Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
British Working Standard for Anti HCV (1 in 8 dilution)
NIBSC code: 19/242-xxx
Instructions for use
(Version 3.0, Dated 13/06/2022)

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.
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The batch label will have a suffix indicating the current batch number.

The British Working Standard for antibodies to Hepatitis C virus (anti-HCV) manufactured by NIBSC have been on the market for approximately 20 years. They serve as the UK Working Standards cited in the Guidelines for Blood Transfusion Services in the United Kingdom, 8th Edition March 2013. www.transfusionguidelines.org.uk

The 1 in 8 dilution of the British Working Standard for anti-HCV is intended for use in the field of in vitro diagnostics, in conjunction with diagnostic immunoassay test kits/systems for the detection of anti-HCV, to monitor the performance of these systems. It can be used to monitor the consistency of test performance using statistical process control on a daily basis and over a period of time as a retrospective monitor of batch performance. However, it is for the user to establish suitability of purpose. When used on kits of high analytical sensitivity It is expected that this material will be detected in every series of tests.

This material should be used in addition to the positive and negative controls supplied with each lot of kit. Only the controls supplied with each lot of kit by the manufacturer are used to determine the validity of assays and to calculate the cut-off value that forms the basis for donor screening or diagnosis.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.
The preparation contains a dilution of human plasma known to be positive for antibody to HCV. This plasma has been tested and found negative for Hepatitis B surface antigen and antibodies to HIV 1 and HIV 2.

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

No unitage is assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom.

The British Working Standard for antibodies to Hepatitis C virus (anti-HCV) 1 in 8 Dilution contains approximately 3ml of liquid, containing:

Human plasma containing antibodies to HCV, (PCR positive)
Phosphate buffered saline
5% human albumin
0.05% sodium azide as preservative.

5. STORAGE

Vials should be stored at 2-8°C on receipt as indicated on the label

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

THIS MATERIAL IS SUPPLIED FOR USE IN ITS FINAL FORM AND MUST NOT BE FURTHER DILUTED OTHER THAN AS REQUIRED IN INDIVIDUAL TEST PROCEDURES.

Users should be aware that different batches of the same assay kit, and/or different assay conditions, may give different values with this reagent.

The Result Reporting System (RRS) has been developed by the National Institute for Biological Standards and Control (NIBSC) for the data monitoring of its serology and NAT quality control (QC) reagents. These include the Quality Control Reagent Unit (QCRU) and Clinical Virology Network (CVN) reagents. The system has been successfully running for serology assays for several years, collecting thousands of data points a year; and more recently for data derived from reagents used in Nucleic Acid-based Technologies (NAT) assays. https://www.nibsc.org/products/rrs.aspx

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 previous batches of working standard has been monitored. These materials have not lost potency when stored at 2-8°C over a period of 18 months. The shelf life assigned to working standard will be 18 months when stored at 2-8°C.

The expiry date is given on the vial label. Once opened a vial may be used for up to 3 months. It should be stored at 2-8°C between each use.

Users who have data supporting any deterioration in the characteristics of any Working Standard are encouraged to contact NIBSC.

9. REFERENCES

Not applicable

10. ACKNOWLEDGEMENTS

EC REP: Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

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

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: Liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	Yes (contains sodium azide)
Flammable:	No	Handling:See caution, Section 2	
Other (specify):	Contains material of human origin and may contain 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: 3g per vial
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** No