# EVALUATION OF THE TOSOH ST AIA-PACK D-DIMER

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## Introduction

D-dimer, a fibrin degradation product, testing has been proposed as diagnostic marker with high sensitivity for exclusion of an inappropriate blood clot (thrombus) like in deep vein thrombosis and pulmonary embolism.
The TOSOH ST AIA-PACK D-dimer performed with the AIA-360 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

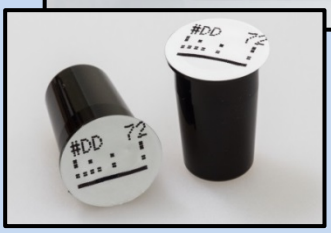
## Aim

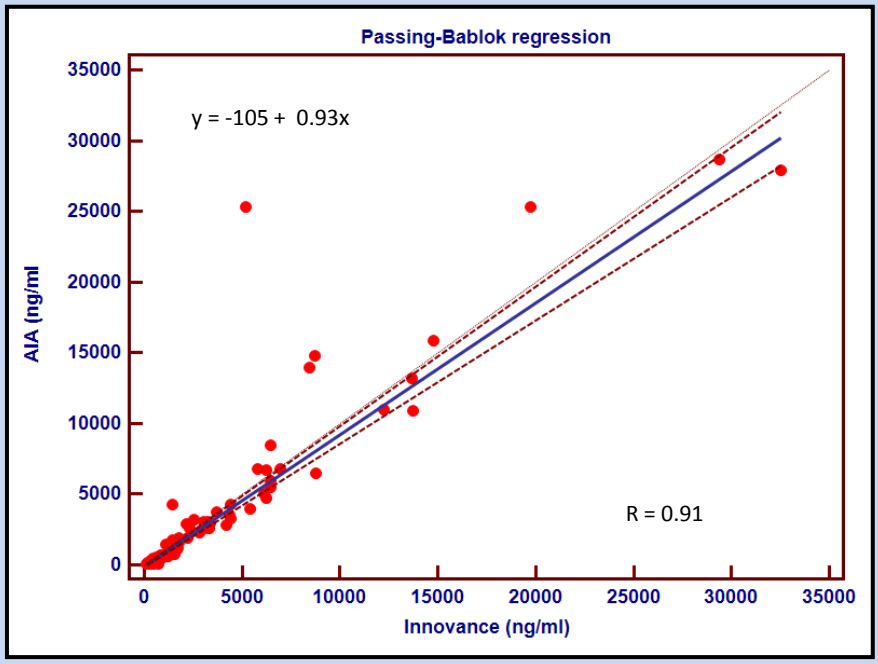
In this study the general characteristics of Tosoh ST AIA-PACK D-Dimer performed with the small AIA-360 were evaluated and comparison with the Siemens Innovance test was done.

## Method

The ST AIA-PACK D-Dimer reagent is an enzyme immunoassay which is performed entirely in a single cup. D-Dimer in the sample is bound with monoclonal antibody immobilized on magnetic beads and alkaline phosphatase-labelled monoclonal antibody. After 10 minutes incubation at 37°C the beads are washed to remove unbound materials and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate. The amount of enzyme-labelled monoclonal antibody that binds to the beads is directly proportional to the D-Dimer concentration in the sample.

| | Intra assay precision | | | Inter assay precision | |
|---|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 |
| Mean D-Dimer conc. (ng/ml) | 347 | 567 | 2809 | 477 | 7329 |
| N | 12 | 12 | 12 | 15 | 15 |
| SD | 8 | 20 | 62 | 19 | 264 |
| % CV | 2.3 | 3.5 | 2.2 | 4.1 | 3.6 |


## Conclusion

The TOSOH Biosciences ST AIA-PACK D-dimer assay performed on the AIA-360 automate is a user friendly , robust system with high levels of reproducibility and linearity over a wide concentration range (up to approx.16000ng/ml without the need for pre analysis dilution.