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REF 1300036382

REAGENT 12 x 3 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
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FRANCE

Yumizen G TT

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

In vitro diagnostic reagent for determination of thrombin time test by coagulometry.

Application Release

	Test name
Yumizen G1500/G1550	TT
Yumizen G1500h/G1550h	TT
Yumizen G800	TT
Yumizen G800h/G850h	TT
Yumizen G405	TT
Yumizen G400/G400 DDi	TT
Yumizen G200	TT

Intended Use

For *in vitro* diagnostic use only.
Yumizen G TT is a freeze-dried reagent used for determination of Thrombin Time (TT).

Clinical Interest (1, 2) [a]

The TT reagent is elevated in Disseminated Intravascular Coagulation (DIC) (Fibrin Degradation Products-FDP-interfere with polymerization), low fibrinogen levels, dysfibrinogenemia and heparin (very sensitive) only.

Method

The TT test is performed by adding thrombin to plasma. The added thrombin directly clots fibrinogen of tested plasma.

Reagents

Yumizen G TT is freeze-dried.
This reagent is human thrombin in buffered medium with calcium and preservative.

Human thrombin	8 - 10 NIH U/mL
Bovine thrombin	< 10 g/L
$CaCl_2$*$2H_2O$	< 1 g/L
Sodium azide	< 1 g/L

Yumizen G TT should be used according to this notice. 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 3 mL of deionized or purified 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. Mix thoroughly the vial once more before use.
6. **For automated analyzers only:** place the vial in the reagent holder without cap.

For optimal performance remove the reagent from the instrument after use, close the vial and store at 2 - 8°C.

[a]Modification: § "Clinical Interest" changed.

Yumizen G TT

An analysis of the control must be carried out on a daily basis at the same time as the patient samples.
The frequency of the controls depends on the laboratory requirements.
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

To calculate the ratio of the test (TT), you could use the mean value (MNTT) provided in the enclosed annex.
According to the CLSI H47-A2 document every laboratory should determine its own MNTT value. (1)

Control

For internal quality control, use:

- **Yumizen G CTRL I & II** (1300036412) (not included)
  5 x 1 mL + 5 x 1 mL

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.

Semi-Automated Analyzers Procedure

Yumizen G TT can be used on semi-automated analyzers (Yumizen G Line), according to the following procedure.
Duplicated measurement is recommended.

1	Add the sample into the cuvette.	100 µL
2	Incubate at 37°C.	2 min
3	Add the reagent.	100 µL
4	Start immediately the measurement at 640 nm.	1 min

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

Materials Required but not Provided

- HORIBA analyzers (Yumizen G Line) are recommended.
- Control: **Yumizen G CTRL I & II** (1300036412)
- Deionized or purified water
- Standard laboratory equipment

Specimen

Plasma

- 3.2% (109 mmol/L) sodium-citrate anticoagulated plasma in primary tube.
- 3.2% (109 mmol/L) sodium-citrate, theophylline, adenosine and dipyramidole (CTAD) anticoagulated plasma in primary tube.

Mix the blood carefully.

Specimen centrifugation

Speed	Time	Temperature
1500 g	15 min	room temperature

Specimen Stability (3)

- At 20 - 25°C: 4 hours

Test plasmas containing heparin within 2 h.
Collect the plasma supernatant, and store until tested at 20 - 25°C.
For additional information, please refer to CLSI document H21-A5.

Reference Range

Each laboratory should establish its own reference ranges.
The values given here are used as guidelines only.

Normal adult range	Mean	From	To
Second	18.5	15.6	22.2

Storage and Stability

Stability before opening

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

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Stability after reconstitution

	20 - 25°C	2 - 8°C
Yumizen G TT	3 days	15 days

Stability on board

Automated Analyzers

	15 - 19°C
Yumizen G TT	7 days

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

- 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).
- **Warning:** This product is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (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.

Performance

The performance data listed below are representative of performance on HORIBA systems.

Lot to Lot Variability

The comparison of plasma samples tested consecutive lots of reagent shows that the lot to lot variability is within specification.

Sample Volume

Instrument	Volume
Yumizen G1500/G1550	100 µL
Yumizen G1500h/G1550h	100 µL
Yumizen G800	100 µL
Yumizen G800h/G850h	100 µL
Yumizen G405	100 µL
Yumizen G400/G400 DDi	100 µL
Yumizen G200	100 µL

Precision

Repeatability (on automated analyzers)

Repeatability according to the recommendations found in the CLSI (NCCLS), H57-A (6), EP05-A3 (7) (data obtained on internal study).

- 1 control (10 runs)
- 1 specimen (20 runs)

	Mean value Second	CV %
Control specimen	26.8	2.006
Specimen	17.1	2.303

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Maximum acceptance criteria (CV %): < 5%

Reproducibility (on automated analyzers)

Reproducibility according to the recommendations found in the CLSI (NCCLS), H57-A (6) (data obtained on internal study).

- 1 control (10 runs)

	Mean value Second	CV %
Control specimen	26.0	2.882

Maximum acceptance criteria (CV %): < 10%

Measuring Range

The measuring range is 10 - 120s on the Yumizen G Line instruments.

Correlation

Specimens are correlated with a commercial reagent taken as reference on HORIBA analyzers (Yumizen G Line).
Number of samples: < 50

- Bland et Altman plot procedure: 0.991 (second difference)

Interferences (8)

Haemoglobin: No significant influence is observed up to 3.40 g/L.
Triglycerides: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 4.00 mmol/L.
Bilirubin: No significant influence is observed up to 240 µmol/L.

Clinical Performance

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this test.
This is largely attributed to the fact that this thrombin time is a screening test.
To arrive at a diagnosis and a course of treatment, results from others routine coagulation tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Precautions of Characteristics

The measurement data was generated during a performance evaluation and is not recommended as an acceptance criterion.

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. Latallo ZS. Thrombin clotting assays. In: Thrombosis and Bleeding Disorders: Theory and Methods. Nils U. Bang NU, Beller FK, Deutsch E, Mammen EF, Ed. Academic Press (1971), New York: 183.
3. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays. Approved Guideline, 5th ed., CLSI (NCCLS) document H21-A5 (2008).
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.
6. Protocol for the Evaluation, Validation, and Implementation of Coagulometers. Approved Guideline, 1th ed., CLSI (NCCLS) document H57-A (2008).
7. Evaluation of Precision of Quantitative Measurement Procedures. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP05-A3 (2014).
8. Interference Testing in Clinical Chemistry. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP07-A2 (2005).