

Performance Evaluation of the New Integrated Antibody Identification Software IH-A^bID

S. Krohto², N. Heu³, L. S. Er³, J. D. Sweeney², T. Nester³, B. Mathison¹, P. Lamonby⁴, A. Reggiani⁴

¹Bio-Rad Laboratories, Seattle, WA, USA

²The Miriam Hospital, 164 Summit Avenue, Providence, RI 02906, USA

³Bloodworks Northwest, 921 Terry Avenue, Seattle, WA 98104, USA

⁴Bio-Rad Laboratories, DiaMed GmbH, Cressier, CH



Introduction

Antibody identification is carried out to assign a specificity and evaluate its clinical significance in a transfusion or antenatal context. It is a challenging task as it requires in-depth knowledge of antibody behavior, rules to exclude or identify the specificity as well as zygosity and dosage phenomenon.

Objective

IH-A^bID is the integrated antibody identification software for IH-Com and is FDA cleared. These data are the result of a performance study comparing the automated interpretation provided by IH-A^bID to the standard practice using manually completed worksheets.

Methods

The IH-A^bID Software was evaluated at two sites, The Miriam Hospital and Bloodworks Northwest, involving three users with various levels of expertise in blood banking. Each site provided 20 leftover samples containing one or more clinically significant antibodies directed against antigens from several blood group systems (Rh, Kidd, Duffy, Kell, MNS). In addition, eight well-characterized samples were provided by Bio-Rad. Samples were tested using IH-Cards AHG Anti-IgG and red blood cell panels on the IH-500 System and interpreted by the IH-A^bID Software. Samples were tested blinded and multiple times. Results from the IH-500 System were also provided to a reference operator for blinded manual interpretation using AABB standard practices (Figure 1). The agreement was determined by the number of identical antibody identifications between the automated and manual interpretations.

Table 1. Antibody identifications with automated (IH-A^bID) and manual interpretations

The Miriam Hospital				Bloodworks Northwest							
Antibody Identification				Antibody Identification				Antibody Identification			
#	Sample ID	IH-A ^b ID	Manual Op. 1	#	Sample ID	IH-A ^b ID	Manual Op. 1	#	Sample ID	IH-A ^b ID	Manual Op. 2
1	IABW001	UNID	UNID	1	IABL001	Anti-Jk ^a	Anti-Jk ^a	1	IABL002	Anti-Jk ^a	Anti-Jk ^a
2	IABW002	Anti-D,-C	Anti-D,-C	2	IABL003	Anti-Fy ^a	Anti-Fy ^a	2	IABL004	Anti-Fy ^a	Anti-Fy ^a
3	IABW003	Anti-E	Anti-E	3	IABL005	Anti-Fy ^a	Anti-Fy ^a	3	IABL006	Anti-Fy ^a	Anti-Fy ^a
4	IABW004	Anti-Fy ^a	Anti-Fy ^a	4	IABL007	Anti-Jk ^a	Anti-Jk ^a	4	IABL008	Anti-Jk ^a	Anti-Jk ^a
5	IABW005	Anti-D,-C	Anti-D,-C	5	IABL009	Anti-S	Anti-S	5	IABL010	Anti-S	Anti-S
6	IABW006*	Anti-E,-K,-M	Anti-E,-K, can't r/o Anti-M	6	IABL011	Anti-D	Anti-D	6	IABL012	Anti-D	Anti-D
7	IABW007	UNID	UNID	7	IABL013	Anti-K	Anti-K	7	IABL014	Anti-K	Anti-K
8	IABW008	Anti-D,-C	Anti-D,-C	8	IABL015	Anti-E	Anti-E	8	IABL016	Negative	Negative
9	IABW009	Anti-K	Anti-K	9	IABL017	Anti-s	Anti-s	9	IABL018	Anti-Fy ^a	Anti-Fy ^a
10	IABW010	Anti-E	Anti-E	10	IABL019	Anti-E	Anti-E	10	IABL020	Anti-Fy ^a	Anti-Fy ^a
11	IABW011	Anti-Jk ^a	Anti-Jk ^a	11	IABL021	Anti-c	Anti-c	11	IABL022	Anti-c	Anti-c
12	IABW012	Anti-D	Anti-D	12	IABL023	Anti-C,-D	Anti-C,-D	12	IABL024 [†]	Anti-C,-D,-E	Anti-C,-D
13	IABW013	Anti-K	Anti-K	13	IABL025	Anti-E	Anti-E	13	IABL026	Anti-E	Anti-E
14	IABW014	Anti-Jk ^a	Anti-Jk ^a	14	IABL027	Anti-E	Anti-E	14	IABL028	Anti-E	Anti-E
15	IABW015*	Anti-K,-M	Anti-K, UNID, can't r/o Anti-M	15	IABL029	Anti-K	Anti-K	15	IABL030	Anti-K	Anti-K
16	IABW016	Anti-D	Anti-D	16	IABL031	Anti-E,-Fy ^a	Anti-E,-Fy ^a	16	IABL032	Anti-E,-Fy ^a	Anti-E,-Fy ^a
17	IABW017	Anti-Jk ^a	Anti-Jk ^a	17	IABN009* [†]	Anti-E,-Jk ^a , -K,-N	Anti-E,-Jk ^a , can't r/o Anti-K	17	IABL033	Anti-E	Anti-E
18	IABW018	Anti-S	Anti-S	18	IABN010	Anti-D,-C	Anti-D,-C	18	IABN001	Anti-D,-C	Anti-D,-C
19	IABW019	Anti-D	Anti-D	19	IABN011	Anti-D,-C	Anti-D,-C	19	IABN002	Anti-D,-C	Anti-D,-C
20	IABW020	Anti-K	Anti-K	20	IABN012 [†]	Anti-S,-D,-K	Anti-S,-D	20	IABN003	Anti-D,-C	Anti-D,-C
21	IABN001	Anti-D,-C	Anti-D,-C	21	IABN013	Anti-D,-C	Anti-D,-C	21	IABN004	Anti-D,-C	Anti-D,-C
22	IABN002	Anti-D,-C	Anti-D,-C	22	IABN014	Anti-E,-K	Anti-E,-K	22	IABN005	Anti-c	Anti-c
23	IABN003	Anti-D,-C	Anti-D,-C	23	IABN015	Anti-c	Anti-c	23	IABN006	Anti-E,-Jk ^a	Anti-E,-Jk ^a
24	IABN004	Anti-D,-C	Anti-D,-C	24	IABN016 [§]	Anti-C,-E	Anti-D,-C				
25	IABN005	Anti-c	Anti-c								
26	IABN006	Anti-E,-Jk ^a	Anti-E,-Jk ^a								
27	IABN007	Anti-S,-D	Anti-S,-D								
28	IABN008	Anti-E,-K	Anti-E,-K								

Op. 1: Operator 1
Op. 2: Operator 2
UNID: Unidentified antibody
r/o: rule out

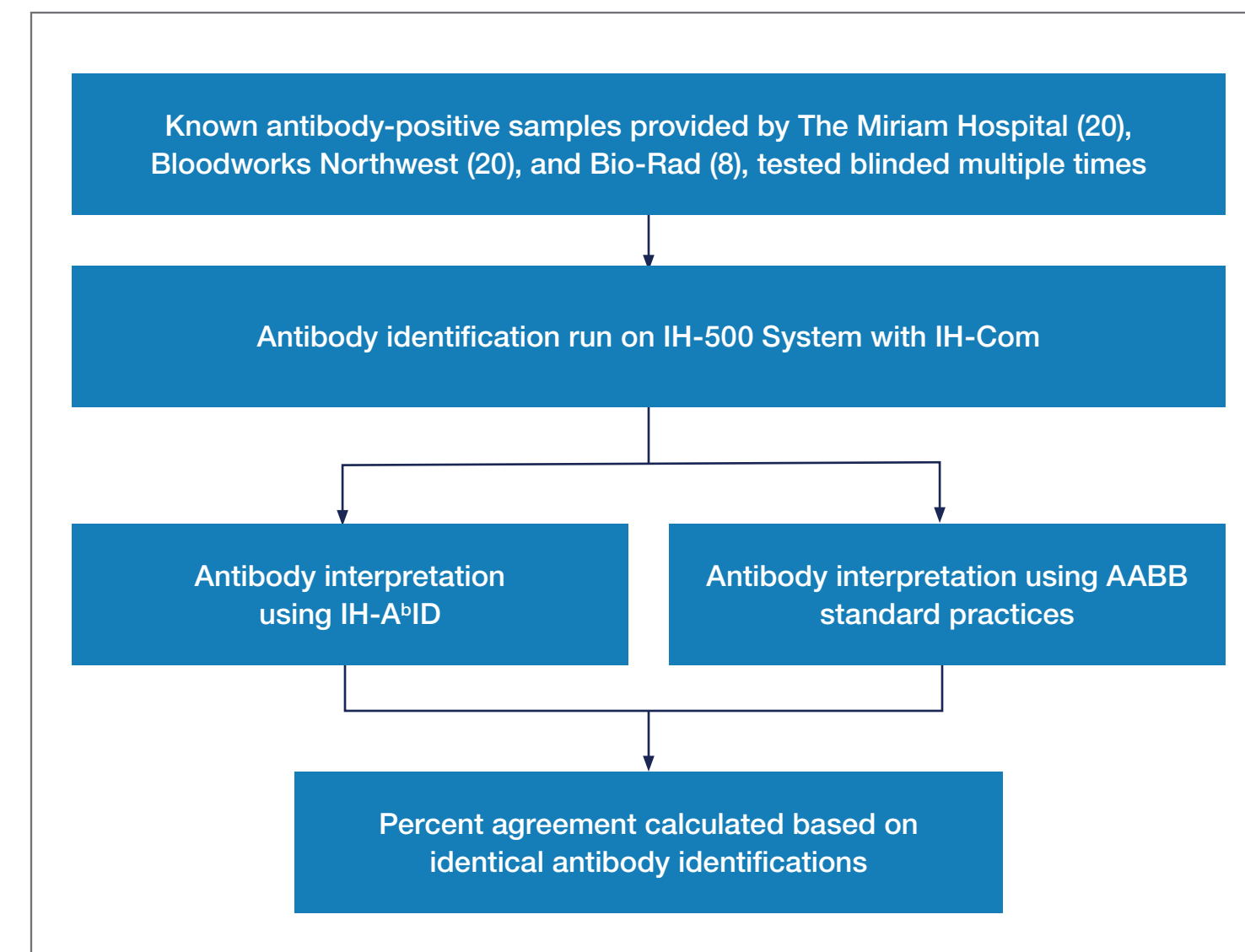


Figure 1. Study flowchart

Results

The performance evaluation showed 92% strict agreement between the automated and the manual interpretation (Table 1). Out of the 48 samples tested, 34 had a single red cell antibody and 14 samples presented with more than one specificity.

For three samples,* the IH-A^bID Software correctly identified the specificities with two anti-M and one anti-K categorized as “possible.” These three antibodies could not be ruled out due to limited availability of reagent red cells for manual testing.

For two other samples,† the software reported the correct specificities and listed an additional anti-N and an anti-K as “possible,” which were reported as “not ruled out” in manual interpretation after a second review.

For another sample,‡ specificities were correctly reported by IH-A^bID along with an anti-E reported as “possible,” which was ruled out in manual testing using a single dose cell in the presence of anti-D.

For just one sample§ with multiple antibodies, discrepant specificities were reported. The sample was tested three times and correctly interpreted twice (anti-D,-C), but on the third occasion, IH-A^bID interpretation was anti-C,-E. This was due not to the software but to the difference in the result with one red blood cell.

Conclusion

Performance evaluation of the IH-A^bID Software compared to manual interpretation showed excellent concordance. There was no discrepant result attributable to the software. These results demonstrate the powerful capabilities of IH-A^bID to help systematize the antibody identification process. It is a user-friendly tool and has the greatest utility for off-shifts where laboratory personnel are typically less experienced in antibody identification.




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