1. INTENDED USE
This product is CE marked for use as an IVD within the EU member states and EEA countries. In all other territories this product can be used for research purposes only.

Anti-HCV QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to hepatitis C virus. The anti-HCV QC1 should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Data obtained with the anti-HCV QC1 can be used to construct quality control charts that can be visually monitored each time the assay is carried out to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere. Anti-HCV QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

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

The anti-HCV QC1 has been prepared from a pool of anti-HCV reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits and confirmed as anti-HCV positive by commercial immunoblot assay. The reactive donations used to prepare anti-HCV QC1 were non-reactive for HBsAg and anti-HIV using commercial EIA kits. The reactive sera were pooled and then diluted in a pool of defibrinated human plasma donations. These samples were non-reactive for HBsAg, anti-HCV and anti-HIV using commercial EIA kits. Bronidox® was added to a concentration of 0.05%(w/v) as a preservative. 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 avoidance of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE
Table 1 gives a summary of the results obtained for anti-HCV QC1 08/B542 These results are intended only as a guide to the approximate levels of reactivity to be expected, and may not be exactly reproduced in other laboratories. In each case, at a minimum, three samples of anti-HCV QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-HCV response of the QC1 sample, to the kit manufacturer’s calculated cut-off.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Ready-to-use reagent
REF QCPRHCVC1 1x4mL Nalgene bottle
Defibrinated Plasma 4mL
Bronidox® (Sigma-Aldrich) 0.05%(w/v)

5. STORAGE
- Reagents are to be kept at 2-8°C upon receipt
- Reagents may be stored at 2-8°C until use by date
- Reagents should be divided into measured sub- aliquots of one use and stored below –20°C to avoid freeze/thaw cycles.

- When thawed for use, store at 2-8°C. Once thawed, use within one month and do not refreeze
- Ensure all containers are properly sealed to avoid drying out of the reagent
- Avoid microbial contamination of this product as this may alter product performance
- Avoid excessively high temperatures or humidity

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
1. Use of this reagent is to be restricted to trained laboratory staff only
2. Use suitable (latex/nitrile) gloves and eye/skin protection
3. Include reagent as a normal sample in routine work list
4. Allow reagent to reach room temperature before use
5. Plot reagent result on a QC chart to monitor performance.

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.

9. REFERENCES

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/standardisation/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
**Physical and Chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance:</td>
<td>Liquid</td>
</tr>
<tr>
<td>Stable:</td>
<td>Yes</td>
</tr>
<tr>
<td>Oxidising:</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>No</td>
</tr>
<tr>
<td>Irritant:</td>
<td>No</td>
</tr>
<tr>
<td>Flammable:</td>
<td>No</td>
</tr>
</tbody>
</table>

Handling: See caution, Section 2

**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**: 5 g
- **Toxicity Statement**: Toxicity not assessed
- **Veterinary certificate or other statement if applicable**: Attached: No
TABLE 1: Results obtained for Anti-HCV QC1 (Lot Number 08/B542) using the following EIA kits.

<table>
<thead>
<tr>
<th>EIA KIT</th>
<th>Method Options</th>
<th>Test to Cut-off Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AxSYM HCV Version 3.0</strong></td>
<td>Automated</td>
<td>Mean: 4.39</td>
</tr>
<tr>
<td>Manufacturer: Abbott Diagnostics</td>
<td></td>
<td>SD (n-1): 0.28</td>
</tr>
<tr>
<td>Catalogue number: 3B44-20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot number: 65030LF01 and 66086LF01</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Access HCV Ab Plus</strong></td>
<td>Automated</td>
<td>Mean: 4.05</td>
</tr>
<tr>
<td>Manufacturer: Bio-Rad</td>
<td></td>
<td>SD (n-1): 0.19</td>
</tr>
<tr>
<td>Catalogue number: 34330</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot number: 894881 and 894882</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Architect System Anti-HCV~</strong></td>
<td>Automated</td>
<td>Mean: 3.34</td>
</tr>
<tr>
<td>Manufacturer: Abbott Diagnostics</td>
<td></td>
<td>SD (n-1): 0.34</td>
</tr>
<tr>
<td>Catalogue number: 6C37-20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot number: 63272HN00 and 61422HN00</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monolisa anti-HCV Plus Version 2</strong></td>
<td>Standard Protocol</td>
<td>Mean: 2.55</td>
</tr>
<tr>
<td>Manufacturer: Bio-Rad</td>
<td></td>
<td>SD (n-1): 0.08</td>
</tr>
<tr>
<td>Catalogue number: 72317</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot number: 08B0057</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Tests performed at William Harvey Hospital and Aintree Hospitals
# Tests performed at Aberdeen Royal Infirmary and St. Richards Hospital
~ Tests performed at Regional Virus Lab, Belfast and Poole General Hospital