WHO International Standard
WHO 2nd International Standard For Hepatitis C Virus RNA for Genomic Amplification Technology Assays
NIBSC code: 96/798
Instructions for use
(Version 5.0, Dated 17/12/2007)

1. INTENDED USE
The Second WHO International Standard for HCV RNA, 96/798, consists of a dilution of a positive donation (genotype 1) in HCV-negative human cryosupernatant. The cryosupernatant is also negative for anti-HIV, anti-HBsAg, HAV RNA and parvovirus B19 DNA. The sample has been lyophilised in 0.5ml aliquots in glass vials and stored at -20°C. The vials were labelled prior to the approval of the material as the International Standard. Consequently, the vials are labelled
Int. Plasma 96/798

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 material has been assigned a titre of 5 x 10¹⁴ International Units (IU) per vial.

Uncertainty: the assigned unitage does not carry an uncertainty associated with its calibration. The uncertainty may therefore be considered to be the variance of the ampoule content and was determined to be +/- 3.20%.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each vial contains lyophilised HCV positive human plasma diluted in HCV negative human cryosupernatant. The cryosupernatant is also negative for anti-HIV, anti-HBsAg, HAV RNA and parvovirus B19 DNA.

5. STORAGE
Vials of lyophilised standard should be stored at -20°C. The stability of the International Standard has been monitored. The material is stable and shows minimal loss of RNA titre after 200 days at -20°C or 200 days at +4°C

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING
Vials have a ‘flip-up’ circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

The International Standard should be used to calibrate in-house standards or working reagents, for example, by determining the genome equivalent titres of the in-house reagent to be calibrated and the International Standard in parallel. The titre of the in-house reagent can then be calibrated in International Units using the ratio of the titres obtained from the assay.

All criteria of assay validity set by individual kit manufacturers should be satisfied.

This material is supplied lyophilised and before use should be reconstituted in 0.5ml of water. If all the reconstituted material is not used immediately, laboratories may aliquot the material into suitable volumes, which should be stored at or below –60°C.

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.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

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 appearance: Freeze dried powder | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: No | Irritant: No |

Physical and Chemical properties

World Health Organization

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
Flammable: No
Handling: See caution, Section 2
Other (specify): Contains material of human origin

### Toxicological properties

**Effects of inhalation:** Avoid - contains infectious HCV
**Effects of ingestion:** Avoid - contains infectious HCV
**Effects of skin absorption:** Avoid - contains infectious HCV

### 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**: 0.5 grams
**Toxicity Statement**: Non-toxic
**Veterinary certificate or other statement if applicable**: Attached: No

### 17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.