

Anti-Syphilis Quality Control Reagent Sample 1

Anti-Syphilis QC1

SUMMARY

Human anti-Syphilis Quality Control Reagent Sample 1 (**Anti-Syphilis QC1** Lot Number **08/B533**) is issued in 4mL volumes.

INTENDED USE

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.

CONTENT OF THE KIT

REF QCRSYPHQC1	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-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. 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-Syphilis QC1 **08/B533**. 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.

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 sub-aliquots of one use 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 QCRSYPHC1

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-Syphilis QC1** (Lot Number **08/B533**) 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: A-1508	Standard Protocol	4.94	0.29
Abbott Murex Syphilis ICE Manufacturer: Abbott Diagnostics Catalogue Number:8E04-02 Lot Number: L111310	Standard Protocol	4.29	0.11
Trepanostika TP Recombinant Manufacturer: BioMérieux Catalogue Number:285034 Lot Number: D38MC	Standard Protocol	5.14	0.46
Newmarket Syphilis EIA II Manufacturer: Newmarket Catalogue Number:60094 Lot number: 706103 / 720605	Standard Protocol	13.27	1.83
Syphilis EIA V2 Manufacturer: Bio-Stat Catalogue Number:382008 Lot Number: 720606	Standard Protocol	14.31	0.67

