

CE Marked Material
QCRHBsGQC1 -HBsAg Quality Control Serum Sample 1
NIBSC code: QCRHBsGQC1
Instructions for use
(Version 6.0, Dated 25/07/2024)

This material is an 'Annex II List A' 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.

HBsAg QC1 (17/B717) is intended for use in the internal laboratory quality control of

immunoassays that detect hepatitis B surface antigen. The HBsAg 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 HBsAg QC1 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.

HBsAg 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 HBsAg QC1 has been prepared from a pool of HBsAg reactive sera (defibrinated plasma), repeatedly reactive in commercial kits and confirmed as positive by neutralization with anti-HBs. The reactive sera used to prepare HBsAg QC1 were non-reactive for anti-HIV and non-reactive for anti-HCV using commercial EIA kits. The reactive sera were pooled and then diluted in a pool of defibrinated human plasma samples. 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 Hepatitis B surface antigen QC1 17/B717. 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 Hepatitis B surface antigen QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the Hepatitis B surface antigen 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 QCRHBsGQC1 1x7mL Blood Tube

Defibrinated Plasma 4mL

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.

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

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 (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 to ensure stated stability.

9. REFERENCES

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

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 (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
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Contact with skin:	Wash thoroughly with water.
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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: 4 g

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No

Table 1:

Results obtained for HBsAg QC1 (Lot Number 17/B717) using the following EIA kits.

EIA Kit	Method Options	Test to Cut-Off Ratio	
		Mean	SD (n-1)
Liaison XL Murex HBsAg Quant Manufacturer: DiaSorin Catalogue Number: 310250 Kit Lot: 132033	Automated	1.7 (IU/mL)	0.1
Bioelisa HBsAg 3.0 Manufacturer: Biokit Catalogue Number: 3000-1158 Kit Lot: B27090	Standard Protocol	10.9	0.8
Murex HBsAg Version 3 Manufacturer: DiaSorin Catalogue Number: 9F80-01 Kit Lot: D481710	Standard Protocol	13.5	2.3
Enzygnost HBsAg 6.0 Manufacturer: Siemens Catalogue Number: OPFM035 Kit Lot: 45184	Standard Protocol	20.3	1.3
Monolisa HBsAg Ultra Manufacturer: Bio-Rad Catalogue Number: 72346 Kit Lot: 6K0087	Standard Protocol	19.9	1.6

