ImmunoFLOW

Mycoplasma IgM Control

Mycoplasma IgM Control contains specific IgM type antibodies to Mycoplasma pneumoniae complement–fixing antigen and is used in conjunction with the appropriate ImmunoFLOW Assay Test System.

Consist of human sera containing antibodies to Mycoplasma pneumoniae complement–fixing antigen.

Substitute for specimen. Otherwise follow the Procedure as described in the ImmunoFLOW Test package insert.

0.5 mL

CE

IVD

CAT **3925**

LOT **160666**

20**26**-07

2-8°C

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Demo

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Warnings and Precautions

For In Vitro Diagnostic Use: Reagents have been optimized for use as a system. Do not substitute other manufacturers' reagents. Dilution or adulteration of these reagents may affect the performance of the test. Do not use kit if evidence of microbial contamination (cloudiness) is present. Do not use any kits beyond the stated expiration date. Close adherence to the test procedure will assure optimal performance. Do not shorten or lengthen stated incubation times since this may result in poor assay performance.
Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. It may be harmful if enough is ingested (more than supplied in kit). On disposal of liquids, flush with a large volume of water to prevent azide build-up (1). This dilution is not subject to GHS, US HCS and EU Regulation 2008/1272/EC labeling requirements.
The safety data sheet (SDS) is available at support.genbio.com or upon request.
Human source material. Material used in the preparation of this product has been tested and found non-reactive for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C virus (HCV), and antibodies to human immunodeficiency virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease (2). Follow recommended Universal Precautions for bloodborne pathogens as defined by OSHA (3), Biosafety Level 2 guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (4), WHO Laboratory Biosafety Manual (5), and/or local, regional and national regulations.

Materials Required but not Provided

ImmunoFLOW Test Kit

Quality Control

Use in accordance with laboratory accreditation requirements and/or individual laboratory guidelines.

Interpretation

Refer to the appropriate test kit package insert.

Limitations

This reagent is optimized for use with other GenBio reagents. Dilutions or adulteration of the reagent may affect performance.

Expected Results

A positive result is expected.

Bibliography

1. US Centers for Disease Control. Manual Guide – Safety Management No. CDC–22 Decontamination of Laboratory Sink Drains to Remove Azide Salts. Atlanta : Centers for Disease Control, 1976.
2. —. HHS Publication No. (CDC) 93-8395, 3rd ed: Biosafety in Microbiological and Biomedical Laboratories. Washington DC : US Government Printing Office, 1993.
3. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030, Occupational safety and health standards, bloodborne pathogens.
4. US Department of Health and Human Services. HHS Publication No. (CDC) 21-11: Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington DC : US Government Printing Office, 2009.
5. World Health Organization. Laboratory Biosafety Manual 3rd ed. Geneva : World Health Organization, 1991.