

## Anti-HIV-2 Quality Control Reagent Sample 3

Anti-HIV-2 QC3

### SUMMARY

Human anti-human immunodeficiency virus type 2 Quality Control Reagent Sample 3 (**Anti-HIV-2 QC3** Lot Number **08/B534**) is issued in 4mL volumes.

### INTENDED USE

Anti-HIV-2 QC3 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to human immunodeficiency virus type 2. The anti-HIV-2 QC3 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-HIV-2 QC3 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 elsewhere<sup>1</sup>. Anti-HIV-2 QC3 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

### CONTENT OF THE KIT

REF QCRHIV2QC3	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.

It contains heat inactivated (+56°C for 60 minutes) human sera known to be reactive for anti-HIV-2.

### TRANSPORT INFORMATION

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

### PREPARATION

The anti-HIV-2 QC3 has been prepared from a pool of heat inactivated (+56°C for 60 minutes) anti-HIV-2 reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits and confirmed as anti-HIV-2 positive/anti-HIV-1 negative by commercial Western Blot kits. The reactive donations used to prepare anti-HIV-2 QC3 were non-reactive for HBsAg and anti-HCV using commercial EIA kits. The reactive donations were pooled and then diluted in a pool of defibrinated human plasma samples. These samples were non-reactive for HBsAg, anti-HCV and anti-HIV1/2 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-HIV-2 QC3 **08/B534**. 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-HIV-2 QC3 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-HIV-2 response of the QC3 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

## REF QCRHIV2QC3

### 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-HIV-2 QC3** (Lot Number **08/B534**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
<b>Access HIV 1/2 New<sup>#</sup></b> Manufacturer: Beckman/Coulter Catalogue Number: 34020 Lot Number: 791034 and 791033	Automated	2.30	0.26
<b>Vironostika HIV Uniform II Plus 0</b> Manufacturer: BioMerieux Catalogue Number: 284017 Lot Number: A48LB	Standard Protocol	5.67	0.49
<b>AxSYM HIV Ag/Ab Combo<sup>*</sup></b> Manufacturer: Abbott Diagnostics Catalogue Number: 2G8311 Lot Number: 62002LF01 and 64044LF01	Automated	2.69	0.31
<b>Vironostika HIV Uniform II Ag/Ab</b> Manufacturer: BioMerieux Catalogue Number: 284138 Lot Number: A58ME	Standard Protocol	4.72	0.23
<b>BAYER CENTAUR<sup>^</sup></b> Manufacturer: ADVIA Catalogue number: 01463908 Lot number: 033 and 035	Automated	7.72 (Index/CO)	1.18
<b>Architect System HIV Ag/Ab Combo<sup>*</sup></b> Manufacturer: Abbott Diagnostics Catalogue number: 4J2730 Lot number: 57779HN00	Automated	4.17	0.15
<b>Genetic Systems HIV-1 Ag<sup>ψ</sup></b> Manufacturer: Bio-Rad Catalogue number: 71120 Lot number: 7B1035	Standard Protocol	0.53	N/A

# Test s performed at St. Richards Hospital and Aberdeen Royal Infirmary

\* Tests performed at The William Harvey Hospital and Northwick Park Hospital

¥ Tests performed at Regional Virus Lab, Belfast

^ Tests performed at Cambridge HPA and St. Mary's Hospital

ψ Result showing HIV-1 Ag status of this reagent lot.