

## Anti-Hepatitis B e Antigen Quality Control Reagent Sample 1

Anti-HBe QC1

### SUMMARY

Human anti-hepatitis B e antigen Quality Control Reagent Sample 1 (**Anti-HBe QC1** Lot Number **08/B554**) is issued in 4mL volumes.

### INTENDED USE

Anti-HBe QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to hepatitis B e antigen. The anti-HBe 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-HBe 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<sup>1</sup>. Anti-HBe QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

### CONTENT OF THE KIT

REF QCRHBeQC1	Ready-to-use reagent 1x4mL Nalgene bottles
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### COMPOSITION

Defibrinated Plasma	4mL
Bronidox <sup>®</sup> (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 anti-HBe QC1 has been prepared from a pool of anti-HBe reactive defibrinated plasma donations, repeatedly reactive in commercial kits. The reactive sera used to prepare anti-HBe QC1 were non-reactive for HBsAg, anti-HIV and anti-HCV using commercial EIA kits. The reactive donations were pooled and then diluted in a pool of defibrinated human plasma donations non-reactive for anti-HBe. These samples were also non-reactive for HBsAg, anti-HCV and anti-HIV using commercial EIA kits. Bronidox<sup>®</sup> 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 anti-HBe QC1 **08/B554**. 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-HBe QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-HBe 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 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 QCRHBeQC1

### 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 **Anti-HBe QC1** (Lot Number **08/B554**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
<b>ARCHITECT SYSTEM Anti-HBe*</b> Manufacturer: Abbott Diagnostics Catalogue number: 8L44 Lot number: 68318HN00/67396HN00	Automated	0.10	0.02
<b>AxSYM Anti-HBe^</b> Manufacturer: Abbott Diagnostics Catalogue Number: 7D27-20 Lot Number: 69367HN00/63607HN00	Automated	0.08	0.01
<b>ETI AB-EBK PLUS</b> Manufacturer: Diasorin Catalogue Number: N0139 Lot Number: 0490330B	Standard Protocol	5.85	1.01

\* Tested at Queen Alexandra Hospital and Brighton Microbiology Laboratory

^ Tested at Aintree Hospital and East Kent Microbiology Laboratory