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Comparison of sensitivity and specificity of the Bio-Rad ID Cards LISS/Coombs with the Grifols Gel Coombs cards in a manual approach

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Background

Antibody screening and identification is, besides blood grouping, an important part of the patient pre-transfusion process. As the Swiss immunohematology reference laboratory uses the Bio-Rad ID coombs cards it is very important to know if the method used has a good sensitivity and specificity in comparison with similar systems like Grifols.

Aim

The aim of this study was to compare the sensitivity and specificity of the two methods used by most immunohematology laboratories in Switzerland.

Methods

A total of 1001 frozen random samples from a German hospital (anonymous) and 200 samples with known antibodies were investigated. These antibodies were chosen due to their clinical relevance and weak antibody reactivity or due to their unspecific reactivity (antibodies against substances in the stabilisation solution = anti-stabi). These were determined using ID coombs cards (ID/IAT) and in-house test cells and kept at 4°C for 2-4 months. Both sample collections were tested with a set of 3 test cells from Bio-Rad (ID-DiaCell I-III DiaMed, Switzerland) and Grifols (Serascan Diana 3, Medion Grifols Diagnostics AG, Dudingen, Switzerland) using the ID/IAT and Grifols Gel Coombs cards (Gel/IAT).

Table 1. Summary of antibodies found among 1001 random samples.

Antibody specificity	Detected by in-house system	Detected by BioRad	Detected by Grifols
No antibody 986x	✓	✓	✓
Anti-K	✓	✓	✓
Anti-Jk(a)	✓	✓	✓
Anti-D	✓	✓	✓
Anti-D, Anti-C	✓	✓	✓
Anti-M	✓	✓	✓
Anti-K	✓	✓	✓
Anti-K	✓	✓	✓
Anti-S, Anti-Fy(a)	✓	✓	✓
Anti-K	✓	✓	✓
Anti-E, Anti-Jk(a)	✓	✓	✓
Anti-E	✓	✓	✓
Anti-K	✓	✓	✓
Anti-Stabi	✓	✓	✓
Anti-Stabi	no	no	✓
Anti-Stabi	no	✓	no

Table 2. Summary of discrepancies among 200 samples with known antibodies.

Antibody specificity	Detected by In-house system	Detected by BioRad	Detected by Grifols
Anti-Stabi 21x	only with fresh serum	no	no
Anti-Stabi 2x	✓	no	✓
Anti-Stabi 1x	✓	✓	no
Anti-D	✓	✓	no
Anti-Lu(a)	✓	✓	no
Anti-M	✓	✓	no
Anti-Le(a)	✓	✓	no
Anti-M	✓	no	✓
Anti-K	✓	no	✓
Anti-Kp(a) 5x*	✓	no	✓
Anti-Cw 2x*	✓	✓	no

* Antigen not present on screening cells

Results

For 999 of the 1001 random samples no difference between the systems was observed. Both systems showed each with one sample a reaction that could not be confirmed by the in-house system. In 13 of the 999 samples antibodies were detected, of which one anti-stabi. In 48 of 200 antibody containing samples differences between Bio-Rad and/or Grifols and our in-house system were observed. Twenty-one of 24 samples with anti-stabi were only detectable with fresh serum, whereas two were detected by Grifols only and one by Bio-Rad only. For the 24 samples showing very weak reacting antibodies, eleven reacted in both systems, one anti-D, one anti-Lu(a), one anti-M and one anti-Le(a) were not detected by Grifols and one anti-K and one anti-M by Bio-Rad. Five anti-Kp(a) (Bio-Rad) and two anti-Cw (Grifols) could not be detected as the antigens were not present on the screening cells.

Summary / Conclusions

Both screening systems showed an equal good performance, with a sensitivity of 100% and a specificity of 99.8% for the 1001 random samples. From the 200 samples with known antibodies, only four very weak reacting antibodies were not detected by Grifols and two by Bio-Rad systems respectively. However, both systems detected all anti-Fy and anti-Jk antibodies. Both test sets lacked a mandatory antigen according to the Swiss regulations (but not to other regulations): Cw for Grifols and Kp(a) for Bio-Rad. The samples with anti-stabi were sent to our laboratory from all-over Switzerland and in all cases the observed reactions could be confirmed in ID/IAT with our in-house cells. However, the anti-stabi samples could only be detected in two out of 24 samples by Grifols and in one of 24 samples by Bio-Rad. The negative reactions could be due to the sample storage at 4°C and a putative instability of IgM antibodies.

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