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PENTAPHARM LTD

Pefakit® APC-R Factor V Leiden Controls

REF **502-21**

CE

IVD - For In-Vitro Diagnostic Use

Intended Use and Application

Control plasmas for confirmation of factor V Leiden mutation (FV:Q^{506}) in assays for determination of the functional phenotype for activated protein C resistance caused by the factor V Leiden mutation.

Introduction

Pefakit® APC-R Factor V Leiden Controls is a kit containing pooled plasmas from donors genotyped for the factor V Leiden mutation (FV:Q^{506}). Controls contain pooled plasmas of donors with either heterozygous FV:Q^{506} mutation or normal wild-type pattern. The genetic type of each blood donor has been checked and verified by PCR typing.

The controls are intended to be used in combination with Pefakit® APC-R Factor V Leiden (REF 502-01), a plasma based functional assay for the determination of resistance to activated protein C caused by the factor V Leiden mutation (FV:Q^{506}) [1], or an equivalent APC Resistance test.

Contents

Controls	Content
C1	**FV-L Negative Control** (human plasma) 3 vials (lyophilized, to be reconstituted in 1.0 ml of deionized water per vial)
C2	**FV-L Heterozygous Control** (human plasma) 3 vials (lyophilized, to be reconstituted in 1.0 ml of deionized water per vial)

Materials required but not provided

- Deionized water
- Calibrated pipette (1000 µl)
- Automated or semi-automated coagulation instruments which employ mechanical or optical detection methods

  Note: When using automated or semi-automated coagulation analyzers refer always to manufacturer's operator manual or ask for a detailed adaptation protocol.

Preparation and use of Pefakit® APC-R Factor V Leiden Controls

Prepare controls in the following way:

Reconstitute negative and heterozygous control in 1.0 ml deionized water, incubate in closed vials for 30 min. at room temperature and swirl gently before use. **Attention:** Extended incubation of controls C1 and C2 may - due to their high protein content - cause a phase separation characterized by a clear solution with a fine whitish layer on its surface. This may be erroneously interpreted as coagulation. Therefore, the controls should absolutely be brought in their initial homogeneous and cloudy form just before use.

Storage and Stability

The control kit may be used up to the expiry date given on the label when stored unopened at 2-8°C.

Stability of the reagents after reconstitution:

Controls	Stability	
C1	-20°C	6 months
	15-25°C	8 hours (on-board)
C2	-20°C	6 months
	15-25°C	8 hours (on-board)

The control plasmas should be thawed at 37°C and gently mixed before use. Freeze only once.

Certified Ranges

Different clotting times will be obtained with different types of instruments depending on the clot detection principle. The table (see separate page) shows the individual ranges of ratios for all instruments where a certification of the controls was carried out (KC-4 A™ Micro, BCS®, CA-1500/CA-7000, ACL 9000™, AMAX CS-190™, STA® C).

If values outside these ranges are obtained using the controls, the test results are not valid and shall not be used for diagnostic purposes.

When controls are used in combination with another suitable test or instrument, expected ratio values may be different and have to be determined locally under appropriate conditions.

Precautions

Each donor unit used in the preparation of the control plasmas has been tested for antibodies against HIV Type 1 and 2, Hepatitis C-Virus antibodies, Treponema pallidum antibodies as well as Hepatitis B surface-antigen and Hepatitis C genome by PCR. The tests used are all CE certified tests according to list A of the European Directive for IVDs (98/79/EC) and are under supervision by the responsible European governmental authority. The plasmas were found to be negative on the tested parameters. However, since no test can completely rule out the presence of blood borne diseases these control plasmas have to be handled as potentially infectious material.

Bibliography

1. Greengard JS, Sun X, Xu X, Fernandez JA, Griffin JH, Evatt B. Activated protein C resistance caused by Arg506Gln mutation in factor Va. Lancet 1994; 343: 1361-2.

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