Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
IFU for QCRHIV1QC2 code: 17/B720-xxx
NIBSC code: 17/B720-xxx
Instructions for use
(Version 1.00, Dated 22/10/2019)

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 EU member states and EEA countries. In all other territories this product can be used for research purposes only.
Please complete this section manually by typing over this text

2. CAUTION

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

Please complete this section if choosing the last option above 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

Please complete this section manually by typing over this text

4. CONTENTS

Country of origin of biological material: United Kingdom.
Please complete this section manually by typing over this text

5. STORAGE

Please complete this section manually by typing over this text

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

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

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

Please complete this section manually by typing over this text

10. ACKNOWLEDGEMENTS

Please complete this section manually by typing over this text

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

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

Physical and Chemical properties			
Physical appearance: Please complete		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Please complete		

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.

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

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: Please complete
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No Please add vet cert numbers separated by a space

TABLE 1: Results obtained for Anti-HIV1QC2 (Lot Number: 17/B720) using the following kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
Genscreen HIV-1/2 Version 2 Manufacturer: Bio-Rad Catalogue number: 72278 Lot number: 7E0104	Standard Protocol	7.8	0.5
Murex HIV-1.2.O Manufacturer: Diasorin Catalogue number: 9E25-01 Lot number: D521010	Standard Protocol	3.1	0.2
Murex HIV Ag/Ab Combination Manufacturer: Diasorin Catalogue number: 7g79-09 Lot number: D582110	Standard Protocol	1.5	0.2
Genscreen ULTRA HIV Ag/Ab Manufacturer: Bio-Rad Catalogue number: 72386 Lot number; 7C0115	Standard Protocol	8.7	0.4
Bioelisa HIV-1+2 3.0 Manufacturer: Biokit Catalogue number: 3000-1172 Lot number: B23096	Standard Protocol	10.7	1.1
Enzynost HIV Integral 4 Manufacturer: Biokit Catalogue number: OPKR03 Lot number: 46383	Standard Protocol	7.7	0.5
Architect System – HIV Ag/Ab Combo* Manufacturer: Abbott Diagnostics Catalogue number: 4J27 Lot number76564I100	Automated Protocol	5.2	0.3
Liaison XL Murex HIV Ab Manufacturer: Diasorin Catalogue number: 310260 Lot number: 139033	Automated Protocol	8.0	0.3
VIDAS HIV DUO Ultra (HIV5)* Manufacturer: BioMerieux Catalogue number: 30443 Lot number: 1005549850	Automated Protocol	3.9	0.4

*Tests performed at Royal Sussex County Hospital & Poole General Hospital