Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
QCRHIV1RTDQC1- HIV-1 Rapid Test Device Quality Control Serum Sample 1
NIBSC code: QCRHIV1RTDQC1
Instructions for use
(Version 4.0, Dated 13/03/2024)

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.

HIV-1 RTD QC1 is intended for use in the internal laboratory quality control of rapid test devices (RTD's) that detect antibodies to human immunodeficiency virus type 1. HIV-1 RTD QC1 should be included as part of a continuing quality control programme to monitor the performance of RTD's used in the laboratory and at point of care (POC) services. Data obtained with the HIV-1 RTD QC1 can be used to monitor and assess consistency of performance in a manner acceptable to the user. HIV-1 RTD QC1 is not intended to be used to compare the sensitivity of particular assays.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The HIV-1 RTD QC1 (16/B687) has been prepared from heat inactivated (+56C for 60 minutes) anti-HIV-1 reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits and confirmed and characterised as anti-HIV-1 positive/anti-HIV-2 negative by commercial western blot. The reactive donations were pooled together. The reactive pool used to prepare HIV-1 RTD QC1 was reactive for anti-HCV, anti-CMV and anti-Rubella using commercial EIA kits. The reactive pool was then diluted in a pool of defibrinated human plasma donations that were non-reactive for anti-HCV, HBsAg and anti-HIV1/2 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 the results obtained for HIV-1Rapid Test Device QC1 16/B657 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-1Rapid Test Device QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the HIV-1Rapid Test Device response of the QC1 sample, to the kit manufacturer's calculated cut-off.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ready-to-use reagent
REF QCRHIVRTDQC1 1 x 1mL Blood Tubes
Defibrinated Plasma 1mL
Bronidox® 0.05% (w/v)

5. STORAGE

o Reagents are to be kept at 2-8ºC upon receipt
o Reagents may be stored at 2-8ºC until use by date
o It is recommended that reagents be divided into measured single use sub-aliquots and stored below -20ºC to avoid freeze/thaw cycles. Do not use after expiry.
o When thawed for use, store at 2-8ºC. Once thawed, use within one month and do not refreeze
o 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
o 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 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.

Stability studies are carried out 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;

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

CE 1434

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: 1 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

1: Results obtained for **HIV-1 RTD QC1** (Lot Number **16/B687**) using the following RTD kits.

EIA KIT	Method Options	Result
DETERMINE HIV-1/2 Manufacturer: Alere Catalogue Number: 7D2346 Lot Number: 66912K100B	Serum / Plasma Protocol	Positive
DETERMINE HIV Combo Manufacturer: Alere Catalogue Number: 7D2846 Lot Number: 67074K100C	Serum / Plasma Protocol	Positive Ab, Negative Ag
INSTI HIV1/2 Manufacturer: Biolytical Laboratories Catalogue Number: 90-1015 Lot Number: 1510BB0376	Serum / Plasma Protocol	Positive
Geenius HIV ½ Confirmatory Assay Manufacturer: Bio-Rad Catalogue Number: 72460 Lot Number: 5J0022	Serum / Plasma Protocol	Negative – gp36 & gp140 Weak Positive – gp31 & p24 Positive - gp160 & gp41