

## Hepatitis B Surface Antigen Quality Control Reagent Sample 2

### HBsAg QC2

#### SUMMARY

Human hepatitis B surface antigen Quality Control Reagent Sample 2 (**HBsAg QC2** Lot Number **07/B503**) is issued in 4mL volumes.

#### INTENDED USE

HBsAg QC2 is intended for use in the internal laboratory quality control of immunoassays that detect hepatitis B surface antigen. The HBsAg QC2 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 QC2 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>. HBsAg QC2 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

#### CONTENT OF THE KIT

REF QCRHBsGQC2	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 HBsAg QC2 has been prepared from a pool of hepatitis B surface antigen reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits and confirmed as positive by neutralization with anti-HBs. The reactive donations used to prepare HBsAg QC2 were 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 donations. These samples were non-reactive for HBsAg, anti-HBs, 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 HBsAg QC2 **07/B503**. 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 QC2 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 QC2 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 QCRHBsGQC2

### 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 **HBsAg QC2** (Lot Number **07/B503**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
<b>Murex HBsAg version 3</b> Manufacturer: Abbott Diagnostics Catalogue Number: GE36 Lot number: J259411	Standard Protocol	2.77	0.15
<b>AxSYM HBsAg (V2)*</b> Manufacturer: Abbott Diagnostics Catalogue number: 7A40-22 Lot number: 53381LU03	Automated	1.27	0.05
<b>Vitros Eci HBsAg<sup>®</sup></b> Manufacturer: Ortho-Clinical Diagnostics Catalogue Number: 8435307 Lot number: 1890	Automated	2.89	0.09
<b>VIDAS HBsAg Ultra (HBS)<sup>#</sup></b> Manufacturer: BioMérieux Catalogue Number: 30315 Lot number: 080519-0 & 080613-0	Automated	<sup>^</sup> RFV/S1 0.36	0.02
<b>ETI-MAK-4 HBsAg</b> Manufacturer: DiaSorin Catalogue Number: N0019 Lot number: 0370510A	Standard Protocol	2.45	0.23
<b>Monolisa HBsAg Ultra</b> Manufacturer: Bio-Rad Catalogue Number: 72346 Lot number: 7E0030	Standard Protocol	3.37	0.22
<b>Bayer Centaur<sup>ψ</sup></b> Manufacturer: Advia Catalogue Number: 03393362 Lot number: 99439128	Automated	3.68 (Index/CO)	0.13
<b>Beckman Coulter<sup>¥</sup></b> Manufacturer: Access Catalogue Number: A24291 Lot number: 792311	Automated	2.24 (Index)	0.07
<b>Architect<sup>∅</sup></b> Manufacturer: Abbott Diagnostics Catalogue Number: 6C36 Lot Number: 54244LF00 & 53034LU00	Automated	~IU/mL 0.15	0.03

Testing performed at:

- \* Whittington Hospital & Aintree Hospital
- ∞ HPA Southwest
- # Basildon Hospital & The London Clinic
- ψ St Mary's NHS Trust
- ¥ Aberdeen Royal Infirmary
- ∅ Queen Alexandra Hospital & Poole General Hospital

<sup>^</sup> RFV/S1 derived from the manufacturers own calibration.

RFV = Relative fluorescence value

S1 = QC provided by the manufacturer

~ IU/mL values derived from manufacturers own calibrations