Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
NIBSC Anti-HCV Monitor Sample
NIBSC code: 24/214-xxx
Instructions for use
(Version 3.0, Dated 15/07/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

This reagent is intended for performance monitoring of immunoassays detecting antibodies to Hepatitis C virus.

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

The reagent is not intended to be used for assay calibration purposes, or for in vitro diagnostic use.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.
This reagent contains material of human origin. It contains a dilution of human plasma sample known to be positive for antibodies to HCV. This plasma has been tested and found negative for HBsAg and anti-HIV-1/2.

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 reagent

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial coded 24/214-xxx contains a 3.0 mL solution consisting of:

Pooled and diluted Anti-HCV-positive plasma
Phosphate buffered saline (PBS-A)
5% Human serum albumin
0.05% sodium azide as a preservative.

5. STORAGE

On receipt this reagent should be stored at 2-8°C until use.

Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

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 reagent should be tested in addition to the positive and negative controls supplied with the assay kit and treated as if it were a routine test sample. Only the controls supplied by the manufacturer with each kit lot should be used to determine the validity of assays and to calculate the cut-off value that forms the basis for donor screening or diagnosis.

The reagent should be used without further dilution other than as required by individual test procedures.

Once opened each vial should be stored at 2-8°C and then be used within three months (as long as the expiry date is not exceeded), after which the reagent should be discarded.

Users are encouraged to provide information on the performance of the reagent in their assay(s), either by e-mail (refer to section 12) or via the Result Reporting System (RRS), a tool developed by NIBSC for the data monitoring of its serology and NAT reagents. Users are encourage to sign up here: https://nibsc.org/products/rrs.

8. STABILITY

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

This reagent has a shelf-life of 36 months from the date of manufacture.

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.

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

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:	No
Flammable:	No	Handling: See caution, Section 2	
Other (specify):	Contains material of human and animal origin, and may contain infectious virus.		
Toxicological properties			
Effects of inhalation:	May contain infectious virus, avoid inhalation		
Effects of ingestion:	May contain infectious virus, avoid ingestion		
Effects of skin absorption:	May contain infectious virus, 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: 3.0 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

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