



**CE Marked Material**  
**QCRLYMEQC1 - Anti-Lyme QC1**  
**NIBSC code: QCRLYMEQC1**  
**Instructions for use**  
**(Version 4.0, Dated 13/12/2023)**

**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.**

**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-Lyme QC1 (15/B658) is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to the *Borrelia* sp. The anti-Lyme 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-Lyme 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 elsewhere<sup>1</sup>. Anti-Lyme 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-LymeQC1 has been prepared from a pool of anti-Lyme donations repeatedly reactive in commercial EIA kits. The reactive donation used to prepare anti-Lyme 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-Lyme. These samples were also non-reactive for HBsAg, anti-HCV and anti-HIV using commercial EIA kits. Bronidox<sup>®</sup> 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-Lyme QC1 15/B658. 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-LymeQC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-Lyme 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 QCRLYME QC1 1x4mL Nalgene bottles or Blood Tubes  
Defibrinated Plasma 4mL

Bronidox<sup>®</sup> (Sigma-Aldrich) 0.05% (w/v)

### 5. STORAGE

Reagents are to be kept at 2-8°C upon receipt  
o Reagents may be stored at 2-8°C until use by date. Do not use after expiry date  
o Reagents should be divided into measured sub-aliquots of one use and stored below -20°C to avoid freeze/thaw cycles  
o When thawed for use, store at 2-8°C. Once thawed, use within one month and do not refreeze  
o Ensure all containers are properly sealed to avoid drying out of the reagent

### 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

### 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;

This material: [enquiries@nibsc.org](mailto: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](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](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:<br>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](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**

|   |
|---|
| <b>Country of origin for customs purposes*:</b> United Kingdom<br>* 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. |
| <b>Net weight:</b> 10 g   |
| <b>Toxicity Statement:</b> Toxicity not assessed  |
| <b>Veterinary certificate or other statement if applicable.</b>   |
| <b>Attached:</b> No   |



**TABLE 1:** Results obtained for **Anti-Lyme QC1** (Lot Number **15/B658**) using the following EIA kits.

| <b>EIA KIT</b>   | <b>Method Options</b> | <b>Mean</b>    | <b>SD (n-1)</b> |
|--|-----------------------|----------------|-----------------|
| <b>Liaison XL Borrelia IgG</b><br>Manufacturer : DiaSorin<br>Catalogue Number : 310880<br>Lot number : 089057X | Automated System      | 22.3 AU/ml     | 0.9             |
| <b>Platelia Lyme IgG</b><br>Manufacturer : Bio-Rad<br>Catalogue Number : 72951<br>Lot number : 4K002           | Standard Method       | 1.7 OD/CO      | 0.1             |
| <b>VIDAS Lyme IgG*</b><br>Manufacturer : BioMérieux<br>Catalogue Number : 30320<br>Lot number : 1003560430     | Automated System      | 0.3 Test Value | 0.0             |

# Royal Sussex County Hospital