Increased Reactivity of Immucor Capture-P® Indicator Red Cells and Platelet Antibody Screens

Sarai Paradiso¹, Ellen Christenson¹, Kim Greco¹, Donna Strauss¹
¹Core Operations, New York Blood Center, NY

BACKGROUND

Immucor Capture-P® Indicator Red Cells are coated with Anti-IgG and are used in conjunction with the Capture-P Ready Screen solid phase assay for the detection of IgG antibodies to platelets. Immucor issued a recall in March 2013 due to reduced reactivity observed with the Capture-P® Indicator Red Cells. Customers had reported weaker than expected reactions for the Positive control in the assay and reduced reaction strength as the Capture-P® Indicator Red Cells approached expiration. Immucor identified an issue with the raw material used and manufacturing process, and took steps to correct the problems. New Capture-P® Indicator Red Cells were released for use in early 2014.

MATERIALS AND METHODS

Platelet Antibody screening data from the past ten years was analyzed to see what effect, if any, the new Capture-P® Indicator Red Cells had on the percentage of positive antibody screens observed.

SCREENING RESULTS

The Laboratory performed an annual average of 220 Platelet Antibody Screens using the Capture-P Ready Screen solid phase assay with Capture-P® Indicator Red Cells, prior to the recall. Positive reactions indicating the presence of an antibody were consistently low, averaging at 29% from 2006 to 2012. The laboratory ceased testing in 2013 due to the unavailability of the Capture-P® Indicator Red Cells and resumed testing in 2014, after the performance issues were corrected by Immucor. Stronger reactions were observed with the use of the modified Capture-P® Indicator Red Cells. There was also a marked increase in the number of positive platelet antibody screens. Data was compiled for testing performed from 2014 to 2016, and platelet antibodies were detected at a rate of 67% - 74%.

CONCLUSIONS

The vast majority of these contained only HLA antibodies at 69%. Since the implementation of the modified Capture-P® Indicator Red Cells, there has been a steady increase in the detection of both antibody types that is directly proportional to the decrease of samples expressing only HLA antibodies. Rate of detection of both antibody types in samples tested from 2014 to 2016 was 58%, 66% and 75%, respectively. With the exception of a higher percentage in 2007, the number of positive samples expressing only platelet-specific antibodies has remained relatively unchanged averaging at 5%.

The laboratory performed further testing on positive antibody screens in order to classify the type of antibodies detected. The positive Capture-P Ready Screen plates were treated with Chloroquine to remove HLA antigens from the cells. This method is used to determine if the positive reactions are due to the presence of platelet-specific antibodies, HLA antibodies, or a combination of both. Samples with positive reactions that turn negative after the Chloroquine treatment are classified as expressing only HLA antibodies. The data collected from 2006 to 2016 was further analyzed to evaluate any changes in the type of antibodies detected as a result of the modification to the Capture-P® Indicator Red Cells. Typically, the presence of both HLA and platelet-specific antibodies were detected in 55% of the positive antibody screens obtained from 2006 to 2011. There was a dramatic shift in 2012 (the year preceding the recall) and detection of both antibody types was observed in only 28% of the samples.

The vast majority of these contained only HLA antibodies at 69%. Since the implementation of the modified Capture-P® Indicator Red Cells, there has been a steady increase in the detection of both antibody types that is directly proportional to the decrease of samples expressing only HLA antibodies. Rate of detection of both antibody types in samples tested from 2014 to 2016 was 58%, 66% and 75%, respectively. With the exception of a higher percentage in 2007, the number of positive samples expressing only platelet-specific antibodies has remained relatively unchanged averaging at 5%.

The laboratory performed further testing on positive antibody screens in order to classify the type of antibodies detected. The positive Capture-P Ready Screen plates were treated with Chloroquine to remove HLA antigens from the cells. This method is used to determine if the positive reactions are due to the presence of platelet-specific antibodies, HLA antibodies, or a combination of both. Samples with positive reactions that turn negative after the Chloroquine treatment are classified as expressing only HLA antibodies. The data collected from 2006 to 2016 was further analyzed to evaluate any changes in the type of antibodies detected as a result of the modification to the Capture-P® Indicator Red Cells. Typically, the presence of both HLA and platelet-specific antibodies were detected in 55% of the positive antibody screens obtained from 2006 to 2011. There was a dramatic shift in 2012 (the year preceding the recall) and detection of both antibody types was observed in only 28% of the samples.

The vast majority of these contained only HLA antibodies at 69%. Since the implementation of the modified Capture-P® Indicator Red Cells, there has been a steady increase in the detection of both antibody types that is directly proportional to the decrease of samples expressing only HLA antibodies. Rate of detection of both antibody types in samples tested from 2014 to 2016 was 58%, 66% and 75%, respectively. With the exception of a higher percentage in 2007, the number of positive samples expressing only platelet-specific antibodies has remained relatively unchanged averaging at 5%.

The vast majority of these contained only HLA antibodies at 69%. Since the implementation of the modified Capture-P® Indicator Red Cells, there has been a steady increase in the detection of both antibody types that is directly proportional to the decrease of samples expressing only HLA antibodies. Rate of detection of both antibody types in samples tested from 2014 to 2016 was 58%, 66% and 75%, respectively. With the exception of a higher percentage in 2007, the number of positive samples expressing only platelet-specific antibodies has remained relatively unchanged averaging at 5%.

The vast majority of these contained only HLA antibodies at 69%. Since the implementation of the modified Capture-P® Indicator Red Cells, there has been a steady increase in the detection of both antibody types that is directly proportional to the decrease of samples expressing only HLA antibodies. Rate of detection of both antibody types in samples tested from 2014 to 2016 was 58%, 66% and 75%, respectively. With the exception of a higher percentage in 2007, the number of positive samples expressing only platelet-specific antibodies has remained relatively unchanged averaging at 5%.