Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

**CE Marked Material**
**IFU for QCRPARVB19IgMQC1**
**NIBSC code: 20/B774-xxx**
**Instructions for use**
**(Version 3.0, Dated 17/03/2021)**

**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.**

IgM Anti-Parvovirus B19 QC1 is intended for use in the internal laboratory quality control of immunoassays that detect IgM antibodies to Parvovirus B19. The IgM Anti-Parvovirus B19 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 IgM Anti-Parvovirus B19 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[1]. IgM Anti-Parvovirus B19 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 IgM Anti-Parvovirus B19 QC1 has been prepared from an Anti-Pavovirus IgM donation, repeatedly reactive in commercial EIA kits and commercial line blot assays. The reactive donation used to prepare IgM Anti-Parvovirus B19 QC1 was non-reactive for anti-HIV 1/2, HBsAg, anti-HCV, anti-HTLV, anti-SYPHILIS using commercial EIA kits. The reactive donations were then diluted in a pool of defibrinated human plasma samples which were also non-reactive for for anti-HIV 1/2, HBsAg, anti-HCV, anti-HTLV, anti-SYPHILIS using commercial EIA kits. Sodium Azide 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 IgM Anti-Parvovirus B19 QC1 20/B774. 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 IgM Anti-Parvovirus B19 QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the IgM Anti-Parvovirus B19 response of the QC1 sample, to the kit manufacturer's calculated cut-off.

## 4. CONTENTS

Country of origin of biological material: United Kingdom
REF QCRPARVB19IgMQC1 1 x 7ml Blood Tubes
Defibrinated Plasma 1mL
Sodium Azide 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.
  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.

## 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.

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
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

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

## 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.<br>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<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. |
| **Net weight:** 1g |
| **Toxicity Statement:** Toxicity not assessed |
| **Veterinary certificate or other statement** if applicable**.**<br>**Attached:** No |

**Table 1:** Results obtained for QCRPARVB19IgMQC1 (Lot: 20/B774) using the following kits.

| KIT | Method Options | Test Cut-Off Ratio | |
|---|---|---|---|
| | | **Mean** | **SD (n-1)** |
| **Kit:** Liaison Biotrin Parvovirus B19 IgM<br>**Manufacturer:** Diasorin<br>**Distributor:** Diasorin<br>**Catalogue number**: 317010<br>**Lot number:** 129048 and 129050 | Automated Protocol | 2.7<br>(Index) | 0.2 |

**Table 2:** The following kits were found to be ***unsuitable*** for QCRPARVB19IgMQC1 (Lot: 20/B774).

| KIT | Method Options | Test Cut-Off Ratio | |
|---|---|---|---|
| | | **Mean** | **SD (n-1)** |
| **Kit:** Novagnost Parvovirus B19 IgM<br>**Manufacturer:** Nova Tec Immundiagnostic GmbH<br>**Distributor:** Diasorin<br>**Catalogue number**: RE57291<br>**Lot number:** PARM-170 | Standard Protocol | 0.75<br>(OD/CO) | 0.1 |
| **Kit:** IBL Parvovirus B19 IgM<br>**Manufacturer:** IBL International<br>**Distributor:** TECAN<br>**Catalogue number**: PARM370DB<br>**Lot number:** PARM-168R1 | Standard Protocol | 0.55<br>(OD/CO) | 0.1 |