



Yumizen G TT

THROMBIN TIME REAGENT

Cat. No.: 1300036382

12 x 3 ml

PRODUCT NAME

Yumizen G TT

INTENDED USE**(For In Vitro Diagnostic Use Only)**

Yumizen G TT is a freeze-dried reagent used for determination of Thrombin Time (TT).

SUMMARY AND BACKGROUND

The TT test is designed for the assessment of fibrin formation. The TT is only affected by factors that interfere with thrombin or fibrinogen. The TT is elevated in DIC (FDPs interfere with polymerisation), low fibrinogen levels, dysfibrinogemia and heparin (very sensitive) only.

PRINCIPLE

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

ACTIVE INGREDIENTS

Yumizen G TT is a freeze-dried, human thrombin in buffered medium with calcium and stabilizer.

PRECAUTIONS

- Person installing the Yumizen G TT reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Yumizen G TT due to its ingredients should be handled with care, observing the precautions recommended for biohazardous material!
- Reagent coming into contact with specimens and all materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions.
- Avoid microbial contamination of the reagent or erroneous results may occur.
- Each donor unit used in the preparation of this reagent tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All reagents, waste and utilized disposable laboratory equipments should be considered as hazardous waste. Their handling and

disposal should be done according to the valid hazardous material processing regulation.

- Do not use the reagent beyond the expiration date printed on the label!

PREPARATION

Yumizen G TT reagent is dissolved with the required amount of distilled water, which is indicated on the label. Keep the reagent at room temperature (20-25°C) for at least 30 minutes for proper reconstitution. Swirl the vial gently, horizontally more times (5-10) before using it, but do not shake. Wait until the reagent reaches the working temperature!

SPECIMENS

Yumizen G TT test requires freshly decalcified plasma.

To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate (3,2%; 109 mmol/L). The use of higher concentration of trisodium citrate (3,8%; 129 mmol/L) is not recommended. Mix the blood carefully and centrifuge plasma before testing. The measurement must be performed within 4 hours. Do not store the sample at 2-8°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

INSTRUCTION FOR USE ON SEMI-AUTO ANALYSER

Yumizen G TT test is a TT test, which is suitable for manual techniques according to the protocol detailed below and for automated assays according to the instructions outlined in the instrument manual. Duplicate determinations are recommended.

Bring the sufficient volume of Yumizen G TT reagent to room temperature.

1. Add 100µl plasma (control or patient's) to the test cuvette.
2. Incubate plasma at 37°C for 2 minutes.
3. Add 100µl Yumizen G TT reagent and simultaneously start the timer.
4. Determine the coagulation time.

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program.

In case of determination by automated coagulometer, please follow the instructions of the manual.

- Yumizen G SORB (Cat. No.: 1300036418) for Yumizen G800 / 850 and Yumizen G1500 / 1500.

STORAGE AND STABILITY

Yumizen G TT reagent in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in the table below:

| | | | |
|-------|-------|-------|-----|
| T(°C) | 20-25 | 15-19 | 2-8 |
| Day | 3 | 7 | 15 |

EXPECTED RESULTS

Yumizen G TT test results can be reported in the following units, lot specific sheet in the box will help in the calculation:

1. Seconds, which means the observed clotting time.
2. Ratio (Ratio=TT/MNTT), which means the clotting time of the sample divided by the mean normal TT (MNTT). Method dependent MNTT value in the value sheet is only for information, because it depends on the measuring circumstances and population.

Every laboratory should determine its own MNTT value and reference range. Our reference range is the following on Yumizen G line:

| Reference | Mean | Range from | Range to |
|-----------|------|------------|----------|
| Second | 18.5 | 15.6 | 22.2 |

LIMITATIONS

The result of TT test with Yumizen G TT reagent may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on Yumizen G line analysers with the following result:

| Hemoglobin | Triglycerid | Bilirubin |
|------------|-------------|------------|
| 3.4 g/L | 4 mmol/L | 240 µmol/L |

PERFORMANCE CHARACTERISTICS

The reproducibility test of Yumizen G TT reagent on automated coagulometer gives the following results:

| | Intra-Assay | Inter-Assay |
|-------------------|-------------|-------------|
| Sample | 1 | 1 |
| n | 10 | 10 |
| Mean (sec) | 26.8 | 26.0 |
| CV (%) | 2.006 | 2.882 |

MATERIALS REQUIRED BUT NOT PROVIDED

- Normal control for quality control (Yumizen G CTRL I & II; Cat. No.: 1300036412).
- Optical coagulation analysers (Yumizen G line) for measuring.

BIBLIOGRAPHY

1. CLSI: Collection, Transport, and Processing of Blood. Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline- Fifth Edition. CLSI document: H21-A5; 28:5; 2008.
2. Latallo ZS: Thrombin clotting assays. In Bang NU, Beller FK, Deutsch E, Mammen EF: Thrombosis and Bleeding Disorders: Theory and Methods. Academic Press, New York; 183; 1971.

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