ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) LIQUID REAGENT

IVD For *In-Vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C CE

INTENDED USE

The Activated Partial Thromboplastin Time (APTT) Kit is a common screening test done to evaluate function of the intrinsic clotting system.

PRINCIPLE

During testing at 37℃, citrated specimen is dispensed into the APTT reagent, which contains a factor activator and platelet substitute. In presence of Calcium chloride a stable clot is formed. Activated partial thromboplastin time (APTT) is the time required for clotting formation. The degree of prolongation is proportional to the severity of single factor deficiency, or in a cumulative deficiency of all the factors involved.

MATERIALS

***Material Provided**

- APTT Liquid Reagent: Suspended liquid (0.05% Ellagic acid, 0.2% cephalin, 0.2% sodium chloride. 0.1% Sodium benzoate,
- $CaCl_2$ (0.025 M) (Optional).
- Plasma Normal and Abnormal Control (Optional).
- Package Insert.

***Material Required but not Provided**

- Plastic test tubes.
- Calibrated micropipettes and tips.
- Timer.

STORAGE AND STABILITY

- The kit should be stored at (2-8°C).
- The APTT Reagent is stable for 30 days after opening when stored at (2-8°C).
- *Do not use the kit beyond the specified expiry date and stop using the kit if there are any signs of deterioration.
- Do not **FREEZE.**

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use the test beyond the labeled expiry date.
- Protective clothing should be worn when handling the reagents.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Follow the instructions for use carefully before testing.
- Do not use these reagents if the label is not available or damage.
- Do not use the kit if damaged or the glass vial are broken or leaking and discard the contents immediately.
- Wash hands and test tabletop with water and soap once the testing is done.
- Close the vial tightly after each test.
- Do not freeze the reagent.
- Do not mix components from kits with different lot number.
- During testing all test tubes, syringes and pipettes should be plastic.
- In order to prevent the loss of factor V and Ⅷ in the process of measurement, the pre temperature time should be 180s accurately, and the pre temperature should be kept at 36.5 ℃ - 37.5 ℃.
- If spillage of reagent occurs clean with disinfectants (used could be irritable so handle with care).
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.
- Control sera are recommended to monitor the performance of assay procedures.
- If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.
- Turbid solution of $CaCl_2$ may be indicative of product deterioration.
- CaCl2 solution is easy to evaporate in the pre temperature zone of 37 ℃, which leads to the change of its concentration and makes the test inaccurate. Therefore, it should be capped in time after pre temperature and use to prevent evaporation.
- *Washing the area of contact with water immediately if contact occur.
- *Do not drink or ingest the reagent.
- *Use a clean pipette tip for each specimen.
- *Failure in following the instructions may give incorrect results or facing safety hazards.
- *Do not use the reagents if the label is missing, damaged, or unclear.
- *Perform the test in a well-lit area with very good visibility.
- *Do not use the reagent if contaminated or if there are signs of performance or physical deterioration.
- *Handle the used disinfectant with care.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

SPECIMEN COLLECTION AND PREPARATION

- A sample of the patient's blood is obtained by venipuncture. Plasma obtained from whole blood samples that had been collected in a tube with 0.109M sodium citrate as an anticoagulant, nine parts of freshly collected whole blood should be immediately added to one part of anticoagulant to prevent the clotting process from starting before the test. The blood cells are separated from the liquid part of blood (plasma) by centrifugation at 3000xg for 10 minutes.
- *If hematocrit is less than 20% or more than 55%, adjust the proportion of blood sample and anticoagulant according to the following formula: anticoagulant dosage = 0.00185 × blood volume (mL) × (100 patient hematocrit).
- Heparin and EDTA should not be used for anticoagulation of the plasma to be tested.
- Hemolytic samples shall not be used and must be resampled.
- Perform the activated partial thromboplastin time assay within 2 hours. The test is delayed for more than 2 hours; the plasma samples must be stored at - 20 ℃ (2 weeks). When retested, frozen plasma samples should be thawed rapidly at 37 ℃ and tested immediately.
- Reconstitute the control plasmas (normal control plasma, abnormal control plasma) according to the package insert included with the control.
- Allow the PTT reagent to reach room temperature before use.
- Pre-warm $CaCl_2$ for >20 minutes at 37°C before use.

PROCEDURE

***Allow the reagents and samples to reach room temperature; the sensitivity of the test may be reduced at low temperatures.**

Manual method

1. Pipette **50 µl** of PTT reagent into each tube.
2. Pipette **50 µl** of sample, controls to the tubes prepared in step 2.
3. Incubate for **3 minutes** at 37°C.
4. Add **50 µl** of pre-warmed $CaCl_2$ solution to each tube, start the stop watch, mix in a water bath (37°C), then record the time required for clot formation.

INTERPRETATION OF TEST RESULTS

- The test results of activated partial thromboplastin time should be reported as APTT in seconds (s).
- The measured value of the examinee is longer than that of the normal control for more than 10s before it has pathological significance. A test time less than or greater than this limit indicates an abnormal condition in the patient's coagulation system.

REFERENCE VALUES

- The reference value of normal population in 95% confidence interval of normal distribution was determined to be 26-35 seconds through clinical trials on 130 normal population
- It is suggested that each laboratory establish its own reference value range

QUALITY CONTROL

- Each laboratory must have a set of quality control procedures, which include the use of normal and abnormal controls to evaluate instruments, reagents and technical operations to determine the average value and standard deviation of daily plasma. If the data obtained by quality control plasma is not within the reference range, indicating that the reagent may deteriorate, then the patient's determination result is invalid and the result is not reported.
- *For some special groups (such as newborns, infants) or some types of automatic or semi-automatic instruments, the normal reference range should be re established.

LIMITATIONS OF TEST

- Due to different proficiency and operation methods of laboratory inspectors, the test value of APTT will vary with different laboratories. Clotting test method, preheat time, type of anticoagulant and sample storage method and time are very

important. Therefore, each laboratory should establish its own reference range. In addition, we should also pay attention to the collection and preservation of samples to avoid hemolysis and the use of hyperlipidemia and jaundice samples.

- *Clinical diagnosis should not be based on the findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTARISTICS

1. **Precision:** The precision (Within Run and Between Run) of ATLAS APTT reagent has been tested using normal and abnormal controls. The results show that the precision is ≤ 5%.

2. **Interference Substances:** The following potentially substances were added to normal and abnormal samples.
   A) Heparin: 0.5 IU/ml
   B) Bilirubin: 20 mg/dL
   C) Hemoglobin: 15 g/dL
   The result show that these tested interference substances do not appear to interfere with ATLAS APTT reagent when present at concentrations below those indicated.

3. **Clinical Study**: Atlas APTT reagent was compared with APTT commercial reagent. The study was performed using 30 samples obtained from two clinical instuations. The results obtained did not show systematic when compared other commercial kits.

REFERENCES

1. Basu, D; Gallus.; Hirsh, j. N. Eng. J. Med. 287: 324,1972
2. Young, D.; Pestaner, L.; Gibberman, V. Clin. Chen. 21: 355 D, 1975
3. Quick A. J., The PARTIAL THROMBOPLASTIN TIME in Hemophilia and in Obstructive Jaundice.J.Biol.Chem,:109,73-74:1935
4. Biggs R.ed, Human Blood Coagulation Hemostasis and Thrombosis Second Ed.Blackwell Scientific Publications, London 1976.
5. Peterson C.E., K waan H.C., Current ConcePTTs of Warfarin Therapy, Arch Intern. Med. 146:581-584,1986

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

PPI1465A01
Rev F (28.08.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

***: Indication of the introduced modifications.**