Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
IFU for QCRTOXOQC1 NIBSC code: 17/B710-xxx
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Instructions for use
(Version 2.0, Dated 20/07/2022)

This material is an 'Annex II List B' 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.
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.
Anti-Toxoplasma gondii QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to Toxoplasma gondii.
QCRTOXOQC1 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-TOXO 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 elsewhere.
QCRTOXOQC1 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.

QCRTOXOQC1 has been prepared from an anti-Toxoplasma gondii reactive serum sample. This reactive serum was non-reactive for HBsAg, anti-HCV, anti-HTLV, anti-Syphilis, HIV-1 p24 and anti-HIV 1/2 using commercial EIA kits. The reactive sera was then diluted in a pool of difibrinated human plasma samples that were non-reactive for HBsAg, anti-HCV, anti-HTLV, anti-Syphilis, HIV-1 p24, anti-HIV 1/2 and anti-Toxoplasma gondii using commercial EIA kits.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 Anti-Toxoplasma gondii QC1 17/B710. 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-Toxoplasma gondii QC1 were tested on three occasions. The results are expressed in International Units per millilitre (IU/ml).

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ready-to-use reagent
REF QCRTOXOQC1 1x7mL Blood Tubes
Defibrinated Plasma 4mL
Bronidox® 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.
- Reagents should be divided into measured sub-aliquots of one use and stored below -20ºC to avoid freeze/thaw cycles.
- Reagents may be stored at -20ºC until use by date.
- When thawed for use, store at 2-8ºC. 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.

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.

Stability studies are carried out to ensure stated stability.

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 Anti-Toxoplasma *gondii* QC1 (Lot Number 17/B710) using appropriate commercial kits.

EIA Kit	Method Options	IU/ml	
		Mean	SD (n-1)
Liaison Toxo IgG Manufacturer: DiaSorin Catalogue Number: 310780 Lot Number: 4071	Automated	21.5	1.3
Bioelisa Toxo IgG Manufacturer: Biokit Catalogue Number: 3000-1214 Lot Number: B26735	Standard Protocol	71.8	4.4
Platelia Toxo IgG Manufacturer: Bio-Rad Catalogue Number: 72840 Lot Number: 6F0033	Standard Protocol	53.7	7.2
Toxoplasma IgG Manufacturer: DRG Diagnostics Catalogue Number: DX-EIA-3863 Lot Number: TOXG-054	Standard Protocol	149.2	13.6
Toxoplasma IgG Manufacturer: IBL International Catalogue Number: RE57101 Lot Number: TOXG-054	Standard Protocol	149.3	13.7
NovaLisa Toxo IgG Manufacturer: NovaTec Catalogue Number: 774TOXG460DX Lot Number: TOXG-054	Standard Protocol	149.4	13.6
Enzygnost Toxoplasmosis IgG Manufacturer: Siemens Catalogue Number: OUNA275 Lot Number: 46263A	Standard Protocol	28.5	9.1
Toxoplasma IgG Manufacturer: Testline Catalogue Number: TgG096 Lot Number: 0100016731	Standard Protocol	40.1	6.8

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

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