

Anti-Hepatitis B Surface Antigen Quality Control Sample 1

Anti-HBs QC1

SUMMARY

Human anti-hepatitis B surface antigen Quality Control Reagent Sample 1 (**Anti-HBs QC1** Lot Number **07/B515**) is issued in 4mL volumes.

INTENDED USE

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

CONTENT OF THE KIT

REF QCRHBsQC1	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.

The product has not been pasteurised or subjected to any other procedure that might render it non-infectious for Hepatitis B virus or other pathogens.

TRANSPORT INFORMATION

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

PREPARATION

The anti-HBs QC1 has been prepared from a pool of human serum donations reactive for antibodies to hepatitis B surface antigen. These samples were non-reactive for HBsAg, anti-HCV and anti-HIV using currently available commercial EIA kits. The reactive sera were pooled and then diluted in a pool of negative defibrinated human plasma donations. These samples were non-reactive for HBsAg, anti-HBs, anti-HCV and anti-HIV using currently available 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 anti-HBs QC1 **07/B515**. 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-HBs QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-HBs 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 results 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

REF QCRHBsQC1

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.

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

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.

TABLE 1: Results obtained for **Anti-HBs QC1** (Lot Number **07/B515**) using the following EIA kits.

EIA KIT	Method Options	[^] mIU/mL as specified by each test.
		Mean (± 2 SD) of 6 replicate tests
Murex anti-HBs Manufacturer: Abbott Diagnostics Catalogue number: 2K95-01 Lot number: L076210	Standard Protocol	166.31 (156.32 – 176.31)
ETI-AB-AUK-3 Anti-HBs Manufacturer: DiaSorin Catalogue number: P001603 Lot number: 9230500A/1	Standard Protocol	97.84 (79.46 – 116.23)
Bioelisa anti-HBs Manufacturer: Biokit (Launch) Catalogue number: 3000-1101 Lot number: A-4207	Standard Protocol	109.56 (105.51 – 113.61)
AxSYM AUSAB~ Manufacturer: Abbott Diagnostics Catalogue number: 7A39-22 Lot number: 56396LF00	Automated	(S/CO) 82.90 (74.07 – 91.73)
Vitros Eci anti-HBs# Manufacturer: Ortho-Clinical Catalogue number: 1787753 Lot number: 1390	Automated	(IU/mL) 178.22 (171.68 – 184.76)
Architect¥ Manufacturer: Abbott Diagnostics Catalogue number: 7C18-20 / 25 / 30 Lot number: 51296M100 / 51297M100 / 52550M200	Automated	314.96 (294.26 – 335.66)
Vidas Anti-HBs Total Quick∞ Manufacturer: BioMerieux Catalogue number: 30238 Lot number: 813659101	Automated	103.67 (72.68 – 134.65)

~ Tests performed at The William Harvey Hospital

Tests performed at HPA South West, Bristol

¥ Tests Performed at Queen Alexandra Hospital; Poole General Hospital & Old Medical School, Leeds

∞ Tests Performed at Basildon Hospital