

Negative Quality Control Reagent Sample 1

Negative QC1

SUMMARY

Negative Quality Control Reagent Sample 1 (**Negative QC1** Lot Number **08/B539**) is issued in 4mL volumes.

INTENDED USE

Negative QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to hepatitis B surface antigen, anti-HBs, HIV-1 p24 antigen, anti-HIV-1 and anti-HIV-2, anti-HTLV-I, anti-HCV and anti-syphilis antibodies. Negative QC1 should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Negative QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRNEGQC1	Ready-to-use reagent 1x4mL Nalgene bottle
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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.

The product has not been pasteurised or subjected to any other procedure that might render it non-infectious for any pathogens.

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.

PREPARATION

The Negative QC1 has been prepared from a pool of human serum donations that was tested and found to be negative for hepatitis B surface antigen, anti-HBs, HIV-1 p24 antigen, anti-HIV-1 and anti-HIV-2, anti-HTLV-I, anti-HCV and anti-syphilis antibodies using currently available commercial EIA kits. The pool was then defibrinated. Bronidox® was added to a concentration of 0.05%(w/v) as a preservative.

TRANSPORT INFORMATION

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

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

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

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.

HEALTH PROTECTION AGENCY

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VERSION 2-08/B539 2008-11

