

## HIV-1 p24 Antigen Quality Control Reagent Sample 1

HIV-1 p24 QC1

### SUMMARY

Human immunodeficiency virus type 1 p24 antigen Quality Control Reagent Sample 1 (**HIV-1 p24 QC1** Lot Number **07/B519**) is issued in 4mL volumes.

### INTENDED USE

HIV-1 p24 QC1 is intended for use in the internal laboratory quality control of immunoassays that detect human immunodeficiency virus type 1 p24 antigen. The HIV-1 p24 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 HIV-1 p24 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 elsewhere<sup>1</sup>. HIV-1 p24 QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

### CONTENT OF THE KIT

REF QCRHIV1p24QC1	Ready-to-use reagent 1x4mL Nalgene bottle
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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

HIV-1 p24 QC1 was prepared using recombinant HIV-1 p24 antigen produced in a baculovirus expression system. The HIV-1 p24 antigen is recognised by monoclonal and polyclonal anti-p24 (HIV-1) antibodies in commercial EIA kits. The reactive material used to prepare HIV-1 p24 QC1 was non-reactive for HBsAg, anti-HIV and anti-HCV using commercial EIA kits. The reactive sera were pooled and then diluted in a pool of defibrinated human plasma donations non-reactive for HIV-1 p24 antigen. 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 HIV-1 p24 QC1 **07/B519**. 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 HIV-1 p24 QC1 were tested on three separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the HIV-1 p24 antigen 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

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- 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.

### 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 **HIV-1 p24 QC1** (Lot Number **07/B519**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
<b>VIDAS HIV DUO Quick (HIV6 - FV) *</b> Manufacturer: BioMerieux Catalogue number: 30447 Lot number: 080401-0 & 080529-0	Automated	<sup>^</sup> RFV/S1 17.99	RFV/S1 3.15
<b>Vironostika HIV Uni-Form II Ag/Ab</b> Manufacturer: Biomerieux Catalogue number: 285046 Lot number: A58FE	Standard Protocol	2.77	0.30
<b>Genscreen Plus HIV Ag-Ab</b> Manufacturer: Bio-Rad Catalogue number: 72375 Lot number: 6M0065	Standard Protocol	8.89	0.29
<b>Enzygnost HIV Integral II</b> Manufacturer: Dade Behring Catalogue number: OPAA05 Lot number: 37010	Standard Protocol	19.46	1.32
<b>AxSYM HIV Ag/Ab Combo #</b> Manufacturer: Abbott Diagnostics Catalogue number: 2G8320 Lot number: 57226LF00	Automated	26.69	2.12
<b>VIDAS HIV DUO Ultra ~</b> Manufacturer: BioMerieux Catalogue number: 30443 Lot number: 812672901	Automated	<sup>^</sup> RFV/S1 6.73	RFV/S1 0.45
<b>Abbott PRISM HIV Ag/Ab COMBO+</b> Manufacturer: Abbott Diagnostics Catalogue number: 7G46-48 Lot number: 55915HN00	Automated	14.94	0.63
<b>Murex HIV-1.2.0<sup>ψ</sup></b> Manufacturer: Abbott Diagnostics Catalogue number: 9E25-01 Lot number: J090510	Standard Protocol	0.18	N/A

+ Tests performed at Scottish Blood Transfusion Service

\* Tests performed at Basildon Hospital & Poole General Hospital

# Tests performed at The William Harvey Hospital

~ Tests performed at Royal Sussex County Hospital

RFV/S1 derived from the manufacturers own calibration.

RFV = Relative fluorescence value

S1 = QC provided by the manufacturer

<sup>ψ</sup> Result showing anti-HIV-1/2 status of this reagent lot.