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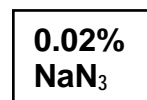
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**VITACLOT  
PT REAGENT**

**PACKAGE INSERT  
INSTRUCTIONS AND INFORMATION**

Store at 2-8°C



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Product Code: 400 0160  
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## 1. INTENDED USE

VitaClot PT Reagent, containing calcium, is used for the determination of the prothrombin time (PT), the INR (International Normalised Ratio) and for the activity for factors II, V, VII, and X.

## 2. INTRODUCTION

The prothrombin time (PT) is used to for the determination for clotting disorders in the extrinsic and common pathways. It is used for the detection and monitoring of anticoagulant therapy and can be used for checking the liver function.

## 3. PRINCIPLE OF THE TEST

When a mixture of human tissue factor and calcium ions are added to plasma the clotting mechanism is initiated. The time to form a fibrin clot is then measured.

## 4. KIT COMPONENT

1. 10x5mL PT reagent. Black Cap. Ready for Use.

## 5. COMPOSITION

PT Reagent , ready for use, : <1ug/mL recombinant human tissue factor, phospholipids, calcium chloride, buffers, salts and stabilizers.

## 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. Coagultaion 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 (1).

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.
- PT Reagent is READY FOR USE

### FOR MANUAL TESTING

1. Add 0.1mL of test plasma to the test tube and pre-warm at 37°C for 3 mins.
2. Add 0.2mL of pre-warmed reagent to test plasma. Mix.
3. Simultaneously with the addition of the PT reagent start a stop watch or timer and determine the clotting time.

### FOR AUTOMATED TESTING

Refer to the specific operators manual.

## 10. CALCULATION AND INTERPRETATION OF RESULTS

Clotting times for plasma are usually reported in seconds. Reports may also be reported in % of the norm or in International Normalised Ratio (INR).

$$PR = \frac{\text{Clotting time of sample(s)}}{\text{Mean Normal clotting time}}$$

$$INR = \frac{ISI}{PR}$$

The ISI is lot dependant for the PT reagent. If the results obtained on known QC plasmas are within the confidence interval it is not necessary that the laboratory establish its' own reference curve.

## 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. PT 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.
- 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

- Known 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.
- Each laboratory should establish its own QC ranges based on assigned values and ranges provided by the control manufacturer or based on values determined by the laboratory.

## 14. TECHNICAL PERFORMANCE

The precision of the PT reagent was determined by assaying normal and pathological control plasmas. The intra-run precision ranged from 0.5% to 5% and the inter-run precision ranged from 1.5% to 8%.

## 15. REFERENCES

1. 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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