

## Anti-Syphilis Quality Control Reagent Sample 2

### Anti-Syphilis QC2

#### SUMMARY

Human anti- Syphilis Quality Control Reagent Sample 2 (**Anti-Syphilis QC2** Lot Number **09/B559**) is issued in 4mL volumes.

#### INTENDED USE

Anti-Syphilis QC2 is intended for use in the internal laboratory quality control of immunoassays that detect immunity to *Treponema pallidum* infection. The anti-Syphilis QC2 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 QC2 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-Syphilis QC2 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

#### CONTENT OF THE KIT

REF QCRSYPHC2	Ready-to-use reagent 1x4mL Nalgene bottles
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#### 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 instructions	PI-650

#### PREPARATION

The anti-Syphilis QC2 has been prepared from an anti-Syphilis donation, repeatedly reactive in commercial EIA kits and commercial line blot assay. The reactive donation used to prepare anti-Syphilis QC2 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<sup>®</sup> was added to a concentration of 0.05%(w/v) as a preservative.

#### SUMMARY OF RESULTS OBTAINED

**Tables 1 and 2** give a summary of the results obtained for anti-Syphilis QC2 **09/B559**. 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 QC2 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 QC2 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 QCRSYPHC2

### 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 QC2** (Lot Number **09/B559**) using the following EIA kits.

EIA KIT	Method Options	Cut-off to test Ratio	
		Mean	SD (n-1)
<b>Pathozyme Syphilis Competition</b> Manufacturer: Omega Diagnostic Catalogue number: OD117 Lot number: 7021708 & 7022517	Standard Protocol	1.69	0.25

**TABLE 2:** Results obtained for **Anti-Syphilis QC2** (Lot Number **07/B514**) using the following agglutination assays.

AGGLUTINATION ASSAY	Method Options	Mean Result	
		SPC	LIA
<b>Syphilis TPHA OC 2000 (Olympus)*</b> Manufacturer: Newmarket Catalogue number: 72507 Lot number: 834401	Automated	3	0
<b>MAST Serodia TPPA~</b> Manufacturer: Fujirebio Inc Catalogue Number: 223253 Lot Number: YM80704	Automated	2	0

Testing Carried Out At:

- \* NBS Tooting & NBS Sheffield
- ~ NBS Colindale & NBS Brentwood