

Anti-HIV-2 Quality Control Reagent Sample 2

Anti-HIV-2 QC2

SUMMARY

Human anti-human immunodeficiency virus type 2 Quality Control Reagent Sample 2 (**Anti-HIV-2 QC2** Lot Number **08/B544**) is issued in 4mL volumes.

INTENDED USE

Anti-HIV-2 QC2 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 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 anti-HIV-2 QC2 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-2 QC2 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHIV2QC2	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.

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 QC2 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 QC2 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 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-2 QC2 **08/B544**. 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 QC2 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 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
- 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

REF QCRHIV2QC2

1. Levey, S. and Jennings, E.R. (1950) The use of control charts in clinical laboratories. Am.J.Clin.Pathol. 20, 1059-1066

area with appropriate bactericidal/virucidal agent. Rinse area with water.

Treat all absorbent material used to clean up spill as biological hazardous waste.

ACCIDENTAL RELEASE MEASURES

In the event of a spill or leakage, wear suitable eye/skin protection. Use absorbent material to soak up spill. Wipe

TABLE 1: Results obtained for **Anti-HIV-2 QC2** (Lot Number**08/B544**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio		SD (n-1)
		Mean	Range ($\pm 2SD$)	
Murex HIV-1.2.0 Manufacturer: Abbott Diagnostics Catalogue number: 9E25-01 Lot number: L123910	Standard Protocol	4.26	3.51 – 5.01	0.38
Anti HIV Tetra Elisa Manufacturer: Biotest Catalogue number: 807007 Lot number: 3809121	Standard Protocol	9.70	7.80 - 11.59	0.95
Enzygnost Anti-HIV 1/2 Plus Manufacturer: Dade Behring Catalogue number: OQFK13 Lot number: 37533	Standard Protocol	2.27	2.06 – 2.47	0.10
Genscreen HIV 1/2 V2 Manufacturer: Bio-Rad Catalogue number: 72278 Lot Number:8D0077/ 7H0075	Standard Protocol	8.63	4.63 - 12.63	2.00
Genscreen Ultra HIV Ag-Ab Manufacturer: Bio-Rad Catalogue number: 72386 Lot Number: 8D0029	Standard Protocol	4.99	3.67 – 6.32	0.66
VIDAS HIV DUO (HIV6)[#] Manufacturer: BioMérieux Catalogue number: 30447 Lot number: 09115-0/ 090605-0	Automated	18.08 (RFV/S1)	14.98 - 21.18	1.55
AxSYM HIV Ag/Ab Combo* Manufacturer: Abbott Diagnostics Catalogue number: 2G8311 Lot Number: 67075LF00 / 68108LF00 / 66450LF01	Automated	11.85 Signal/CO	9.68 - 14.03	1.09
ARCHITECT~ Manufacturer: Abbott Catalogue number: 4J27-20 / 4J27-30 Lot number: 65644HN00/ 65268HN00	Automated	15.93 Signal/CO	14.10 - 17.76	0.91
Genetic Systems HIV-1 Ag^ψ Manufacturer: Bio-Rad Catalogue number: 71126 Lot number: 7G0036	Standard Protocol	0.45	0.33 - 0.56	0.06
RAPID TEST KIT	Method	Result		
Determine HIV-1/2 Manufacturer: Inverness Medical Catalogue number: 7D23-47 Lot number: 660444200	Serum / Plasma Protocol	Weak Positive		

Testing Performed at:

- # Poole General Hospital and Kettering General Hospital
- * The William Harvey Hospital and St Georges' Hospital
- ~ Poole General Hospital and Queen Alexandra Hospital

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