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REF 1300036381

REAGENT 12 x 4 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
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FRANCE

Yumizen G APTT Liq 4

- **Yumizen G200**
- **Yumizen G400/G400 DDi/G405**
- **Yumizen G800/G800h/G850h**
- **Yumizen G1500/G1550/G1500h/G1550h**

In vitro diagnostic reagent for determination of activated partial thromboplastin time test by coagulometry.

Application Release

	Test name
Yumizen G1500/G1550	APTT Liq
Yumizen G1500h/G1550h	APTT Liq
Yumizen G800	APTT Liq
Yumizen G800h/G850h	APTT Liq
Yumizen G405	APTT Liq
Yumizen G400/G400 DDi	APTT
Yumizen G200	APTT

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).

Clinical Interest

The APTT test is a sensitive screening test for the intrinsic coagulation pathway.
Yumizen G APTT Liq 4 as a reagent for APTT is highly sensitive to decreased level of factors in intrinsic pathway (factor FVIII, FIX, FXI and FXII), hereditary or acquired coagulation disorders and liver failure.

Method

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 and mechanical coagulation analyzers.

Reagents

Yumizen G APTT Liq 4 is ready-to-use.
This reagent is a phospholipid from rabbit brain, which contains ellagic acid in buffered medium with preservative.

Rabbit brain phospholipid	< 2.5 g/L
Ellagic acid	< 1 g/L

Yumizen G APTT Liq 4 should be used according to this notice.
The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Wait until the reagent reaches the working temperature.
2. Mix thoroughly the vial horizontally (5 - 10 times).
3. **For automated analyzers only:** place the vial in the reagent holder without cap.

For optimal performance remove the reagent from the instrument after use, close the vial and store at 2 - 8°C.
An analysis of the control must be carried out on a daily basis at the same time as the patient samples.
The frequency of the controls depends on the laboratory requirements.
Each laboratory must establish the quality assurance procedures to be followed. These must conform to the

Yumizen G APTT Liq 4

current accreditation requirements and pertinent regulations.

Care should be taken not to interchange the caps with others products.

Calibrator

To calculate the ratio of the test (APTT), you could use the mean value (MNAPTT) provided in the enclosed annex.
According to the CLSI H47-A2 document every laboratory should determine its own MNAPTT value. (1)

Control

For internal quality control, use:

- **Yumizen G CTRL I & II** (1300036412) (not included)
  5 x 1 mL + 5 x 1 mL

The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.
Each control should be assayed daily.

Semi-Automated Analyzers Procedure

Yumizen G APTT Liq 4 can be used on semi-automated analyzers (Yumizen G Line), according to the following procedure.
Duplicated measurement is recommended.

1	Incubate **Yumizen G CaCl2 4** at 37°C.	30 min
2	Add the sample into the cuvette.	50 µL
3	Add the **Yumizen G APTT Liq 4**.	50 µL
4	Incubate at 37°C.	3 min
5	Add **Yumizen G CaCl2 4**.	50 µL
6	Start immediately the measurement at 640 nm.	~2 min

In case of determination by any other hemostasis analyzers, please follow the instructions of the manual.

Materials Required but not Provided

- HORIBA analyzers (Yumizen G Line) are recommended.
- Control: **Yumizen G CTRL I & II** (1300036412)
- Buffer solution: **Yumizen G CaCl2 4** (1300036386)
- Standard laboratory equipment

Specimen

Plasma

- 3.2% (109 mmol/L) sodium-citrate anticoagulated plasma in primary tube.
- 3.2% (109 mmol/L) sodium-citrate, theophylline, adenosine and dipyramidole (CTAD) anticoagulated plasma in primary tube.

Mix the blood carefully.

Specimen centrifugation

Speed	Time	Temperature
1500 g	15 min	room temperature

Specimen Stability (2)

- At 20 - 25°C: 4 hours
- Between -22°C to -26°C: 8 months (only the plasma)
- Between -72°C to -76°C: 24 months (only the plasma)

Specimens suspected to contain unfractionated heparin should be kept at room temperature and centrifuged within one hour of collection.
To thaw plasma:

1. Place the sample in a water bath: 5 min at 37°C.
2. Centrifuge the sample.

For additional information, please refer to CLSI document H21-A5.

Reference Range

Each laboratory should establish its own reference ranges.
The values given here are used as guidelines only.

Normal range	Mean	From	To
Second	28.2	23.2	35.2

The therapeutic reference range may vary depending on the clinical indication of therapy.

Yumizen G APTT Liq 4

Storage and Stability

Stability before opening

Stable up to the expiry date on the label if stored at 2 - 8°C.

Stability after opening

	20 - 25°C	2 - 8°C
Yumizen G APTT Liq 4	7 days	14 days

Stability on board

Automated Analyzers

	15 - 19°C
Yumizen G APTT Liq 4	10 days

Expected Results [a]

Yumizen G APTT Liq 4 test results can be reported in the following units:

- **Second:** observed clotting time of the sample.
- **Ratio (APTT / MNAPTT):** clotting time of the sample divided by the mean normal partial thromboplastin time (MNAPTT).

Precautions of Calculation

- The MNAPTT value depends on the population (race, gender) and measuring circumstances (sampling tube, etc.).
- By calculating with inappropriate data or using the supplied data improperly, erroneous results can be obtained.

Waste Management

Please refer to local legal requirements.

General Precautions

- This product is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning:** This product 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 (3).
- Do not pipette by mouth.
- Do not replenish the products.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The product vials should be discarded after use. Disposal of all waste material should be in accordance with local guidelines.
- Please refer to the SDS associated with the product.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the product used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.
- Using of third-party hemostasis analyzers may cause a risk of system un-harmonization.
- It is the user’s responsibility to evaluate the risk of using a third-party hemostasis analyzers.

Performance

The performance data listed below are representative of performance on HORIBA systems.

Lot to Lot Variability

The comparison of plasma samples tested consecutive lots of reagent shows that the lot to lot variability is within specification.

Sample Volume

Instrument	Volume
Yumizen G1500/G1550	50 µL
Yumizen G1500h/G1550h	50 µL
Yumizen G800	50 µL
Yumizen G800h/G850h	50 µL

[a]Modification: chapter added.

Yumizen G APTT Liq 4

Instrument	Volume
Yumizen G405	50 µL
Yumizen G400/G400 DDi	50 µL
Yumizen G200	50 µL

Precision

Repeatability (on automated analyzers)

Repeatability according to the recommendations found in the CLSI (NCCLS), EP15-A3 (4), EP05-A3 (5), H47-A2 (6) (data obtained on internal study).

- 2 controls (10 runs)
- 2 specimens (20 runs)

	Mean value Second	CV %
Control specimen 1	35.8	0.405
Control specimen 2	68.2	0.317
Specimen 1	33.3	0.604
Specimen 2	52.8	0.580

Maximum acceptance criteria (CV %): < 2%

Reproducibility (on automated analyzers)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 (5), H47-A2 (6) (data obtained on internal study).

- 2 controls (10 runs)

	Mean value Second	CV %
Control specimen 1	34.6	1.085
Control specimen 2	64.1	1.340

Maximum acceptance criteria (CV %): < 5%

Measuring Range

The measuring range is 20 - 210s on the Yumizen G Line instruments.

Correlation

Specimens are correlated with a commercial reagent taken as reference on HORIBA analyzers (Yumizen G Line).
Number of samples: 40

- Bland et Altman plot procedure: 0.610 (second difference)
- Linear regression: 1.035 (slope)

Interferences (7)

Haemoglobin: No significant influence is observed up to 3.40 g/L.
Triglycerides: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 10.0 mmol/L.
Bilirubin: No significant influence is observed up to 240 µmol/L.

Clinical Performance

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this test.
This is largely attributed to the fact that this test is a screening test.
To arrive at a diagnosis and a course of treatment, results from others routine coagulation tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Precautions of Characteristics

The measurement data was generated during a performance evaluation and is not recommended as an acceptance criterion.

Reference

1. One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test. Approved Guideline, 2nd ed., CLSI (NCCLS) document H47-A2 (2008) 28:20.
2. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays. Approved Guideline, 5th ed., CLSI (NCCLS) document H21-A5 (2008).
3. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
4. User Verification of Precision and Estimation of Bias. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP15-A3 (2014).
5. Evaluation of Precision of Quantitative Measurement Procedures. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP05-A3 (2014).
6. One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test. Approved Guideline, 2nd ed., CLSI (NCCLS) document H47-A2 (2008).

Yumizen G APTT Liq 4

7. Interference Testing in Clinical Chemistry. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP07-A2 (2005).