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Malfunction Coatron X: Poor correlation of Blue D-Dimer to STAGO Liatest D-Di

Error description:
Teco Instrument+Reagent give different D-Dimer results in compare to Stago for some patients. Sometimes negative at TECO, but positive at Stago or high positive at TECO, but low or mid positive at Stago or reverse.

	Coatron A 6+			Stago			Teco	Stago
	Normal run	1:5 run	1:10 run	Normal run	1:5 run	1:10 run		
Patient 1	0.06	0.09	0.12	0.97	0.19	0.12	True negative	False positive
Patient 2	5.99	1.04	0.39	3.76			True positive	True positive
Patient 3	2.27			2.15			True positive	True positive

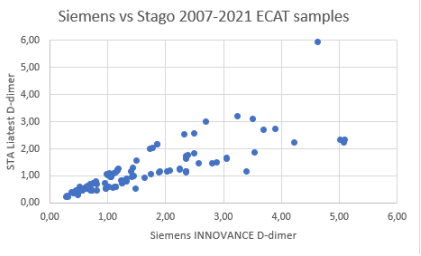
Table-1: Shows D-Dimer concentrations expressed in µg/mL (FEU). Sample pre-dilution can help to verify trueness.

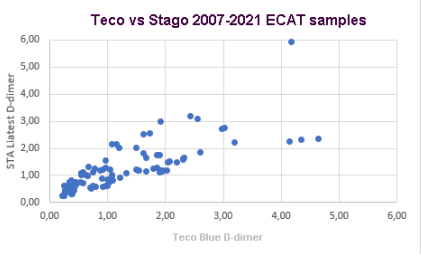
Reasons:

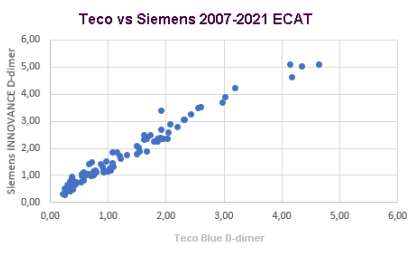
a) Confusion of DDU vs. FEU
Between DDU and FEU is a factor 2.5 (200ng/mL DDU is equivalent to 500 ng/mL)
It is important, that both systems uses equivalent calibration.

b) High Dose Hook effects
This effect leads to false negative due to lack of antibodies. It can be detected by re-run sample prediluted 1:10. If a negative sample (eg. 200ng) gives 5-10x higher results with 1:10 predilution, then it was measured false negative.

c) Type of antibodies in the latex suspension
Teco Blue D-Dimer reagent uses MA-8D3. It is a monoclonal antibody only sensitive to D-Dimer (D-fragments). STAGO uses two antibodies (MA-8D2 and 2.1.16) and is sensitive to D-Dimer and FDP (fibrinogen degradation products like E fragment). Samples with high FDP concentration can lead to overestimation of D-dimer levels and reverse. The charts below show the correlation between Teco Blue d-dimer versus Siemens Innovance D-Dimer versus Stago Liatest D-Di.







Who is true and who is false?

Patient 1 was repeated 1:5 and 1:10 prediluted on Teco and gives every time D-dimer close to zero. The high dose hook effect can be excluded. The sample is D-Dimer negative, but FDP positive. Again, D-Dimer and FDP is not the same!

Patient 2 was repeated 1:5 and 1:10 prediluted on Teco and gave around 5 and 10x less DD concentration. This is a very high indicator, that patient is true 6µg/mL (FEU). There might be a high dose hook effect with Stago. Or the difference was caused by different D-Dimer calibrators.

General

TECO	Other	Possible reasons
DD positive	DD negative	-High Dose Hook Effect on Other
DD negative	DD positive	-High Dose Hook Effect on Coatron -Patient has high FDP (E-fragments), but TECO reagent is only sensitive to D-fragments.