

IgM Anti-HBc Quality Control Reagent Sample 1

IgM Anti-HBc QC1

SUMMARY

Human IgM anti-hepatitis B core antigen Quality Control Reagent Sample 1 (**IgM Anti-HBc QC1** Lot Number **07/B498**) is issued in 1mL volumes only.

INTENDED USE

IgM anti-HBc QC1 is intended for use in the internal laboratory quality control of immunoassays that detect IgM antibodies to hepatitis B core antigen. The IgM anti-HBc 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 IgM anti-HBc 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 elsewhere¹. IgM anti-HBc QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHBcIgMQC1	Ready-to-use reagent 1x1mL Sarsdedt Bottles
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COMPOSITION

Defibrinated Plasma	1mL
Bronidox [®] (Sigma-Aldrich)	0.05% (w/v)

MATERIALS REQUIRED BUT NOT PROVIDED

- Micropipette for dispensing

WARNINGS AND PRECAUTIONS

This reagent is for *in-vitro* use only.

As this reagent contains material of human origin, it is possible that infectious agents could be present and therefore this reagent, waste washing fluids, and any apparatus (pipette tips etc.) that come into contact with it, must be suitably decontaminated and handled in accordance with Good Laboratory Practice.

TRANSPORT INFORMATION

Shipping Name:	Diagnostic Specimen
Class/Division	6.2
UN	3373
Packing Instruction	PI-650

PREPARATION

The IgM anti-HBc QC1 has been prepared from a pool of IgM anti-HBc reactive defibrinated donations, repeatedly reactive in commercial EIA kits. The reactive donation used to prepare IgM anti-HBc QC1 was non-reactive for HBsAg, anti-HIV and anti-HCV using commercial EIA kits. The reactive serum was then diluted in a pool of defibrinated human plasma samples non-reactive for IgM anti-HBc. These samples were also 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.

SUMMARY OF RESULTS OBTAINED

Table 1 gives a summary of the results obtained for IgM anti-HBc QC1 **07/B498**. 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 IgM anti-HBc QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the IgM anti-HBc response of the QC1 sample, to the kit manufacturer's calculated cut-off.

INSTRUCTIONS FOR USE

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

HANDLING AND STORAGE CONDITIONS

- Avoid contact with skin and eyes
- 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 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

REF QCRHBcIgMQC1

DISPOSAL CONSIDERATIONS

It is the responsibility of each user to handle waste and effluents produced according to their type and degree of hazard and to treat and dispose of them in accordance with any applicable regulations.

Treat this reagent as clinical waste and dispose of according to clinical waste policies in place.

ACCIDENTAL RELEASE MEASURES

In the event of a spill or leakage, wear suitable eye/skin protection. Use absorbent material to soak up spill. Wipe area with appropriate bactericidal/viricidal agent. Rinse area with water.

Treat all absorbent material used to clean up spill as biological hazardous waste.

LITERATURE REFERENCES

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

TABLE 1: Results obtained for **IgM Anti-HBc QC1** (Lot Number **07/B498**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
Monolisa Anti-HBc IgM Manufacturer: Bio-Rad Catalogue number: 72382 Lot number: 7A0021	Standard Protocol	2.07	0.08
AxSYM Core-M * Manufacturer: Abbott Diagnostics Catalogue number: 7A44-20 Lot number: 48477LUOO & 47166LUOO	Automated	1.24	0.04
Bioelisa HBc IgM Manufacturer: Biokit Catalogue number: 3000-1103 Lot number: K-3506	Standard Protocol	2.90	0.24
Murex Anti-HBc IgM Manufacturer: Abbott Diagnostics Catalogue number: 9E25-01 Lot number: J267510	Standard Protocol - Qualitative	1.52	0.10
Bayer Centaur ~ Manufacturer: ADVIA Catalogue number: 00504619 Lot number: 9382213	Automated	1.61	0.08

* Tests performed at Northwick Park Hospital and The William Harvey Hospital

~ Tests performed at St. Mary's Hospital