

## Anti-CMV Quality Control Reagent Sample 1

Anti-CMV QC1

### SUMMARY

Human anti-cytomegalovirus Quality Control Reagent Sample 1 (**Anti-CMV QC1** Lot Number **08/B549**) is issued in 4mL volumes.

### INTENDED USE

Anti-CMV QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to cytomegalovirus. The anti-CMV 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-CMV QC1 can be used to construct quality control charts that can be visually monitored daily 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-CMV QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

### CONTENT OF THE KIT

|               |   |
|---------------|---|
| REF QCRCMVQC1 | Ready-to-use reagent<br>1x4mL Nalgene bottles |
|---------------|---|

### COMPOSITION

|                                       |             |
|---------------------------------------|-------------|
| Defibrinated Plasma                   | 4mL         |
| Bronidox <sup>®</sup> (Sigma-Aldrich) | 0.05% (w/v) |

### MATERIALS REQUIRED BUT NOT PROVIDED

- Micropipette for dispensing

### WARNINGS AND PRECAUTIONS

This reagent is for *in-vitro* use only.

As this reagent contains material of human origin, it is possible that infectious agents could be present and therefore this reagent, waste washing fluids, and any apparatus (pipette tips etc.) that come into contact with it, must be suitably decontaminated and handled in accordance with Good Laboratory Practice.

### TRANSPORT INFORMATION

|                       |                     |
|-----------------------|---------------------|
| Shipping Name         | Diagnostic Specimen |
| Class/Division        | 6.2                 |
| UN                    | 3373                |
| Packaging Instruction | PI-650              |

### PREPARATION

The anti-CMV QC1 has been prepared from a pool of anti-CMV reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits. The reactive donations used to prepare anti-CMV QC1 were non-reactive for HBsAg, anti-HIV and anti-HCV using commercial EIA kits. The reactive donations were pooled and then diluted in a pool of defibrinated human plasma samples. These samples were non-reactive for anti-CMV, 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.

### SUMMARY OF RESULTS OBTAINED

**Table 1** gives a summary of the results obtained for anti-CMV QC1 **08/B549**. 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-CMV QC1 were tested on two occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-CMV response of the QC1 sample, to the kit manufacturer's calculated cut-off.

### INSTRUCTIONS FOR USE

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

### HANDLING AND STORAGE CONDITIONS

- Avoid contact with skin and eyes
- Reagents are to be kept at 2-8°C upon receipt
- Reagents may be stored at 2-8°C until use by date
- Reagents should be divided into measured suitable sub-aliquots and stored below -20°C to avoid freeze/thaw cycles.
- When thawed for use, store at 2-8°C. 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

## REF QCRCMVQC1

### DISPOSAL CONSIDERATIONS

It is the responsibility of each user to handle waste and effluents produced according to their type and degree of hazard and to treat and dispose of them in accordance with any applicable regulations.

Treat this reagent as clinical waste and dispose of according to clinical waste policies in place.

### ACCIDENTAL RELEASE MEASURES

In the event of a spill or leakage, wear suitable eye/skin protection. Use absorbent material to soak up spill. Wipe area with appropriate bactericidal/viricidal agent. Rinse area with water.

**Treat all absorbent material used to clean up spill as biological hazardous waste.**

### LITERATURE REFERENCES

1. Levey, S. and Jennings, E.R. (1950) The use of control charts in clinical laboratories. Am.J.Clin.Pathol. 20, 1059-1066

**TABLE 1:** Results obtained for **Anti-CMV QC1** (Lot Number **08/B549**) using appropriate commercial EIA kits.

| EIA KIT  | Method Options    | Test to Cut-off Ratio                                 |                                  |
|--|-------------------|---|----------------------------------|
|  |                   | Mean  | SD (n-1)                         |
| <b>VIDAS CMV IgG<sup>#</sup></b><br>Manufacturer: BioMerieux<br>Catalogue number: 821639201<br>Lot number: 090517-1  | Automated         | *RFV/S1<br>26.33<br>Range 24.33-28.33                 | 1.00                             |
| <b>Bioelisa CMV IgG</b><br>Manufacturer: Biokit<br>Catalogue number: 3000 - 1216<br>Lot number: D-2308   | Standard Protocol | 3.08  | 0.08                             |
| <b>LIASON CMV IgG<sup>*</sup></b><br>Manufacturer: DiaSoin<br>Catalogue number: 310740<br>Lot number: 380310   | Automated         | 1.37<br>(IU/ml)                                       | 0.09                             |
| <b>Architect Systems<sup>™</sup></b><br>Manufacturer: Abbott Diagnostics<br>Catalogue number: 6C1520 / 6C1525<br>Lot number: 67166LF00 / 64166LF00 / 62316LF00<br><b>AxSYM CMV IgG %</b><br>Manufacturer: Abbott Diagnostics<br>Catalogue number: 4B47-20<br>Lot number: 64395M200 / 66577M100 / 60676M100 | Automated         | <sup>^</sup> AU/mL                                    |                                  |
|  |                   | <b>Mean / Range</b>                                   | <b>SD (n-1)</b>                  |
|  |                   | Automated   | 37.59 AU/ml<br>Range 33.10–42.09 |
|  | Automated         | <b>Mean/Range</b><br>41.36 AU/ml<br>Range 33.68-49.04 | 3.84                             |

# Test performed at Basildon Hospital

\* Tests Performed at HPA Bristol

% Tests Performed at the William Harvey Hospital, NPHS Cardiff and Aintree Hospital

“ Tests Performed at Regional Virus Lab Belfast, Queen Alexandra Hospital, States of Jersey Pathology Lab

\* RFV/S1 derived from the manufacturers own calibration.

RFV= Relative fluorescence value

S1= Calibrator provided by the manufacturer

^ AU/ml derived from the manufacturers own calibration