UK NEQAS for Microbiology, P O Box 63003, NW9 1GH
Tel: +44 (0)20 8905 9890 Fax: +44 (0)20 8205 1488 email: 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 - 17.00 hours) +44 (0) 20 8905 9890

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

Product:

Simulated clinical specimens for detection of various microbiological agents as described in the scheme type or in the instruction sheet 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 name	Information on components
AAFB microscopy	Glass slides of smears prepared from human sputum that may contain *Mycobacterium tuberculosis*.
Blood parasitology	Human blood from patients, some of whom were infected with pathogenic parasites, fixed by methanol or acetone* on to glass slides (* thick films).

2.2 Simulated clinical specimens in plastic vials

Scheme name	Information on components
Antifungal susceptibility Mycology (identification of fungi by culture)	Liquid material containing fungal spores of hazard group 2, some or all of which are virulent human pathogens.
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 Ag/Ab 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 HIVAg/Ab.

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2.2 continued

Scheme name	Information on components
Blood donor screen	Human serum, some or all of the material is positive for hepatitis B surface antigen (HBsAg), anti-HCV, HIV Ag/Ab, anti-HTLV and treponemal Ab.
Cryptococcal antigen detection	Human serum, simulated and/ cerebrospinal fluid (CSF) spiked with a filtrate of *Cryptococcus neoformans*. The serum has been tested and found to be negative for HBsAg, and for HIV Ag/Ab and hepatitis C antibodies.
Diagnostic serology: acute hepatitis	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 Ag/Ab and hepatitis C antibodies.
Faecal parasitology	Formalin fixed suspensions of faeces, some or all of which contain human pathogenic parasites of hazard group 2.
Fungal biomarkers	Human serum spiked and or bronchoalveolar lavage (BAL) with a filtrate of *Aspergillus fumigatus* species complex. The serum has been tested and found to be negative for HBsAg, and for HIV Ag/Ab and hepatitis C antibodies.
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 HIV Ag/Ab 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 and HCV Ag. The serum has also been tested for HBsAg and HIV Ag/Ab; however samples positive for these markers may be included.
Hepatitis E Serology	Human serum, some or all of the material contains IgG/IgM antibodies to hepatitis E. The serum has been tested and found to be negative for HBsAg, and for HIV Ag/Ab and hepatitis C antibodies.
HIV serology HIV Point of Care	Human serum, some or all of the material is positive for HIV. The serum has also been tested for HBsAg and anti-HCV; however samples positive for these markers may be included in the HIV serology scheme only.
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 Ag/Ab and hepatitis C antibodies.
Measles & Mumps IgG serology	Human serum, some or all of the material contains measles & mumps antibodies. The serum has been tested and found to be negative for HBsAg, and for HIV Ag/Ab 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.
Molecular detection of *Chlamydia trachomatis & Neisseria gonorrhoeae*	Simulated urine consisting of water (92.33%), glycerol (7.64%) and sodium hydroxide (0.03%)., some or all of the material is positive for *Chlamydia trachomatis* DNA and/or *Neisseria gonorrhoeae* DNA. These specimens may contain viable bacteria.
Parasite serology	Human serum, some or all of the material contains strongyloides, amoeba, schistosoma, toxocara, hydatid and *Trypanosoma cruzi* antibodies.

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2.2 continued

Scheme name	Information on components
Parvovirus B19 and Rubella Serology	Human serum, some or all of the material contains antibodies to Parvovirus B19 or Rubella. The serum has been tested and found to be negative for HBsAg, and for HIV Ag/Ab and hepatitis C antibodies.
Respiratory rapid: RSV	Cell suspension, some of which may be infected with RSV.
Rubella IgG serology	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 Ag/Ab and hepatitis C antibodies.
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 Ag/Ab and hepatitis C antibodies.
Toxoplasma serology	Human serum, some or all of the material contains antibodies to Toxoplasma gondii.
Urinary Antigens	Human urine, some or all of the material is positive for *Legionella pneumophila* antigens and /or *Streptococcus pneumoniae* antigens.
Virus identification	Liquid or semi-liquid material, some or all of which contain live virus of hazard group 2 capable of causing infection.

2.3 Simulated clinical specimens in glass vials and freeze dried

Scheme name	Information on components
Antimicrobial susceptibility	Material containing a mixture of bacteria of hazard group 2, pathogenic to humans.
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, HIV Ag/Ab and HBsAg.
EBV DNA quantification	Human plasma, some or all of the material is positive for EBV DNA. Plasma samples have been screened negative for anti-HCV, HIV Ag/Ab and HBsAg.
General bacteriology *Clostridium difficile* Community medicine Faecal pathogens Genital pathogens MRSA screening	Material containing a mixture of bacteria of hazard group 2, pathogenic to humans.
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 HIV Ag/Ab; however samples positive for these markers may be included.

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2.3 continued

Scheme name	Information on components
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 HIV Ag/Ab; however samples positive for these markers may be included.
HEV RNA detection	Human plasma, some or all of the material is positive for HEV RNA. The plasma samples have also been tested for HBsAg and HIV Ag/Ab and anti-HCV; 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 *Chlamydia trachomatis & Neisserria gonorrhoeae*	Simulated vaginal material- consisting of 5% sucrose and 0.3% bovine serum albumin (BSA).Some or all of the material is positive for *Chlamydia trachomatis* DNA and/or *Neisseria gonorrhoeae* DNA. These specimens may contain viable bacteria.
Molecular detection of malaria Malaria rapid (rapid diagnostics for malaria)	Lysed human blood containing *Plasmodium falciparum* or other *Plasmodium* sp.
Molecular detection of mycobacteria Mycobacterium culture	Material some of which contain virulent species of mycobacteria including *M. tuberculosis*, a hazard group 3 pathogen.
Molecular detection of respiratory viruses	Simulated freeze-dried nasopharyngeal aspirate some or all of which contain human viruses, (hazard group 2), including influenza viruses, adenovirus, respiratory syncytial viruses, human enteroviruses, rhinoviruses, human metapneumovirus, bocavirus, human parechoviruses, human coronaviruses and human parainfluenza viruses.
Molecular detection of viruses in cerebrospinal fluid	Simulated cerebrospinal fluid (CSF) consisting of 5% sucrose and 0.3% BSA, some or all of the material is positive for viral DNA/RNA and may contain viable virus.
Viral gastroenteritis	Human faeces, some or all of which contain human viruses of hazard group 2. (Norovirus, Rotavirus and Adenovirus 40,41) Faecal samples are screened negative for Salmonella sp, E coli O157 and Shigella sp.

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3. 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.

4. Fire fighting measures

Not applicable

Exceptions:

Molecular detection of human papillomavirus: Flammable.

5. Accidental release measures

Not applicable

6. Hazards identification

6.1 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.

6.2 Environmental hazard

Not applicable

6.3 Health hazard

Scheme name	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.
Blood parasitology	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.
Malaria rapid (rapid diagnostics for malaria) Molecular detection of malaria	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.

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6.3 continued

Scheme name	Health hazard information
Antifungal susceptibility Antimicrobial susceptibility *Clostridium difficile* Community medicine Cryptococcal antigen detection (CSF) Cytomegalovirus DNA quantification Diagnostic serology: acute hepatitis EBV DNA quantification Faecal pathogens Fungal biomarkers (BAL) General bacteriology Genital pathogens HBV DNA quantification HCV RNA detection HEV RNA detection HIV-1 RNA quantification Molecular detection of *Chlamydia trachomatis* & *Neisseria gonorrhoeae* Molecular detection of mycobacteria Molecular detection of respiratory viruses Molecular detection of viruses in cerebrospinal fluid Mycobacterium culture Mycology MRSA screening Respiratory rapid: RSV Viral gastroenteritis Virus identification	Risk of infection. Good laboratory practice at Containment level II should be observed when handling the material (organism dependant)
Blood borne virus serology Blood donor screen Hepatitis B serology Hepatitis C serology Hepatitis E 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.
Diagnostic serology (Acute hepatitis) screen Parvovirus B19 and Rubella serology	Risk of infection. Some or all specimens may contain Parvovirus B19. Normal safe microbiological practice should be observed when handling material.
Anti-HBs detection Cryptococcal antigen detection (serum) Fungal biomarkers (serum) Immunity screen (detection of IgG antibodies to hepatitis A virus, cytomegalovirus and varicella zoster virus) Measles & Mumps IgG serology Parasite serology (schistosoma, amoeba, hydatid, toxocara, *Trypanosoma cruzi* and strongyloides serology) Rubella IgG serology Syphilis serology Toxoplasma serology	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.

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6.3 continued

Scheme name	Health hazard information
Faecal parasitology	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 HIV Point of Care	Risk of infection. The HIV positive specimens have been heat treated at 56℃ for 30 minutes in order to reduce the risk of infection, but this risk cannot be assumed to have been eliminated. An additional inactivation step is done by adding 1% tween-80 for the HIV point of care specimens. Normal safe microbiological practice should be observed when handling the material.
Urinary Antigens	This preparation contains human urine. 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.

7. Handling and storage

7.1 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: antimicrobial susceptibility, *Clostridium difficile*, community medicine, cytomegalovirus DNA quantification, detection of mycobacteria by culture, faecal pathogens, EBV DNA quantification, general bacteriology, genital pathogens, HBV DNA quantification, HCV RNA detection, HEV RNA detection, HIV-1 RNA quantification, malaria (molecular), malaria rapid, molecular detection of *Chlamydia trachomatis*, molecular detection of mycobacteria, molecular detection of respiratory viruses, molecular detection of viruses in cerebrospinal fluid and MRSA screening.

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.

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.

7.2 Storage

The ideal storage temperature for specimens for all scheme types* is +4℃. Specimens can be kept at ambient or room temperature for the purposes of transportation. Do not freeze specimens. For storage of re-constituted samples see the general instruction sheets that come with the specimens.

*Antifungal susceptibility and the Mycology scheme: Vials of spore suspensions must only be stored at ambient temperatures.

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 name	Properties	Biological agent group
Slides	AAFB microscopy	Not applicable	Hazard Group 3
	Blood parasitology	Not applicable	Hazard Group 2
Wet preparation	Molecular detection of human papillomavirus	Alcohol-based liquid	Hazard group 2
Liquid serum	Blood donor screen Blood borne virus serology Hepatitis B serology Hepatitis C serology Hepatitis E serology HIV serology HIV Point of Care	Odourless straw coloured liquid	Hazard group 3
Liquid serum	Anti-HBs detection Cryptococcal antigen detection Diagnostic serology (Acute hepatitis) screen Fungal Biomarkers Immunity screen (detection of IgG antibodies to hepatitis A virus, cytomegalovirus and varicella zoster virus) Measles & Mumps IgG serology Parasite serology Parvovirus B19 and Rubella serology Rubella IgG serology Syphilis serology Toxoplasma serology	Odourless straw coloured liquid	Hazard group 2
Liquid faecal suspension	Faecal parasitology	Brown coloured liquid containing particulate matter, odour of formalin	
Liquid urine	Urinary Antigens Molecular detection of *Chlamydia trachomatis & Neisserria gonorrhoeae*	Straw coloured liquid	
Liquid suspension	Antifungal susceptibility Cryptococcal antigen detection (CSF) Fungal Biomarkers (BAL) Mycology (identification of fungi by culture) Respiratory rapid: RSV	Odourless, colourless liquid	
Freeze dried	HBV DNA quantification HCV RNA detection HEV RNA detection HIV-1 RNA quantification Molecular detection of mycobacteria Mycobacterium culture	Dry, inert odourless material	Hazard group 3

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9 continued

Format	Scheme name	Properties	Biological agent group
Freeze dried	Malaria rapid (rapid diagnostics for malaria) Molecular detection of malaria	Dry, inert odourless material	Hazard group 3* (*P. falciparum* only)
Freeze dried	Antimicrobial susceptibility *Clostridium difficile* Community medicine Cytomegalovirus DNA quantification EBV DNA quantification Faecal pathogens General bacteriology Genital pathogens Molecular detection of *Chlamydia trachomatis & Neisseria gonorrhoeae* Molecular detection of respiratory viruses Molecular detection of viruses in cerebrospinal fluid MRSA screening Viral gastroenteritis	Dry, inert odourless material	Hazard group 2
Variable	Virus identification	Depending on the virus(es) – 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

All specimen types can be transported within UK and between UK and overseas countries at ambient temperature and stored as described in section 7.2 upon arrival at their final destination.

15. Regulatory information

All products are classified under UN 3373 as Biological Substance, Category B.

16. Other information

Nil