Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
QCRHEVIgMQC1 - IgM Anti-Hepatitis E Quality Control Reagent
NIBSC code: QCRHEVIgMQC1
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.
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.
QCRHEVIgMQC1 (17/B728) is intended for use in the internal laboratory quality control of immunoassays that detect IgM antibodies to hepatitis E. QCRHEVIgMQC1 should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Data obtained with QCRHEVIgMQC1 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.
QCRHEVIgMQC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.t

2. CAUTION

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

QCRHEVIgMQC1 has been prepared from a pool of defibrinated plasma donations that were repeatedly reactive in commercial EIA kits for IgM antibodies to hepatitis E. The reactive donations used to prepare QCRHEVIgMQC1 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 IgM anti-hepatitis E QC1; 17/B728. 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 QCRHEVIgMQC1 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 IgM 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 QCRHEVIgMQC1
1x2mL Sarstedt bottles
Defibrinated Plasma 1mL
Bronidox® 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 Reagents should be divided into measured sub-aliquots of one use and stored below -20°C to avoid freeze/thaw cycles.
o Reagents may be stored at -20°C until use by date.
o When thawed for use, store at 2-8°C. Once thawed, use within one month
and 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

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.

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
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

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

CE

Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
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

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:	No	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 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: 1g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

Table 1

Results obtained using QCRHEVIgMQC1 (lot number 17/B728) using the following EIA Kits

Kit Details	Method Option	Test to Cut-Off Ratio	
		Mean	SD (n-1)
HEV IgG Manufacturer: Fortress Diagnostics Catalogue Number: BXE0902 Kit Lot: MV-1707-1	Standard Protocol	2.0	0.5
recomWell HEV IgM Manufacturer: Mikrogen Diagnostik Catalogue Number: 5005 Kit Lot: EHE021701	Standard Protocol	164.4 *(U/mL)*	8.8
recomWell HEV IgM Manufacturer: Mikrogen Diagnostik Catalogue Number: 5005 Kit Lot: EHE021701	Standard Protocol	8.2	0.4
Bioelisa HEV IgM Manufacturer: Biokit Catalogue Number: 3000-1251 Kit Lot: B28032	Standard Protocol	1.8	0.3