

# Thrombosis diagnosis in an efficient & simple way.

The new Yumizen G D-Dimer reagent is available on the complete range of HORIBA Medical hemostasis systems, from semi-automatic to fully automated in liquid format, ready to use and precalibrated.

The D-Dimer parameter is a key measurement and the reference exclusion test for the diagnosis of deep vein thrombosis or pulmonary embolism, and may be used for monitoring Disseminated Intravascular Coagulation.

On semi-automatic systems, the combination of the Immuno-turbidimetric measurement capability of the Yumizen semi-automated range and precalibrated D-Dimer reagent provides a unique solution enhancing diagnostic capability of small laboratories.

## • Easy to use:

Pre-calibrated / Liquid format / Automatic configuration by barcode scan : Ready to run in simple steps

#### Cost efficient :

No calibrator required High stability with convenient reagent volumes (around 50 tests per vial / 2 weeks open stability)

## • High performances :

NPV 99%\*

No hook effect under 25 µg FEU/mL Slope check and post dilution function (from software version 2.02 for Yumizen G200, 2.06 for Yumizen G400) Linearity 0.22-4 µg FEU/mL

Cut off: 0.5 µg FEU/mL





D-Dimer reagents are also compatible with our fully automated hemostasis systems (Yumizen G800, G1500 & G1550).

(\*value determined on fully automatic Yumizen G systems)

## Yumizen G D-Dimer 2 (Cat. No.: 1300036391)

#### Method:

Particle enhanced immunoturbidimetric Test (Turbidimetry measurement at 570 nm)

### Package contents:

3 x 6.5 mL Buffer (nickel sulfate and preservative) 3 x 2.5 mL Latex (latex particle coated with monoclonal anti-human D-Dimer antibody)

165 tests/reagent kit

55 tests/vial (variable, depending on Yumizen G analyzer used)

#### Calibration:

Pre-determined Calibration Curve provided (Data entered by barcode)

#### Stability:

Stability after opening in the original vials of 2 weeks

#### **Specifications:**

Limit of Detection (LoD): 0.22 µg FEU/mL\* \*(on Yumizen G1550)

Measuring Range: 0.22-4.0 µg FEU/mL

High dose Hook Effect: No high dose Hook effect observed up to a

concentration of 25 µg FEU/mL. **Negative Predictive Value (NPV):** 

NPV ≥ 95%. The NPV was 99% in a clinical multicenter study on 162 samples.

#### Precision

	Intra-Assay		Inter-Assay	
Sample	1	2	3	4
n	20	20	10	10
Mean (µg FEU/mL)	0.609	2.910	0.602	2.883
CV (%)	6.444	4.202	3.475	3.953

## Additional Materials required:

Yumizen G CTRL DDi I & II; Cat. No.: 1300036414.

Yumizen G IMIDAZOL (Dilution Buffer); Cat. No.: 1300036385.

## **Known limitations:**

No interference detected with Rheumatoid factor under a concentration of 50 IU/mL

No cross-reactivity of the antibody with fibrinogen and E fragment. A low cross-reactivity is observed with the D fragment and the high molecular weight fragments, fibrin X and Y.























