



**CE Marked Material**  
**QCRHEVQC1 - Anti-Hepatitis E Quality Control**  
**NIBSC code: QCRHEVQC1**  
**Instructions for use**  
**(Version 4.0, Dated 23/01/2024)**

**This material is a self certified IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC"**

### 1. INTENDED USE

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

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QCRHEVQC1 (17/B723) is intended for use in the internal laboratory quality control of immunoassays that detect IgG antibodies to hepatitis E. QCRHEVQC1 should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Data obtained with QCRHEVQC1 can be used to construct quality control charts that can be visually monitored each time the assay is run, to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere.

QCRHEVQC1 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**

QCRHEVQC1 has been prepared from a pool of defibrinated plasma donations that were repeatedly reactive in commercial EIA kits for IgG antibodies to hepatitis E. The reactive donations used to prepare QCRHEVQC1 were nonreactive for anti-HIV, HBsAg and anti-HCV using commercial EIA kits. The reactive donations were pooled and then diluted in a pool of defibrinated human plasma donations. These samples were non-reactive for HBsAg, anti-HBs, anti-HCV, anti-HTLV, anti-Syphilis, HIV-1 p24 and anti-HIV 1/2 using commercial EIA kits. 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

Table 1 gives a summary of the results obtained for anti-hepatitis E QC1; 17/B723. 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 QCRHEVQC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-hepatitis E IgG response of the QC1 sample, to the kit manufacturer's calculated cut-off, unless otherwise stated.

### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
Ready-to-use reagent  
REF QCRHEVQC1  
1x4mL Nalgene bottles or 1x7mL Blood Tubes

Defibrinated Plasma 4mL  
Bronidox® (Sigma-Aldrich) 0.05% (w/v)

### 5. STORAGE

- o Reagents are to be kept at 2-8°C upon receipt
- o Reagents may be stored at 2-8°C until use by date
- o For single use only reagents should be divided into measured aliquots of one use and stored below -20°C to avoid freeze/thaw cycles. Once thawed use immediately. Do not refreeze
- o Ensure all containers are properly sealed to avoid drying out of the reagent
- o Avoid microbial contamination of this product as this may alter product performance
- o 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 to monitor performance

The Result Reporting System (RRS) has been developed by the National Institute for Biological Standards and Control (NIBSC) for the data monitoring of its serology and NAT quality control (QC) reagents. These include the Quality Control Reagent Unit (QCRU) and Clinical Virology Network (CVN) reagents. The system has been successfully running for serology assays for several years collecting thousands of data points a year. The system has recently been developed to accept data for Nucleic Acid-based Technologies (NAT) reagents and associated assays.

<https://www.nibsc.org/products/rrs.aspx>

### 8. STABILITY (Add or amend as necessary)

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

Real Time stability studies are carried out on this product to ensure stability of the reagent.

### 9. REFERENCES

1. Levey, S. and Jennings, E.R. (1950) The use of control charts in clinical laboratories. Am.J.Clin.Pathol. 20, 1059-1066

### 10. ACKNOWLEDGEMENTS

EC REP Advena Ltd. Tower Business Centre, 2nd Floor, Swatar, BKR 4013, Malta

### 11. FURTHER INFORMATION

Further information can be obtained as follows;  
This material: [enquiries@nibsc.org](mailto: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](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](http://www.nibsc.org/terms_and_conditions.aspx)  
 NIBSC Results Reporting System  
<http://www.nibsc.org/products/rrs.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](mailto: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 (Add or amend as necessary)**

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):	
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](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**

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 10g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement if applicable.</b> <b>Attached:</b> No





**Table 1**

Results obtained using QCRHEVQC1 (lot number 17/B723) using the following EIA kits.

Kit Details	Method Option	Test to Cut-Off Ratio	
		Mean	SD (n-1)
<b>HEV IgG</b> Manufacturer: Fortress Diagnostics Catalogue Number: BXE0901A Kit Lot: EV-1611-2	Standard Protocol	2.2	0.3
<b>recomWell HEV IgG</b> Manufacturer: Mikrogen Diagnostik Catalogue Number: 5004 Kit Lot: EHE011701	Standard Protocol	44.9 <i>(U/ml)</i>	3.4
<b>recomWell HEV IgG</b> Manufacturer: Mikrogen Diagnostik Catalogue Number: 5004 Kit Lot: EHE011701	Standard Protocol	2.2	0.2
<b>HEV Ab</b> Manufacturer: Fortress Diagnostics Catalogue Number: BXE0745A Kit Lot: EB-1705-1	Standard Protocol	17.9	1.0
<b>Bioelisa HEV IgG</b> Manufacturer: Biokit Catalogue Number: 3000-1233 Kit Lot: B26739	Standard Protocol	1.2	0.2