Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
QCRSYPHQC1 - Anti-Syphilis Quality Control Reagent Sample 1
NIBSC code: 15/B673-xxx
Instructions for use
(Version 2.0, Dated 18/02/2020)

This material is a self certified 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.

Anti-Syphilis QC1 is intended for use in the internal laboratory quality control of immunoassays that detect IgG antibodies to Treponema pallidum. The anti-Syphilis QC1 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-Syphilis QC1 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-Syphilis 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 anti-Syphilis QC1 has been prepared from an anti-Syphilis donation, repeatedly reactive in commercial EIA kits and commercial line blot assays. The reactive donation used to prepare anti-Syphilis QC1 was non-reactive for anti-HIV, HBsAg and anti-HCV using commercial EIA kits. The reactive donations were then diluted in a pool of defibrinated human plasma samples non-reactive for anti-Syphilis. These samples were also non-reactive for HBsAg, anti-HCV and anti-HIV using commercial EIA kits. BronidoxP®P 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 anti-Syphilis QC1 15/B673 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-Syphilis QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-Syphilis 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 QCRSYPHQC1 1x4mL Nalgene bottles/Blood tube
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 Do not use after expiry date
• Reagents should be divided into measured sub-aliquots of one use and stored below –20ºC to avoid freeze/thaw cycles. Do not use after expiry date
• When thawed for use, store at 2-8ºC. Once thawed, use within one month and do not refreeze. Do not use after expiry date.
• 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. Mix well before use.
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

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.

Stability studies are carried out to ensure 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

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

1: Results obtained for **Anti-Syphilis QC1** (Lot Number **15/B673**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio Mean	SD (n-1)
Bioelisa Syphilis 3.0 Manufacturer: Biokit Catalogue number: 3000-1148 Lot number: B24356	Standard Protocol	3.2	0.3
Murex Syphilis ICE Manufacturer: Diasorin Catalogue Number: 8E04-02 Lot Number: D127810	Standard Protocol	2.3	0.3
Captia Syphilis TA EIA Manufacturer: Trinity Biotech Catalogue Number: 2322170 Lot number: 022	Standard Protocol	10.8	1.2
Architect Syphilis TP* Manufacturer: Abbott Diagnostics Catalogue Number: 8D06 Lot Number: 54355L100	Automated Protocol	S/CO 3.9	0.1
Liason XL Treponema Screen Manufacturer: Diasorin Catalogue Number: 310840 Lot Number: 91057	Automated Protocol	Index 3.4	0.1

Testing performed by:
*Royal Sussex County Hospital