Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis E, Human Immunodeficiency Virus-1 and Parvovirus B19 reagent for Nucleic Acid Amplification Testing (Blood Virology Multiplex II).
NIBSC code: 16/154-XXX
Instructions for use
(Version 2.0, Dated 13/12/2019)

This material is an 'Annex II List A' IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC".

1. INTENDED USE

This product is CE marked for use as an IVD within the UK, EU member states and EEA countries. In all other territories this product can be used for research purposes only.
The Blood Virology Multiplex Reagent II is designed as a low positive control material to assure the sensitivity of PCR assays for any of Hepatitis A (Genotype 1a), Hepatitis B (Genotype A2), Hepatitis C (Genotype 3a), Hepatitis E (Genotype 3a), Human Immunodeficiency Virus 1 (subtype B) and Parvovirus B19 (Genotype 1). This reagent is NOT intended for use as a nucleic acid sequencing control. The reagent contains low concentrations of all six viruses diluted in normal human plasma. The reagent should be considered infectious. The product may be positive for the presence of antibodies to HAV, HBsAg, HCV, HEV, HIV and Parvovirus B19. The product must not be diluted and once thawed must only be extracted once. If the packaging is damaged the products cannot be used. Unused product should be discarded. It is the responsibility of the recipient laboratory to determine whether or not this product is suitable for their requirements.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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 should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

This reagent is supplied with a nominal unitage determined by NIBSC after assays of the NIBSC Blood Virology Multiplex II against the appropriate current International Standard. The unitage is

Hepatitis A 290 IU/ml (SD 26 IU/ml)
Hepatitis B 280 IU/ml (SD 51 IU/ml)
Hepatitis C 240 IU/ml (SD 94 IU/ml)
Hepatitis E 1940 IU/ml (SD 440 IU/ml)
Human Immunodeficiency Virus -1 1190 IU/ml (SD 720 IU/ml)
Parvovirus B19 800 IU/ml (SD 90 IU/ml)

These figures are NOT absolute values but are provided for guidance only.
The determination of a precise unitage of an unknown sample can only be achieved by performing a titration of that sample against the appropriate International Standard. The NIBSC Blood Virology Multiplex product is designed to assure assay performance as a run-control and therefore this material MUST NOT be used for any calibration purposes at all.

Due to the slight variation between batches users are advised to revalidate their assays when using a new batch of control.

4. CONTENTS

Country of origin of biological material: United Kingdom.
The reagent consists of a batch of vials coded 16/154-XXX containing a dilution of HAV, HBV, HCV, HEV, HIV and Parvovirus B19. Each vial contains 2.0ml of liquid. Users are encouraged to inform NIBSC of the performance of the preparation from reviews of their data monitoring. Any user who has data supporting any deterioration in the characteristics of any reference preparation is encouraged to contact NIBSC.

5. STORAGE

The NIBSC Blood Virology Multiplex II reagent should be stored at or below -70°C until use and each vial should be used once and then discarded.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The NIBSC Blood Virology Multiplex II is intended for use by hospital and other diagnostic laboratories and should be included in every series of NAT assays for HAV, HBV, HCV, HEV, HIV and Parvovirus B19. A series of assays is defined as the number of tests set up at the same time under the same conditions and processed in a similar manner.
This reagent is NOT intended for use as a nucleic acid sequencing control.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

The stability of this product has not been fully assessed. However similar materials have not lost potency when stored at or below -70°C over a period of six years from the date of manufacture. The shelf life of these products is 5 years as indicated on the label.

9. REFERENCES

Fryer JF, Heath AB, Wilkinson DE, Minor PD; Collaborative Study Group. A collaborative study to establish the 3rd WHO International Standard for hepatitis B virus for nucleic acid amplification techniques. Biologicals. 2017 Mar;46:57-63.

Saldanha J, Lelie N, Yu MW, Heath A; B19 Collaborative Study Group. Establishment of the first World Health Organization International Standard for human parvovirus B19 DNA nucleic acid amplification techniques. Vox Sang. 2002 Jan;82(1):24-31.

10. ACKNOWLEDGEMENTS

None.

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

CE 1434

http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties			
Physical appearance: Frozen Liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	Unknown
Flammable:	No	Handling:See caution, Section 2	
Other (specify):	Contains human plasma and Infectious virus.		

Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin

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.

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.
Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: Less than 10 grammes.
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No