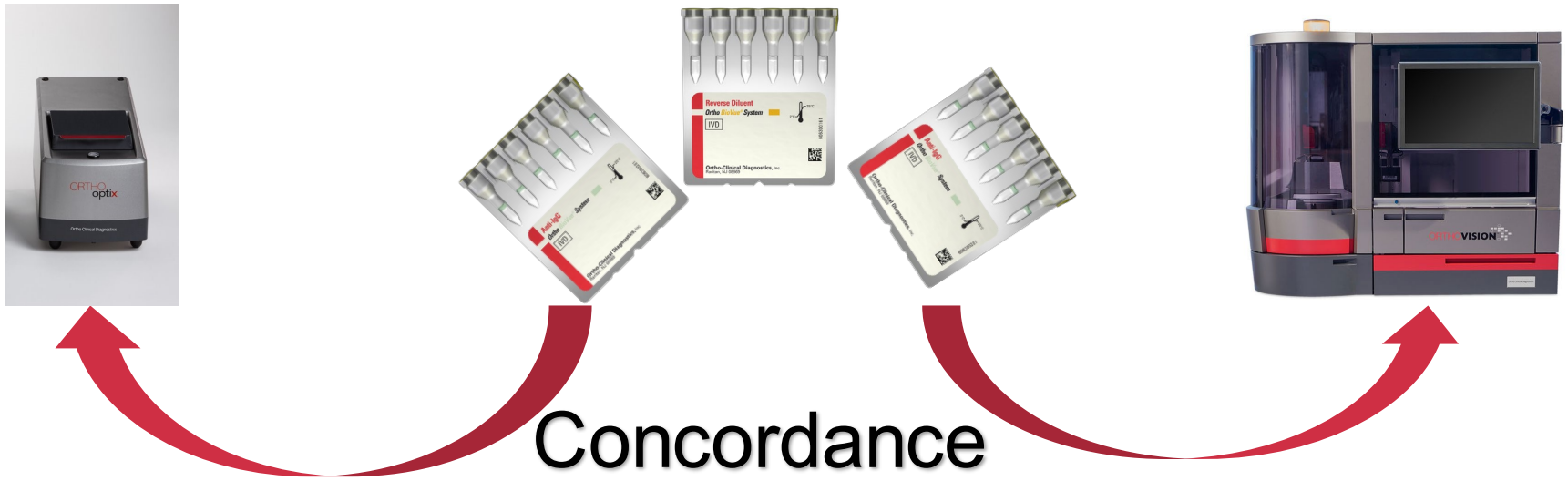
Manual Testing	
Visual Confirmation Only	
• Manual Sample Identity	
• Manual Reagent Identity	
• Sample Added Manually	
• Reagent Added Manually	
• Test Processed Manually	
• Test Centrifuged Manually	
• Test Read Manually	
• Test Rxn Recorded Manually	
• Test Interpreted Manually	
• Manuel Computer Entry	

Semiautomated Centrifuge/Reader/Software		
Most CCP Automated		
• Sample/Test ID	• Barcode/ SW	✓
• Reagent ID	• Barcode /SW	✓
• Sample Added	• Manual	
• Reagent Added	• Manual	
• Test Processed	• Manual	
• Test Centrifuged	• Automated	✓
• Test Read	• Reader	✓
• Test Rxn Capture	• Software	✓
• Test Interpreted	• Software	✓
• Result Transfer	• LIS interface	✓

Fully Automated		
All CCP Automated		
• Sample/Test ID	• Barcode/ SW	✓
• Reagent ID	• Barcode /SW	✓
• Sample Added	• Automated	✓
• Reagent Added	• Automated	✓
• Test Processed	• Automated	✓
• Test Centrifuged	• Automated	✓
• Test Read	• Automated Read	✓
• Test Rxn Capture	• Software	✓
• Test Interpreted	• Software	✓
• Result Transfer	• LIS interface	✓

Aim

Using sub-systems of the current full automation (ORTHO VISION® Analyzer (VISION) reader and software, a new single cassette reader workstation (ORTHO OPTIX™) utilizing ORTHO BioVue® System cassettes (a six column glass bead based test method) was developed for IH testing. This study was undertaken to verify the concordance between the new reader workstation and the fully automated instrument.



Aim

A variety of BioVue® cassettes (Table 1) were utilized in testing of various tests and test profiles.

Table 1: Cassette Type Tested, Test Method, Columns Tested

ORTHO BioVue® Cassette Type	Cassette Configuration	Test Method	# Columns Tested
ABO-Rh/Reverse	A/B/D/CT/RD/RD	Direct Agglutination	360
Rh/K	C/E/c/e/K/CT	Direct Agglutination	300
Rh/K II (second clone)	C/E/c/e/K/CT	Direct Agglutination	300
ABDD/K	A/B/D/D/K/CT	Direct Agglutination	726
ABO(FWD)-D/CDE-44	A/B/A,B/D/CDE/CT	Direct Agglutination	750
AHG Polyspecific/ Neutral	AHG-PS X 3 / Neut x 3	IAT /Enzyme	401
Reverse Diluent (RD)	RD x 6	Direct Agglutination	428
DAT/IDAT	IgG/C3d/CT x 2	DAT/IAT	234
AHG Polyspecific (AHG-PS)	AHG-PS x 6	IAT	680
AHG Anti-IgG	IgG x 6	IAT	662

AHG - Anti-Human Globulin (antiglobulin),
DAT-Direct Antiglobulin Test,
IAT- Indirect Antiglobulin Test
CT- Control Column

Methods

- Testing included direct agglutination - ABO/RH, antigen phenotyping and indirect agglutination antibody detection, crossmatch and direct antiglobulin test (DAT).
- Various ORTHO reagent red blood cells for antibody detection and identification as well as donor red cells were used in testing
- Two ORTHO VISION™ and three ORTHO OPTIX™ readers were used. The reader used with each automated instrument was rotated each test day so that all readers were used with both VISIONs.
- Samples and cassettes were processed on the automated system then read on the automated instrument and immediately read on the paired reader
- Results were evaluated for concordance on column-by-column basis.
- Acceptance criteria for concordance
  - Direct agglutination ≥99.4% at a lower bound 95% confidence interval
  - Direct and indirect antiglobulin was ≥98.0% at a lower bound 95% confidence interval.

discordant column was repeated on the same original systems.

Results

Comparison testing by direct agglutination was executed on a total of 598 samples (Table 2) generating 3125 column results (1461 positive/1664 negative) that were analyzed for concordance. The concordance achieved was 100%. The overall concordance at the lower bound 95% confidence interval (CI) was 99.9% for direct agglutination.

Table 2 : Overall Column Result % Agreement for Direct Agglutination Tests

		ORTHO OPTIX					
ORTHO VISION	598 Samples	Positive	Negative	Total		Concordance	
	Positive	1461	0	1461*		Overall Concordance %	100%
	Negative	0	1664	1664*		Lower Bound of the 95% Confidence Interval	99.9%
	Total	1461	1664	3125		Direct Agglutination Acceptance Criteria	99.4%

*corrected in this table- note the abstract indicates 1464 positive and 1661 negative)

Results

Comparison of direct/indirect antiglobulin testing was executed on a total of 669 samples (Table 3) generating 1716 columns (223 positive/1492 negative/1 discordant) with an overall concordance of 99.9% with a 99.7 at the lower bound 95% confidence interval. Both direct and indirect antiglobulin testing achieved acceptance criteria.

Table 3: Overall Column Result % Agreement for Direct and Indirect Antiglobulin Tests

		ORTHO OPTIX					
ORTHO VISION	669 Samples	Positive	Negative	Total		Concordance	
	Positive	223	0	223		Overall Concordance %	99.9%
	Negative	1	1492	1493		Lower Bound of the 95% Confidence Interval	99.7%
	Total	224	1492	1716		Direct/Indirect Antiglobulin Acceptance Criteria	≥98.0%

Results

The one discordant test was negative by full automation and positive by the new reader and when repeated was negative on both systems (Table 4) . Manually read, the reaction was interpreted as an indeterminate (IND) reaction. This discordant result remained in the analysis of concordance.

Test	Test Profile	Reagent	ORTHO VISION Result	ORTHO Reader Result	Manual Read Result
Crossmatch Initial Test	Poly AHG XM	Anti-IgG, -C3b/d	Negative	Positive	IND
Crossmatch Repeat Test	Poly AHG XM	Anti-IgG, -C3b/d	Negative	Negative	NA

Conclusions

- The testing demonstrated that the concordance acceptance criteria was achieved by the ORTHO OPTIX™ Reader*.
- A reader system developed using common components from an established fully automated system will provide for IH laboratories the desired consistency and increased security of their test results.
- The ORTHO OPTIX ® Reader delivers
  - Positive sample/patient identification through LIS interfacing and barcode
  - Identified sample linked to cassette by barcode
  - Reader linkage of cassette barcode to patient record and reaction grading
  - Software interpretation
  - Data and image storage

ORTHO OPTIX ™ Reader has received CE clearance. Product availability in different countries may vary and be subject to local regulatory approval