Evaluation of the TOSOH Bioscience ST AIA-Pack DDimer performed with the AIA-360 automate

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Introduction

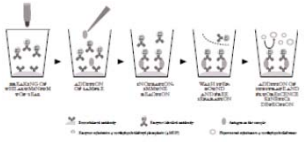
- Ddimer is a degradation product formed as a result of the action of plasmin on cross-linked fibrin
- Raised Ddimer levels are observed in diseases and conditions associated with increased coagulation activation and can also be used in the exclusion of thromboembolic events (VTE) e.g. deep vein thrombosis or pulmonary embolism
- The TOSOH ST AIA-PACK D-dimer performed with the AIA system analyser provides a portable benchtop system offering random access and continuous loading of both samples and reagents with a 90 day calibration stability, interfacing for potential connection to a laboratory information system and full on-board QC package, thus making it suitable for satellite (off site) laboratory testing

Aim

A critical evaluation of the TOSOH ST AIA-PACK Ddimer test on the AIA-360 automate

Fig. 1
TOSOH AIA-360 Instrument

Fig 2. AIA 2-site immunoenzymometric test cup system



Method

The TOSOH ST AIA-PACK Ddimer is a 2-site immunoenzymometric assay which, for the purpose of this study, was performed entirely on the TOSOH automated enzyme immunoassay system AIA 360 instrument (Fig. 1) in the ST AIA-PACK Ddimer test cups (Fig. 2)

Our study included:

- An assessment of the overall suitability of the TOSOH reagent/analyser test system
- Inter- and intra-assay precision at two Ddimer concentration levels
- Comparison of TOSOH AIA data with that obtained using Siemens Innovance, including 'normal' subjects, and subjects for exclusion of VTE and investigation of possible disseminated intravascular coagulation (DIC)

Results

Assay Calibration:

Ddimer assay calibration curves spanned a concentration range of approximately 0–19000ng/ml.

Three 6-point calibration curves were performed over the course of the study with R^2 values ranging from 0.9997 – 1.0000

Linearity

Linearity of the assay was assessed using plasma from patients with significantly increased Ddimer concentrations: 8000, 14000 and 20000ng/ml (approx.)

The calculated R^2 values for a range of dilutions (1/1 - 1/64) from each of the three plasmas were 0.9988, 0.9992 and 0.9985 respectively.

Fig 3: Normals

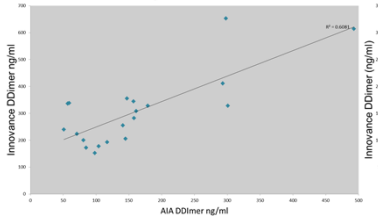


Fig 4: Suspected DVT

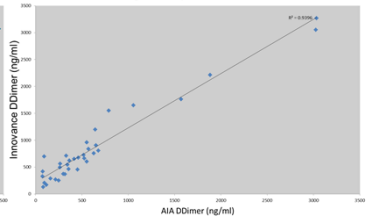


Fig 5: Possible DIC (n=41)

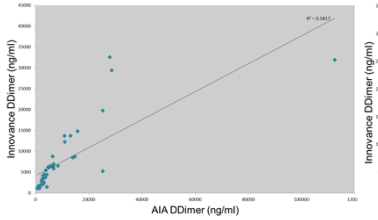


Fig 6: Possible DIC (excluding 2 outliers n=39)

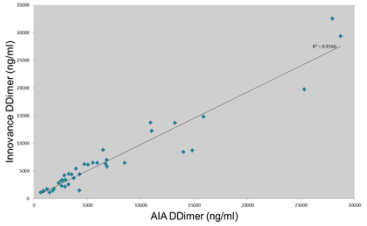


Fig 7: All clinical groups

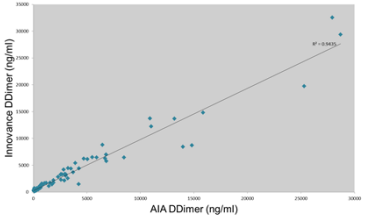


Table 1: Intra assay precision of TOSOH Ddimer AIA test system

	Level 1	Level 2	Level 3
Mean Ddimer concentration (ng/ml)	350	570	2810
N	12	12	12
SD	10	20	60
CV (%)	2.3	3.5	2.2

Table 2: Inter assay precision of TOSOH Ddimer AIA test system

	Control 1	Control 2
Mean Ddimer concentration (ng/ml)	477	7329
N	15	15
SD	19	264
CV (%)	4.1	3.6

Table 3: Comparison of TOSOH AIA and Siemens Innovance Ddimer (Normals and Patient groups)

	Normals		VTE exclusion		? DIC		? DIC (minus 2 outliers)	
	AIA	Innovance	AIA	Innovance	AIA	Innovance	AIA	Innovance
N	20	20	35	35	41	41	39	39
Mean Ddimer concentration (ng/ml)	160	306	621	846	10028	7539	7010	6974
Observed range	51-493	152-653	74-3033	131-653	616 -112474	1093-32538	616-28698	1093-32538
Correlation coefficient	r=0.7798		r=0.8925		r=0.9245		0.9574	
Significance (paired t test)	p<0.0001		p<0.0001		ns		ns	

Discussion

- Inter- and intra-assay precision of the AIA test system were consistently less than 5% (Table 1 and Table 2)
- Significant differences (p<0.0001) were observed between the mean Ddimer concentration as measured by the TOSOH AIA and Siemens Innovance Ddimer assay systems in 'Normal' and VTE exclusion subject groups (Table 3)
- Comparison of Ddimer concentrations in 'Normal', VTE exclusion, possible DIC and 'All clinical groups combined' demonstrated correlation of the TOSOH AIA and Siemens Innovance assay systems with 'r' values of 0.7798, 0.9693, 0.9574 (excluding two outliers) and 0.9713 respectively (Figs 3 – 7)

Conclusion

- The TOSOH Biosciences ST AIA-PACK Ddimer assay performed on the AIA-360 automate is a user friendly , robust system with acceptable levels of reproducibility and linearity over a wide concentration range (up to approx.16000ng/ml without the need for pre analysis dilution).
- In agreement with manufacturer's recommendations it would be necessary for each laboratory to determine a reference interval corresponding to the characteristics of the population to be tested.