Hemostasis Innovation is Here.

D-dimer for the Exclusion of venous thromboembolism (VTE)

Fact

VTE is the third-most-common cardiovascular disease worldwide, with 10 million estimated cases annually resulting in close to a million deaths.[1]

What is VTE?

VTE, also known as blood clots, can occur at any age and cause serious illness, disability, or death.

VTE refers to two conditions:

Deep Venous Thrombosis (DVT): A clot that forms in the deep veins, most commonly in the lower extremities.

- Affects up to 900,000 patients/year in the US[2]
- Incidence increases with age[3]
- 21% one-year mortality rate in the elderly[4]
- ~33% of individuals will have a recurrence within 10 years[2]

Pulmonary Embolism (PE): As DVT starts to lyse, clot fragments may break off and reach the pulmonary arteries.

- Represents 5–10% of all hospital deaths[5]
- 10–30% of patients will die within one month of diagnosis[2]
- 10% of patients who die from PE do so within the first hour of symptom onset[6]

Why a D-dimer assay?

Clinical utility of the D-dimer assay

For patients with a low or moderate pre-test probability (PTP) assessment model or score, a negative D-dimer assay can exclude the diagnosis of DVT or PE.

Because 90% of patients sent for a venous ultrasound for DVT are negative,[8] significant cost savings and reduced radiation exposure can result when unnecessary imaging studies are avoided.[9]

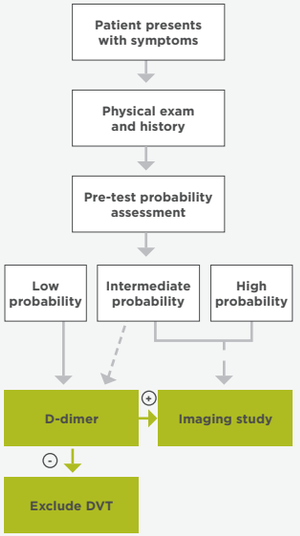
Therefore, significant cost savings can be realized by excluding VTE in the emergency department.[9]

The power of NPV

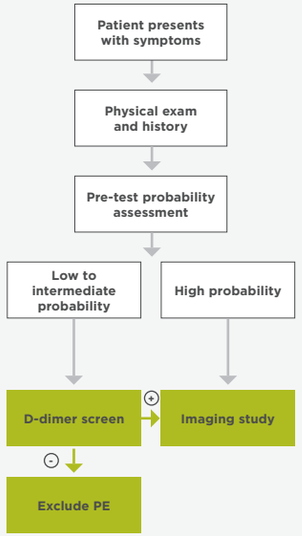
A positive D-dimer result does NOT confirm the presence of DVT or PE. The power of the D-dimer assay lies in its negative predictive value (NPV)—the ability to exclude the presence of DVT and/or PE, when used with a PTP score.

How to exclude VTE

DVT diagnostic algorithm[7]



PE diagnostic algorithm[7]



Selecting a D-dimer assay

Selection considerations for a D-dimer assay to exclude VTE:

- High NPV of the assay—100% is desirable
- Fast time to result
- 24/7 availability
- Reporting units: D-dimer Unit (DDU) or Fibrinogen Equivalent Unit (FEU)
- Well-established cutoff value
- Precision of the assay at the threshold value
- Cleared by regulatory authorities for "exclusion"

The performance characteristics of **HemosIL® D-Dimer HS** and **HemosIL D-Dimer HS 500 assays**, when used with a PTP score, make them the D-dimer assays of choice for the exclusion of VTE.[10,11]

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*The HemosIL D-Dimer Assay Panel includes: HemosIL D-Dimer, HemosIL D-Dimer HS, HemosIL D-Dimer HS 500 and HemosIL D-Dimer 500.

**HemosIL D-Dimer 500 is not 510(k)-cleared.

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Pre-test assessment models

Wells Scores for DVT and PE

The HemosIL D-Dimer Assay Panel* is intended for the exclusion of VTE, in conjunction with a PTP score (e.g., Wells scoring method).**

DVT

Clinical Characteristic	Score
Active cancer	1
Paralysis, paresis, plaster immobilization of lower extremity	1
Bedridden within 3 days, major surgery within 12 weeks	1
Local tenderness along deep venous system	1
Entire leg swollen	1
Calf swelling 3 cm > asymptomatic leg	1
Pitting edema on symptomatic leg	1
Collateral superficial veins	1
Alternative diagnosis at least as likely	-2
Previously documented DVT	1

Total score

>2 High probability

1–2 Intermediate/moderate probability

<1 Low probability

PE

Clinical Characteristic	Score
Clinical signs/symptoms of DVT	3
Previous DVT/PE	1.5
Immobilization or surgery in the previous 4 weeks	1.5
Malignancy	1
Hemoptysis	1
Heart rate >100 bpm	1.5
Alternative diagnosis is less likely	3

Total score

>6 High probability

2–6 Intermediate/moderate probability

<2 Low probability

CLSI guideline H59-A[12]

In 2011, The Clinical & Laboratory Standards Institute (CLSI) published guideline H59-A for the D-dimer assay, recommending the following characteristics:

- NPV ≥98%
- Sensitivity ≥97%
- Sufficient specificity to provide discrimination
- Good reproducibility at the level of the threshold for exclusion of VTE
- Well-established diagnostic threshold or cutoff value

D-dimer can be reported in different units:

- FEU: Mass of fibrinogen unit from which the D-dimer is derived
- DDU: Mass of the D-dimer

FEU is approximately 2x the mass of a DDU.

To avoid reporting results with incorrect units, CLSI H59-A recommends not converting between DDU and FEU.