

Reduction of Errors in Manual Antigen Phenotyping Processes

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Background There are no automated methods currently licensed to perform testing used for labeling units as antigen negative for Fya, Fyb, Jka, Jkb, S and s. Therefore, manual typing processes must be as sensitive, specific and error-proof as possible. Our laboratory performs thousands of antigen typings per month and although errors were rare, we sought to make process improvements designed to virtually eliminate them.

Methods Process improvements included changing manual typing for the six antigens on each sample from only one tester to two different testers, use of increased volume of antisera and increased incubation time to the maximum allowed for each by package insert for Fya and Fyb antigens and improved screening methods to ensure licensed manual typing was performed on the fewest number of samples possible. Manual typing errors, as determined by either donor phenotype history or confirmation typing by the collection facility, were tracked for 16-months (January 2006 – April 2007) for which routine manual tube typing was performed. The error rate was compared to the rate of equivalent manual typing errors for 10-months (May 2007 – March 2008) after implementation of the multiple process improvements.

Results The number of antigens tested each day varied, however, all antigen typing for the entire period of time started with 100 samples each day. The total number of tests performed between January 2006 and April 2007 was approximately 48,000 and the reported number of typing errors was 92. The total number of tests performed between May 2007 and March 2008 was approximately 30,000 and the reported number of typing errors was only 9. The error rate per sample for the baseline period was 0.19 % and the error rate per sample after process improvements were made was 0.03%. This represents a reduction in manual process errors of over 84%

Conclusion The process improvements implemented were successful at significantly reducing the number of manual typing errors. The cost of performing the testing increased due to use of more labor and reagents per sample. However, the additional expense associated with these process improvements was mitigated by using unlicensed antisera or donor plasma for antigen screening and for one set of the duplicate manual typing tests.

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