

APTT

Cephalin Silica

Code: HC00100 5 x 4 ml

Store at 2- 8°C

Activated Partial Thromboplastin Time (APTT) in plasma validation.

Intended use

The APTT reagent is intended for the determination of the activated partial thromboplastin time in human plasma.
For in vitro diagnostic use only.
For professional use only.

Clinical significance

The APTT kit from Cypress Diagnostics allows testing of the intrinsic coagulation pathway. The APTT reagent, a rabbit brain extract phospholipid, is highly sensitive to decreased levels of factors VIII, IX, XI and XII, prekallikrein and kininogen (intrinsic coagulation pathway) and factors II, V, X and fibrinogen (common end of coagulation pathway), as well as to hereditary or acquired coagulation disorders and liver failure. Therefore, the APTT kit from Cypress Diagnostics is intended for presurgical screening, monitoring during heparin therapy, and determination of the activity of the intrinsic coagulation pathway.

Principle

The reagent is cephalin, a brain phospholipid extract that performs as a platelet substitute. Micronised silica is used as an activator of factor XII. When these reagents and calcium chloride are added to citrated plasma, the factors of the intrinsic coagulation pathway are activated, the time for the plasma to clot is then measured.

Reagent Composition

Reagent 1	Rabbit brain cephalin Micronised silica Buffered medium with preservative Lyophilised
Reagent 2	Calcium chloride 25 mmol/L Buffered medium with preservative

Preparation

R1. : Bring the vial at room temperature. Add 4 ml of distilled water. Let stand for 5 minutes before swirling the vial gently in upright position a few times to mix it. Prevent contact of the fluid with the stopper. Keep the reagent at room temperature (20-25°C) for at least 30 minutes until complete reconstitution.

Just before use, swirl the vial gently 5-10 times in upright position. Do not shake.

R2. Ready-to-use.

Storage and stability

All the components of the kit are stable at 2-8°C up to the date of expiration as specified. Do not freeze!

Stability of reagent 1 after reconstitution: 14 days at 2-8°C, 10 days at 15-19°C and 1 day at 20-25°C in the original vial.

Stability of reagent 2 after opening: 8 weeks at 2-19°C and 1 day at 37°C in the original vial.

Additional material required, not provided

- Optical or mechanical coagulation reader
- General laboratory equipment

Precautions

1. Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All reagents and contaminated waste such as patient samples and used material should be properly disposed of in accordance to the relevant national regulations.
2. According to the present knowledge the reagent doesn't contain infectious agents that can be transmitted from animal to human.
3. Do not use the reagent beyond the expiration date printed on the label.
3. Avoid microbial contamination of the reagent or erroneous results may occur.

Samples

SAMPLE: Plasma obtained from whole blood anti-coagulated with 3.2% (109 mmol/l) sodium citrate. The use of higher concentrations of sodium citrate (3.8%, 129 mmol/l) is not recommended.

SAMPLE COLLECTION: Immediately add nine parts of freshly collected whole blood to one part of anticoagulant.

SAMPLE PREPARATION: Mix the blood carefully and centrifuge the sample to obtain the plasma, place it in a test tube, keep at room temperature (20-25°C) and perform the test within 4 hours. Do not store the sample at 2-8°C. For longer storage times, the plasma can be kept at -20°C for up to 2 weeks. Refer to the Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

Procedure

Each sample should be tested at least twice.

1. Bring reagent R.1 at room temperature.
Bring reagent R.2 at 37°C for at least 15 minutes.
2. Continuously stirring with a stirring bar/ball or regularly swirling of the reagent R.1 is needed to keep the reagent homogeneous during testing.
3. Transfer in a cuvette:

Sample R.1	100µl 100µl
Mix and incubate 3 min at 37°C. Gently swirl the vial with R.2 just before use and add abruptly:	
R.2	100µl
Start the timer immediately. Measure time of clot formation.	

If using an instrument to perform this test, refer to the appropriate Instrument Operator's Manual for detailed instructions.

Results

The result can be reported in the following units:

1. Seconds: observed clotting time.
2. Ratio (clotting time of the sample divided by the mean normal APTT (MNPTT)). The MNPTT values for different readers given in the included table are only for orientation purpose. The MNPTT depends on the measuring circumstances and population. Therefore, every laboratory should determine its own MNPTT value.

Expected values:

Normal APTT values: 25 – 43 seconds

The normal range is influenced by several factors (age, gender, hematocrit, etc.). Therefore, every lab should determine its own reference ranges.

Quality control

Normal and pathological controls (HC00500) are recommended for verifying the measurement. Each laboratory should establish its own quality control program.

Limitations

1. Every laboratory should determine its own MNPTT value (the geometric mean of the APTT of at least 20 healthy, untreated people) and reference range.
2. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.
3. The results obtained for APTT may be influenced by drugs and other pre-analytical interfering agents.

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

12.2019, Rev. 5.1



**APTT
TCA**



Code / Réf.: HC00100 5 x 4 ml

Store at / Conserver entre 2 -8°C

Lot	991233A
Exp. Date / Date de Pérem.	28/12/2021
Coagulation analyzer / analyseur	MNPTT / TCA Normal Moyen
CYANCoag line - Mechanical Readers Ligne CYANCoag - Lecteurs Mécaniques	33,2 sec
Sysmex CA line - Optical Readers Ligne Sysmex CA - Lecteurs Optiques	33,4 sec
Stago line - Mechanical Readers Ligne Stago - Lecteurs Mécaniques	34,2 sec

The mean normal partial thromboplastin time (MNPTT) is for information only. The value depends on population, race, gender, sampling tube, etc. According to the CLSI every laboratory should determine its local MNPTT.

Le Normal Moyen de temps de céphaline activée (TCA Normal Moyen) est donné à titre informatif uniquement. La valeur dépend de la population, la race, le sexe, tube de prélèvement, etc. Selon le CLSI chaque laboratoire doit déterminer son TCA Normal Moyen local.

