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Coag QA: Why are we Different?



































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THE FRITSMA FACTOR Your Interactive	Lot to Lot: ACL Units (ACUs) Variance Limit 10%; Systematic Error?					
Hemostasis Resource	Initial run (Unacceptable)	Old Kit ACUs	New Kit ACUs	% Variance		
	Low specimen	7	6	-14%√		
	Mid-low specimen (Mix)	12	12	0%		
	Middle specimen (Mix)	20.5	19.4	-5%		
	Mid-high Specimen (Mix)	31	27	-20%√		
	High specimen	48	48	0%		
	Low control (from kit)	9	11	+8%		
VORIE	Middle control (from kit)	22	24	+8%		
AND -	High control (from kit)	48	49	+2%		





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THE FRITSMA FACTOR Your Interactive Hemostasis Resource	Comparing Methods for Clinical Efficacy Assay ≥30 specimens – Include low, mid-range, high levels 				
	Disease or Condition:	Absent	Present	Title	
	Or Reference Test:	Normal	Abnormal	Iotal	
	New Test Normal	True Neg	False Neg	Sum	
	New Test Abnormal	False Pos	True Pos	Sum	
SHOK	Total	Sum	Sum	Grand Sum	
	User Protocol for Evaluation of Guideline - Second Edition. C	of Qualitative Test LSI Document E	t Performance; A P12A2. CLSI, W	approved ayne, PA, 2008. 40	









THE FRITSMA FACTOR Your Interactive Hemostasis Resource	Detection Rate for Clopidogrel P_2Y_{12} Receptor Blockade Determine % sensitivity: TP ÷ (TP+FN) × 100						
	Detection rates of P ₂ Y ₁₂ -receptor blockade by clopidogrel						ogrel
	Method	PFA P2Y 3.2%	PFA P2Y 3.8%	VN P2Y12	LTA 20 µM ADP	WBA 5 µM ADP	WBA 10 µM ADP
	Sensitivity	59%	95%	60%	88%	89%	72%
PFA P2Y: Siemens PFA 100/200 P2Y12 cartridge; VN: Accumetrics VerifyNow P2Y12 cartridge; LTA: light transmittance aggregometry; WBA: whole blood aggregometry						WBA:	
		y.					45

THE FRITSMA FACTOR Your Interactive	% Concordance Among Detection Methods Using The Clinical Sensitivity Formula
Hemostasis Resource	Concordance with P5472 5 µM 10 µM 20 µM ADP ADP
	71% 64% 65% 69%
	VN WBA WBA LTA Concordance with P2Y12 5 μM 10 μM 20 μM
	71% 90% 90% 76%
YORK	Concordance with 5-ML 10-ML 20-ML
R	VN P2Y12 5 µM 10 µM 20 µM
	68% 67% 72%
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THE FRITSMA FACTOR	ROC Analysis	
Your Interactive Hemostasis Resource	 Receiver operating characteristic analysis A graph of the true positive rate versus the false positive rate in a binary system as its discrimination threshold (limit, "cutoff") is incrementally varied Assay quality is assessed as area under the curve (AUC) 	
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