1st International Genetic Reference Panel for Factor V Leiden, Human gDNA
04/224

Version no. 2; 24.11.04.

1. INTRODUCTION
The ampoules contain freeze-dried purified gDNA samples extracted from EBV transformed cell lines. They are intended for use as reference reagents in genetic tests for Factor V Leiden.

2. UNITAGE
There is no unitage assigned to these materials.

3. CONTENTS
The panel comprises three 10 µg samples of human gDNA samples;
   03/254 Wild Type Factor V
   03/248 Factor V Leiden Heterozygote
   03/260 Factor V Leiden Homozygote
The DNA samples were extracted using a ‘salting out’ method and suspended in Tris/EDTA buffer with 5 mg/ml Trehalose as an excipient before freeze-drying. The factor V gene in all three preparations has been sequenced from position 166250329 to 166251029. Only the expected G>A polymorphism at position 166250731 was detected. The remaining sequence in all three preparations was identical to the published sequence Ensemble Gene ID ENSG00000056213.

4. CAUTION

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.

The preparation contains material of human origin, which has been tested and found negative for HBsAg, HIV antibody, HCV antibody and HCV RNA by PCR.

As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.
5. DIRECTIONS FOR OPENING THE DIN AMPOULE

DIN ampoules have an ‘easy-open’ coloured stress point, where the narrow ampoule stem joins the wider ampoule body.

Tap the ampoule gently to collect the material at the bottom (labeled) end. Ensure that the disposable ampoule safety breaker provided is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar.

Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

6. USE OF AMPOULED MATERIAL

a. Store all unopened ampoules of the freeze-dried preparations at -20°C or below.
b. Open ampoules as described in Section 5. above.
c. Reconstitute freeze-dried material at room temperature with 100 µL of sterile nuclease-free water.
d. Transfer the entire contents to nuclease-free tubes.
a. Keep all reconstituted samples in sealed tubes between +2 to +8°C if the samples are to be tested within 3 months. For longer periods, store in aliquots at -20°C or below.

7. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Accelerated degradation experiments indicate that the freeze-dried materials in ampoules are stable and suitable for use after storage at +56°C and +45°C for at least 3 months.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.
8. CITATION

In all publications including data sheets in which this material is referenced, it is important that the WHO status of the preparation, specified by the title of the preparation, the name and address of the WHO International Laboratory for Biological Standards at NIBSC and the NIBSC code number are cited and cited correctly.

9. PRODUCT LIABILITY

Information emanating from NIBSC is given after the exercise of all reasonable care and skill in its compilation, preparation and issue, but is provided without liability in its application and use.

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NIBSC accepts no liability whatsoever for any loss or damage arising from the use of this product, whether loss of profits, or indirect or consequential loss or otherwise, including, but not limited to, personal injury other than as caused by the negligence of NIBSC. In particular, NIBSC accepts no liability whatsoever for:

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In the event of any replacement of goods following loss or damage a customer accepts as a condition of receipt of a replacement product, acceptance of the fact that the replacement is not to be construed as an admission of liability on NIBSC's behalf.
10. MATERIAL SAFETY SHEET

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<td>Effects of ingestion:</td>
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<td>Effects of skin absorption:</td>
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**Suggested First Aid**

- **Inhalation**: Seek medical advice
- **Ingestion**: Seek medical advice
- **Contact with eyes**: Wash with copious amounts of water. Seek medical advice.
- **Contact with skin**: Wash thoroughly with water.

**Action on Spillage and Method of Disposal**

Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water.

Absorbent materials used to treat spillage should be treated as biological waste.