A total of 269 partial D and weak D samples were tested. The analysis of results allowed identification of various partial D types, many of which were new. The kit contains 12 monoclonal IgG anti-D antibodies. Cell lines and identification used were: Anti-D' X LHM75/65, Anti-D' B LHM76/59, Anti-D' C LHM74/102, Anti-D' LHM93/28, Anti-D' E LHM94/171, Anti-D' G LHM75/65, Anti-D' H LHM77/66, Anti-D' Y LHM78/47, Anti-D' J LHM59/91, Anti-D' K LHM58/98 and Anti-D' L LHM57/98. The Partial RhD Typing Kit (SRK, UK) or DiaMed AG, Switzerland, was used as a reference where appropriate and consist of cell lines and identification: Anti-D T LHM169/80, Anti-D'A' LHM170/88, Anti-D' Y LHM168/90, Anti-D' D LHM70/45, Anti-D' D' LHM76/55, Anti-D' D' LHM77/66, Anti-D' D' LHM78/79, Anti-D' D' LHM169/80, Anti-D' D' LDM1 (all were IgG except LDM1). The product is in compliance with the USP. The type and number of most samples tested were known as partial Rh D samples (confirmed or not confirmed by molecular testing). All test samples in the evaluation had been collected for the purpose of routine blood grouping or stored as part of the SCARF system.

The evaluation and reference kit were tested using standard serological indirect haemagglutination assay (Coombs test) using cells suspended in phosphate buffered saline (PBS) or low ionic strength saline (US). Haemagglutination reactions were graded using the standard method in use at each test laboratory. Where anti-IgG was used, participants used their routine anti-human IgG (anti-IgG, anti-IgM, anti-IgA) reagents. The reference kit was supplied by the manufacturer. Some of the samples tested for haemagglutination using a gel matrix test (LISS-Coombs 37ºC, Direct/ID Micro Typing System, OCD). Red cell samples used were either EDTA or citrate anticoagulated blood samples collected from patients or frozen and recovered, and all were washed in PBS before use.

Results

The results were reported by each test centre using their standard grading systems. All test samples were evaluated and reaction patterns were variable. While it was noticed kit component 1 gave the highest incidence of negative reactions, otherwise 75% of weak D were positive throughout. Weak D types 2 and 3 were positive throughout with type 4 showing most variation. Two type 15 tested reacted as D'F'N'.

Conclusions

A total of 269 partial D and weak D samples were tested. The analysis of results allows many partial D to be identified serologically, due to their unique reaction patterns with the panel of anti-D reactive reagents. While generally there was generally a good consensus of results, the product, therefore, allows a number of partial D types to be identified by haemagglutination assay and D'F'N' reaction pattern. The range of partial D's defined by this kit is more comprehensive than any other D typing panel currently available. The kit has the advantage of allowing rapid, reliable and low cost screening by haemagglutination for patients requiring identification of partial D types, some of which could previously only be characterised by molecular analysis. Weak D samples may react with all kit components to varying degrees due to a variation in the antisera titer. In the future, the composition of each kit component may be adjusted to improve the identification of weak D, which can give variable reactions. There were insufficient numbers of cells of partial D types DAB, D'B, D' and DIM to confirm reaction profiles. If further samples of these types were available and evaluated, it is hoped that the reaction profile would be further extended. The new kit is now CE Marked but is available in the US as a 'Reference Use Only' product.

Acknowledgements

For their valued participation in the performance evaluation of the kit, we would like to acknowledge the following people and organisations:

C. Lomas-Francis
New York Blood Centre, NY, USA
G. Garretty
American Red Cross, Pomona, CA, USA
I. Bromlow
DiaMed AG, Switzerland
J. Poole
International Blood Group Reference Laboratory, Bristol, UK
J. R. Story
Blood Centre University Hospital Lund, Sweden
K.J. Reirs
Ortho Clinical Diagnostics Product Support, Raritan, NJ, USA
M. K. Moulds
Immucor Gamma, Houston, TX, USA
M. R. Crooks
Duke University Hospital, Durham, NC, USA
S.T. Johnson
Irish Blood Transfusion Service, Dublin, Ireland
F. Toffa
Immunohaematology Reference Laboratory, Milwaukee, WI, USA
W. J. Judd
New York State Blood Bank, Ann Arbor, MI, USA

We would also like to acknowledge Noel Brown of Alba Bioscience Inc., NC, USA, for his assistance in facilitating the evaluation.

References