

Anti-HIV-1 Quality Control Reagent Sample 1

Anti-HIV-1 QC1

SUMMARY

Human anti-human immunodeficiency virus type 1 Quality Control Reagent Sample 1 (**Anti-HIV-1 QC1** Lot Number **08/B538**) is issued in 4mL volumes.

INTENDED USE

Anti-HIV-1 QC1 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 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 anti-HIV-1 QC1 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. Anti-HIV-1 QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHIV1QC1	Ready-to-use reagent 1x4mLNalgene 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.

It contains heat inactivated (+56°C for 60 minutes) human sera known to be reactive for anti-HIV1.

TRANSPORT INFORMATION

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

PREPARATION

The anti-HIV-1 QC1 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 QC1 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 donations. 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 anti-HIV-1 QC1 **08/B538**. 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 QC1 were tested on two occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-HIV-1 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 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

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

VERSION 3-08/B538 2008-11



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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 QC1** (Lot Number **08/B538**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
AxSYM HIV Ag/Ab Combo* Manufacturer: Abbott Diagnostics Catalogue Number: 2G8320 Lot Number: 650921F00	Automated	16.11	0.66
Enzygnost Anti-HIV 1/2 Plus Manufacturer: Dade Behring Catalogue number: OQFK 12/13 Lot number: 37533	Standard Protocol	4.89	0.35
Genetic Systems HIV-1 Ag^ψ Manufacturer: Bio-Rad Catalogue number: 71120 Lot number: 7G0036	Standard Protocol	0.41	N/A

* Tested at William Harvey Hospital - Microbiology Department

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

TABLE 2: Results obtained for **Anti-HIV-1 QC1** (Lot Number **08/B538**) using the following Rapid Test kits.

EIA KIT	Method Options	Result
Determine HIV-1/2 Manufacturer: Abbott Diagnostics Catalogue Number: 7D23-46 Lot Number: 58928U101	Serum / Plasma Protocol	Positive