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REF **95012 / 1300130703**

CAL 12 x 1 mL

IVD CE

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# Dia-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

The **Dia-CAL** is a freeze-dried calibrator plasma is intended to calibrate of the following coagulation tests:

- prothrombin time (PT)
- fibrinogen (FIB)
- antithrombin (AT)
- coagulation factors II, V, VII, VIII, IX, X, XI, XII

### Clinical Interest

Not applicable.

### Method (1, 2, 3)

Dia-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

**Dia-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 |

**Dia-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

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 (5 - 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 (5 - 10 times) before using it, but do not shake.

For optimal performance remove the reagent from the instrument after use, close the vial and store at 20 - 25°C.
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.

### Calibrator

For calibration calculation use the target value in the lot number specific value sheet of the calibrator.

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## Control

For internal quality control, use:

- **Dia-CONT I-II** (91020 / 1300130704) (not included)
  2 x 10 x 1 mL (lyophilisate)

The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.
Each control should be assayed daily.

## Materials Required but not Provided

- HORIBA Medical analyzers (Yumizen G Line) are recommended.
- Control: **Dia-CONT I-II** (91020 / 1300130704)
- Buffer solution: **Yumizen G IMIDAZOL** (1300036385)
- Standard laboratory equipment

**Reagents for calibrating PT test:**

- Yumizen G PT 5
- Yumizen G PT Liq 4
- Yumizen G PT Reco 5, Yumizen G PT Reco 10

**Reagents for calibrating FIB test:**

- Yumizen G FIB 2, Yumizen G FIB 5 with Yumizen G IMIDAZOL

**Reagents for calibrating coagulation factor tests:**

- Dia-DEF II, Dia-DEF V, Dia-DEF VII, Dia-DEF X with Yumizen G IMIDAZOL and PT test
- Dia-DEF VIII, Dia-DEF IX, Dia-DEF XI, Dia-DEF XII with Yumizen G IMIDAZOL, APTT test and Yumizen G CaCl2 4

**Reagents for calibrating inhibitor test:**

- Yumizen G AT

## Specimen

Not applicable.

## Semi-Automated Analyzers Procedure

The calibration is a calibrator dilution based process that can be used with HORIBA Medical analyzers (Yumizen G Line).
Duplicated measurement is recommended.

**prothrombin time (PT)**

| | | |
|---|---|---|
| 1 | Prepare different calibrator dilutions with Yumizen G IMIDAZOL: 1:1, 1:2, 1:3, 1:4. | |
| 2 | Add the diluted calibrator into the cuvette. | 50 µL |
| 3 | Incubate at 37°C. | 2 min |
| 4 | Add PT reagent into the cuvette. | 100 µL |
| 5 | Simultaneously start the timer. | ~1 min |
| 6 | Prepare a calibration curve from the results (second and relevant 1/% derived from calibrator value according to dilution). | |

**fibrinogen (FIB)**

| | | |
|---|---|---|
| 1 | Prepare different calibrator dilutions with Yumizen G IMIDAZOL: 1:7, 1:10, 1:20, 1:30. | |
| 2 | Add the diluted calibrator into the cuvette. | 100 µL |
| 3 | Incubate at 37°C. | 2 min |
| 4 | Add FIB reagent into the cuvette. | 50 µL |
| 5 | Simultaneously start the timer. | ~1 min |
| 6 | Prepare a calibration curve from the results (logarithmic second and relevant logarithmic g/L derived from calibrator value according to dilution). | |

**PT based factors**

| | | |
|---|---|---|
| 1 | Prepare different calibrator dilutions with Yumizen G IMIDAZOL: 1:3, 1:5, 1:10, 1:20, 1:40, 1:80. | |
| 2 | Add the diluted calibrator into the cuvette. | 40 µL |
| 3 | Add factor deficient plasma into the cuvette. | 40 µL |
| 4 | Incubate at 37°C. | 150 s |
| 5 | Add PT reagent into the cuvette. | 80 µL |
| 6 | Simultaneously start the timer. | ~3 min |
| 7 | Prepare a calibration curve from the results (second and relevant % derived from calibrator value according to dilution). | |

**PTT based factors**

| | | |
|---|---|---|
| 1 | Prepare different calibrator dilutions with Yumizen G IMIDAZOL: 1:3, 1:5, 1:10, 1:20, 1:40, 1:80. | |
| 2 | Add the diluted calibrator into the cuvette. | 25 µL |

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| | | |
|---|---|---|
| 3 | Add factor deficient plasma into the cuvette. | 25 µL |
| 4 | Incubate at 37°C. | 120 s |
| 5 | Add PTT reagent into the cuvette. | 50 µL |
| 6 | Add **Yumizen G CaCl2 4** start reagent into the cuvette. | 50 µL |
| 7 | Simultaneously start the timer. | ~3 min |
| 8 | Prepare a calibration curve from the results (second and relevant % derived from calibrator value according to dilution). | |

**antithrombin (AT)**

| | | |
|---|---|---|
| 1 | Prepare different calibrator dilutions with Yumizen G IMIDAZOL: 1:20, 1:40, 1:60, Yumizen G IMIDAZOL. | |
| 2 | Add the diluted calibrator into the cuvette. | 50 µL |
| 3 | Incubate at 37°C. | 30 s |
| 4 | Add Thrombin reagent into the cuvette. | 50 µL |
| 5 | Incubate calibrator and reagent. | 2 min |
| 6 | Add the substrate reagent into the cuvette. | 50 µL |
| 7 | Simultaneously start the reading of the absorbance (OD/min). | 10 - 40 s |
| 8 | Prepare a calibration curve from the results (OD/min and relevant % derived from calibrator value according to dilution). | |

In case of determination by any other hemostasis analyzers, please follow the instructions of the manual.

## Reference Range

Not applicable.

## 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 |
|---|---|---|
| **Dia-CAL** | 4 hours | 30 days |

The reconstituted calibrator can be frozen and thawed back only once. Thawing should be performed within 10 minutes at 37°C. Thawed calibrator should be used within two hours, when stored at 20-25°C.

## Expected Results

The test specific calibrator target values for each of the parameters may vary from lot to lot. Check the lot specific target values in the value sheet in the box.

### Precautions of Calculation

- By calculating with inappropriate data or using the supplied data improperly, erroneous results can be obtained.
- The calibration curve is valid for the actual lot of the used reagent.
- New calibration is necessary, if the lot of reagent and/or the measurement circumstances are changed.
- Normal and pathological controls are recommended for verification of calibration curve.
- In case of unexpected control values, new calibration is needed.

## Waste Management [a]

- Please refer to local legal requirements.
- This product contains less than 1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

## General Precautions

- **Dia-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. Each donor unit used in the preparation of this product tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive. Consequently, it should be treated as potentially infectious and handled with the appropriate precautions.
- Do not pipette by mouth.
- Do not replenish the products.
- Do not swallow. Avoid contact with skin and mucous membranes.

[a]Modification: § "Waste Management" changed.

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- 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 Medical 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.

## Performance

### Homogeneity

Dia-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).