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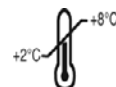
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**VitaPlas  
Coagulation Controls**

PACKAGE INSERT  
INSTRUCTIONS AND INFORMATION

Store at 2-8°C



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Product Code: VP1 400 0010  
VP2 400 0020  
VP3 400 0030  
Document Number : KBK-0034  
Issue No: 3

## **1. INTENDED USE**

VitaPlas controls are lyophilised citrated plasmas intended to provide consistent quality control reference values in prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT) and most other tests of haemostatic function.

## **2. INTRODUCTION**

Clotting tests are used to identify patients at risk of bleeding from acquired or inherited deficiency states. They are also used to monitor anticoagulants such as heparin and warfarin to ensure low risk and optimal therapeutic benefit. Conversely they may be also used to detect thrombotic risk factors such as lupus anticoagulant and resistance to activated protein C.

Laboratories which perform PT, APTT and other tests of haemostatic function are required by most regulatory authorities to include quality control plasmas in their testing protocols because there are many possible causes of erroneous results ranging from instrument problems to reagent changes. These problems can be identified from the use of a regular internal quality control program and corrected accordingly.

The ideal quality control plasma would be a pool of fresh plasma from 20 healthy individuals but this is inconvenient for routine work. VitaPlas 1 (VP1) provides a near normal plasma after reconstitution whereas VitaPlas 2 (VP2) and 3 (VP3) are abnormal plasmas representing lower and higher degrees of abnormality. The VitaPlas plasmas are internally colour coded for simple visual recognition using dyes which do not interfere with instruments in current use. Thus VP1 is yellow, VP2 green and VP3 pink.

## **3. KIT COMPONENTS**

Ordering Code : 400 0010 VP1 – 10 x 1mL vials. Lyophilised. Yellow in colour.

Ordering Code : 400 0020 VP2 – 10 x 1mL vials. Lyophilised. Green in colour

Ordering Code : 400 0030 VP3 – 10 x 1mL vials. Lyophilised. Pink in colour.

1 Package Insert

## **4. OTHER EQUIPMENT REQUIRED BUT NOT SUPPLIED**

1. PURIFIED WATER

2. 1.0ML PIPETTE

## **5. ASSAY PROCEDURE**

- Review all instructions thoroughly before testing.
- Room temperature incubations should be performed at 20 – 24°C.
- All reagents, samples and controls should be brought to room temperature before use.
- The controls should not be left at room temperature for longer than the procedure requires.

- Control material from different lot numbers should not be interchanged.
- To ensure accurate quantification, it is essential that all pipettes used in the assay are calibrated and a fresh tip is used for reagent, controls and samples.

Reagent preparation:

Reconstitute each vial of VitaPlas with 1.0ml of purified water. Allow to stand for 20 minutes with gentle mixing before use.

Directions for use:

Use the reconstituted VitaPlas controls in exactly the same way as patient plasmas when carrying out coagulation test procedures.

## **6. INTERPRETATION OF RESULTS**

VitaPlas 1 should give results within +/- 10% of those given by pooled normal plasma.

VitaPlas 2 should give INR results close to 2.5;

VitaPlas 3 should give INR values close to 3.5.

For quality control, VitaPlas controls should be accumulated over approximately 20 determinations and then plotted on a time course with upper and lower action limits defined by mean value plus and minus 2 standard deviations.

## **7. PRECAUTIONS**

1. All components containing material of human origin have been tested and found NOT DETECTED for HBsAg, anti-HCV and antibodies to HIV. They should still, however, be treated as though they were potentially infectious.
2. Clean up any spillages with diluted bleach or 70% alcohol. Dispose of waste materials with an acceptable method such as mixing liquid waste with 0.5% hypochlorite for at least 30 minutes or autoclave for 60 minutes at 121C or incinerate disposable materials.
- 3 Performing the assay at temperatures other than those stated may cause erroneous results.
4. Do not use controls after the expiry date stated on the label.
5. Care should be taken to reduce microbial contamination of controls.
6. To avoid cross-contamination do not interchange caps of controls.

## 8. REAGENT STORAGE AND SHELF LIFE

Unreconstituted vials are stable for 1 year or until the expiration date printed on the label when stored at 2-8C. After that time the product should not be used. Reconstituted products are stable for 24 hours at 20C or 4C.

## 9. LIMITATIONS

Laboratories should note that results may vary according to patient age and individual characteristics as well as to preanalytical conditions, reagents and instruments. Therapeutic intervals may be subject to even more important variables including clinical and pharmacologic guidelines.



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