

REF QCRTHAVQC1

Total Anti-Hepatitis A Virus Quality Control Reagent Sample 1

Total Anti-HAV QC1



SUMMARY

Human total anti-hepatitis A virus Quality Control Reagent Sample 1 (**Total Anti-HAV QC1** Lot Number **07/B497**) issued in 4mL volumes.

INTENDED USE

Total Anti-HAV QC1 is intended for use in the internal laboratory quality control of immunoassays that detect total antibodies to hepatitis A virus. The Total Anti-HAV 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 total Anti-HAV QC1 can be used to construct quality control charts that can be visually monitored each time the assay is carried out to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere¹. Total Anti-HAV QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

| | |
|----------------|---|
| REF QCRTHAVQC1 | Ready-to-use reagent 1x4mL Nalgene bottles |
|----------------|---|

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 Instruction | PI-650 |

PREPARATION

The total Anti-HAV QC1 has been prepared from a pool of anti-HAV total antibody reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits. The reactive donations used to prepare total Anti-HAV QC1 were non-reactive for HBsAg, anti-HIV and anti-HCV using commercial EIA kits. The reactive sera were pooled and then diluted in a pool of defibrinated human plasma donations non-reactive for total anti-HAV. 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 total Anti-HAV QC1 **07/B497**. 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 total Anti-HAV QC1 were tested on two occasions. The results are expressed as the ratio of mean optical density or other measurement of the total Anti-HAV QC1 response, 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

HEALTH PROTECTION AGENCY

Centre for Infections
Quality Control Reagents Unit
61 Colindale Avenue, London NW9 5HT. Telephone: +44 (0)20 8327 6933. Fax: +44 (0)20 8327 6081

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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.

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 **Total Anti-HAV QC1** (Lot Number **07/B497**) using the following EIA kits.

| EIA KIT | Method Options | Test to Cut-off Ratio | |
|--|-------------------|-------------------------------|----------|
| | | Mean | SD (n-1) |
| ARCHITECT* Manufacturer : Abbott Diagnostics Catalogue number: GC2925 Lot number: 44079HN00 | Automated | 3.34 | 0.08 |
| AxSYM Total anti-HAV # Manufacturer: Abbott Catalogue number: 6C7020 Lot number: 48339LU00 | Automated | 0.24 | 0.02 |
| ETI-AB-HAVK plus Total HAV Manufacturer: DiaSorin Catalogue number: NO136 Lot number: 9570270B | Standard protocol | 3.34 | 0.40 |
| VIDAS Total anti-HAV^ Manufacturer: BioMérieux Catalogue number: 30312 Lot number: 080201-0 | Automated | Range 66.14 – 77.42 mIU/mL | |

* Tests performed in Poole General Hospital

#Tests performed in Aintree Hospitals, Liverpool & William Harvey Hospital, Kent

^ Tests performed in Basildon Hospital & The London Clinic