2025/06/12
A02A00011DEN

REF 1300036416
CAL 12 x 1 mL

IVD CE 2797

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

Yumizen G CAL

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

Calibrator plasma for *in vitro* diagnostic coagulation test.

Intended Use [a] [b]

Yumizen G CAL is a freeze-dried calibrator plasma intended to calibrate the following test:

- prothrombin time (PT)
- fibrinogen (FIB)
- antithrombin (AT)
- factor FII, FV, FVII, FX
- factor FVIII, FIX, FXI, FXII

Method (1, 2, 3) [c]

Yumizen G CAL is dedicated for calibration of coagulation tests.
There are test specific calibrator target values in the lot specific value sheet for the given reagents.
The target values relate to values of healthy adult population or second international standards.

Characteristics

Yumizen G CAL is derived from pooled, citrated normal human plasma, which contains preservative.
The kit is composed of: 12 vials x 1 mL (after reconstitution).

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

Yumizen G CAL 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 [d]

1. Allow the vial to stand for at least 5 min (20 - 25°C) before reconstitution.
2. Reconstitute the content of one vial with 1 mL of distilled water.
   Be careful when opening the rubber cap as some lyophilized material may be lost.
3. Replace the cap and gently invert the bottle (8 - 10 times) to disperse the contents (avoid foaming).
4. Allow the vial to stand for at least 30 min (20 - 25°C).
5. Gentle horizontal mixing is recommended during reconstitution.
6. Swirl the vial horizontally gently several times (8 - 10 times) before using it, but do not shake.
7. **For automated analyzers only:** transfer in Eppendorf cup and place in the STAT holder without cap.

Please, refer to the reagent notice for further explanations concerning the use of this calibrator on the instrument.
Care should be taken not to interchange the caps with others products.

Materials Required but not Provided [e]

- HORIBA analyzers (Yumizen G Line) are recommended.

[a]Modification: § "Intended Use" changed.
[b]Modification: modification of CE mark.
[c]Modification: § "Method" changed.
[d]Modification: § "Handling" changed.
[e]Modification: § "Material Required but not Provided" changed.

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Yumizen G CAL

- Distilled water
- Standard laboratory equipment

Assigned Value

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

Stability before opening

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

Stability after reconstitution

	20 - 25°C	≤ -20°C
Yumizen G CAL	4 hours	30 days

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.

Waste Management

- Please refer to local legal requirements.
- This product contains less than 0.01% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

General Precautions [f]

- **Yumizen G CAL** should be used only for the determination of the calibration curve.
- 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. (4, 5).
- 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).

Traceability of Calibrators and Control Materials [g]

HORIBA controls and calibrators are traceable to the following standard reference methods or materials:

Parameter	Traceability to
PT%	Healthy adult population
FIB g/L	3rd International Standard for Fibrinogen Plasma (NIBSC code: 09/264)

[f]Modification: § "General Precautions" changed.
[g]Modification: modification of traceability.

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Parameter	Traceability to
AT%	3rd International Standard for Antithrombin Plasma (NIBSC code: 08/258)
Factor II	4th International Standard, 2010/15 (NIBSC code: 09/172)
Factor V	1st International Standard, 2005 (NIBSC code: 03/116)
Factor VII	4th International Standard, 2010/15 (NIBSC code: 09/172)
Factor X	4th International Standard, 2010/15 (NIBSC code: 09/172)
Factor VIII	6th International Standard, 2009 (NIBSC code: 07/316)
Factor IX	4th International Standard, 2010/15 (NIBSC code: 09/172)
Factor XI	2nd International Standard, 2016 (NIBSC code: 15/180)
Factor XII	Assigned to 2nd International Standard for FXI, 2016 (NIBSC code: 15/180)

Performance

Homogeneity

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

Traceability

This calibrator has been standardized against the international standard, for which parameter is relevant.

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. Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay. 2nd ed., CLSI document H48-ED2 (2016).
4. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
5. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

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