



**1st World Health Organization International
Standard for Hepatitis C Virus (HCV) core antigen**

PEI code 129096/12

**Instructions for Use
(Version 1.0, dated 21/11/2014)**

1. INTENDED USE

The 1st World Health Organization (WHO) International Standard for Hepatitis C Virus (HCV) core antigen is intended to be used in the standardization and calibration of quantitative and/or qualitative diagnostic HCV core antigen assays, for the determination of analytical sensitivity and for quality control purposes. The establishment of an international standard is an urgent need for the standardization, harmonization and quality control of HCV core antigen (Ag) assays. The material may be used for HCV core Ag assays that detect HCV antigen in the presence of specific antibodies.

The standard represents a lyophilized plasma preparation originating from a HCV genotype 1a infected blood donor. The material has been lyophilized in 0.5 ml aliquots and stored at -20°C. The material has been evaluated in an international collaborative study involving 12 laboratories performing six different HCV core antigen- detecting assays. Further details of the collaborative study are available in the report WHO/BS/2014.2247.

Please note that the material contains low level antibodies that may interfere with HCV Ag/Ab combination tests.

2. UNITAGE

This reagent has been assigned a unitage of 3,200 International Units/ml. The results of the collaborative study undertaken to characterize this preparation revealed major differences of the sensitivity of HCV core Ag detecting assays. Consequently, the unitage has been assigned taking into account the results of one quantitative HCV core Ag assay only.

3. CONTENTS

Each vial contains 0.5 ml of a lyophilized plasma preparation containing infectious HCV.

4. CAUTION

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.

The preparation contains material of human origin and infectious HCV. It was characterized as follows: high positive for HCV RNA and HCV core antigen. The material tested negative for markers of HIV and HBV infection. This preparation should be regarded as hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be taken in opening ampoules or vials, to avoid cuts.

5. USE OF MATERIAL

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

The material is supplied lyophilized and should be stored at or below -20°C. Each vial should be **reconstituted in 0.5 ml sterile ultrapure water**. The product should be reconstituted just prior to use, once reconstituted, multiple

freeze thawing of the product are not recommended. If not all the material is used immediately, laboratories may aliquot the remaining material into suitable volumes which should be stored at or below -20°C. Do not store the reconstituted material in the refrigerator. It may not be stable at 4-8°C.

6. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

The reference materials are held at the PEI within assured, temperature-controlled storage facilities. Reference materials should be stored on receipt as indicated on the label. Once diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact PEI.

7. REFERENCES

Nick S., Volkens P., Ross S., Scheiblauber H., and the Collaborative Study Group: Collaborative Study to Establish a World Health Organization International Standard for Hepatitis C Virus core antigen. WHO Report, WHO/BS/2014.2247.

8. ACKNOWLEDGEMENTS

We thank the participants and laboratories staff for their expertise and contribution.

9. FURTHER INFORMATION

Further information for this material can be obtained as follows: pei-ivd@pei.de or whoccidv@pei.de
WHO Biological Reference Preparations:
http://www.who.int/bloodproducts/ref_materials/en/

10. 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 pei-ivd@pei.de or whoccidv@pei.de.

11. CITATION

In any circumstance where the recipient publishes a reference to PEI materials, it is important that the correct name of the preparation, the PEI code number, the name and the address of PEI are cited correctly.

12. MATERIAL SAFETY SHEET

Physical properties (at room temperature)	
Physical appearance:	Lyophilized powder
Fire hazard:	None
Chemical properties	
Stable:	Yes, when stored as recommended
Corrosive:	No
Hygroscopic:	No
Oxidising:	No
Irritant:	No
Flammable:	No
Other (specify):	CONTAINS HUMAN PLASMA & INFECTIOUS HEPATITIS C VIRUS (HCV)
Handling:	See caution, section 4
Toxicological properties (contains infectious HCV)	
Effects of inhalation:	Avoid
Effects of ingestion:	Avoid
Effects of skin absorption:	Avoid
Suggested First Aid (contains infectious HCV)	
Inhalation:	Seek medical advice.
Ingestion:	Seek medical advice.
Contact with eyes:	Wash thoroughly with water. Seek medical advice.
Contact with skin:	Wash thoroughly with water. Seek medical advice.
Action on Spillage and Method of Disposal	
Spillage of vial 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 collect spillage should be treated as biological waste.	

disposal of the Material by the recipient, unless the loss or damage is caused by gross negligence or wilful misconduct on the part of the Paul-Ehrlich-Institut.

13. WARRANTY AND INDEMNIFICATION

The Material and (if provided) the relevant information is experimental in nature. Therefore, no warranties of any kind, especially no warranties of merchantability or fitness for a particular purpose, either express or implied, with respect to the Material are given — except for the purposes describe in section 1 above. Neither are warranties given that the use of the Material will not infringe any patent, copyright, trade secret, trademark or other rights of third parties.

The recipient of the Material shall bear all risks to its employees, agents and other comparable persons or organisations (such as corporate affiliates) resulting from any use, storage or disposal of the Material, directly or indirectly.

To the extent permitted by law, the recipient shall indemnify, defend and hold harmless the Paul-Ehrlich Institut and its employees, agents and other comparable persons or affiliated organisations for any liability for claims for damages, loss or demand against it by third parties which may arise from the use, the storage or