

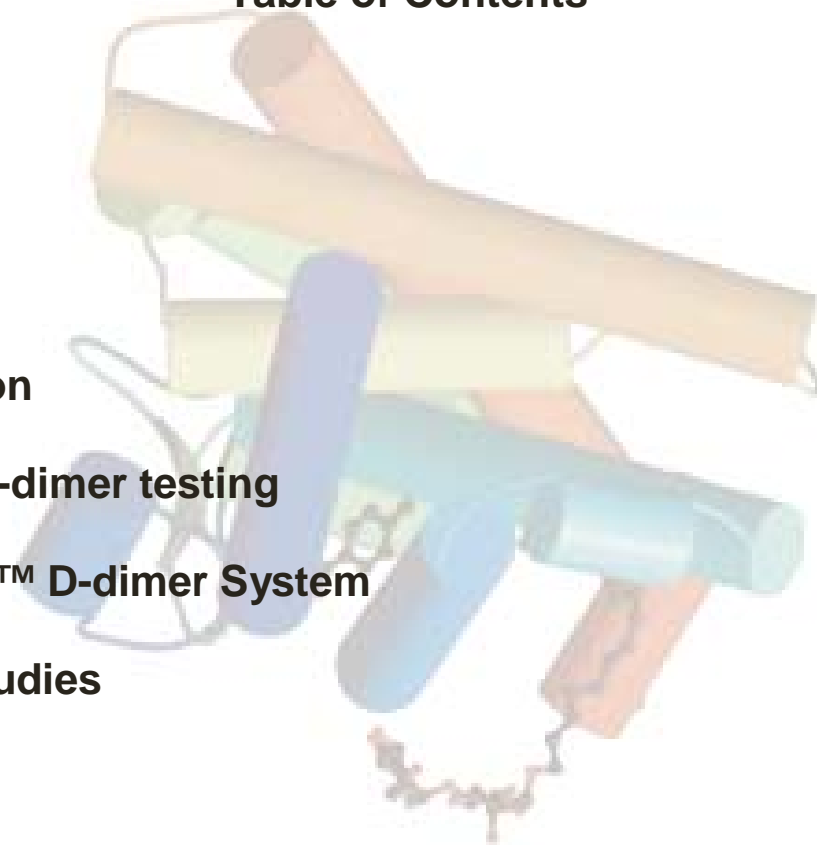
MiniQuant™ D-dimer System

By
Trinity Biotech, Inc.



Scientific Package

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A 3D ribbon diagram of a protein structure, likely a D-dimer, shown in various colors (orange, blue, green, yellow) to represent different parts of the molecule. The structure is complex and multi-domain.

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Everse, S.J., Spraggon, G., Verrapandian, L., Doolittle, R.F.: Crystal structure of fragment double – D from human fibrin with two different bound ligands. *Biochemistry* 37 pp 8637 (1998)

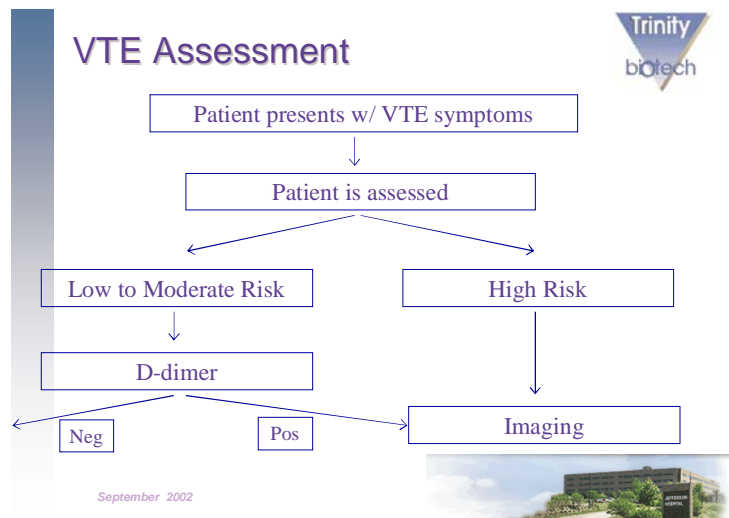
Introduction

The frequency of diagnosed venous thromboembolism (VTE) in the U.S. general population is approximately 1.5 percent.¹ VTE is diagnosed primarily through the use of imaging studies, which are expensive, time-consuming and carry a level of morbidity and mortality. A variety of clinical conditions mimic the symptoms of VTE - only 30% of Emergency Room patients presenting with VTE symptoms are diagnosed with VTE. Because of this low positive percentage, coupled with the disease's consequences and severity, VTE diagnosis needs to be cost-effective, rapid and accurate. It is not cost-effective or worth patient risk to subject all patients presenting with VTE symptoms to imaging studies. D-dimer, a marker for fibrinolysis, is sensitive for VTE and when used in conjunction with preclinical assessment and imaging studies, this assay provides a cost-effective utility in the diagnosis of VTE.²

Utility of the D-dimer assay

Diagnosis of deep venous thrombosis (DVT) and pulmonary embolism (PE) is often achieved through the use of diagnostic algorithms (figure 1) including a pre-clinical probability categorization, imaging studies, and the use of D-dimer assays.^{3,4} A patient presenting with a negative D-dimer test and a low clinical probability is at low risk for VTE and may be ruled out for further testing (imaging).^{3,5}

Figure 1 – Typical algorithm for VTE Assessment



1 Bick RL, Kaplan H. Syndromes of Thrombosis and Hypercoagulability. Medical Clinics of North America May 1998; 82: 409-458.

2 Perrier A, Bounameas H, Cost-effective diagnosis of deep venous thrombosis and pulmonary embolism. Thromb Haemost Jul 2001; 86(1): 475-87.

3 Perrier A, Desmarais G, Harrison K, et al. Non-invasive diagnosis of venous thromboembolism in outpatients. Lancet. 1999; 353:190.

4 Melnick J, Goldstein N, Kollef M, et al. D-Dimer testing in the evaluation of acute pulmonary embolism and deep vein thrombosis. Barnes-Jewish Hospital Newsletter 2000; 6:(3) 1.

5 Hansson P, Eriksson H, Eriksson E, et al. Can laboratory testing improve screening strategies for deep vein thrombosis at an emergency unit? J Int Med. 1994; 235:143.

When used in testing algorithms a D-dimer assay with good predictive values coupled with a short turn-around-time provides an effective screen for ruling out patients with low risk for VTE. It can be an effective tool, controlling hospital costs and providing quality patient care. Table 1 demonstrates the use of D-dimer assays in different testing algorithms as related to patient care costs and patient outcome.

Table 1 - Cost Effectiveness of the D-dimer Assay in DVT/PE Strategy†

DVT Strategy	Lives Saved/1000 Patients	Cost/Additional QALY Saved (\$)
<i>-Venography (\$15,475/QALY)</i>	4.3	15,475
-Venography & D-dimer	4.3	14,934
-Clinical Probability & Venography	4.4	14,339
-Clinical Probability, D-dimer, & Venography	4.2	13,115
PE Strategy	Lives Saved/1000 Patients	Cost/Additional QALY Saved (\$)
<i>-Helical CT (HCT) (\$3,439/QALY)</i>	28	3,439
-Lung Scan, Angiography	37	3,202
-Clinical Probability w/ D-dimer, Ultrasonography, HCT, Angiography	35	2,700
-Clinical Probability w/ D-dimer, Ultrasonography, Lung Scan, Angiography	38	2,467
-Clinical Probability w/ D-dimer, Ultrasonography, Lung Scan, HCT	36	2,447

†Perrier A, Bounameaux H, “Cost-effective diagnosis of deep venous thrombosis and pulmonary embolism”. *Thromb Haemost* Jul 2001, 86(1) p475-87.

QALY – Quality adjusted life year gained

MiniQuant™ D-dimer System



Specifications

- 2 channel LED analyzer
 - Capability to store the standard curve
 - Comes with printer and pipette
 - Uses MiniQuant™ D-dimer Reagent
- Methodology
 - Quantitative immunoturbidimetric assay
 - Antibody – MA8D3
 - Assay time – Less than 3 minutes
- Assay Range: 75-5000 $\mu\text{g/L}$ (D-dimer units)
(Samples $>3200 \mu\text{g/L}$ require dilution and re-assay)
No prozone (high dose) effect up to 225 000 $\mu\text{g/L}$ D-dimer
- Cutoff value: 200 $\mu\text{g/L}$ (D-dimer units)
- Precision
 - At levels of 250 $\mu\text{g/L}$ CV<10%
 - At levels of 700-5600 $\mu\text{g/L}$ CV<5%
- Predictive Values
 - 100% Negative Predictive Value for PE*
- MiniQuant™ D-dimer Reagent
 - Latex Stability: 4 weeks at 2-8 °C
 - Kit includes controls and calibrators

* Gosselin R, Owings J, Utter G, Jacoby R, Larkin E. A new method for measuring D-dimer using immunoturbidometry: a study of 255 patients with suspected pulmonary embolism and deep vein thrombosis. *Blood Coagulation and Fibrinolysis* 2000; 11:715-721.



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