

HIV-1 p24 Antigen Quality Control Reagent Sample 2

HIV-1 p24 QC2

SUMMARY

Human immunodeficiency virus type 1 p24 antigen Quality Control Reagent Sample 2 (**HIV-1 p24 QC2** Lot Number **08/B536**) is issued in 4mL volumes.

INTENDED USE

HIV-1 p24 QC2 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 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 HIV-1 p24 QC2 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 elsewhere¹. HIV-1 p24 QC2 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHIV1p24QC2	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
Packaging Instruction	PI-650

PREPARATION

HIV-1 p24 QC2 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 QC2 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[®] 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 QC2 **08/B536**. 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 QC2 were tested on two 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 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 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

HEALTH PROTECTION AGENCY

Centre for Infections
Quality Control Reagents Unit
61 Colindale Avenue, London NW9 5HT. Telephone: +44 (0)20 8327 6933. Fax: +44 (0)20 8327 6081

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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 QC2** (Lot Number **06/B477**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
Genetic Systems HIV -1 Ag Manufacturer: Bio-Rad Catalogue number: 71120 Lot number: 7B1035	Standard Protocol	7.02	0.46
VIDAS DUO HIV Quick (HIV 6) * Manufacturer: BioMerieux Catalogue number: 30447 Lot number: 820811001	Automated	Test Value~ 1.65	0.08
Murex HIV Ag/Ab Combination Manufacturer: Abbott Diagnostics Catalogue number: 7G79 - 01 Lot number: L177210	Standard Protocol	2.57	0.09
Architect System HIV Ag/Ab Combo** Manufacturer: Abbott Diagnostics Catalogue number: 4J27 - 20 Lot number: 62163HN00/59756HN00	Automated	2.31	0.22
Murex HIV 1.2.0^Ψ Manufacturer: Abbott Diagnostics Catalogue number: 9E25 - 01 Lot number: L101110	Standard Protocol	0.20	N/A
Enzygnost HIV Integral II Manufacturer: Dade Behring Catalogue number: OPAA05 Lot number: 37305	Standard Protocol	2.05	0.52

* Test performed at Basildon Hospital and Poole General Hospital

** Test performed at Dumfries and Galloway Royal Infirmary, Regional Virus Lab., Belfast and Poole General Hospital

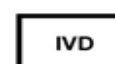
Ψ Result showing anti-HIV-1/2 status of this reagent lot.

~ Test value= Patient RFV / Standard RFV

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