HORIBA Medical

INSTRUCTION FOR USE

Yumizen G APTT 4

ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT

Cat. No.: 1300036377 **6 x 4 ml**

PRODUCT NAME

Yumizen G APTT 4 activated partial thromoplastin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Yumizen G APTT 4 is a rabbit brain phospholipid reagent used for determination of Activated Partial Thromboplastin Time (APTT).

SUMMARY AND PRINCIPLE

Yumizen G APTT 4 reagent is a rabbit brain extract phospholipid. The APTT test is a sensitive screening test for the intrinsic coagulation pathway. Yumizen G APTT 4 is highly sensitive to decreased level of factors in intrinsic pathway (factor I, II, V, VIII, IX, X, XI and XII), hereditary or acquired coagulation disorders and liver failure. Therefore, the APTT by Yumizen G APTT 4 reagent is optimally used for presurgical screening and monitoring for heparin therapy, as well. Yumizen G APTT 4 reagent with the corresponding deficient plasmas is also suitable for determination of activity of intrinsic coagulation pathway.

PRINCIPLE

Yumizen G APTT 4 reagent initiates the activation of the intrinsic coagulation pathways in the presence of standardized amount of phospholipid and contact activator (micronized silica). After incubation, the addition of calcium induces the formation of fibrin clot. The time of this clotting process is measurable manually or with optical coagulation analysers.

ACTIVE INGREDIENTS

Yumizen G APTT 4 reagent is a freeze-dried, phospholipid from rabbit brain, which contains micronized silica in buffered medium with stabilizer.

PRECAUTIONS

- Person installing the Yumizen G APTT 4 reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Yumizen G APTT 4 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 APTT 4 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!

Using of magnetic stirrer is necessary during the measurement!

SPECIMENS

Yumizen G APTT 4 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.

TEST PROCEDURE FOR SEMI-AUTOMATED COAGULATION ANALYSERS

Yumizen G APTT 4 test is an APTT test, which can be used with semi-automated coagulation analysers according to the protocol detailed below. The duplicated measurement is recommended.

1.	**$CaCl_2$ reagent warming up to 37°C**	**~15min**

2.	Adding sample into cuvette	50µl
3.	Adding APTT reagent into cuvette	50µl
4.	Sample and reagent incubation	3min
5.	Adding $CaCl_2$ reagent into cuvette	50µl
6.	Simultaneously start the timer	~2min

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. Use only Yumizen G CaCl2 4 solution in order to achieve correct result!

STORAGE AND STABILITY

Yumizen G APTT 4 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)	20-25	15-19	2-8
Days	1	10	14

Do not freeze it!

EXPECTED RESULTS

Yumizen G APTT 4 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=APTT/MNAPTT), which means the clotting time of the sample divided by the mean normal APTT (MNAPTT). Method dependent MNAPTT value in the issued sheet is only for information, because it depends on the measuring circumstances and population.

Every laboratory should determine its own MNPATT value and reference range. Our reference range is the following on Horiba Medical analysers (Yumizen G line):

Reference	Mean	Range from	Range to
Seconds	33.9	28.4	40.2

LIMITATIONS

The result of APTT test with Yumizen G APTT 4 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:

Hemoglobin	Triglicerides	Bilirubin
6.8 g/L	10 mmol/L	240 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Yumizen G APTT 4 reagent on automated coagulometer (Yumizen G1500) gives the following results:

	Intra-Assay		Inter-Assay	
Sample	1	2	3	4
n	10	10	10	10
Mean (sec)	41.3	64.3	41.4	66.0
CV (%)	0.576	0.458	1.226	2.096

MATERIALS REQUIRED BUT NOT PROVIDED[a]

- CaCl2 for measuring (Yumizen G CaCl2 4; Cat. No.: 1300036386).
- 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 (Yumizen G line) are recommended.
- Magnetic stirrer for mixing (Magnetic stirrer; Cat. No.: 1300039490).

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. CLSI: How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline-Second Edition. CLSI document: C28-A2; 20:13; 2000.
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.

MANUFACTURER

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[a]Modification: modification of materials required