

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K042760

B. Purpose for Submission:

To obtain clearance for Pefakit[®] APC-R Factor V Leiden Controls, a device kit containing pooled plasmas from donors genotyped for the factor V Leiden mutation (FV: Q506) intended to be used in connection with the device Pefakit[®] APC-R Factor V Leiden.

C. Analyte:

These controls are intended to be used for quality assurance in connection with the IVD device Pefakit[®] APC-R Factor V Leiden.

D. Type of Test:

Quality Control

E. Applicant:

Pentapharm Ltd.

F. Proprietary and Established Names:

Pefakit[®] APC-R Factor V Leiden Controls

G. Regulatory Information:

1. Regulation section:
21 CFR 864.5425
2. Classification:
Class II
3. Product Code:
GGN
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
These controls are intended to be used in connection with the device Pefakit[®] APC-R Factor V Leiden for the confirmation of factor V Leiden mutation (FV: Q506) in assays for determination of the functional phenotype for activated protein C resistance.

2. Indication(s) for use:

The device is a box containing lyophilized pooled plasmas from donors genotyped for the factor V Leiden mutation (FV: Q506) to be reconstituted with water by the user. Controls contain pooled plasmas of either donor with heterozygous FV: Q506 mutation or normal wild-type pattern. These controls are intended to be used for quality assurance in connection with the IVD device Pefakit® APC-R Factor V Leiden.

3. Special condition for use statement(s):

Not applicable

4. Special instrument Requirements:

Not applicable

I. Device Description:

Pefakit® APC-R Factor V Leiden Controls is an in vitro diagnostic controls kit containing 3 vials each of the following lyophilized plasmas:

C1: pooled human plasma from donors confirmed to be normal wild-type by factor V Leiden PCR testing.

C2: pooled human plasma from donors confirmed to be heterozygous by factor V Leiden PCR testing.

J. Substantial Equivalence Information:1. Predicate device name(s):

(a) COATEST® APC™ RESISTANCE V/ COATEST® APC™ RESISTANCE VS

2. Predicate K number(s):

(a) K963111

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample Type:	Pefakit® APC-R Factor V Leiden Controls Pooled and lyophilized citrated human plasma	Coatest APC Resistance V/Coatest APC Resistance VS Pooled and lyophilized citrated human plasma
Genotype status confirmed by:	PCR	PCR

Differences		
Item	Device	Predicate
Stability: Controls at 15-25° C (on board, once opened or after reconstitution)	8 hours	6-8 hours
Controls at -20° C (once opened or after reconstitution)	6 months	3 months

K. Standard/Guidance Document Referenced (if applicable):**L. Test Principle:**

Not applicable

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Plasmas tested for factor V Leiden genotype by PCR

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

2. Comparison studies:a. *Method comparison with predicate device:*

Not applicable

b. *Matrix comparison:*

Not applicable

3. Clinical studies:a. *Clinical sensitivity:*

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a and b are not applicable):

Stability:

The Pefakit[®] APC-R Factor V Leiden reagents (described in a separate 510(k) submission, were used for testing stability of the control plasmas of Pefakit[®] APC-R Factor V Leiden Controls. Clotting times and ratios for stability verification were determined using an Amelung KC-10 A[™] micro equipment.

In stress tests the lyophilized controls C1 and C2 were exposed to 37° C for several days. Samples of the controls were reconstituted on day 0-4, on day 7, day 9, day 11 and day 14. The +APC and –APC clotting times were measured using freshly reconstituted reagent from an unstressed released test kit (Pefakit[®] APC-R Factor V Leiden). The clotting times were slightly rising over this time period but the ratio remained stable during at least 8 days of exposure. It was concluded that the controls are stable for at least 1 year. This has been confirmed by the real-time long-term stability studies.

After reconstitution, the open controls were tests for on-board reagent stability (15° – 25° C) using freshly prepared reagents of Pefakit[®] APC-R Factor V Leiden. The controls were tested at 1 hour intervals over a period of 8 hours. During this time period, the clotting times of the +APC measurement especially for the normal wild-type control (C1) were slightly rising, but still within predefined acceptable range.

Reconstituted sample of reagents and control were frozen and stored at -20° C. After 6 months, the reagent and controls were thawed and clotting times and ratios for C1 and C2 were determined. Clotting times and ratios measured were within the predefined acceptable ranges. No shift was observed. It was concluded that the controls are stable when frozen at -20° C for at least 6 months.

C1	After reconst.	1 hr	2 hr	3 hr	4 hr	5 hr	6 hr	7 hr	8 hr
+APC	156.6	166.0	163.8	166.1	172.9	176.7	182.7	175.4	186.5
-APC	25.4	26.1	25.9	26.0	25.9	26.0	26.5	26.7	27.1
Ratio	6.2	6.4	6.3	6.4	6.7	6.8	6.9	6.6	6.9

C2	After reconst.	1 hr	2 hr	3 hr	4 hr	5 hr	6 hr	7 hr	8 hr
+APC	43.9	44.0	45.8	45.4	45.7	47.1	46.8	47.2	46.9
-APC	28.0	28.7	28.2	28.3	29.4	28.7	29.1	29.8	29.7
Ratio	1.6	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Not applicable

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.