

IgM Anti-Hepatitis A Virus Quality Control Reagent Sample 2

IgM Anti-HAV QC2

SUMMARY

Human IgM anti-hepatitis A virus Quality Control Reagent Sample 2 (**IgM Anti-HAV QC2** Lot Number **09/B572**) is issued in 1mL volumes.

INTENDED USE

IgM anti-HAV QC2 is intended for use in the internal laboratory quality control of immunoassays that detect IgM antibodies to hepatitis A virus. The IgM anti-HAV 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 IgM anti-HAV QC2 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. IgM anti-HAV QC2 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

CONTENT OF THE KIT

REF QCRHAVIgMQC2	Ready-to-use reagent 1x1mL Sarstedt Tubes
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COMPOSITION

Defibrinated Plasma	1mL
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 IgM anti-HAV QC2 has been prepared from a pool of anti-HAV IgM reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits. The reactive donations used to prepare IgM anti-HAV QC2 were non-reactive for HIV1 Ag, 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 IgM 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 IgM anti-HAV QC2 **09/B572**. These results are intended only as a guide to the approximate levels of reactivity to be expected, and may not be reproduced in other laboratories. In each case, at a minimum, three replicates of IgM anti-HAV QC2 were tested on three occasions. The results are expressed as the ratio of mean optical density or other measurement of the IgM anti-HAV QC2 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 **IgM Anti-HAV QC2** (Lot Number **09/B572**) using the following EIA kits.

EIA KIT	Method Options	Test to Cut-off Ratio	
		Mean	SD (n-1)
Vitros HAVIgM* Manufacturer: Ortho Clinical Diagnostics Catalogue number: 8450124 Lot numbers: 1890, 1961	Automated	1.71	0.17
AxSYM HAVIgM^ Manufacturer: Abbott Diagnostics Catalogue number: 6C69-90 Lot number: 74507LF00	Automated	1.88	0.12
VIDAS HAVIgM“ Manufacturer: BioMérieux Catalogue number: 30307 Lot numbers: 830757701, 831520801, 833342801	Automated	0.86	0.03
ETI-HA-IGMK PLUS Manufacturer: DiaSorin Catalogue number: N0142 Lot number: 9850290B	Standard Protocol	4.81	0.28
BAYER CENTAUR& Manufacturer:ADVIA Catalogue number: 05004126 Lot numbers: 138, 136	Automated	1.75 (Index/CO)	0.16
Architect System HAVAb-IgM~ Manufacturer: Abbott Diagnostics Catalogue number: 6C300 Lot number: 74723HN00, 75337HN00	Automated	1.35	0.12

* Tested at NPHS Swansea and HPA-Bristol

^ Tested at Whittington and Ipswich Hospitals

“ Tested at Kettering and Vale of Leven Hospitals

& Tested at Leicester Hospital and Barts and the London

~ Tested at Borders General and Queen Alexandra Hospitals

