



CE Marked Material
HBV, HCV and HIV Multiplex 14/198-XXX
NIBSC code: 14/198-XXX
Instructions for use
(Version 7.0, Dated 28/10/2019)

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 Triplex Reagent is designed as a low positive control material to assure the sensitivity of PCR assays for HBV, HCV and HIV and contains a low concentration of each of these analytes in normal human plasma. This reagent contains a dilution of HBV, HCV and HIV in normal human plasma and as such should be considered infectious. The product may be positive for the presence of antibodies to HBsAg, HCV and HIV. The product must not be diluted and must only be used once. If the packaging is damaged the products cannot be used. Unused product should be discarded.

2. CAUTION

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

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 WITHOUT a defined unitage. NIBSC have determined that the product was positive for Hepatitis B Hepatitis C and Human Immunodeficiency Virus 1 in 100% of cases in 120 assays using the Roche MPX version 2.0 assay running on the Roche 6800 analyser.

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

This material MUST NOT be used for any calibration purposes at all but only as a run control.

4. CONTENTS

Country of origin of biological material: United Kingdom.
The reagent consists of a batch of vials coded 14/198-XXX containing a dilution of HBV, HCV and HIV. Each vial contains 3.0ml 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 HBV, HCV and HIV Triplex 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

The NIBSC HBV,HCV and HIV triplex is intended for use by Blood Screening laboratories and should be included in every series of NAT assays for HBV DNA, HCV and HIV RNA. 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.

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 material has not been fully assessed. However similar materials have not lost potency when stored at or below -70°C over a period of 6 years. The shelf life of these standards is 5 years and indicated on the label.

9. REFERENCES

None.

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:
<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 a 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 10grammes
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No