

Anti-HIV-1 Quality Control Reagent Sample 5

Anti-HIV-1 QC5

SUMMARY

Human anti-human immunodeficiency virus type 1 Quality Control Reagent Sample 5 (**Anti-HIV-1 QC5** Lot Number **06/B461**) is issued in 4mL volumes.

INTENDED USE

Anti-HIV-1 QC5 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to human immunodeficiency virus type 1. The anti-HIV-1 QC5 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-1 QC5 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. Anti-HIV-1 QC5 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHIV1QC5	Ready-to-use reagent 1x4mL Nalgene bottles
----------------	---

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.

It contains heat inactivated (+56°C for 60 minutes) human sera known to be reactive for anti-HIV-1.

TRANSPORT INFORMATION

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

PREPARATION

The anti-HIV-1 QC5 has been prepared from a pool of heat inactivated (+56°C for 60 minutes) anti-HIV-1 reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits and confirmed as anti-HIV-1 positive/anti-HIV-2 negative by commercial Western Blot kits. The reactive donations used to prepare anti-HIV-1 QC5 were non-reactive for HBsAg and anti-HCV using commercial EIA kits. The reactive sera were pooled and then diluted in a pool of defibrinated human plasma samples. These donations 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 anti-HIV-1 QC5 **06/B461**. 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-1 QC5 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-HIV-1 response of the QC5 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 QCRHIV1QC5

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-1 QC5** (Lot Number **06/B461**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio		Range (± 2 SD)
		Mean	SD (n-1)	
VIDAS HIV DUO Quick (HIV6) # Manufacturer: BioMerieux VIDAS Catalogue number: 30447 Lot number : 797548601 and 796118001	Automated	14.93 (RFV/S1)	1.17	12.59 - 17.26
AxSYM HIV Ag/Ab Combo ¥ Manufacturer: Abbott Diagnostics Catalogue number: 2G8320 Lot number: 37446LU00, 37184LU00 and 35585LU00	Automated	14.46	0.95	12.56 – 16.37
Biotest Anti HIV Tetra Elisa Manufacturer: Biotest Catalogue number: 807007 Lot number: 1010605 and 1031005	Standard Protocol	6.23	0.50	5.23 - 7.22
Genetic Systems HIV-1 Ag^ψ Manufacturer: Bio-Rad Catalogue number: 71120 Lot number: 5L0030	Standard Protocol	0.10	N/A	N/A

Tests performed at St Mary's Hospital Portsmouth and Preston Hospital

¥ Tests performed at Barnsley Hospital and States of Jersey Path Laboratory

ψ Result showing HIV-1 Ag status of this reagent lot. Test performed at SBVL Colindale