

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9304

Accredited to
ISO 15189:2012

Public Health England, An Executive Agency of the Department of Health and Social Care

Issue No: 003 Issue date: 03 November 2020

Rare and Imported Pathogens
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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	<u>Serological examination activities for the purposes of clinical diagnosis</u>	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 C6 IgG/IgM	DS2
Serum only	Leptospira IgM	DS2/TECAN
	Coxiella burnetii IgG/IgM	DS 2
	Zika IgG/IgM	DS2/TECAN
Serum only	Francisella tularensis IgG/IgM/IgA	DS2
	Dengue IgG/IgM	DS2/TECAN
	West Nile IgG/IgM	DS2
	Chikungunya IgG/ IgM	TECAN



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.
Serum and plasma unless otherwise stated:	Detection of:	Automated Immunoblot assay using Virachip and Virastripe assays, Gemini liquid handling system and Sensospot reader and in-house procedure:
Serum	Borrelia burgdorferi IgG/IgM	SPATH070 Performing the Virastripe Borrelia IgG and IgM Immunoblots
Serum or Plasma	Hantavirus group IgG Chikungunya IgG Sandfly Fever virus group IgG Japanese Encephalitis IgG Tick borne Encephalitis IgG Yellow Fever IgG	Automated Immunofluorescence using EuroImmun Sprinter Immunofluorescent Analyser (IFA) and in-house procedure: SPATH082 Use of the Sprinter
Serum	Detection of: Anaplasma phagocytophilum IgG	Manual Immunofluorescent Assay (IFA) and in-house procedures: 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 burnetii antibodies



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum</p> <p>Serum, plasma and urine unless otherwise stated:</p> <p>Serum/Plasma/CSF/ Tissue/Synovial fluid</p>	<p><u>Serological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of:</p> <p>Rickettsia Spotted Fever Group IgG/IgM</p> <p>Rickettsia Epidemic Typhus group IgG/IgM</p> <p><u>Molecular</u></p> <p>Detection of: pan Borrelia DNA</p>	<p>Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.</p> <p>Manual Immunofluorescent Assay (IFA) and in-house procedures:</p> <p>SPATH028 Indirect Immunofluorescence antibody (IFA) test for anti Rickettsial IgG and IgM antibodies</p> <p>Automated extraction using Qiagen EZ1, MagNAPure or Qiagen manual extraction. QIAgility robot or manual setup, Roche Lightcycler 480, Roche Lightcycler II, ABI Vii7 or Quant StudioFlex 7 thermocyclers and in-house procedures:</p> <p>SPATH036 SPATH122 SPATHW0011 SPATH127</p> <p>SPATH085 detection of pan Borrelia DNA by real-time PCR using ABI Vii7 and Quant Studio Flex 7 thermocyclers</p>



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Serum, plasma and urine unless otherwise stated: Serum/Plasma	<u>Molecular examination activities for the purposes of clinical diagnosis (cont'd)</u> Detection of: Orientia tsutsugamushi DNA	Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed. Automated extraction platforms using Qiagen EZ1, MagNAPure or Qiagen manual extraction. QIAgility robot or manual setup, Roche Lightcycler 480, Roche Lightcycler II, ABI Vii7 or Quant StudioFlex 7 thermocyclers and in-house procedures: SPATH036 SPATH122 SPATHW0011 SPATH127 SPATH040 Detection of Dengue, Chikungunya, Yellow fever, RVF, TBE EEE, VEE, WEE, JE, Mayaro, Nipah, Hendra, Junin, Toscana VIRUS RNA and Rickettsia spp. And Orientia tsutsugamushi bacterial DNA by real-time RT PCR
Serum/Plasma	Dengue virus RNA	SPATH115 Detection of Zika, Dengue, Oropouche, Chikungunya and CCHF virus RNA by Real-time RT-PCR using ABI Vii7 and Quant Studio Flex 7 thermocyclers
Serum/Plasma	Chikungunya virus RNA	SPATH115 Detection of Zika, Dengue, Oropouche, Chikungunya and CCHF virus RNA by Real-time RT-PCR using ABI Vii7 and Quant Studio Flex 7 thermocyclers



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum, plasma and urine unless otherwise stated:</p>	<p><u>Molecular examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of:</p> <p>Japanese Encephalitis virus RNA</p> <p>Tick borne Encephalitis RNA</p> <p>Yellow Fever RNA</p> <p>Crimean Congo Haemorrhagic fever RNA</p> <p>West Nile Virus RNA</p>	<p>Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.</p> <p>Automated extraction platforms using Qiagen EZ1, MagNAPure or Qiagen manual extraction. QIAgility robot or manual setup, Roche Lightcycler 480, Roche Lightcycler II, ABI Vii7 or Quant StudioFlex 7 thermocyclers and in-house procedures:</p> <p>SPATH040 Detection of Dengue, Chikungunya, Yellow fever, RVF, TBE EEE, VEE, WEE, JE, Mayaro, Nipah, Hendra, Junin, Toscana VIRUS RNA and Rickettsia spp and Orientia tsutsugamushi bacterial DNA by real-time RT PCR</p> <p>SPATH115 Detection of Crimean Congo haemorrhagic Detection of Zika, Dengue, Oropouche, Chikungunya and CCHF virus RNA by Real-time RT-PCR using ABI Vii7 and Quant Studio Flex 7 thermocyclers</p> <p>SPATH041: Detection of West Nile virus RNA using Artus WNV LC RT-PCR KIT</p>
<p>Serum, plasma and urine (unless otherwise stated)</p>	<p>Detection of:</p> <p>Leptospira DNA</p> <p>Ebola virus RNA</p> <p>Marburg virus RNA</p>	<p>Manufacturer's instructions for Qiagen EZ1, MagNAPure automated extraction or manual extraction, QIAgility PCR or manual set up and ABI Vii7 thermocyclers and in-house procedures:</p> <p>SPATH084 Taqman assay for the detection and differentiation of pathogenic and non-pathogenic Leptospire</p> <p>SPATH056: Filovirus RT-PCR</p> <p>SPATH056: Filovirus RT-PCR</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Serum, plasma or urine unless otherwise stated</p> <p>Serum/plasma/urine/Bacterial isolate</p>	<p><u>Molecular examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of:</p> <p>Bacillus anthracis DNA</p> <p>Francisella tularensis DNA</p> <p>Coxiella burnetii RNA</p>	<p>Manufacturer's instructions for specified equipment and methods (where relevant) in conjunction with in-house procedures listed.</p> <p>QIAmp DNA mini Kit manual extraction, QIAgility PCR or manual set up and ABI Vii7 thermocycler and in-house procedures:</p> <p>SPATH069: Bacterial Culture and Extraction of nucleic acids from Clinical Samples</p> <p>SPATH 085 Detection of Bacillus anthracis, Coxiella burnetii, Francisella tularensis Brucella spp, Burkholderia spp and RNase P extraction control by Real-Time PCR</p> <p>Manufacturer's instructions for MagNAPure automated or manual extraction, QIAgility PCR or manual set up and ABI Vii7 thermocycler and in-house procedures:</p> <p>SPATH069: Bacterial Culture and Extraction of nucleic acids from Clinical Samples</p> <p>SPATH 085 Detection of Bacillus anthracis, Coxiella burnetii, Francisella tularensis Brucella spp, Burkholderia spp and RNase P extraction control by Real-Time PCR</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis (cont'd)</u>	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:	Manufacturer's instructions for Qiagen EZ1 extraction, MagNAPure automated extraction, QIAgility PCR set up or manual set up and GeneAmp thermocycler and in-house procedure:
Serum/plasma/urine	Lassa virus RNA	SPATH097: Detection of Lassa virus RNA (Lassa Block RT-PCR, Ölschläger assay)
Serum/plasma/urine/semen	Zika RNA E gene or NS1	Manufacturer's instructions for Qiagen EZ1 extraction, MagNAPure automated extraction or manual extraction, QIAgility PCR set up or manual set up and ABI Viia 7 thermocycler and in-house procedure: SPATH 115: Detection of Zika virus RNA by Real-time RT-PCR
Nasal and Throat (Oropharyngeal) Swabs in proprietary UTM, VTM and PCR media or 0.9% physiological saline	detection of SARS-CoV-2 RNA (Covid-19)	Roche COBAS 6800/8800 platform automated PCR SPATH193
END		