

A₂B or not A₂B

Advanced Automation in Blood Group Serology: Validation Results of The BioRad IH-1000

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Introduction

Automation for ABO/Rh D blood grouping was first introduced in the early 1960's. The introduction of the gel test developed by DiaMed (Cressier, Switzerland) in the late 1980's revolutionised blood group serology and is a technique widely used today on automated platforms. In recent years improved optical resolution has led to increased sensitivity and specificity for blood group determination. Current BCSH and ISBT guidelines recommend the use of fully automated systems for blood grouping and antibody screening in order to reduce the risks of interpretation and transcription errors. According to SHOT data over the last decade, the majority of ABO blood grouping errors occurs in manual systems. But what about errors that occurs within automated systems? Here we investigate the concordance rate of two BioRad autoanalysers with a decade of technology between both platforms.

Methods

370 adults were tested for ABO/D group and antibody screen and 47 neonatal samples for ABO/D group. All samples were analysed on the DiaMed-ID *Classic* ID-GelStation (Cressier, Switzerland) and retested on the BioRad IH-1000 (Cressier, Switzerland). Reaction strengths in each well were graded on a five point scale of 0-4.

Results

The rate of concordance of the two methods was very high, with absolute agreement on the 5-point scale (0 to 4) for each ID-well in both adults and neonatal samples ranging from 88% to 100%. Linear weighted Cohen's kappa statistics ranged from 0.955 to 0.997 in the adult sample ID-wells, and equalled 1 for most of the neonatal ID-wells.

Of the 370 adult samples tested, 0.2% (5/2220) of the ID-wells yielded a >1+ reaction strength difference between both platforms (reverse group only). Further investigation revealed that the *Classic* ID-GelStation over-reported the reaction grade (4+) and the IH-1000 under-reported the reaction grade (2+), as visual inspection of the electronic screenshots were similar (3±0.5 reaction grade).

In a single case a discrepancy in positive versus negative rating was observed. This occurred in a neonatal sample against the Anti-A well, where the IH-1000 graded the reaction strength against Anti-A with a generous 2+ score (Group AB), while the *Classic* ID-GelStation graded the reaction in this well as negative (Group B). This sample was referred to a reference laboratory and was confirmed as group AB with weak expression of the A antigen. With newborns it is common for the A antigen expression to be weakened and it is likely that the neonate is A₂B or A₃B. The clinical impact of the discrepancy (potential risk of transfusion of incompatible plasma) was felt to be low due to the weak expression of the A antigen. All other reactions in the neonatal cohort (n=46,98%) were identical between analysers.

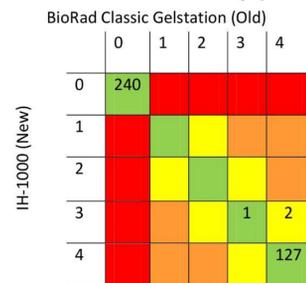
Results



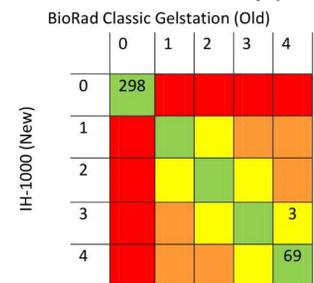
ADULT GROUPS



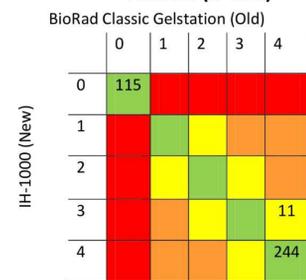
Anti A Forward Group (n=370)



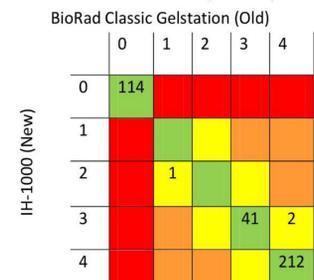
Anti B Forward Group (n=370)



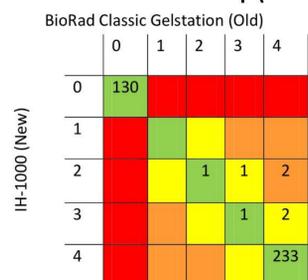
Anti D1 (n=370)



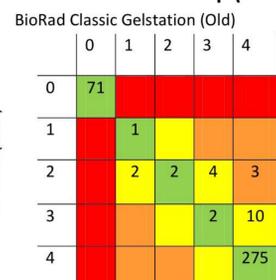
Anti D2 (n=370)



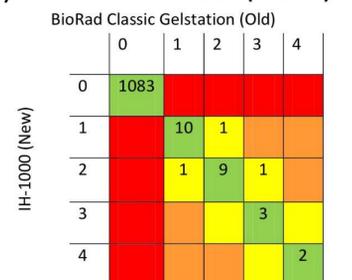
A cells Reverse Group (n=37)



B Cells Reverse Group (n=370)

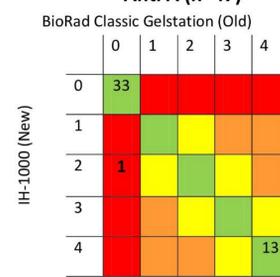


Combined Screen Cells (n=1110)

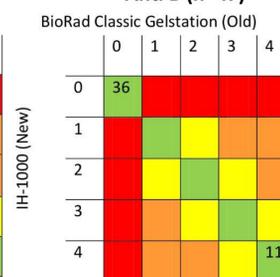


BABY GROUPS

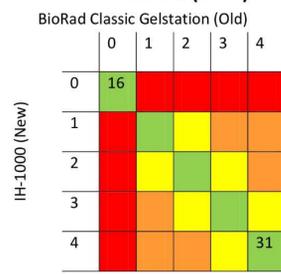
Anti A (n=47)



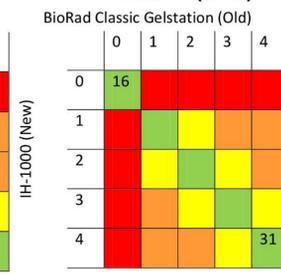
Anti B (n=47)



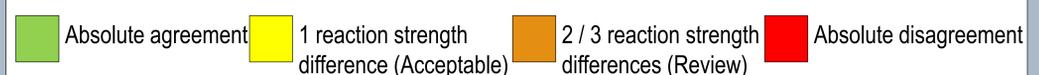
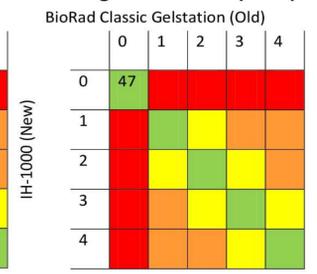
Anti D1 (n=47)



Anti D2 (n=47)



Negative Control (n=47)



Conclusion

Improved optical resolution in automated systems results in significant improvements in detection of weaker reactions in blood group serology. As an advanced in vitro diagnostic system, the BioRad IH-1000 is more sensitive in its detection of weaker results and is therefore more accurate and superior than older platforms.

References:
BCSH (2012) Guidelines for validation and qualification, including change control, for hospital transfusion laboratories. *Transfusion Medicine*, 22, 22, 5-43
ISBT (2010) ISBT guidelines for the validation of automated systems in blood establishments. *Vox Sanguinis*, 98 (Suppl 1), 1-19
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