Non WHO Reference Material
3rd HCV RNA Genotype Panel for Nucleic Acid Amplification Techniques.
NIBSC code: 12/172
Instructions for use
(Version 1.0, Dated 25/03/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE
Hepatitis C virus (HCV) is currently classified into six major genotypes differing by as much as 30% at the nucleotide level. A major requirement of HCV nucleic acid amplification technology (NAT) assay validation is the ability of the assay to detect the six major genotypes of HCV with equivalent sensitivities. The HCV RNA genotype panel (Code 12/172) is enclosed for use in the validation of qualitative HCV RNA assays. Each panel consists of SEVEN vials representing each of the six major genotypes. Vial 12/254 is HCV genotype1a, 12/256 is HCV 1b, 12/158 is HCV 2b, 12/160 is HCV 3a, 12/162 is HCV4r, 12/164 is HCV 5a & 12/166 is 6i).
This product is NOT CE-marked and MUST NOT be used as a diagnostic device.

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

This material contains Hepatitis C virus and must be considered infectious. 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
The panel was prepared by diluting HCV positive donations in HCV RNA negative human plasma, to give a final concentration ranging from 150 to 1500 IU/ml as determined using a Roche HCV v2.0 CAP/CTM assay. These unitages are FOR GUIDANCE ONLY as this panel is NOT designed for quantitation purposes.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each vial of the panel contains 1.0 ml of liquid. Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Once aliquoted or diluted, users should determine the stability of the material according to their own method of preparation, storage and use.

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 HCV RNA genotype panel should be stored at or below -60°C until use and each vial should preferably be used only once and then discarded. The preparation may be used undiluted or diluted in HCV RNA negative human plasma or cryosupernatant.

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 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 HCV RNA genotype panel is intended to be used in the validation of nucleic acid amplification techniques (NAT) assays. This panel is NOT designed for quantification purposes.

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
The first genotype panel was published by John Saldanha and published here.

10. ACKNOWLEDGEMENTS

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: Frozen plasma | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: No | Irritant: No |
| Flammable: No | Handling: See caution, Section 2 |

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WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory
Other (specify): Contains infectious HCV and materials of human origin

<table>
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<th>Toxicological properties</th>
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<td>Effects of inhalation:</td>
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<td>Effects of ingestion:</td>
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<td>Effects of skin absorption:</td>
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**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 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**: 6 grams.
- **Toxicity Statement**: Non-toxic
- **Veterinary certificate or other statement** if applicable.
- **Attached**: No