HORIBA Medical

INSTRUCTION FOR USE

# Yumizen G PT Reco 5

## PROTHROMBIN TIME REAGENT

CE

**Cat. No.: 1300036375** **10 x 5 ml**

### PRODUCT NAME

Yumizen G PT Reco 5 prothrombin time reagent.

### INTENDED USE

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

Yumizen G PT Reco 5 is a recombinant human thromboplastin reagent -produced by genetic technology in *Escherichia Coli* with own solvent used for determination of Prothrombin Time (PT).

### SUMMARY AND PRINCIPLE

Yumizen G PT Reco 5 reagent is a recombinant human thromboplastin, which contains recombinant human tissue factor, lipids and calcium ions. The PT test according to Quick is a sensitive screening test for the extrinsic coagulation pathway. Yumizen G PT Reco 5 is highly sensitive to vitamin K antagonists, decreased level of factors in extrinsic pathway (factor II, V, VII, and X), hereditary or acquired coagulation disorders and liver failure. Therefore, the PT by Yumizen G PT Reco 5 reagent is optimally used for presurgical screening and monitoring for oral anticoagulant therapy (OAT), as well. Yumizen G PT Reco 5 reagent with the corresponding deficient plasmas is also suitable for determination of activity of extrinsic coagulation pathway. Furthermore the Yumizen G PT Reco 5 reagent has an increased sensitivity for certain factors, like Factor VII, due to this characteristics in some cases it might cause prolonged coagulation compared with tissue extract thromboplastins.

### PRINCIPLE

Yumizen G PT Reco 5 reagent as a calcium thromboplastin, induces the formation of fibrin clot when added to patient's plasma. The time of this clotting process is measurable manually or with optical coagulation analysers.

### ACTIVE INGREDIENTS

Yumizen G PT Reco 5 reagent is a freeze-dried, recombinant human thromboplastin from *Escherichia Coli* with lipids and stabilizers.

Solvent is a buffer, which contains calcium ions and sodium azide (<0.01%) as preservative.

### PRECAUTIONS

- Person installing the Yumizen G PT Reco 5 reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Yumizen G PT Reco 5, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Reagent coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent otherwise erroneous results may occur!
- Contains materials of human and / or animal origin. Consequently, it should be treated as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (4, 5).
- All reagents, waste and utilized disposable laboratory equipment 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 PT Reco 5 reagent is dissolved with the entire content of one vial Solvent of the same lot. 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 PT Reco 5 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 24 hours. Do not store the sample at 2-8°C. Refer to

Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

## TEST PROCEDURE FOR SEMI-AUTOMATED COAGULATION ANALYSERS

**Configuration**: For this test a modification of the minimum reading is necessary:

1. Go to **Setup** > **Screening tests** > **PT** screen.
2. Change the "Min. time" to 7s and the "Lag time" to 5s with the user code.
3. Save (if you come back to Yumizen G PT or Yumizen G PT Liq do not forget to change back this "Min.time" to 10s and "Lag time" to 6s).

Yumizen G PT Reco 5 test is a one-stage PT test, which can be used with semi-automated coagulation analysers according to the protocol detailed below. The duplicated measurement is recommended.

| | | |
|---|---|---|
| **1.** | **Reagent warming up to 37°C** | **~15min** |
| **2.** | **Adding sample into cuvette** | **50µl** |
| **3.** | **Sample incubation** | **2min** |
| **4.** | **Adding PT reagent into cuvette** | **100µl** |
| **5.** | **Simultaneously start the timer** | **~1min** |

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program. In case of determination by any other coagulometer, please follow the instructions of the manual.

## STORAGE AND STABILITY

Yumizen G PT Reco 5 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 below table:

| T (°C) | 37 | 20-25 | 15-19 | 2-8 |
|---|---|---|---|---|
| Days | 8 hours | 1 | 5 | 10 |

Do not freeze it!

## EXPECTED RESULTS

Yumizen G PT Reco 5 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=PT/MNPT), which means the clotting time of the sample divided by the mean normal prothrombin time (MNPT). Method dependent MNPT value in the issued sheet is only for information, because it depends on the measuring circumstances and population.
3. Percentage, which means the proportional part of the normal PT activity, which is calculable from the calibration curve. Method dependent master curve in the issued sheet can be used for the calculation.
4. International Normalized Ratio (INR), which means the ratio raised to the power of International Sensitivity Index (ISI) [$INR=(PT/MNPT)^{ISI}$]. Method dependent ISI value in the issued sheet can be used for the calculation. The INR is the only officially recognized dimension of the result at vitamin K antagonists treated patients.

The normal range expressed in INR is 0.8-1.2. Every laboratory should determine its own MNPT value and reference range. Accurate and general conversion of percentage into INR (or back) is not possible!

## LIMITATIONS

The result of PT test with Yumizen G PT Reco 5 reagent may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on Horiba Medical analysers (Yumizen G line) with the following result:

| Heparin | Hemoglobin | Triglicerides | Bilirubin |
|---|---|---|---|
| 1.25 IU/mL | 6.8 g/L | 9 mmol/L | 270 µmol/L |

## PERFORMANCE CHARACTERISTICS

The reproducibility test of Yumizen G PT Reco 5 reagent on Horiba Medical analysers (Yumizen G1500) gives the following results:

| | Intra-Assay | | Inter-Assay | |
|---|---|---|---|---|
| **Sample** | **1** | **2** | **3** | **4** |
| **n** | **10** | **10** | **10** | **10** |
| **Mean (sec)** | **11.3** | **16.2** | **11.8** | **15.5** |
| **CV (%)** | **0.815** | **0.486** | **2.539** | **1.023** |

## MATERIALS REQUIRED BUT NOT PROVIDED[a]

- Different levels of control for quality control (Yumizen G CTRL I & II; Cat. No.: 1300036412).
- This reagent may be performed using manual, semi-automated and automated methods.
- Coagulation analyser for measuring, Horiba Medical analysers are recommended:
  - Yumizen G200
  - Yumizen G400 / Yumizen G400 DDi
  - Yumizen G800
  - Yumizen G1500 / Yumizen G1550

[a]Modification: modification of materials required.

**BIBLIOGRAPHY**

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3. De Caterina R et al: Vitamin K antagonists in heart disease: Current status and perspectives (Section III). Thromb Haemost; 110: 1087-1107; 2013.
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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