



UK NEQAS for Microbiology PO Box 63003, NW9 1GH

Tel: + 44 (0)20 8905 9890 Fax: + 44 (0)20 8205 1488 E-mail: organiser@ukneqasmicro.org.uk web:<http://www.ukneqasmicro.org.uk>

Safety Data Sheet for Quality Assessment Specimens

1. Identification of the establishment and the product

Establishment: UK NEQAS for Microbiology
PO Box 63003
London NW9 1GH

Telephone (9.00 – 17.30 hours) ++44 (0) 20 8905 9890

Telephone (Out of working hours) ++44 (0) 870 084 2000

Product: Simulated clinical specimens for the detection of various microbiological agents as described in the scheme type or in the instruction sheet sent with individual distributions.

Exceptions: AAFB Microscopy and blood parasites where ready prepared glass slides are sent.

Emergency telephone:

In the event of an accident involving exposure of staff to the material contained in the specimens, contact UK NEQAS (++ 44 (0)20 8905 9890) during normal working hours (or the Colindale Duty Safety Officer {++ 44 (0) 870 084 2000} out of hours) who will reveal the identity of the agent(s) in the specimen.

For further safety information concerning this product, participants are advised to read the instruction sheet accompanying the specimens.

2. Composition

2.1 Glass slides

Scheme type	Information on ingredients
AAFB Microscopy	Glass slides of smears prepared from human sputum that may contain <i>Mycobacterium tuberculosis</i> .
Examination of blood parasites	Human blood from patients, some of which were infected with parasites pathogenic to man, fixed by methanol or acetone* on to glass slides (* thick films). The material is designed for use in external quality assessment and the parasite content is that which might be found in equivalent patient specimens.

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2.2 Simulated clinical specimens in plastic vials

Scheme type	Information on ingredients
Anti-HBs detection	Human serum, some or all of the material contains antibodies to hepatitis B surface antigen. The serum has been tested and found to be negative for hepatitis B surface antigen and for HIV and hepatitis C antibodies.
Blood borne virus serology	Human serum, some or all of the material is positive for hepatitis B surface antigen (HBsAg), anti-HCV and anti-HIV.
Diagnostic serology (Acute hepatitis and Exanthem) screens	Human serum, some or all of the material contains antibodies to various infectious agents. The serum has been tested and found to be negative for HBsAg, and for HIV and Hepatitis C antibodies.
Examination for faecal parasites	Formalin fixed suspensions of faeces, some or all of which contain human pathogenic parasites of hazard group 2. The material is designed for use in external quality assessment and the parasite content is that which might be found in equivalent patient specimens
Hepatitis B serology	Human serum, some or all of the material is positive for hepatitis B surface antigen. The serum has also been tested for anti-HIV and anti-HCV; however samples positive for these markers may be included.
Hepatitis C serology	Human serum, some or all of the material is positive for hepatitis C antibodies. The serum has also been tested for HBsAg and anti-HIV; however samples positive for these markers may be included .
HIV serology	Human serum, some or all of the material is positive for HIV antibody. The serum has also been tested for HBsAg and anti-HCV; however samples positive for these markers may be included.
Measles serology (IgG)	Human serum, some or all of the material contains measles antibodies. The serum has been tested and found to be negative for HBsAg, and for HIV and Hepatitis C antibodies.
Molecular detection of human papillomavirus	Suspension of human cells in alcohol-based preservative, some of which may be infected with HPV.
Immunity screen (detection of IgG antibodies to hepatitis A virus, cytomegalovirus and varicella zoster virus)	Human serum, some or all of the material contains IgG antibodies to hepatitis A virus, cytomegalovirus and/or varicella zoster virus. The serum has been tested and found to be negative for HBsAg, and for HIV and Hepatitis C antibodies.
Rapid diagnostics for malaria	Lysed human blood containing trophozoites of <i>Plasmodium falciparum</i> . The blood has been tested and found to be negative for hepatitis B surface antigen and for HIV and hepatitis C antibodies.
Rubella serology (IgG)	Human serum, some or all of the material contains rubella antibodies. The serum has been tested and found to be negative for HBsAg, and for HIV and Hepatitis C antibodies.

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Scheme type	Information on ingredients
Syphilis serology	Human serum, some or all of the material contains treponemal antibodies. The serum has been tested and found to be negative for HBsAg, and for HIV and Hepatitis C antibodies.
Toxoplasma serology (IgG and IgM)	Human serum, some or all of the material contains antibodies to <i>Toxoplasma gondii</i> . The serum has been tested and found to be negative for HBsAg, and for HIV and Hepatitis C antibodies.
Virus identification	Liquid or semi-liquid material, some or all of which contain live virus of hazard group 2 capable of causing infection. The material is designed for use in external quality assessment and the microbiological content mimics that which might be found in equivalent patient specimens. N.B. May come as glass vials of freeze dried material.

2.3 Simulated clinical specimens in glass vials and freeze dried

Scheme type	Information on ingredients
Antimicrobial susceptibility	Material containing a mixture of bacteria of hazard group 2, pathogenic to humans. The material is designed for use in external quality assessment and the microbiological content mimics that which might be found in equivalent patient specimens.
Identification of fungi by culture Antifungal susceptibility	Material containing fungi of hazard group 2, some or all of which are virulent human pathogens. The material is designed for use in external quality assessment and the microbiological content mimics that which might be found in equivalent patient specimens.
Identification of mycobacteria by culture Molecular detection of Mycobacteria	Material some of which contain virulent species of mycobacteria including <i>M. tuberculosis</i> , a hazard group 3 pathogen.
Cytomegalovirus DNA quantification	Human plasma, some or all of the material is positive for CMV DNA. Plasma samples have been screened negative for anti-HCV, anti-HIV and HBsAg.
General bacteriology <i>Clostridium difficile</i> Community medicine Faecal pathogens Genital Pathogens MRSA screening Superficial infections Throat infections	Material containing a mixture of bacteria of hazard group 2, pathogenic to humans. The material is designed for use in external quality assessment and the microbiological content mimics that which might be found in equivalent patient specimens.
HBV DNA detection	Human serum, some or all of the material is positive for HBV DNA. The serum samples have also been tested for anti-HCV and anti-HIV; however samples positive for these markers may be included.

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Scheme type	Information on ingredients
HCV RNA detection	Human plasma, some or all of the material is positive for HCV RNA. The plasma samples have also been tested for HBsAg and anti-HIV; however samples positive for these markers may be included.
HIV-1 RNA quantification	Human plasma, some or all of the material is positive for HIV-1 RNA. The plasma samples have also been tested for HBsAg and anti-HCV; however samples positive for these markers may be included.
Molecular detection of <i>Chlamydia trachomatis</i>	Simulated endocervical material consisting of 5% sucrose. Some or all of the material is positive for <i>Chlamydia trachomatis</i> (hazard group 2) DNA and may contain viable bacteria. The material is designed for use in external quality assessment and the microbiological content mimics that which might be found in equivalent patient specimens.
Molecular detection of viruses in cerebrospinal fluid	Simulated cerebrospinal fluid (CSF) consisting of 5% sucrose, some or all of the material is positive for viral DNA/RNA and may contain viable virus.

3. Hazards identification

3.1 Physico-chemical hazard

Not applicable

Exceptions:

Examination for faecal parasites. Hazard information regarding the concentration of formalin in this product at the final concentration of 0.5% is not available at this time. It is the user's responsibility to read and understand all safety data for formalin in its pure form.

Scheme for molecular detection of human papillomavirus. The preservative solution used in this product contains 30-60% methanol. Inhalation of vapours from the preservative solution may cause non-specific discomfort (nausea), drowsiness with anaesthetic effects and possible blindness. Ingesting as little as 118mL may cause blindness and in extreme cases death.

3.2 Environmental hazard

Not applicable

3.3 Health hazard

Scheme type	Health hazard information
AAFB Microscopy	Risk of infection. The preparation contains sputum of human origin and should be regarded as potentially hazardous to health. The sputa have been gamma-irradiated and the smears fixed by heat. The kinetics of gamma-irradiation induced cell death are such that 100% kill cannot be assumed and normal safe microbiological practice should be observed in handling the slides.

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Scheme type	Health hazard information
Examination of blood parasites	This preparation contains human blood containing pathogenic parasites. The blood parasites are fixed in methanol or acetone. In common with all biological material of human source, the material should still be regarded as presenting a potential risk of infection.
Rapid diagnostics for malaria	This preparation contains material of human origin tested negative for anti-HIV, anti-HCV and HBsAg. The malaria parasites are not alive as a result of a freezing and thawing process. In common with all biological material of human source, the material should still be regarded as presenting a potential risk of infection.
Molecular detection of human papillomavirus	This preparation contains material of human origin suspended in a preservative solution that contains methanol. The material has not been subjected to any inactivation procedure and has not been screened for HIV, HBV or HCV. Therefore it must be handled as if capable of transmitting infection.
Blood borne virus serology Hepatitis B serology Hepatitis C serology	Risk of infection. The serum has not been subjected to any inactivation procedure and therefore must be handled as if capable of transmitting infection.
Antifungal susceptibility Antimicrobial susceptibility <i>Clostridium difficile</i> Community medicine Culture of fungi Culture of mycobacteria Cytomegalovirus DNA quantification Faecal pathogens General bacteriology Genital pathogens HBV DNA quantification HCV RNA detection HIV-1 RNA quantification Molecular detection of <i>Chlamydia trachomatis</i> Molecular detection of Mycobacteria Molecular detection of viruses in cerebrospinal fluid MRSA screening Superficial infections Throat infections Virus identification	Risk of infection. Normal safe microbiological practice should be observed when handling the material.
Diagnostic serology (Acute hepatitis and Exanthem) screens	Risk of infection. Some or all specimens may contain Erythrovirus B19 (Parvovirus B19). Normal safe microbiological practice should be observed when handling material.

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Scheme type	Health hazard information
Anti-HBs detection Immunity screen (detection of IgG antibodies to hepatitis A virus, cytomegalovirus and varicella zoster virus) Measles serology (IgG) Parasite serology (schistosoma, amoeba, hydatid, Toxocara and strongyloides serology) Rubella serology (IgG) Syphilis serology Toxoplasma serology (IgG and IgM)	This preparation contains human serum. Although not known to contain specific microbiological pathogens it should be regarded, in common with all biological material of human source, as presenting a potential risk of infection.
Examination for faecal parasites	This preparation contains human faecal material containing pathogenic parasites. Although fixed in formalin it should be regarded, in common with all biological material of human source, as presenting a potential risk of infection.
HIV serology	Risk of infection. The anti-HIV positive specimens have been heat treated at 56°C for 30 minutes in order to reduce the risk of infection, but this risk cannot be assumed to have been eliminated. Normal safe microbiological practice should be observed when handling the material.

4. First aid measures

If accidental contact with material occurs laboratory staff must follow local first aid procedures that are normally applied following exposure to an equivalent clinical specimen. Following exposure to the material medical advice must be sought.

5. Fire fighting measures

Not applicable

Exceptions:

Molecular detection of human papillomavirus: Flammable.

6. Accidental release measures

Not applicable



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7. Handling and storage

Handling

Samples must be processed in a laboratory environment which, as defined by national regulations or guidelines, is suitable for the practice of clinical microbiology. Staff handling the material should have been trained in the handling of infectious biological material. The material should be treated with the same degree of care as would be exercised with equivalent clinical specimens. The specimens are intended specifically for the purpose of EQA where they will be processed by staff trained to deal with the infectious hazards associated with the handling of clinical material of unknown content. Participants using the specimens for other purposes (e.g. for teaching or internal quality control) do so at their own risk.

Additional comments for freeze-dried material

These are relevant to the following schemes: antifungal susceptibility, antimicrobial susceptibility, *Clostridium difficile*, community medicine, cytomegalovirus DNA quantification, detection of fungi by culture, detection of mycobacteria by culture, faecal pathogens, general bacteriology, genital pathogens, HBV DNA quantification, HCV RNA detection, HIV-1 RNA quantification, molecular detection of *Chlamydia trachomatis*, molecular detection of mycobacteria, molecular detection of viruses in cerebrospinal fluid, MRSA screening, superficial infections, throat infections, and virus identification (dependent on the virus).

7.1 Vials containing freeze-dried material must be opened in an exhaust protective cabinet and reconstituted as specified on the instruction sheet provided with the specimens. Subsequent procedures should be as defined by national regulations.

7.2 Identification of mycobacteria by culture, molecular detection of mycobacteria. Samples must be processed in a laboratory environment which, as defined by national regulations or guidelines, is suitable for the handling of hazard group 3 organisms.

Storage

The ideal storage temperature for specimens for all scheme types is +4°C. Specimens can be kept at ambient or room temperature for the purposes of transportation. Do not freeze specimens.

8 Exposure controls/Personal protection

Use good laboratory practice and wear appropriate laboratory coats, gloves and eye protection.

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9. Physical/chemical properties

Format	Scheme type	Properties	Biological agent group
Slides	AAFB microscopy	Not applicable	Hazard Group 3
	Examination for blood parasites	Not applicable	Hazard Group 2
Wet preparation	Molecular detection of human papillomavirus	Alcohol-based liquid	Hazard Group 2
Liquid serum	Blood borne virus serology Hepatitis B serology Hepatitis C serology HIV serology	Odourless straw coloured liquid	Hazard Group 3
	Anti-HBs detection Diagnostic serology (Acute hepatitis and Exanthem) screens Immunity screen (detection of IgG antibodies to hepatitis A virus, cytomegalovirus and varicella zoster virus) Measles serology Parasite serology Rubella serology Syphilis serology Toxoplasma serology (IgG and IgM)	Odourless straw coloured liquid	Hazard Group 2
Liquid faecal suspension	Examination for faecal parasites	Brown coloured liquid containing particulate matter, odour of formalin	
Lysed blood	Rapid diagnostics for malaria	Lysed blood	
Freeze dried	HBV DNA quantification HCV RNA detection HIV-1 RNA quantification Identification of mycobacterium by culture Molecular detection of Mycobacteria	Dry, inert odourless material	Hazard Group 3

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Format	Scheme type	Properties	Biological agent group
Freeze dried	Antifungal susceptibility Antimicrobial susceptibility <i>Clostridium difficile</i> Community medicine Cytomegalovirus DNA quantification Faecal pathogens General bacteriology Genital pathogens Identification of fungi by culture Molecular detection of <i>Chlamydia trachomatis</i> Molecular detection of viruses in cerebro-spinal fluid MRSA screening Superficial infections Throat infections	Dry, inert odourless material	Hazard Group 2
Variable	Virus identification	Depending on the virus(es) – Dry inert odourless material or Liquid in buffer or Semi-liquid in gelatin	Hazard Group 2

10. Stability and reactivity

Storage is unlikely to increase or decrease the risk of infection associated with handling the material

11. Toxicological information

Not applicable

12. Ecological information

Not applicable

13. Disposal considerations

The used material must be disposed of using an autoclave as for other clinical biological waste

14. Transport information

Refer to national and international regulations for the transport of diagnostic specimens

15. Regulatory information

All products are classified under U.N. ID 3373 as diagnostic specimens

16. Other information

Nil