

Comparison of Antibody Detection Before and After Ortho 0.8% Reformulation

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Background

In January 2006, Ortho Clinical Diagnostics, Inc. issued a notification stating that its 0.8% Selectogen® and 0.8% Resolve® reagent red cells, used for antibody detection in the ID-MTS GEL® system, were in the process of being reformulated. The reformulation was intended to increase sensitivity to weakly reacting antibodies, particularly anti-E and –K. Customers were initially notified of potential low sensitivity to weakly reacting antibodies in December 2003. ACL Laboratories received the reformulated reagents in April 2007 and put them into use on 05/06/2007.

Method

A retrospective study was performed to compare the frequency and specificity of new antibody identification involving two different patient populations, hospital inpatients at Aurora St. Luke's Medical Center (ASLMC) and outreach patients from ACL Laboratories, pre and post implementation of the reformulated red cell reagents. Transfusion Service records were reviewed to collect data on new antibodies and their specificities from 01/01/2007 to 05/05/2007 (prior to reformulation) and from 05/06/2007 to 08/04/2007 (post reformulation).

Results

Total new antibodies detected per total antibody detection tests performed for the pre- and post-reformulation periods was 127 of 6387 (2.0%) and 134 of 4708 (2.8%), respectively for inpatients; and 93 of 8338 (1.1%) and 79 of 6014 (1.3%) respectively for outreach patients. Number and specificity of new antibodies detected is listed in the table below.

Antibody Specificity	Hospital Inpatients				Outreach Patients			
	Pre Reformulation		Post Reformulation		Pre Reformulation		Post Reformulation	
	# Detected	% of Total	# Detected	% of Total	# Detected	% of Total	# Detected	% of Total
D	14	11.0	8	5.9	52	55.9	52	65.8
C	3	2.4	7	5.2	1	1.1	0	0
E	21	16.5	21	15.7	8	8.6	5	6.3
c	7	5.5	7	5.2	1	1.1	0	0
e	0	0	0	0	0	0	0	0
C ^w	1	0.8	4	3.0	0	0	0	0
K	20	15.7	18	13.4	3	3.2	2	2.5
M	4	3.1	3	2.2	8	8.6	4	5.1
S	6	4.7	4	3.0	1	1.1	0	0
P ₁	2	1.6	0	0	0	0	0	0
Kidd	11	8.7	10	7.5	3	3.2	2	2.5
Duffy	10	7.9	11	8.2	1	1.1	0	0
Lewis	1	0.8	5	3.7	9	9.7	8	10.1
WAA	9	7.1	11	8.2	1	1.1	4	5.1
CAA	2	1.6	7	5.2	1	1.1	1	1.3
Other	16	12.6	18	13.4	4	4.3	1	1.3

Total	127	134	93	79
Rate of Detection	1.02 / Day	1.47 / Day	0.74 / Day	0.87 / Day

Conclusion

Reformulation did not significantly impact the number and specificities of new antibodies detected. There was slightly fewer anti-E and –K detected after reformulation; however, this study looked only at detection of new antibodies (no previous history on record) versus testing actual sensitivity using known antibody positive patients as a point of comparison.