

## D-dimer: Empowering every Laboratory



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Venous Thromboembolism (VTE) is a common, lethal disorder affecting hospitalized and non-hospitalized patients. Often overlooked, it recurs frequently and results in long-term complications. VTE consists of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

VTE is one of the most common cardiovascular illness, third only to acute coronary syndrome and stroke.\* It contributes substantially to patient morbidity, mortality and cost of management.

The true incidence of VTE is hard to estimate. Here are some startling statistics:

- Average annual incidence of VTE among whites is 108 per 100,000 person years with about 250,000 incident cases occurring annually among US whites.\*\*
- A study spanning 19 Asian countries revealed that DVT occurred in 41% of patients undergoing major hip joint surgery without thrombo-prophylaxis.\*\*\*
- In another global epidemiological study consisting of 68,183 patients including 2,058 from India, 52% (55% medical and 45% surgical) were found at risk of developing VTE. In that study, 54% of hospitalized (45% medical and 61% surgical) Indian patients had risk factor for VTE.\*\*\*
- In one retrospective study, the incidence of VTE is reported to be 28% in south Indian population. \*\*\*\*
- The overall incidence of PE in adult medical autopsies was 15.9% (159/1,000) in a study from a tertiary care hospital in Northern India which also reported an incidence of 79.87% in younger population; those below the age of 50 years.\*\*\*\*\*

### **Testing Scenario in India**

D-dimer testing is of clinical use when there is a suspicion of VTE and is nowadays a commonly referred test. Unfortunately, not many laboratories in India can perform these tests due to limitations of manual systems. Most of the estimated 40,000 clinical laboratories in India still do not have this testing facility due to financial constraints, demographic challenges, non - availability of reliable tests kits and trained expertise.

### Different D-dimer Assays

There are multiple technologies available for D-dimer testing however, not all are specific, sensitive and at the same time affordable. Another limitation is that these kits are often available in large pack sizes, with reagents of limited expiry. As a result, a lot of prospect centres with a small workload, postpone the procurement decision.

### Comparison of various methods of D-dimer Assay

Method	Sample type	Sensitivity	Specificity	Calibration required	QC possible	System required	Remarks
Microplate ELISA	Plasma	High	Low	Yes	Yes.L-J possible	Manual	Long procedure with ELISA readers
Fluorescence Immuno Assay/ ELFA	Plasma	High	Low	Yes	Yes.L-J possible	Automated	Costly FIA System
Chemilumescence Systems	Plasma	High	Low	Yes	Yes.L-J possible	Automated	Costly CLIA System
Immunofiltration and Sandwich type Systems	Plasma	High	Low-High	No	No	Automated	Low specificity for boronate method
Semi Quantitative Latex agglutination slide tests	Plasma	Moderate	Moderate	No	Basic	Manual	Outdated slide test, manual
Manual Whole Blood agglutination Rapid test	Whole Blood	High-Moderate	Moderate	No	Basic	Manual	Kits not easily available
Second Generation Latex Agglutination Test	Plasma	High	Moderate	Yes	Yes.L-J possible	Automated	Possible only on fully automated system

### Empowering every Laboratory

Transasia Bio-Medicals Ltd., India's leading in-vitro diagnostic company has been at the forefront of offering quality diagnostic solutions at a reasonable cost. In over three decades of its existence, Transasia has regularly introduced innovative and advanced technology based on the requirements of the customers.

The latest semi-automated coagulation analyzers from Transasia, the ERBA ECL 105 and ECL 412 are equipped to perform the D-dimer assay. The ERBA D-dimer reagents are available in a small pack size of 50 tests only, with no reagent reconstitution. Moreover, it is ready to use with a stability of 4 weeks.

The affordability and easy availability of the D-dimer assay, ensures that every laboratory can perform this test, on the ECL 105 or ECL 412 semi automated, coagulation platform.



## References

\*<http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/venous-thromboembolism/Default.htm>)

\*\*<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2873781/>

\*\*\*<http://www.nmji.in/archives/Volume-23/Issue-4/PDF-volume-23-issue-4/Editorial.pdf>

\*\*\*\*<http://www.japi.org/january2007/R-49.htm>

\*\*\*\*\*<http://www.ncbi.nlm.nih.gov/pubmed/18160596>

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