HORIBA Medical

INSTRUCTION FOR USE

Yumizen G DDi 2

QUANTITATIVE D-DIMER TEST

Cat. No.: 1300036391 **3 x 6.5 ml Buffer**
3 x 2.5 ml Latex

PRODUCT NAME

Yumizen G DDi 2.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Yumizen G DDi 2 is a diagnostic test used for quantitative determination of D-dimer in plasma on photometric systems.

SUMMARY AND PRINCIPLE

Yumizen G DDi 2 is a particle enhanced immuno-turbidimetric test.

During plasma coagulation soluble fibrin is generated by the influence of thrombin on fibrinogen. The soluble fibrin is cross-linked to the vessel walls by factor XIIIa. When splitting this cross-linked fibrin, characteristic products called D-dimers are released. Increased D-dimer concentrations are found in thrombotic diseases and micro thrombotic events (e.g. in case of disseminated intravascular coagulation: DIC). D-dimer determination is mainly used to rule out deep vein thrombosis (DVT) of the leg and pulmonary embolism (PE).

PRINCIPLE

Yumizen G DDi 2 test is based on fixed time determination of the D-dimer concentration by photometric measurement of antigen-antibody-reaction between antibodies against D-dimer bound to particles and D-dimer present in the sample.

ACTIVE INGREDIENTS

Yumizen G DDi 2 Buffer (R1) is a buffer.

Yumizen G DDi 2 Latex (R2) is a latex particle coated with monoclonal anti-human D-dimer antibody and contains preservative.

PRECAUTIONS

- Person installing the Yumizen G DDi 2 reagents must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Yumizen G DDi 2 reagents, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Reagents coming into contact with specimens and other materials should be handled as potentially infectious and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent otherwise erroneous results may occur!
- All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the reagent beyond the expiration date printed on the label!

PREPARATION

Yumizen G DDi 2 reagents are ready to use. Swirl gently the vial of Latex reagent (R2), with horizontal movements (5-10 times) before using it, but do not shake. Wait until the reagents reach the working temperature!

SPECIMENS

Yumizen G DDi 2 test requires freshly decalcified plasma. To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate (3.2%; 109 mmol/L). The use of higher concentration of trisodium citrate (3.8%; 129 mmol/L) is not recommended. Mix the blood carefully and centrifuge plasma before testing. The measurement must be performed within 24 hours. The plasma samples may be stored for up to 24 months at -24°C to -74°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5; H59.

TEST PROCEDURE

Yumizen G DDi 2 test is a two steps immuno-turbidimetric test, which can be used with semi-automated coagulation analysers according to the protocol detailed below. The duplicated measurement is recommended.

1.	**Reagents warming up to 20-25°C**	**~15 min**
2.	**Add sample into cuvette**	**10 µL**
3.	**Add Buffer (R1) into cuvette**	**130 µL**
4.	**Sample and Buffer incubation**	**2 min**
5.	**Add Latex (R2) into cuvette. Mix it 5 times**	**30 µL**
6.	**First reading time at 570 nm**	**20 sec**
7.	**Second reading time at 570 nm**	**180 sec**

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program. In case of determination by Yumizen G line automatic analyser (Yumizen G800 / Yumizen G1500 / Yumizen G1550),

the test procedure is already programmed in the test setup. For other automatic analysers, please follow the instructions in the manufacturer's manual.

STORAGE AND STABILITY

Yumizen G DDi 2 reagents in intact vial are stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vials is shown in below table:

T (°C)	15-19	2-8
Days	14	14

Do not freeze it!

EXPECTED RESULTS

Yumizen G DDi 2 test results can be reported in fibrinogen equivalent units (FEU), lot specific value sheet in the box will help in the calculation.

Cut-off value is 0.5 µg FEU/mL, but every laboratory should check if the cut-off value is transferable to its own patient population and instruments and determine its own cut-off value if necessary.

LIMITATIONS

The result of D-dimer test with Yumizen G DDi 2 reagents may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on HORIBA Medical analysers (Yumizen G line) with the following result:

Rheumatoid factor	Hemoglobin	Triglyceride	Bilirubin
90 IU/mL	9.6 g/L	6.14 mmol/L	811 µmol/L

Due to its antibodies, Yumizen G DDi 2 is a specific immunoassay for human D-dimer.

PERFORMANCE CHARACTERISTICS

- **Limit of Detection (LoD):**
  The limit of detection of Yumizen G DDi 2 test is 0.22 µg FEU/mL tested on Yumizen G1500.
- **Measuring Range:**
  The test has been developed to determine D-dimer concentrations within a measuring range of 0.22-5.0 µg FEU/mL without sample dilution. If values exceed this range, samples should be diluted with dilution buffer (Yumizen G IMIDAZOL; Cat. No.: 1300036385).
- **High dose Hook Effect:**
  No high dose Hook effect was observed up to concentration of 25 µg FEU/mL.
- **Negative Predictive Value (NPV) [a]:**
  Yumizen G DDi 2 can be used for Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) exclusion and it is clinically validated by independent institutes to meet specific performance characteristic values required by CLSI:

	NPV	Sensitivity	Sample
Yumizen G800 series	96%	97%	135
Yumizen G1500 / Yumizen G1550	96%	96%	115

Precision:

The precision of Yumizen G DDi 2 test on automated coagulometers give the following results:

	Intra-Assay		Inter-Assay	
Sample	1	2	3	4
n	20	20	25	25
Mean (µg FEU/mL)	0.446	1.852	0.487	1.921
CV (%)	2.713	2.469	7.481	2.437

MATERIALS REQUIRED BUT NOT PROVIDED

- Different levels of control for quality control (Yumizen G CTRL DDi I & II; Cat. No.: 1300036414).
- Dilution buffer (Yumizen G IMIDAZOL; Cat. No.: 1300036385).
- Optical analyser for measuring, HORIBA Medical analysers (Yumizen G line) are recommended.
- Yumizen G SORB (Cat. No.: 1300036418) for automated analyser (Yumizen G800 / Yumizen G1500 / Yumizen G1550).

BIBLIOGRAPHY

1. CLSI: Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline- Fifth Edition. CLSI document: H21-A5; 28:5; 2008.
2. CLSI. Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline. CLSI Document: H59-A; 2011.
3. Wells PS et al: Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis. N Engl J Med; 349(13): 1227-1235; 2003.
4. Dempfle CE: Use of D-dimer assays in the diagnosis of venous thrombosis. Semin Thromb Hemost; 26(6): 631-641; 2000.
5. Pinczés I: A D-dimer-szint meghatározásának jelentősége. LAM; 19(12): 761-767; 2009.
6. Dempfle CE: Validation, calibration and specificity of quantitative D-dimer assays. Semin Vasc Med; 5: 315-320; 2005.

MANUFACTURER

IVD CE

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[a] Modification: NPV.