



**Diagnostic Reagents Limited**

**Finger Prick Control Plasma**

LOT Number: FP92  
 Catalogue Number: CFPN110 (Normal)  
 CFPN120 (Abnormal)

For *in vitro* diagnostic use only.

LOT: FP	INR =	Range	–
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### Intended Use

Diagen Finger Prick Control Plasma is manufactured for use in conjunction with the Diagen Rabbit Brain Capillary Reagent. The control plasma is designed specifically for controlling the reagent-test system, which is used to determine patient INRs in the control of oral anticoagulant therapy using capillary (finger prick) blood.

### Summary and Principle

The Quality Control of Diagen Rabbit Brain Capillary Reagent, using the capillary blood technique, is difficult because there are no true control samples that have exactly the same properties as those of capillary blood. However, the Diagen Finger Prick Control Plasmas are manufactured in such a way as to mimic as closely as possible these properties.

### Reagent

#### Diagen Finger Prick Control Plasma **10 vials**

A buffered human plasma, lyophilised to give values in the normal and abnormal ranges. For reconstitution, remove the cap and rubber stopper and add 0.5 mL of distilled water. Allow 5 to 10 minutes for complete solution.

### Warnings and precautions

#### POTENTIAL BIOHAZARD MATERIAL.

The Finger Prick Control Plasma is of human origin. All donor units used in production of this product have been found negative for anti HIV, anti HCV, HBsAg and Syphilis by approved methods. However, all plasma of human origin should be considered as potentially infectious and handled appropriately. Please refer to the relevant SDS Sheet (CFP) for handling and safety procedures. Dispose of all waste materials according to the stated international, national and local regulations.

### Procedure

#### Materials Provided:

##### Cat. No.

CFPN110 - Normal Finger Prick Control Plasma (10 x 0.5 mL).

CFPA120 - Abnormal Finger Prick Control Plasma (10 x 0.5 mL).

#### Materials and equipment required, but **not** provided:

1. General routine laboratory coagulation equipment.
2. Rabbit Brain Capillary Reagent (RBCR030).
3. Pipettes delivering 50 µL, 250 µL and 0.5 mL.
4. Distilled water.

### Technique

#### Manual

1. 250 µL of the Diagen Rabbit Brain Capillary reagent is measured with a delivery pipette into a clotting tube and placed in a 37°C water bath for 2 minutes.
2. 50 µL of Diagen Finger Prick Control Plasma is then blown into the reagent and a stop-watch started.
3. The tube is gently tilted and the time taken for clot formation is recorded.
4. The clotting time, in seconds, is then converted to the INR by reference to the appropriate reagent calibration table. **Each batch of control plasma has its defined INR printed on the vial label.**

### Defined Value

The defined INR has been assigned using multiple reagent batches, including the house standard (calibrated against the international reference preparation RBT 90) and the house standard Finger Prick Reference Plasma. The range obtained falls within the WHO guidelines of clinical relevance.

### Semi-automated or Automated methods

Reference should be made to appropriate instrument manuals for methodology. With each test system, the Finger Prick Control plasma should be treated as if it were capillary blood.

For instrument use, the Diagen Rabbit Brain Capillary reagent capillary blood ISI and Mean Normal Clotting Time (MNCT) must first be determined in order to calculate the INR. Calibration should be performed against the manual method. For advice please contact: [calibration@diagen.co.uk](mailto:calibration@diagen.co.uk)

### Quality Control

Results obtained using Diagen Finger Prick Control Plasma with Diagen Rabbit Brain Capillary reagent should conform to the value and range defined. Failure to do so indicates a failure in the test system that requires investigation.

### Limitations

Values obtained for the Diagen Finger Prick Control Plasmas are specific for use with Diagen Rabbit Brain Capillary reagent and should **not** be used in conjunction with any other manufacturer's reagents.

### Performance characteristics

Studies have shown that this product will perform as described prior to its expiration date when procedural and storage directions are followed. Values stated on the vial are lot specific and vary from one lot to another.

A coefficient of variation (CV) of less than 3.0% was obtained between vials of Diagen Finger Prick Control Plasma with Diagen Rabbit Brain Capillary Reagent used with the manual technique.

### Storage and stability

The unopened freeze-dried vials are **best stored deep frozen** but may be stored for up to 3 years at 4°C or below without deterioration. Once reconstituted the contents of the vial are then stable for up to 8 hours when held at 2 - 8°C.

### Packaging

10 x 0.5 mL

#### Key guide to symbols

	Manufacturers catalogue number.		Consult instructions for use.
	Manufacturers batch number.		Requires reconstitution.
	For <i>in vitro</i> diagnostic use only.		Product expiry date.
	Biological risks.		Store at 4°C or below. Best stored deep frozen.



Manufacturer.



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