2024/11/05
A02A00014CEN

REF 1300036414
CONTROL I 5 x 1 mL
CONTROL II 5 x 1 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

Yumizen G CTRL DDi I & II

- **Yumizen G200**
- **Yumizen G400 DDi/G405**
- **Yumizen G800h/G850h**
- **Yumizen G1500/G1550/G1500h/G1550h**

Control plasmas for *in vitro* diagnostic D-dimer test.

Intended Use [a] [b]

The **Yumizen G CTRL DDi I & II** is a freeze-dried, two levels (normal and abnormal) control plasmas are intended to control of the following test:

- D-dimer (DDi)

Method (1, 2) [c]

Yumizen G CTRL DDi I & II are dedicated for internal quality control of D-dimer measuring system.
There are instrument and lot specific control ranges in the value sheet for the given reagents.
Yumizen G CTRL DDi I & II represent two different measuring range.

Characteristics [d]

Yumizen G CTRL DDi I & II are derived from pooled, citrated, normal human plasmas, which contain D-dimer antigen from human plasma with enzymatic digestion and stabilizer.

Yumizen G CTRL DDi I

5 vials x 1 mL (after reconstitution)

Human plasma	> 90%
D-dimer antigen	< 1%

Yumizen G CTRL DDi II

5 vials x 1 mL (after reconstitution)

Human plasma	> 90%
D-dimer antigen	< 10%

Yumizen G CTRL DDi I & II should be used according to this notice and as specified in the respective instructions for use of the reagent.
The manufacturer cannot guarantee its performance if used otherwise.

Handling [e]

1. Allow the vials to stand for 5 min (20 - 25°C) before reconstitution.
2. Reconstitute the content of the vials with deionized or purified water as follows:
   - **Yumizen G CTRL DDi I**: 1 mL
   - **Yumizen G CTRL DDi II**: 1 mL

   Be careful when opening the rubber cap as some lyophilized material may be lost.
3. Replace the caps and gently invert the bottles (8 - 10 times) to disperse the contents (avoid foaming).
4. Allow the vials to stand for at least 30 min (20 - 25°C).
5. Mix thoroughly the vials once more before use.
6. **For automated analyzers only:** place the vials in the STAT holder without cap.

For optimal performance remove the reagent from the instrument after use, close the vial and store at 2 - 8°C.
Each laboratory must establish the quality assurance procedures to be followed. These must conform to the

[a] Modification: § "Intended Use" changed.
[b] Modification: new leaflet form.
[c] Modification: § "Method" changed.
[d] Modification: § "Characteristics" changed.
[e] Modification: § "Handling" changed.

Yumizen G CTRL DDi I & II

current accreditation requirements and pertinent regulations.

Care should be taken not to interchange the caps with others products.

Materials Required but not Provided [f]

- HORIBA analyzers (Yumizen G Line) are recommended.
- Deionized or purified water
- Standard laboratory equipment

Assigned Value [g]

Results must be within the range of the defined confidence limits. Each laboratory must establish the procedure to be followed in case the results are outside of the confidence interval given.
The concentration of the constituent(s) is lot specific.
Assigned values are indicated in the enclosed annex.
The annex can also be downloaded from our Web site www.horiba.com.

Storage and Stability [h]

Stability before opening

Stable up to the expiry date on the label if stored at 2 - 8°C.

Stability after reconstitution

	20 - 25°C	2 - 8°C
Yumizen G CTRL DDi I	8 hours	10 days
Yumizen G CTRL DDi II	8 hours	10 days

Waste Management [i]

Please refer to local legal requirements.

General Precautions [j]

- **Yumizen G CTRL DDi I & II** should be used for quality control purpose only.
- This product is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning:** Human source material. Treat as potentially infectious. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HbsAg, HCV and antibody to HIV 1/2. Because no known test method can offer complete assurance that infectious agents are absent, the product should be handled in accordance with good laboratory practices using appropriate precautions. (3, 4).
- Do not pipette by mouth.
- Do not replenish the products.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The product vials should be discarded after use. Disposal of all waste material should be in accordance with local guidelines.
- Please refer to the SDS associated with the product.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the product used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.
- Using of third-party hemostasis analyzers may cause a risk of system un-harmonization.
- It is the user's responsibility to evaluate the risk of using a third-party hemostasis analyzers.

[f]Modification: § "Material Required but not Provided" changed.
[g]Modification: § "Assigned Values" changed.
[h]Modification: § "Storage and Stability" changed.
[i]Modification: chapter added.
[j]Modification: § "General Precautions" changed.

Yumizen G CTRL DDi I & II

Performance

Homogeneity [i]

Yumizen G CTRL DDi I & II achieves the homogeneity performance, to be compliant with ISO 13528:2005 international standards and to be met all specifications thereof.

Precision [i]

The precision performance of control material is reported in the instruction for use of related reagent.

Reference

1. Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease. Approved Guideline, 1st ed., CLSI (NCCLS) document H59-A (2011).
2. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. Approved Guideline, 4th ed., CLSI (NCCLS) document C24-A4 (2016).
3. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
4. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

[i]Modification: chapter added.