

Hepatitis B Surface Antigen Quality Control Reagent Sample 1

HBsAg QC1

SUMMARY

Human hepatitis B surface antigen Quality Control Reagent Sample 1 (**HBsAg QC1** Lot Number **07/509**) is issued in 4mL volumes.

INTENDED USE

HBsAg QC1 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 elsewhere¹. HBsAg QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHBsGQC1	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
Packing Instruction	PI-650

PREPARATION

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 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 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 HBsAg QC1 **07/B509**. 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 HBsAg QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the HBsAg 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 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 QCRHBsGQC1

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 **HBsAg QC1** (Lot Number **07/B509**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
Enzygnost HBsAg 5.0 Manufacturer: Dade Behring Catalogue number: OQPW11 Lot number: 37112	Standard Protocol	6.99	1.50
Bioelisa HBsAg Colour Manufacturer: Biokit (Launch) Catalogue Number: 3000-1130 Lot number: A-2007	Standard Protocol	4.34	0.26
Hepanostika HBsAg Uni-Form II Manufacturer: BioMérieux Catalogue Number: 280251 Lot number: B98HA	Standard Protocol	6.51	0.81
VIDAS HBsAg Ultra* Manufacturer: BioMérieux Catalogue Number: 30315 Lot number: 080519-0 & 080613-0	Automated	[^] RFV/S1 2.66	0.25
AxSYM HBsAg V2[#] Manufacturer: Abbott Catalogue Number: 7A40-22 Lot number: 53381LU03	Automated	6.73	0.25
Monolisa HBsAg Ultra EIA Manufacturer: Bio-Rad Catalogue Number: 72346 Lot Number: 7E0030	Automated	18.23	0.83
ETI-MAK-4 HBsAg EIA Manufacturer: DiaSorin Catalogue number: N0019 Lot Number: 0370510A	Automated	18.88	1.75
Bayer Centaur+ Manufacturer: ADVIA Catalogue number: 03393362 Lot Number: 99439128	Automated	31.39 (Index/CO)	0.74

* Tested by Basildon Hospital & The London Clinic

Tested by Whittington Hospital & Aintree Hospital

+ Tested by: St. Mary's Hospital

[^] RFV/S1 derived from the manufacturers own calibration.

RFV = Relative fluorescence value

S1 = QC provided by the manufacturer