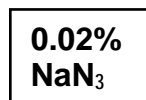




**VITACLOT  
APTT REAGENT  
LR and LS**

**PACKAGE INSERT  
INSTRUCTIONS AND INFORMATION**

Store at 2-8°C



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Product Code: 400 0170 (LR)  
400 0180 (LS)  
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## 1. INTENDED USE

The VitaClot APTT Reagents are for the determination of the Activated Partial Thromboplastin Time (APTT).

## 2. INTRODUCTION

The Activated Partial Thromboplastin Time (APTT) is a widely accepted screening test for abnormalities in the intrinsic coagulation pathway (1). A normal test result is dependent on the proper functioning of contact factors (factors XII, XI, high molecular weight kininogen (Fitzgerald factor) and prekallikrein (Fletcher factor)), also on factors VIII, IX, X, V and II as well to a less degree by fibrinogen. Deficiencies of any of these factors prolong the APTT test result and especially with factors VIII, IX, XI and V may confirm a bleeding risk in a patient. The APTT is also prolonged by heparin and various other therapeutic agents which may be monitored by it (2). It is also affected by coagulation inhibitors such as lupus anticoagulant, though to a variable degree depending on phospholipid concentration (3).

**INTRINSIN LR** (lupus resistant) contains additional phospholipid and is intentionally less sensitive to lupus inhibitors than **INTRINSIN LS** (lupus sensitive). Thus it can provide more reliable factor assay results in the presence of these non specific inhibitors than lupus-sensitive reagents (4).

## 3. PRINCIPLE OF THE TEST

In an APTT test, the reagent is pre-incubated with an equal volume of citrated test plasma at 37°C during which contact activation occurs. It is then mixed with a further volume of calcium chloride. The time required for clot formation is then recorded. The APTT is also used for assaying single factors in the intrinsic pathway and also for inhibitor tests.

## 4. KIT COMPONENT

1. 5x5mL APTT reagent.. Ready for Use.
  - a. APTT LS reagent – pale green liquid with green cap. or
  - b. APTT LR reagent – pale pink liquid with white cap.
2. 5x5mL CaCl<sub>2</sub>. Red Cap Ready to Use.

## 5. COMPOSITION

APTT Reagent includes soybean phospholipids, colloidal silicate contact activator, buffers, stabilisers and 0.02% sodium azide preservative.

CaCl<sub>2</sub>: 5x10ml vials: Contains 0.025M calcium chloride.

NB Sodium Azide is used as a preservative. If the reagent is discarded down the drain flush thoroughly.

## 6. STORAGE AND STABILITY

Unopened vials: stored at 2-8°C expiration date on the label

Used vials: 1 month at 2-8°C. **DO NOT FREEZE.**

## 7. OTHER EQUIPMENT REQUIRED BUT NOT SUPPLIED

- |                            |          |
|----------------------------|----------|
| 1. VitaCal INR Calibrators | 400 0050 |
| 2. VitaPlas 1              | 400 0010 |
| 3. VitaPLas 2              | 400 0020 |
| 4. VitaPlas 3              | 400 0030 |
| 5. Coagulation Analyser    |          |

## 8. SPECIMEN PREPARATION

Mix nine parts of freshly collected patient venous blood with 1 part of 0.109M sodium citrate (recommended by NCCLS).

NCCLS guidelines should be followed (5).

After collection centrifuge for 15 minutes (min) at 2500g. Patient plasma should be tested within 2 hours of collection. Plasma can also be transferred to a secondary plastic tube and frozen at -25°C.

## 9. PROCEDURE

- Review all instructions thoroughly before testing.
- For manual testing pre-warm the reagent to 37°C.
- For automated testing refer to the Instrument Operators Manual.
- APTT Reagent is READY FOR USE

### FOR MANUAL TESTING

1. Pre-warm APTT reagent to 37°C
2. Add 0.1mL of test plasma or control to the test tube, then add 0.1mL of APTT reagent and pre-warm at 37°C for 3 mins.
3. Add 0.1mL of pre-warmed CaCl<sub>2</sub> to test plasma or control. Mix.
4. Simultaneously with the addition of the Calcium Chloride start a stop watch or timer, and determine the coagulation time in seconds.

### FOR AUTOMATED TESTING

Refer to the specific instrument operators manual.

## 10. CALCULATION AND INTERPRETATION OF RESULTS

The time recorded, in seconds, is the patients APTT.

### Interpretation of results

Factor levels below 40% should give APTT results higher than the mean plus 2 SD. Therapeutic heparin levels 0.2-0.4u/ml should give 1.5 times to 2.5 times mean normal APTT. It is possible that some instruments may give false trip values (eg high fibrinogen patient plasmas). Results which are unexpected in view of clinical circumstances should be repeated and investigated with more specific tests.

A mean normal APTT and reference interval should be established by measuring 20 normal health sera.

### Expected results

**INTRINSIN LR** (lupus resistant) is less sensitive to lupus inhibitors than **INTRINSIN LS** (lupus sensitive). Thus a prolonged APTT result with LS followed by a shorter result with LR provides support for the presence of a lupus inhibitor in any test plasma.

## 11. PRECAUTIONS

1. Do not use reagents after the expiry date stated on the label.
2. Haemolysed or clotted specimens should not be used.
3. APTT results may be affected by many commonly administered drugs, the source of anticoagulant and the integrity of the specimen. Further studies should be performed to determine the source of unexpected abnormal result.
4. All specimens should be treated as potentially infectious.
5. Clean all spills and dispose of hazardous material as per GLP.

## 12. SPECIMEN COLLECTION

- Venous Blood should be collected by venepuncture. As per NCCLS Guidelines (5)
- Do not store specimen on ice.
- Do not leave at 37°C for more than 5 mins
- Plasma (after centrifugation) can be aliquoted to a separate plastic tube for freezing for long term storage. Before use-thaw rapidly at 37°C to prevent separation of plasma components.

## 13. QUALITY CONTROL

- Normal and abnormal QC plasmas should be tested in conjunction with patient plasmas.
- It is recommended that controls be tested at least once with every eight hour shift.

## 14. REFERENCES

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. Am.J.Clin.Pathol.1961; 36; 212.
2. Brandt JT, Triplett DA. Laboratory monitoring of heparin . Effect of reagents and instruments on the activated partial thromboplastin time. Am.J.Clin.Pathol.1981;76(suppl); 530.
3. Mannucci PM, Canciani MT, Mari D, et al. The varied sensitivity of partial thromboplastin and prothrombin time reagents in the demonstration of the lupus-like anticoagulant. Scand J Haematol.1979; 22; 423.
4. Brandt TJ, Triplett DA, Rock WA, et al. Effect of lupus anticoagulants on the activated partial thromboplastin time. Arch Pathol Lab Med. 1991; 115; 109.
5. Collection, transport and processing of blood specimens for coagulation testing and performance of coagulation assays. National Committee for Clinical Laboratory Standards, H21-A5,2008.



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