HORIBA Medical

INSTRUCTION FOR USE

Yumizen G APTT Liq 4

ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT

CE

Cat. No.: 1300036381 **12 x 4 ml**

PRODUCT NAME

Yumizen G APTT Liq 4 activated partial thromoplastin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Yumizen G APTT Liq 4 is a liquid, ready to use, rabbit brain phospholipid reagent used for determination of Activated Partial Thromboplastin Time (APTT).

SUMMARY AND PRINCIPLE

Yumizen G APTT Liq 4 reagent is a rabbit brain extract phospholipid. The APTT test is a sensitive screening test for the intrinsic coagulation pathway. Yumizen G APTT Liq 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 Liq 4 reagent is optimally used for presurgical screening and monitoring for heparin therapy, as well. Yumizen G APTT Liq 4 reagent with the corresponding deficient plasmas is also suitable for determination of activity of intrinsic coagulation pathway.

PRINCIPLE

Yumizen G APTT Liq 4 reagent initiates the activation the intrinsic coagulation pathways in the presence of standardized amount of phospholipid and contact activator (ellagic acid). 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 Liq 4 reagent is a phospholipid from rabbit brain, which contains ellagic acid in buffered medium with stabilizer.

PRECAUTIONS

- Person installing the Yumizen G APTT Liq 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 Liq 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!
- This reagent 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 (4).
- 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 Liq 4 reagent is ready to use. 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 APTT Liq 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 Liq 4 test is an APTT test, which can be used with semi-automated coagulation analysers (YUMIZEN G200 / G400 / G400 DDi) 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. Use only Yumizen G CaCl2 4 solution in order to achieve correct result!

STORAGE AND STABILITY

Yumizen G APTT Liq 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	7	10	14

Do not freeze it!

EXPECTED RESULTS

Yumizen G APTT Liq 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 MNAPTT value and reference range. Our reference range is the following on Horiba Medical analysers (Yumizen G line):

Reference	Mean	Range from	Range to
Seconds	28.2	23.2	35.2

LIMITATIONS

The result of APTT test with Yumizen G APTT Liq 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
3.4 g/L	10 mmol/L	240 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Yumizen G APTT Liq 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)	35.8	68.2	34.6	64.1
CV (%)	0.405	0.317	1.085	1.340

MATERIALS REQUIRED BUT NOT PROVIDED

- 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).
- 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. CLSI: How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline-Second Edition. CLSI document: C28-A2; 20:13; 2000.
4. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.

MANUFACTURER

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE