

Anti-Rubella Quality Control Reagent Sample 1

Anti-Rubella QC1

SUMMARY

Human anti-Rubella Quality Control Reagent Sample 1 (**Anti-Rubella QC1** Lot Number **08/B523**) is issued in 4mL volumes.

INTENDED USE

Anti-Rubella QC1 is intended for use in the internal laboratory quality control of immunoassays that detect immunity to Rubella infection. The anti-Rubella 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-Rubella 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-Rubella QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRRUBQC1	Ready-to-use reagent 1x4mL Nalgene bottles
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COMPOSITION

Defibrinated Plasma	4mL
Bronidox [®] (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 instructions	PI-650

PREPARATION

The anti-Rubella QC1 has been prepared from a pool of anti-Rubella donations, repeatedly reactive in commercial EIA kits. The reactive donations used to prepare anti-Rubella QC1 were 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-Rubella. These samples were also non-reactive for HBsAg, anti-HCV and anti-HIV using commercial EIA kits. Bronidox[®] 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-Rubella QC1 **08/B523**. 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-Rubella QC1 were tested on two separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the anti-Rubella 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 suitable sub-aliquots volumes 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

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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.

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

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.

TABLE 1: Results obtained for **Anti-Rubella QC1** (Lot Number **08/B523**) using the following EIA kits.

EIA KIT	Method Options	Mean	°IU/mL SD (n-1)	Range
Enzygnost Anti-Rubella IgG Manufacturer: Dade Behring Catalogue number: OWBF 15 Lot number: 37418	Standard Protocol	22.67	1.41	19.84 – 25.50
VIDAS Rubella IgG II[°] Manufacturer: BioMerieux Catalogue number: 30 221 Lot number: 813658801/816840101	Automated	29.72	5.55	18.62 – 40.82
Access Rubella IgG* Manufacturer: Beckman/Coulter Catalogue number: 34430 Lot number: 790293	Automated	25.87	4.16	25.87 – 34.20
ETI-RUBEK-G Plus Manufacturer: DiaSorin Catalogue Number: P002037 Lot Number: 2280300B	Standard Protocol	25.47	1.57	22.34 – 28.61
LIASON Rubella IgG[‡] Manufacturer: DiaSorin Catalogue Number: 310720 Lot Number: 36043	Automated	20.34	5.04	10.26 – 30.43
Bayer Centaur [^] Manufacturer: ADVIA Catalogue Number: 117710 Lot Number: 17433147	Automated	37.30	1.80	33.70 – 40.90
Architect Systems[¤] Manufacturer: Abbott Diagnostics Catalogue Number: 6C1725 Lot Number: 22222UN07	Automated	20.54	0.69	19.15 – 21.93
Bioelisa Rubella IgG Colour[~] Manufacturer: Biokit (Launch) Catalogue Number: 3000-1149 Lot Number: J-3107	Automated	(OD/CO) 1.66	SD (n-1) 0.11	Range 1.43 – 1.89
Mercia Rubella G[∞] Manufacturer: Microgen Bioproducts Catalogue Number: M5066 Lot Number: 05271	Automated	Mean 1.21	SD (n-1) 0.04	Range 1.12 – 1.30

* Tests performed at St Richards Hospital Chichester and Aberdeen Royal Infirmary

[°] Tests performed at Basildon Hospital and St. Peter's Hospital Chertsey

[‡] Tests performed at HPA Birmingham and HPA Bristol

[∞] Tests performed at NBS Birmingham

[^] Tests performed at St. Georges Hospital, Tooting

[¤] Tests performed at Regional Virus Laboratory, Belfast

[~] Tests performed at Maidstone Hospital and Kettering General Hospital (Results are in OD/CO)

[°] IU/mL values derived from manufacturers own calibrations