



An Assessment of the Reliability of Platelet-Associated Flags Generated by the Sysmex XE-5000 Automated Hematology Analyzer in Detecting Platelet Clumps

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Background

XE-5000 is an automated hematology analyzer utilized by clinical laboratories worldwide to perform CBC and differential leukocyte counts on EDTA-anticoagulated blood specimens. The overall reliability of the results generated by this analyzer has been assessed and found acceptable for clinical use. The CBC results generated on some of the blood specimens are, however, flagged by the analyzer for verification of the result of the flagged parameter by other means. One such parameter of clinical significance is the automated platelet count, which is often unreliable if the blood specimen contains platelet clumps.

Objective

The aim of this study was to determine the sensitivity, specificity, efficiency, predictive value of positive (PVP), and predictive value of negative (PVN) of the two platelet-associated flags generated relatively frequently by this analyzer.

Design

To Determine Sensitivity, Specificity, and Efficiency: The CBC results of 200 selected blood specimens were reviewed for the presence of analyzer-generated platelet-associated flags, which included the abnormal platelet size distribution (PAD) flag and platelet clumps (CLP) flag. One-half of the selected specimens were positive for platelet clumps and/or fibrin strands by microscopic review and the remaining 100 were negative. The sensitivity was defined as the percentage of specimens revealing either or both of the analyzer-generated flags among the morphologically positive cases. The specificity was defined as the percentage of specimens revealing neither flag among the morphologically negative cases. The efficiency was defined as the percentage of specimens correctly flagged by the analyzer as either true positive or true negative among this group of 200 specimens.

To Determine Predictive Value of Positive (PVP): Blood smears of 250 specimens flagged by the analyzer either for the PAD (N=100) or the CLP (N=100), or both flags (N = 50) were reviewed for the presence of platelet clumps and fibrin strands. The PVP was defined as the percentage of flagged specimens revealing platelet clumps and/or fibrin strands by microscopic review.

To Determine Predictive Value of Negative (PVN): Blood smears of 100 specimens not flagged by the analyzer for any of the platelet-associated flags were reviewed for the presence of platelet clumps and fibrin strands. The PVN was defined as the percentage of specimens not revealing significant clumping or any fibrin strands by microscopic review. Significant clumping was defined as the degree of clumping that rendered the automated platelet count unreliable and consequently unreportable.

Results

Among the morphologically positive specimens, 42 were flagged for the PAD and 57 for the CLP, giving us the respective sensitivities of 42% and 57% (Table 1). Among the morphologically negative specimens, 17 were flagged for the PAD and 1 for the CLP, giving us the respective specificities of 83% and 99% (Table 2). The sensitivity did increase to 73% and specificity decreased to 82%, when a specimen was considered flagged for platelet clumps when either of the two flags or both flags were generated by the analyzer (Tables 1,2). The efficiencies for the PAD and the CLP flag, as determined from this set of data, were 63% and 78% respectively (Table 3). The respective PVPs for the PAD and CLP flags for detecting platelet clumps were 1% and 37% (Table 4). The PVN for the blood specimens not flagged by the analyzer for any of the platelet-associated flag was 100% (Table 5).

Table 1. Sensitivity of Sysmex XE 5000 in Detecting Platelet Clumps (N =100)

	# of Specimens		
Platelet-Associated Flag(s)	Flagged by Analyzer	Not Flagged by Analyzer	Sensitivity
Platelet Abnormal Distribution (PAD)	42	58	42%
Platelet Clump (CLP)	57	43	57%
PAD and/or CLP	73	27	73%
PAD and CLP	24	76	24%

Table 2. Specificity of Sysmex XE 5000 in Detecting Platelet Clumps (N =100)

	# of Specimens		
Platelet-Associated Flag(s)	Flagged by Analyzer	Not Flagged by Analyzer	Specificity
Platelet Abnormal Distribution (PAD)	17	83	83%
Platelet Clump (CLP)	1	99	99%
PAD and/or CLP	18	82	82%
PAD and CLP	18	82	82%

Table 3. Efficiency of Sysmex XE 5000 in Detecting Platelet Clumps (N =100)

	# of Specimens Correctly Flagged	
Platelet-Associated Flag(s)	By Analyzer	Efficiency
Platelet Abnormal Distribution (PAD), N = 200	126	63%
Platelet Clump (CLP), N = 200	156	78%
PAD and/or CLP (N = 200)	156	78%
PAD and CLP (N = 50)	24	56%

Table 4. PVP for Platelet-Associated Flags Generated by Sysmex XE 5000 in Detecting Platelet Clumps

	# of Specimens		
Platelet-Associated Flag(s)	Pos for clumps/ fibrin	Neg for clump & fibrin	PVP
Platelet Abnormal Distribution (PAD), N=100	1	99	1%
Platelet Clump (CLP), N=100	37	63	37%
PAD and CLP, N = 50	24	19	56%

Table 5. PVN for Platelet-Associated Flags Generated by Sysmex XE 5000 in Detecting Platelet Clumps (N =100)

	# of Specimens		
Platelet-Associated Flags	Pos for clumps	Pos for fibrin	PVN
None of the two (PAD and CLP)	0	0	100%

Table 6. Sensitivity, Specificity, Efficiency, PVP, and PVN for Platelet-Associated Flags Generated by Sysmex XE 5000 in Detecting Platelet Clumps

Platelet-Associated Flags	Sensitivity	Specificity	Efficiency	PVP	PVN
Generated by the Analyzer	N = 100	N = 100	N = 200	N = 100	N = 100
Platelet Abnormal Distribution Flag (PAD)	42%	83%	63%	1%	NA*
Platelet Clump Flag (CLP)	57%	99%	78%	37%	NA*
PAD and/or CLP	73%	82%	78%	NA*	NA*
PAD and CLP (N = 50**)	24%	82%	53%	50%**	NA*
Neither PAD nor CLP	NA*	NA*	NA*	NA*	100%

Conclusions

Between the two platelet-associated flags assessed for their ability to detect platelet clumps, the CLP was found to be relatively more reliable with a sensitivity of 57%, specificity of 99%, PVP of 37%, and overall efficiency of 78%. The PVN when neither the PAD nor the CLP flag was generated by the analyzer was 100%. The PAD flag by itself or in combination with the CLP flag does not improve either the efficiency or the overall reliability of the analyzer in detecting platelet clumps. In order to maximize the sensitivity while maintaining the specificity, it is highly desirable that (a) users of the XE-5000 analyzer utilize the CLP flag along with one or more additional criteria to verify the automated platelet count by smear review and (b) manufacturer of the analyzer continue efforts to enhance the automatic detectability of platelet clumps to the desirable level of at or close to 100%. The clinical laboratory at our institution routinely verifies automated platelet count by smear review if it is (a) accompanied by the CLP flag, (b) below 100,000 per uL on initial encounter, and/or (c) reveals delta failure with a >/= 50% drop from the recent past count. These criteria were chosen to ensure patient safety in a cost-effective way with the assumption that the likelihood of patient being subjected to unnecessary platelet transfusion, additional diagnostic work-up, and/or other undue measures is very low under such circumstances.

References

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