

Evaluation of the TOSOH ST AIA-PACK D-DIMER

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INTRODUCTION

Plasma D-Dimer, a degradation product of cross-linked fibrin, has been validated as a diagnostic tool to help rule out, diagnose, and monitor diseases and conditions that cause hypercoagulability, a tendency to clot inappropriately. One of the most common of these conditions is DVT (Deep Vein Thrombosis) which involves clot formation in the deep veins of the body, most frequently in the legs. It is possible for a piece of the clot to break off and moved to other parts of the body, where the clot can cause a PE (Pulmonary embolus or embolism). The new Tosoh ST AIA-PACK D-Dimer was evaluated and compared with the Siemens-CA7000.

MATERIALS and METHODS

ST AIA-PACK D-Dimer (FEIA) (Tosoh Bioscience, Tokio, Japan): an enzyme immunoassay which is performed entirely in the test cups. The sample is automatically pipette into the test cup. D-Dimer present in the sample bind to the antibodies coated on the beads and binds to enzyme-labeled anti-d-dimer antibody. After 10 minutes incubation at 37°C, the magnetic beads are washed to remove unbound materials and are then incubated at 37°C with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme labeled antibody that binds to the magnetic beads is directly proportional to the concentration of D-Dimer in the sample.

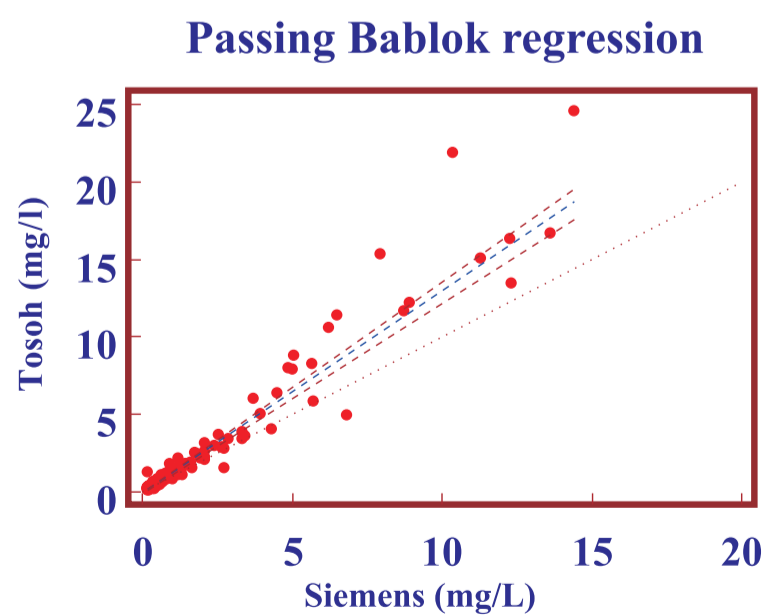
CORRELATION: a correlation study was performed using 137 patient samples (males and females of different ages) with a routine request for D-Dimer. Results were compared with the Siemens Innovance D-dimer kit, an immunoturbidimetric enhanced latex system on the CA7000 (Siemens). The cut-off of this method is 0.50 mg/L FEU; the imprecision is 7.3% CV for normal values and 8.0% CV for pathological values

REPRODUCIBILITY: A 20 day reproducibility was performed using AIA-PACK D-dimer control.

RESULTS

	Siemens (X)	Tosoh (Y)
Lowest	0.18	0.1
Highest	14.4	24.5
Mean	1.95	2.59
Median	0.78	1
Slope	1.3	
Intercept	-0.07	

Table 1: correlation data



Date	Control 1	Control 2
1	0.92	4.74
2	0.83	5.01
3	0.75	4.64
4	1.06	4.25
5	1.06	5.49
6	0.96	5.34
7	0.92	5.30
8	0.95	5.16
9	0.88	5.33
10	0.87	5.22
11	0.86	4.81
12	0.90	4.79
13	0.85	4.58
14	0.89	4.96
15	0.86	4.95
16	0.96	5.07
17	0.85	4.94
18	0.92	5.01
19	0.87	4.98
20	1.03	5.32
Mean	0.91	4.99
SD	0.08	0.30
% CV	8.6	6.1

Table 2: reproducibility

DISCUSSION

The TOSOH ST AIA-PACK D-Dimer correlates well with the Siemens – CA7000 with the Passing Bablok linear regression equation: $Tosoh = 1.3 * Siemens - 0.07$, and a correlation coefficient of 0.97. The Tosoh test showed a linearity from 12 mg/L to 0.5 mg/L. Our results demonstrate that TOSOH ST AIA-PACK D-Dimer shows a good performance and can be adopted to monitor and diagnose the hypercoagulability.