Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
QCRHIV1p24QC2 - HIV-1 p24 Quality Control Serum Sample 2
NIBSC code: QCRHIV1p24QC2
Instructions for use
(Version 4.0, Dated 05/03/2024)

This material is an 'Annex II List A' IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC"

1. INTENDED USE

This product is CE marked for use as an IVD within the UK, EU member states and EEA countries. In all other territories this product can be used for research purposes only.
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HIV-1 p24 QC2 (20/B758) 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 run, 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 or for the calibration of assays

2. CAUTION

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA.This preparation is not for administration to humans or animals in the human food chain.

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-HCV, anti-HIV 1/2, anti-HTLV I+II and Syphilis 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, anti-HIV 1/2, anit-HTLV I+II and Syphilis using commercial EIA kits. Bronidox® was added to a concentration of 0.05% (w/v) as a preservative.
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

Table 1 gives a summary of results obtained for HIV-1 p24 QC2 Lot No: 20/B758. 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 three separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the HIV-1 p24 response of the QC2 sample, to the kit manufacturer's calculated cut-off. Assays that have produced positive results and are validated for use with this reagent have been listed in this table.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ready-to-use reagent
REF QCRHIV1p24QC2 1x7mL Blood tubes
Defibrinated Plasma 4mL
Bronidox® (Sigma-Aldrich) 0.05% (w/v)

5. STORAGE

- Reagents are to be kept at 2-8ºC upon receipt
- Reagents may be stored at 2-8ºC until use by date
- For single use only, reagents should be divided into measured aliquots of one use and stored below -20ºC to avoid freeze/thaw cycles. Once thawed use immediately. Do not refreeze
- Ensure all containers are properly sealed to avoid drying out of the reagent o Avoid microbial contamination of this product as this may alter product performance
- Avoid excessively high temperatures or humidity

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

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

The Result Reporting System (RRS) has been developed by the National Institute for Biological Standards and Control (NIBSC) for the data monitoring of its serology and NAT quality control (QC) reagents. These include the Quality Control Reagent Unit (QCRU) and Clinical Virology Network (CVN) reagents. The system has been successfully running for serology assays for several years collecting thousands of data points a year. The system has recently been developed to accept data for Nucleic Acid-based Technologies (NAT) reagents and associated assays.
https://www.nibsc.org/products/rrs.aspx

8. STABILITY (Add or amend as necessary)

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

Real-Time Stability studies take place to ensure stated stability of this product

9. REFERENCES

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

10. ACKNOWLEDGEMENTS

EC REP Advena Ltd. Tower Business Centre, 2nd Floor, Swatar, BKR 4013, Malta

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET (Add or amend as necessary)

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties			
Physical appearance: Liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:See caution, Section 2	
Other (specify):			
Toxicological properties			
Effects of inhalation:		Not established, avoid inhalation	
Effects of ingestion:		Not established, avoid ingestion	
Effects of skin absorption:		Not established, avoid contact with skin	
Suggested First Aid			
Inhalation:	Seek medical advice		
Ingestion:	Seek medical advice		
Contact with eyes:	Wash with copious amounts of water. Seek medical advice		
Contact with skin:	Wash thoroughly with water.		

Action on Spillage and Method of Disposal
Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.
Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 4g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

Table 1: Results obtained for QCRHIV1p24QC2 (Lot Number 20/B758) using the following EIA kits.

EIA KIT	Method Options	Test Cut-Off Ration	
		Mean	**SD (n-1)**
Kit: Liaison XL Murex HIV Ab/Ag **Manufacturer**: Diasorin **Distributor**: Diasorin **Catalogue number**: 310260 **Lot number**: 139041 and 139042	Automated Protocol	5.4 (S/CO)	0.3
Kit: Murex HIV Ab/Ag Combination **Manufacturer**: Diasorin **Distributor**: Diasorin **Catalogue number**: 7G70-09 **Lot number**: D735710	Standard Protocol	4.6 (OD/CO)	0.5
Kit: Biokit Bioelisa HIV Ag/Ab **Manufacturer**: Biokit **Distributor**: WERFEN **Catalogue number**: B31870 **Lot number**: B32280	Standard Protocol	12.9 (OD/CO)	0.7
Kit: Genscreen ULTRA HIV Ag/Ab **Manufacturer**: BioRad **Distributor**: BioRad **Catalogue number**: 72386 **Lot number**: 9L0129	Standard Protocol	6.4 (OD/CO)	1.2

Kit: Genscreen HIV-1 Ag **Manufacturer:** BioRad **Distributor:** BioRad **Catalogue number:**71120 **Lot number:** 9J0062	Standard Protocol	9.4 (OD/CO)	0.9