HORIBA Medical

INSTRUCTION FOR USE

Yumizen G PT 5

PROTHROMBIN TIME REAGENT

CE

Cat. No.: 1300036338 **5 x 5 ml**

PRODUCT NAME

Yumizen G PT 5 prothrombin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Yumizen G PT 5 is a rabbit brain thromboplastin reagent with own solvent used for determination of Prothrombin Time (PT).

SUMMARY AND PRINCIPLE

Yumizen G PT 5 reagent is a rabbit brain extract thromboplastin, which contains 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 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 5 reagent is optimally used for presurgical screening and monitoring for oral anticoagulant therapy (OAT), as well. Yumizen G PT 5 reagent with the corresponding deficient plasmas is also suitable for determination of activity of extrinsic coagulation pathway.

PRINCIPLE

Yumizen G PT 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 and mechanical coagulation analysers.

ACTIVE INGREDIENTS

Yumizen G PT 5 reagent is a freeze-dried, tissue thromboplastin from rabbit brain with stabilizers. Solvent is a buffer which contains calcium ions and sodium azide (<0.01%) as preservative.

PRECAUTIONS

- Person installing the Yumizen G PT 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 5 reagent, 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 5 reagent is dissolved with the entire contents of one vial Solvent of the same lot. Keep the reagent warm (37°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!

Using of stirring bar is necessary during the measurement!

SPECIMENS

Yumizen G PT 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[a]

Yumizen G PT 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.

[a]Modification: § test procedure changed.

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 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
Day	8 hours	1	5	12

Do not freeze it!

EXPECTED RESULTS

Yumizen G PT 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 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	Triglycerides	Bilirubin
0.75 IU/mL	6.8 g/L	9 mmol/L	270 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Yumizen G PT 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)	12.4	23.0	12.0	21.3
CV (%)	0.864	1.775	1.731	3.047

MATERIALS REQUIRED BUT NOT PROVIDED

- Different levels of control for quality control (Yumizen G CTRL I & II; Cat. No.: 1300036412).
- Magnetic stirrer for mixing (Magnetic stirrer; Cat. No.: 1300039490).
- Optical coagulation analyser for measuring, Horiba Medical analysers are recommended:
  - Yumizen G200
  - Yumizen G400 / Yumizen G400 DDi
  - Yumizen G800
  - Yumizen G1500 / Yumizen G1550

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. CLSI: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline-Second Edition. CLSI document: H47-A2; 28:20; 2008.
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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