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REF 1300036412
CONTROL I 5 x 1 mL
CONTROL II 5 x 1 mL

IVD CE 2797

HORIBA ABX SAS
Parc Euromédecine
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FRANCE

Yumizen G CTRL I & II

- **Yumizen G200**
- **Yumizen G400/G400 DDi/G405**
- **Yumizen G800/G800h/G850h**
- **Yumizen G1500/G1550/G1500h/G1550h**

Control plasmas for *in vitro* diagnostic coagulation test.

Intended Use [a]

Yumizen G CTRL I & II is a freeze-dried control plasma, two levels (normal and abnormal), intended to control the following test:

- prothrombin time (PT)
- activated partial thromboplastin time (APTT)
- fibrinogen (FIB)
- thrombin time (TT) (only for Yumizen G CTRL I)
- antithrombin (AT)
- factor FII, FV, FVII, FX
- factor FVIII, FIX, FXI, FXII

Method (1, 2, 3, 4)

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

Characteristics

Yumizen G CTRL I & II are derived from pooled, citrated, normal human plasmas, which contain preservative.

Yumizen G CTRL I

5 vials x 1 mL (after reconstitution)

Human plasma	> 90%
Sodium azide	< 1 g/L

Yumizen G CTRL II

5 vials x 1 mL (after reconstitution)

Buffered human plasma	> 90%
Sodium azide	< 1 g/L

Yumizen G CTRL 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

1. Allow the vials to stand for 5 min (20 - 25°C) before reconstitution.
2. Reconstitute the content of the vials with distilled water as follows:
   - **Yumizen G CTRL I**: 1 mL
   - **Yumizen G CTRL 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:** transfer in Eppendorf cup and place in the STAT holder without cap.

Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

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

[a]Modification: new leaflet form.

Yumizen G CTRL I & II

Materials Required but not Provided

- HORIBA analyzers (Yumizen G Line) are recommended.
- Distilled water
- Standard laboratory equipment

Storage and Stability [b]

Stability before opening

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

Stability after reconstitution

	20 - 25°C
Yumizen G CTRL I	4 hours
Yumizen G CTRL II	4 hours

Reconstitution stability of the product may be extended by freezing the reconstituted product preparation. It can only be de-frozen once. After de-frozen, the reconstituted product is stable 2 hours at 20 - 25°C.

Expected Results

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.
Expected values are provided in the enclosed lot and method specific table of assigned values.
These values are provided as a guideline only.
It is recommended that each laboratory establish its own target range.
Each laboratory must establish the procedure to be followed in case the results are outside of the confidence interval given.

Waste Management

- Please refer to local legal requirements.
- This product contains less than 0.01% of sodium azide as a preservative.

General Precautions

- **Yumizen G CTRL 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 (5, 6).
- 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.
- The Summary of Safety and Performance (SSP) of the product is available in Eudamed (https://ec.europa.eu/tools/eudamed).

[b]Modification: modification of storage temperature.

Yumizen G CTRL I & II

Performance

Homogeneity

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

Precision

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

Reference

1. One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test. Approved Guideline, 2nd ed., CLSI (NCCLS) document H47-A2 (2008) 28:20.
2. Procedure for the Determination of Fibrinogen in Plasma. Approved Guideline, 2nd ed., CLSI (NCCLS) document H30-A2 (2001).
3. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. Approved Guideline, 4th ed., CLSI (NCCLS) document C24-A4 (2016).
4. Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay. 2nd ed., CLSI document H48-ED2 (2016).
5. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
6. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.