Schedule of Accreditation

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK



9304

Accredited to ISO 15189:2022

UK Health Security Agency, An Executive Agency of the Department of Health and **Social Care**

Issue No: 011 Issue date: 28 August 2024

Rare and Imported Pathogens

Laboratory

Manor Farm Road

Porton Down

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	Serological examination activities for the purposes of clinical diagnosis	Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.
Serum or Plasma unless otherwise stated:	Detection of:	Automated ELISA using Dynex DS2 or Tecan (where specified) and in-house procedures: SPATH031: Operation of the DS2 automated platform for use with commercially available ELISA kits SPATH102: ELISA Bench assay instructions SPATH125: Processing ELISAs on the TECAN Freedom EVOlyzer-2
Serum only	Borrelia burgdorferi IgG/IgM	Zeus or AccuDiag Borrelia VIsE1 / pepC10 / IgG/IgM ELISA kit TECAN
Serum only	Leptospira IgM	Panbio IgM ELISA kit /TECAN
	Coxiella burnetii IgG/IgM	Virion Serion Coxiella Phase 2 IgG VS and IgM VS ELISA kits DS 2
	Zika IgG/IgM	Euroimmun Anti-Zika virus IgM/ IgG ELISA, TECAN
	Francisella tularensis IgG/IgM/IgA	Serazyme anti-Francisella tularensis IgG/A/M ELISA DS2

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Serum or Plasma unless otherwise stated:		Automated ELISA using Dynex DS2 or Tecan (where specified) and in-house procedures: SPATH031: Operation of the DS2 automated platform for use with commercially available ELISA kits SPATH102: ELISA Bench assay instructions SPATH125: Processing ELISAs on the TECAN Freedom EVOlyzer-2
Serum only	Dengue IgG/IgM	Panbio Dengue IgG indirect and IgM capture ELISA kits, TECAN
	West Nile IgG/IgM	Virion serion WNV IgM and Focus WNV IgG ELISA,DS2
	Chikungunya IgG/ IgM	Euroimmun Chikungunya IgM/IgG ELISA kits, TECAN
Serum and plasma unless otherwise stated:		Automated Immunoblot assay using Virachip and Virastripe assays, Gemini liquid handling system and Sensospot reader and in-house procedure:
	Detection of:	
Serum	Borrelia burgdorferi IgG/IgM	SPATH163 Virachip Borrelia IgG and IgM Immunoblots

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	Detection of:	
Serum or Plasma	Hantavirus group IgG	Automated Immunofluorescence using EuroImmun Sprinter
	Chikungunya IgG	Immunofluorescent Analyser (IFA) and in-house procedure:
	Sandfly Fever virus group IgG	SPATH082 Use of the Sprinter
	Japanese Encephalitis IgG	
	Tick borne Encephalitis IgG	
	Yellow Fever IgG	
	Detection of:	Manual Immunofluorescent Assay (IFA) and in-house procedures:
Serum	Anaplasma phagocytophilum IgG	SPATH018 Focus immunofluorescence assay for the detection of IgG class antibodies to Anaplasma phagocytophilum in clinical samples
Serum	Coxiella IgG/IgM/IgA	SPATH029 Use of Viracell commercial IFA slides for detection of Coxiella burnetti antibodies
	Detection of:	Manual Immunofluorescent Assay (IFA) and in-house procedures:
Serum	Rickettsia Spotted Fever Group IgG/IgM	SPATH028 Indirect Immunofluorescence antibody (IFA) test for anti Rickettsial IgG and IgM
	Rickettsia Epidemic Typhus group IgG/IgM	antibodies

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Serum, plasma and urine unless otherwise stated:	Molecular examination activities for the purposes of clinical diagnosis	Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.
		Automated extraction using MagNAPure or Qiagen manual extraction. QIAgility robot or manual setup, Roche Lightcycler 480, Roche Lightcycler II, ABI Viia7 or Quant StudioFlex 7 thermocyclers and in-house procedures: SPATH122 SPATH127
	Detection of:	
Serum/Plasma	Rickettsia DNA	SPATH040 Detection of Yellow fever, TBE EEE, VEE, WEE, JE,
	Orientia tsutsugamushi DNA	Mayaro, Nipah, Hendra, Junin, Toscana virus RNA and Rickettsia
	Tick borne Encephalitis RNA	spp. and Orientia tsutsugamushi bacterial DNA by real-time RT PCR
	Yellow Fever RNA	
Serum/Plasma	Dengue virus RNA	SPATH115 Detection of Zika, Dengue, Oropouche, Chikungunya, RVF and CCHF virus RNA by Real- time RT-PCR using ABI Viia7 and Quant Studio Flex 7 thermocyclers
Serum/Plasma	Chikungunya virus RNA	
	Crimean Congo Haemorrhagic fever RNA	
Serum/plasma/urine/semen	Zika RNA E gene or NS1	

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular examination activities for the purposes of clinical diagnosis (cont'd)	Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.
Serum, plasma and urine unless otherwise stated:	Detection of:	Automated extraction platforms using MagNAPure or Qiagen manual extraction. QIAgility robot or manual setup, Roche Lightcycler 480, Roche Lightcycler II, ABI Viia7 or Quant StudioFlex 7 thermocyclers and in-house procedures: SPATH122 SPATH127
Serum and Plasma	West Nile Virus RNA	SOP SPATH221 using MagNAPure 24 or 96 extraction platforms and LightCycler 480 real-time PCR machine using Altona WNV PCR kit 2.0
	Leptospira DNA	SPATH084 Taqman assay for the detection and differentiation of pathogenic and non-pathogenic Leptospires
	Ebola virus RNA Marburg virus RNA	SPATH009956: Filovirus real time RT-PCR
Serum/Plasma/CSF/ Tissue/Synovial fluid	pan Borrelia DNA	SPATH085 Bacterial detection by Real Tme PCR
Plasma	Lassa virus RNA	SPATH229: using MagNAPure 96 extraction platforms and LightCycler 480 real-time PCR machine using Altona Realstar Lassa RT-PCR 2.0

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HUMAN TISSUES AND FLUIDS (cont'd)	Molecular examination activities for the purposes of clinical diagnosis (cont'd)	Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.
Serum, plasma or urine unless otherwise stated	Detection of:	QIAmp DNA mini kit manual extraction, QIAgility PCR or manual set up and ABI Viia7 thermocycler and in-house procedures: SPATH069: Manual extraction of nucleic acids from clinical samples
Serum/plasma/urine/Bacterial isolate	Bacillus anthracis DNA Francisella tularensis DNA Coxiella burnetii RNA	SPATH085 Bacterial detection by Real-Time PCR
END		

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