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REF **91020 / 1300130704**

CONTROL I 10 x 1 mL

CONTROL II 10 x 1 mL

IVD CE

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# Dia-CONT 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

The **Dia-CONT I-II** is a freeze-dried, two levels (normal and abnormal) control plasmas are intended to control of the following test:

- prothrombin time (PT)
- activated partial thromboplastin time (APTT)
- fibrinogen (FIB)
- thrombin time (TT) (only for Dia-CONT I)
- antithrombin (AT)
- coagulation factors II, V, VII, VIII, IX, X, XI, XII

### Clinical Interest

Not applicable.

### Method (1, 2, 3, 4)

Dia-CONT 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.
Dia-CONT I-II represent two different measuring range.

### Characteristics

**Dia-CONT I-II** are derived from pooled, citrated, normal human plasmas, which contain preservative.

**Dia-CONT I**

10 vials x 1 mL (after reconstitution)

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

**Dia-CONT II**

10 vials x 1 mL (after reconstitution)

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

**Dia-CONT 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:
   - **Dia-CONT I**: 1 mL
   - **Dia-CONT 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 (5 - 10 times) to disperse the contents (avoid foaming).
4. Allow the vials 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.

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

## Calibrator

Not applicable.

## Control

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.
- Third-party analyzers can also be used, where the clotting and chromogenic based methods and free test setup access are allowed, under the responsibility of the laboratory manager.
- Standard laboratory equipment

**Reagents for controlling PT test:**

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

**Reagents for controlling APTT test:**

- Yumizen G APTT 4 with Yumizen G CaCl2 4
- Yumizen G APTT Liq 2, Yumizen G APTT Liq 4 with Yumizen G CaCl2 4

**Reagents for controlling FIB test:**

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

**Reagents for controlling TT test:**

- Yumizen G TT

**Reagents for controlling 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 controlling inhibitor test:**

- Yumizen G AT

## Specimen

Not applicable.

## Test Procedure

**Dia-CONT I-II** controls are to be used as that of patients' plasmas as investigated with coagulation tests. In case of determination by coagulation analyzer, 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-CONT I** | 4 hours | 30 days |
| **Dia-CONT II** | 4 hours | 30 days |

The reconstituted control can be frozen and thawed back only once. Thawing should be performed within 10

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minutes at 37°C. Thawed control should be used within two hours, when stored at 20-25°C.

## Expected Results

The instrument specific control ranges for each of the parameters may vary from lot to lot. Compare the measured value with the declared one on the value sheet. The obtained results:

- have to be within the reference range declared, but to get the exact mean is not obligatory,
- should be considered as a guidance, but every laboratory should determine its own control ranges.

### Precautions of Calculation

- By calculating with inappropriate data or using the supplied data improperly, erroneous results can be obtained.
- To check the accuracy of the reported result join and perform external quality assurance program in regular intervals.
- In case of unexpected control values check all components of the test system are functioning correctly.

## Waste Management

- 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-CONT 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. 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.
- 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-CONT 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).

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4. Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay. 2nd ed., CLSI document H48-ED2 (2016).