

Total Anti-HBc Quality Control Reagent Sample 1

Total Anti-HBc QC1

SUMMARY

Human total anti-hepatitis B core antigen Quality Control Reagent Sample 1 (**Total Anti-HBc QC1** Lot Number **07/B506**) is issued in 4mL volumes.

INTENDED USE

Total anti-HBc QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to the hepatitis B core antigen. The total 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 total anti-HBc QC1 can be used to construct quality control charts that can be visually monitored each time the assay is carried out to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere¹. Total anti-HBc QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRTHBcQC1	Ready-to-use reagent 1x4mL Nalgene bottle
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COMPOSITION

Defibrinated Plasma	4mL
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
Packaging Instructions	PI-650

PREPARATION

The total anti-HBc QC1 has been prepared from a pool of total anti-HBc reactive defibrinated plasma donations,

repeatedly reactive in commercial EIA kits. The reactive donations used to prepare total anti-HBc QC1 were reactive for HBsAg and non-reactive for anti-HIV and anti-HCV using commercial EIA kits. The reactive donations were pooled and then diluted in a pool of defibrinated human plasma samples non-reactive for total 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 total anti-HBc QC1 **07/B506**. 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 total anti-HBc QC1 were tested on two occasions. The results are expressed as the ratio of mean optical density or other measurement of the total 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 of one use 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

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.

REF QCRTHBcQC1

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

area with appropriate bactericidal/viricidal agent. Rinse area with water.

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

ACCIDENTAL RELEASE MEASURES

In the event of a spill or leakage, wear suitable eye/skin protection. Use absorbent material to soak up spill. Wipe

TABLE 1: Results obtained for **Total Anti-HBc QC1** (Lot Number **07/B506**) using appropriate commercial EIA kits.

EIA KIT	Method Options	Cut-off to Test Ratio	
		Mean	SD (n-1)
AxSYM Total anti-HBc # Manufacturer: Abbott Diagnostics Catalogue number: 7A4120 Lot number: 51375LU00 & 53073LU02	Automated	0.14 (S/CO)	0.03
Bioelisa anti-HBc Manufacturer: Launch Diagnostics Catalogue number: 3000-1102 Lot number: A-3107	Standard Protocol	1.71	0.18
ETI-AB-COREK Plus Manufacturer: DiaSorin Catalogue number: N0137 Lot number: 9910310C/1	Standard Protocol	82.12	32.25
Monolisa anti-HBc Manufacturer: Bio-Rad Catalogue number: 72315 Lot number: 7A0048	Standard Protocol	4.34 (OD/CO)	1.54
Murex Total anti-HBc Manufacturer: Abbott Diagnostics Catalogue number: 8G21-01 Lot number: L002110	Standard Protocol	12.60	0.77
VIDAS* Manufacturer: Biomerieux Catalogue number: 30314 Lot number: 813113401 & 810899401	Automated	0.34 (RFV/S1)	0.06
Bayer Centaur[®] Manufacturer: ADVIA Catalogue number: 07566733 Lot number: 98636015	Automated	1.06 (Index/CO)	0.31
Architect System Anti-HBc[£] Manufacturer: Abbott Diagnostics Catalogue number: 7C17 Lot number: 45985M100 & 52596M100	Automated	3.40 (S/CO)	0.67

#Tests performed at East Kent Microbiology Laboratory and Barnet Hospital

* Tests performed at Wycombe General Hospital and Basildon and Thurrock University Hospital

£ Tests performed at St Mary's NHS Trust and Cambridge HPA

£ Tests performed at Poole General Hospital and Queen Alexandra Hospital