

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to
ISO 15189:2022

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

Issue No: 012 Issue date: 19 October 2024

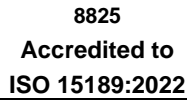
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Website: <https://www.gov.uk/government/organisations/uk-health-security-agency>

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 BODY FLUIDS AND TISSUES Tissue culture isolate, swab in VTM Plain, untreated swabs from any infected location in Viral Transport Medium (VTM) Whole blood/EDTA plasma/Serum CSF Vesicle fluid Vitreous /aqueous humour	<u>Virology examination activities for the purposes of clinical diagnosis</u> Herpes Simplex Virus 1 & 2 Phenotypic Drug resistance Detection of Herpes simplex virus types 1 and 2 thymidine kinase (TK) and DNA polymerase (pol) genes as indicators of genotypic resistance Nucleic acid extraction for the purposes of referral to specialist centre for sequencing Nucleic acid sequence data	In-house documented procedures based on manufacturer's instructions Plaque reduction Method: HSV Antiviral Plaque Reduction (V5756) Cells: Culture of commercial cells (Vero, ECACC) Culture system: CO2 incubator (Thermo Fisher Heracell 150i) Method: Genotypic antiviral resistance testing of HSV using Sanger sequencing NA Extraction using Qiagen QIAamp DNA kit (V7291) PCR amplification (V7292) Gel Electrophoresis and PCR cleanup using ThermoFisher ExoSAP=IT Quantification of amplicons: Qubit 3.0 Fluorimeter (V7287) Sanger sequencing of HSV genotypic resistance (V7256) and analysis using ReCall Software (V7257)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)

EDTA plasma, serum,

Nucleic acid sequence data

Type of test/Properties measured/Range of measurement

Virology examination activities for the purposes of clinical diagnosis (cont'd)

Human Immunodeficiency Virus
type 1 (HIV-1) genotypic resistance

Nucleic acid extraction for the purpose of referral to specialist centre for sequencing

HIV genotypic resistance

Standard specifications/ Equipment/Techniques used

In-house documented procedures based on manufacturer's instructions

Sequencing

Method: in-house Genotypic antiretroviral resistance testing of HIV using Sanger sequencing (V7270)

Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions)

Amplification: Bio-RAD Dyad DNA engine thermal cycler

Gel electrophoresis and PCR cleanup using ThermoFisher ExoSAP-IT (V7255)

Quantification of amplicons: ThermoFisher Qubit 2.0 fluorimeter (V7064)

Preparing Sanger sequencing reactions for antiviral resistance testing (V7256)

Analysis and reporting of outsourced nucleic acid sequence data

Data analysis: ReCall software (V7257)

Interpretation: Stanford HIV drug resistance database (V7260)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
EDTA whole blood, plasma, serum	HIV-1 tropism Nucleic acid extraction for the purpose of referral to specialist centre for sequencing	Method: in-house - Genotypic antiretroviral resistance testing of HIV using Sanger sequencing (V7270) Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions) Amplification: Bio-RAD Dyad DNA engine thermal cycler Gel Electrophoresis and PCR cleanup using ThermoFisher ExoSAP-IT (V7255)
Nucleic acid sequence data	HIV-1 proviral tropism	Quantification of amplicons: ThermoFisher Qubit 2.0 Fluorimeter (V7064) Preparing Sanger sequencing reactions for antiviral resistance testing (V7256) Analysis and reporting of outsourced nucleic acid sequence data Data analysis: ReCall Software (V7257) Interpretation: Geno2Pheno (web service provided by Max Planck Institute) (V7260)
Serum, plasma	Hepatitis A genotyping/phylogenetics Nucleic acid extraction for the purpose of referral to specialist centre for sequencing	Sequencing Method: in-house (V5201) Nucleic acid extraction: Roche MP96 automated platform, with MagNAPure 96 DNA Viral Nucleic Acid Small Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control) (V7040) Amplification: Bio-RAD Dyad DNA engine thermal cycler PCR product purification: Cytiva GFX columns, centrifuge Analysis and reporting of outsourced nucleic acid sequence data



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
Nucleic acid sequence data	Hepatitis A genotyping/phylogenetics	Analysis and reporting of outsourced nucleic acid sequence data Analysis: DNASTar/Seqman Genotyping: MegAlign
Oral fluids	Hepatitis A anti HAV- IgG	Manual EIA (in-house) anti-HAV IgG kit Microimmune plates and Diasource conjugate (V7373) EIA plate washer (Tecan Columbus Pro), EIA plate reader (Biotek EL-808)
Oral fluids	Hepatitis A anti HAV- IgM	Manual EIA (in-house) anti- HAV IgM Microimmune plates and Diasource conjugate (V7372) EIA plate washer (Tecan Columbus Pro) EIA plate reader (Biotek EL-808)
Serum, plasma	Hepatitis B Virus sequencing- Pre-core/BCP mutation screen Nucleic acid extraction for the purpose of referral to specialist centre for sequencing	Sequencing Method: in-house (V7046, V7039, V7497) Nucleic acid extraction: Roche MP96 automated platform, with MagNAPure 96 DNA Viral Nucleic Acid Small Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control) (V7040) Amplification: Bio-RAD Dyad DNA engine thermal cycler PCR product purification: Cytiva GFX columns, centrifuge
Nucleic acid sequence data	Hepatitis B Virus sequencing- Pre-core/BCP mutation screen	Analysis and reporting of outsourced nucleic acid sequence data Analysis: DNASTar/Seqman/MegAlign Mutation determination: Manual: BioEdit (V7039) Automated: Git and Anaconda (V7497)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Serum, plasma	HBV sequencing for surface/polymerase region	Sequencing
	Nucleic acid extraction for the purpose of referral to specialist centre for sequencing	Method: in-house (V7046, V7039, V7497)
		Nucleic acid extraction: Roche MP96 automated platform, with MagNApure 96 DNA Viral Nucleic Acid Small Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control) (V7040)
		Amplification: Bio-RAD Dyad DNA engine thermal cycler
		PCR product purification: Cytiva GFX columns, centrifuge
Nucleic acid sequence data	HBV sequencing for surface/polymerase region	Analysis and reporting of outsourced nucleic acid sequence data
		Analysis: DNASTar/Seqman/MegAlign
		Mutation determination: Manual: BioEdit (V7039)
		Automated: Git and Anaconda (V7497)
PHE Central Sequencing Laboratory (CSL)		
Serum, plasma	Quantitative Hepatitis D RNA	Roche MagNA Pure 96 Extraction (V7040)
		ABI 7500 Real Time PCR system & Altona RealStar RT-PCR assay (V7424)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Serum, plasma, faeces	Hepatitis E Virus RNA	Real-time PCR. Method: in-house (V6867) Nucleic acid extraction: Roche MP96 automated platform, with MagNApure 96 DNA Viral Nucleic Acid Small Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control) (V7040) Amplification/quantification: Applied Biosystems ABI 7500 real time thermal cycler with Qiagen Quantitect probe RT-PCR kit reagents Analysis: ABI 7500 software
Serum, plasma	Anti-HBc	Manual EIA. (V7152) Murex anti-HBc (total) EIA, 8G21-01) EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Tecan Sunrise)
Dried Blood Spot (DBS)	Anti HBc	Manual EIA (In house) Biorad Monoelisa anti-HBc Plus EIA (V5142) plate washer (Biotek ELx50), plate reader (Tecan Sunrise)
Dried Blood Spot (DBS)	HBsAg	Manual EIA (in-house) Murex HBsAg EIA v3 reagents (V5734) plate washer (Biotek ELx50), plate reader (Tecan Sunrise)
Dried Blood Spot (DBS)	Confirmation HBsAg	Manual EIA. (in-house) Murex HBsAg EIA v3 reagents (V5735) plate washer (Biotek ELx50), plate reader (Tecan Sunrise)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Faeces	Adenovirus (enteric) DNA	Real-time PCR (In-house) Nucleic acid extraction: Roche MP96 automated platform or Qiasymphony, with MagNApure 96 DNA Viral Nucleic Acid large Volume kit reagents (as per manufacturer's instructions or Qiasymphony mini virus kit, with in-house addition of internal control) (V7201 Qiasymphony, V7244 MP96) Amplification: Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V7346) PCR: Applied Biosystems ABi fast 7500 real time thermal cycler with (V6771) Invitrogen platinum qPCR super mix UDG (V7346)
Faeces	Astrovirus RNA	Real-time PCR (in-house). Nucleic acid extraction: Roche MP96 automated platform V7244 or Qiasymphony, with MagNApure 96 DNA Viral Nucleic Acid large Volume kit reagents (as per manufacturer's instructions or Qiasymphony mini virus kit V7201, with in-house addition of internal control) Amplification: Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V7346) PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with Invitrogen platinum qPCR super mix UDG (V7346)



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy Nucleic acid sequence data	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u> Enterovirus RNA Enterovirus Genotyping Nucleic acid extraction for the purpose of referral to specialist centre for sequencing Enterovirus Genotyping	In-house documented procedures based on manufacturer's instructions Real-time PCR (in-house). Nucleic acid extraction: Qiasymphony using Qiasymphony mini virus kit V7201, with in-house addition of internal control (as per manufacturer's instructions) Amplification: PCR: (V7199) Applied Biosystems ABi fast 7500 real time thermal cycler with Invitrogen platinum qPCR super mix UDG Sequencing. (In house) QIAGEN Qiasymphony nucleic acid extraction platform (V7201) reverse(V7244), reverse transcription (V6895), block thermocycler Biorad T100 Thermocycler, MJ Research PTC-200 Thermocycler, Biorad Tetrad 2. electrophoresis equipment Consort E844 power pack (V5342) Analysis and reporting of outsourced nucleic acid sequence data Data analysis: Bionumerics version 6.1 by Applied Maths Genotyping: Enterovirus Typing Tool version 1.0 by RIVM and Blastn suite by NCBI



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Faeces	Norovirus RNA	Real-time PCR (in-house). Nucleic acid extraction: Roche MP96 automated platform V7244 or Qiasymphony, with MagNApure 96 DNA Viral Nucleic Acid large Volume kit reagents (as per manufacturer's instructions or Qiasymphony mini virus kit V7201, with in-house addition of internal control) Amplification: Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V7346) PCR: (V6771) Applied Biosystems ABI fast 7500 real time thermal cycler with Invitrogen platinum qPCR super mix UDG (V7346)
Faeces	Norovirus genotyping Nucleic acid extraction for the purpose of referral to specialist centre for sequencing	Sequencing (in-house) Nucleic acid extraction: Roche MP96 automated platform V7244 (V6895), block thermocycler Biorad T100 Thermocycler, MJ Research PTC-200 Thermocycler, Biorad Tetrad 2, electrophoresis equipment Consort E844 power pack (V6897) Data analysis: Bionumerics version 6.1 by Applied Maths Genotyping: Norovirus Typing Tool version 2.0 by RIVM and Blastn suite by NCBI



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Nucleic acid sequence data	Norovirus genotyping	Analysis and reporting of outsourced nucleic acid sequence data Data analysis: Bionumerics version 6.1 by Applied Maths Genotyping: Norovirus Typing Tool version 2.0 by RIVM and Blastn suite by NCBI
Faeces	Rotavirus	Real-time PCR (in-house). Nucleic acid extraction: Roche MP96 automated platform V7244 or Qiasymphony, with MagNApure 96 DNA Viral Nucleic Acid large Volume kit reagents (as per manufacturer's instructions or Qiasymphony mini virus kit V7201, with in-house addition of internal control) Amplification: Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V7346) PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with Invitrogen platinum qPCR super mix UDG (V7346)
Faeces	Rotavirus genotyping Nucleic acid extraction for the purpose of referral to specialist centre for sequencing	Sequencing (in-house) QIAGEN QIASYMPHONY nucleic acid extraction platform (V7201), , reverse transcription (V6895), block thermocycler Biorad T100 Thermocycler, MJ Research PTC-200 Thermocycler, Biorad Tetrad 2, electrophoresis equipment Consort E844 power pack (V6897)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Nucleic acid sequence data	Rotavirus genotyping	Analysis and reporting of outsourced nucleic acid sequence data Data analysis: Bionumerics version 6.1 by Applied Maths Genotyping: Blastn suite by NCBI
Faeces	Sapovirus DNA	Real-time PCR (in-house). Nucleic acid extraction: Roche MP96 automated platform V7244 or Qiasymphony, with MagNApure 96 DNA Viral Nucleic Acid large Volume kit reagents (as per manufacturer's instructions or Qiasymphony mini virus kit V7201, with in-house addition of internal control) Amplification: Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V7346) PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with Invitrogen platinum qPCR super mix UDG (V7346)
Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy	Enterovirus EV-D68	Real-time PCR (in-house). Nucleic acid extraction: Qiasymphony, with Qiasymphony mini virus kit V7201, with in-house addition of internal control (as per manufacturer's instructions) Amplification: Applied Biosystems ABi fast 7500 real time thermal cycler V7119 with Applied Biosystem Taqman fast virus 1 step mastermix



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Skin swabs, scabs, skin lesion curettage, biopsies, faeces, sputum, vomitus, vesicular fluid, bronchoalveolar lavage (BAL), nasal aspirate, cerebral spinal fluid (CSF), serum, plasma, tissue culture supernatants, tissue culture cell extracts Genital and oral swabs, liquid based cytology, tissue biopsy, urine Serum, plasma, DBS, swab Serum, plasma, dried blood spot	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u> Visualisation and identification of virus particles Human Papillomavirus Genotyping HPV Pseudovirus-based neutralisation assay HPV IgG	In-house documented procedures based on manufacturer's instructions Electron microscopy: (In house) Negative staining and direct visualisation using JEOL JEM-1400, 120kV high-contrast transmission electron microscope digital camera for image acquisition Grid preparation: Cressington 208C, high vacuum carbon coater (V5315, V5314) Sample preparation: V7149, V6977, V5319, V5320 Grid examination: V5310, V7194 In house method Genotyping (in-house) automated nucleic acid extraction platform (Qiagen Universal Bio Robot), or manual extraction protocol, thermocycler (MJ Research DNA Engine PTC 200), heat block (Techne DB3; Techne DB2A; Eppendorf ThermoStatC, Luminex Bio Rad-BioPlex 200 (V6949) In house method 37 ± 2°C incubator (Thermo Scientific Heracell 150i), centrifuge, ultracentrifuge Plate reader (Promega GloMax, Multi Detection Plate Reader). (V6887) Automated Luminex based HPV serology assay using BioRad Bioplex 200 System with HTF (high-throughput fluidics) (V7359)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
Paired serum, CSF	Herpes simplex virus type specific (1&2) intrathecal antibody testing.	Manual EIA. Focus Diagnostics HerpeSelect® 1 ELISA IgG assay (V6993) ThermoScientific/well wash (Cox scientific Ltd), Biotek 50TS8 washer Tecan Sunrise plate reader (V7361)
Paired serum, CSF	Quantification of intrathecal (IgG) antibodies to Herpes simplex virus	EIA. Euroimmun anti-Herpes simplex virus IgG ELISA (V7376) ThermoScientific/well wash (Cox scientific Ltd), Biotek 50TS8 washer Tecan Sunrise plate reader (V7361)
CSF, serum, plasma, whole blood and tissue	Human Herpesvirus 6 integration studies and genotyping	TaqMan Real Time HHV-6 PCR Altona (V7333) Nucleic acid extraction. Biomerieux Easy mag extractor (V6805) Real time PCR. ABI TaqMan 7500 real time PCR system thermal cycler (V7333) Actin control PCR Real time PCR: ABI TaqMan 7500 Fast real time PCR System thermal cycler (V5889)
CSF, serum, plasma, whole blood	Human Herpesvirus 7 DNA	Block-based PCR. (in-house) Biorad C1000 touch thermal cycler, E-gel apparatus, Gel Doc (V7217) Nucleic acid extraction. Biomerieux EasyMag extractor (V6805)
Serum, plasma	Measles IgM	Manual EIA. Euroimmun Anti Measles IgM(V7469) EIA plate washer Biotek ELx50, plate reader (Tecan Sunrise)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Serum, plasma, oral fluids	Measles IgG / IgM	EIA. Microimmune Measles IgM capture EIA (Clin-Tech Ltd) Microimmune Measles IgG Capture EIA (Clin-Tech Ltd) (V5660) Manual: EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise)
Serum	Measles IgG	Trinity Capita anti-Measles Virus manual ELISA (IgG) (V7414)
Paired serum, CSF	Quantification of Intrathecal(IgG) antibodies to Measles virus	EIA. Euroimmun anti-measles virus IgG (V7376) Plate washer ThermoScientific/well wash (Cox scientific Ltd), Biotek 50TS8 Tecan Sunrise plate reader
Oral fluid, mouth swab, throat swab, urine, EDTA whole blood. Tissue samples by prior arrangement	Measles genotyping	Block-based PCR. Biorad C1000 touch thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system (V6980)
Nucleic acid sequence data	Measles genotyping	Analysis and reporting of outsourced nucleic acid sequence data Data analysis: Bionumerics version 6.1, produced by Applied Maths Genotyping: Maximum Similarity, reference strains defined by WHO
Oral fluids, serum, EDTA whole blood, mouth/throat swabs, urine	Measles RNA	QIA Symphony extraction (V6860) ABI 7500 Real Time PCR system & TaqMan 7500 Fast Measles One Step Real Time PCR assay (V7117)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
Serum, plasma, oral fluid	Mumps IgG / IgM	EIA. Microimmune Mumps IgM capture EIA (Clin-Tech Ltd) (V5658) Microimmune Mumps IgG Capture EIA (Clin-Tech Ltd) (V5631) Manual: EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise)
Serum, plasma	Mumps IgG	EIA. Euroimmun anti-Mumps IgG (V7468) Manual: EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise)
Serum, plasma	Mumps IgG Immunity screening	EIA. Euroimmun anti-Mumps IgG (V7468) Manual: EIA plate washer (Biotek ELx50), plate reader (Biotek EL-808)
Oral fluid, Throat swabs, Nasopharyngeal aspirate	Mumps RNA	QIASymphony extraction (V6860) ABI 7500 Real Time PCR system & TaqMan 7500 Fast Mumps One Step Real Time PCR assay (V7151)
Serum, plasma	Parvovirus IgG/IgM	EIA. Euroimmun Parvovirus B19 IgG EIA (V7344) Euroimmun Parvovirus B19 IgM EIA (V7344) Manual: EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise)



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Serum, plasma, whole blood, tissue, amniotic fluid	Parvovirus B19 DNA	BioMérieux NucliSENS easyMAG extraction (V6805) ABI 7500 Fast Real Time PCR & Altona RealStar Parvovirus B19 PCR kit (V7436)
CSF, urine, tissue, serum or plasma, EDTA whole blood	Polyomavirus JC DNA	Real time PCR. Altona RealStar real-time PCR ABI TaqMan 7500 Fast real time PCR System thermal cycler V7095) Extraction NucliSENS EasyMag extractor
Oral fluid	Rubella IgM	Manual EIA. Microimmune Rubella IgM capture EIA (Clin-Tech Ltd) (V5632). EIA plate washer (Biotek ELx50), plate reader (Biotek EL-808)
Serum, plasma.	Rubella IgM	EIA Euroimmun Rubella anti—IgM (V7469) Manual: EIA plate washer (Biotek ELx50), plate reader (Biotek EL-808)
Serum, plasma.	Rubella IgG antibody status	EIA Euroimmun anti-Rubella IgG (V7468) Manual: EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise))
Serum, plasma	Rubella IgG avidity testing	EIA. Euroimmun Rubella IgG avidity (V6884) ThermoScientific/well wash (Cox scientific Ltd), Biotek 05TS8 Plate reader Tecan Sunrise



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Paired Serum/CSF</p> <p>Serum, plasma, EDTA whole blood, oral fluid, throat swab, nasopharyngeal aspirate, urine, CSF, amniotic fluid, frozen placenta tissue, frozen foetal tissue</p> <p>Nucleic acid sequence data</p> <p>Serum, plasma</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Quantification of Intrathecal antibodies (IgG) to Rubella virus</p> <p>Rubella RNA detection / genotyping</p> <p>Nucleic acid extraction for the purposes of referral to specialist centre for sequencing</p> <p>Rubella genotyping</p> <p>Varicella zoster IgG</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>EIA Euroimmun IgG ELISA anti Rubella IgG (V7376) ThermoScientific/well wash (Cox scientific Ltd), Biotek 05TS8 Plate reader Tecan Sunrise</p> <p>PCR (in house)</p> <p>Nucleic acid extraction. Nucleic acid extraction: BioMérieux EasyMag automated platform (V6805), with NucliSENS extraction reagents (as per manufacturer's instructions)</p> <p>Block-based PCR. Detection V5798 Genotyping V7122 Biorad C1000 touch thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system(V5798)</p> <p>Analysis and reporting of outsourced DNA/RNA Sequence data</p> <p>Data analysis: Bionumerics version 6.1, produced by Applied Maths</p> <p>Genotyping: Maximum Similarity, reference strains defined by WHO</p> <p>EIA. VaccZyme™ VZV Glycoprotein IgG Low Level EIA (V5599)</p> <p>Manual: ThermoScientific/well wash (Cox scientific Ltd), Biotek 50TS8 Plate reader Tecan Sunrise</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Paired serum, CSF	Quantification of intrathecal antibodies (IgG) to Varicella zoster	EIA. Euroimmun anti-Varicella zoster IgG (V7376) Manual: ThermoScientific/well wash (Cox scientific Ltd), Biotek 50TS8 Plate reader Tecan Sunrise
Serum	Varicella zoster IgM	EIA. Biorad Platelia anti VZV IgM (V7356) Manual: ThermoScientific/well wash (Cox scientific Ltd), Biotek 50TS8 Plate reader Tecan Sunrise
Plasma, vesicle fluid, oral fluid, human cutaneous and mucocutaneous lesion swabs.	Varicella zoster DNA	Real time PCR. Taqman real time VZV RealStar/Altona qPCR (V7377) Nucleic acid extraction. Microbiological safety cabinet class 1 or 2, Biomerieux Easy mag extractor (V6805)
Oral fluids, dried blood spots	Total IgG	EIA (in house) (V5790) Manual EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808) Total human IgG coated plates (Clin-Tech Ltd)



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Respiratory secretions, nose swab, throat swab, tissue culture fluid</p> <p>Nucleic acid sequence data</p> <p>Respiratory secretions, including lower respiratory tract secretions e.g. sputum/BAL and upper tract respiratory secretions e.g. nose and throat swabs</p> <p>Upper respiratory samples: nose/throat swabs, and nasopharyngeal aspirates</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Adenovirus detection/sequencing</p> <p>Nucleic acid extraction for the purposes of referral to specialist centre for sequencing</p> <p>Adenovirus sequencing</p> <p>Coronavirus MERS-CoV RNA detection/confirmation</p> <p>Detection of SARS CoV2 RNA (ORF1ab/E/IC)</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>Real-time PCR (in house).</p> <p>BioMérieux EMAG automated nucleic acid extraction platform, Rotor-Gene Q real-time thermal cycler (V6921)</p> <p>Block-based PCR (in house). BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, agarose gel tank/Invitrogen E-gel, block-based thermal cycler PCR Max Alpha Cyclor (V5376)</p> <p>Analysis and reporting of outsourced nucleic acid sequence data</p> <p>Analysis/genotyping: DNASTar (V5376)</p> <p>Real-time RT-PCR (in house).</p> <p>BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, ABI TaqMan 7500 Fast Thermal Cycler (V6991)</p> <p>Real Time RT-PCR triplex (in-house)</p> <p>Biomerieux eMag (V7336), EasyMag (V5489), Roche MP96 (V7379) and Perkin Elmer Chemagic extractor (V7390) and amplification using ABI QuantStudio 7 Flex (V7389)</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Upper respiratory samples: Nose/throat swabs Nasopharyngeal aspirates</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Determination of SARS-CoV-2 Lineage/Variant</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>Real Time RT-PCR STP Dragonfly (V7456) Janus Workstation (V7459, V7467) Roche MagNA Pure 96 extraction (V7379) Perkin Elmer Chemagic extraction (V7390) BioMérieux easyMAG extraction (V5489)</p> <p>PCRmax Alpha or BioRad Tetrad thermal cyclers amplification (V7371)</p> <p>Plate preparation for Whole Genome Sequencing & Bioinformatics by separate UKHSA ISO 15189:2012 accredited laboratories</p> <p>Analysis and reporting of Lineages/Variants</p>
<p>Combined Nose & Throat swabs, nasopharyngeal aspirates, serum</p>	<p>Seasonal Human Coronaviruses RNA</p>	<p>BioMérieux NucliSENS easyMAG (V7336), Roche MagNAPure 96 (V7379), Perkin Elmer Chemagic (V7390) extraction ThermoFisher QuantStudio 7 Flex Real Time PCR system & in-house multiplex Real Time RT-PCR (V7391)</p>
<p>Respiratory secretions, nose and throat swabs, tissue culture fluid</p>	<p>Influenza strain typing</p>	<p>Haemagglutination inhibition by reference ferret serum antibody. (In house). Can be performed manually or automated. using Tecan Freedom Evo-96 channel liquid handling robot (V5397)</p>
<p>Combined Nose & Throat swabs, nasopharyngeal aspirates, culture fluids from virus isolates</p>	<p>Seasonal Influenza RNA</p>	<p>BioMérieux NucliSENS easyMAG (V7336), Perkin Elmer Chemagic (V7390) extraction ThermoFisher QuantStudio 7 Flex Real Time PCR system & in-house multiplex Real Time RT-PCR (V7395)</p>
<p>Combined Nose & Throat swabs, nasopharyngeal aspirates</p>	<p>RSV A, RSV B, hMPV RNA</p>	<p>BioMérieux NucliSENS easyMAG (V7336), Roche MagNAPure 96 (V7379), Perkin Elmer Chemagic (V7390) extraction ThermoFisher QuantStudio 7 Flex Real Time PCR system & in-house multiplex Real Time RT-PCR (V7394)</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
Respiratory sample in lysis buffer, respiratory secretions, nose and throat swabs, tissue culture fluid	Avian influenza confirmation of H5, H7 or H9 subtype virus	Real-time PCR (in house). BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform. ABI TaqMan 7500 Fast thermal cycler, Qiagen Rotor-Gene Q thermal cycler (V7080, V5394, V7082, V7084, V7019)
Respiratory sample in lysis buffer, respiratory secretions, nose and throat swabs, tissue culture fluid	Influenza genome sequencing	Block-based PCR and sequencing (in house).
	Nucleic acid extraction for the purposes of referral to specialist centre for sequencing	BioMérieux EMAG automated nucleic acid extraction platform, Block-based thermal cycler or PCR Max Alpha Cycler, agarose gel tank/Invitrogen E-Gel, (V7103, V7115)
Nucleic acid sequence data	Influenza genome sequencing	Analysis and reporting of outsourced nucleic acid sequence data Analysis and interpretation: Data analysis: Mega: BioEdit: Bionumerics version 6.1, produced by Applied Maths
Serum, plasma	Anti-HAV IgG/IgM	Automated CMIA. Architect HAVAb-IgG (Abbott Laboratories) Architect HAVAb-IgM (Abbott Laboratories) (V5733)
Serum, plasma	HBsAg	Automated CMIA. Architect HBsAg (Abbott Laboratories) (V5733)
Serum, plasma	HBsAg quantification	Automated CMIA. Architect HBsAg (Abbott Laboratories) (V5733)



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
Serum, plasma	HBsAg neutralisation	Manual EIA. Murex HBsAg Confirmatory v 3 (DiaSorin) (V5729) Biotek plate washer, Biotek plate reader (V5729)
Serum, plasma	HBeAg	Automated CMIA. Architect HBe (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBc	Automated CMIA. Architect HBc II (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBc IgM	Automated CMIA. Architect anti-HBc IgM (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBs	Automated CMIA. Architect anti-HBs (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBe	Automated CMIA. Abbott Architect Architect Anti-HBe (Abbott Laboratories) (V5733)
EDTA plasma, serum	HBV DNA viral load	Real-time PCR (in-house) Nucleic acid extraction: Roche MP96 automated platform V6838, with MagNApure 96 DNA Viral Nucleic Acid Small Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control) Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler (V5764) with Qiagen Quantitect probe kit reagents



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
EDTA plasma, serum	HCV confirmation service: antibody testing and HCV viral load	Manual EIA. -Ortho HCV 3.0 ELISA (Ortho) V5020 Manual DiaPro HCV Antibody Enzyme Immunoassay (V7461) EIA plate washer (Biotek ELx50), plate reader (Biotek EL-808)
Serum, EDTA plasma	Quantitative Hepatitis C RNA	Roche MagNA Pure 96 Extraction (V6838) ABI 7500 Real Time PCR system & ThermoFisher TaqMan RT-PCR reagents (V5763)
Serum and Plasma	Hepatitis C Virus DAA genotypic resistance Nucleic acid extraction for the purposes of referral to specialist centre for sequencing	Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions) (V5489) Amplification: Applied Biosystems 7500 Fast Real-time PCR System (V7329) Library clean up: Perkin Elmer Zephyr and Janus systems Quantification of amplicons: Qubit 3.0 Fluorimeter (V7287)
Nucleic acid sequence data	Hepatitis C Virus DAA genotypic resistance	Library Preparation: Perkin Elmer Sciclone G3 NGSx Workstation: Takara SMARTer® Stranded Total RNA-Seq Kit v2 Capture and enrichment using the Twist capture kit with Twist Probes Sequencing (WGS) Illumina MiSeq System



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on manufacturer's instructions
PHE Central Sequencing Laboratory (CSL)		
Serum, plasma	Hepatitis Delta Virus Anti-HDV IgG	Manual EIA. DiaPro anti-HDV total antibody (V7326) EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise))
Serum, plasma	Hepatitis Delta Virus Anti-HDV IgM	Manual EIA. Commercial Kit: DiaPro anti-HDV IgM (V7323) EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise))
Serum, plasma	Hepatitis E Virus Anti-HEV IgG	Manual EIA. Fortress Hepatitis E Virus IgG ELISA (V5901) EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)
Serum, plasma	Hepatitis E Virus Anti-HEV IgM	Manual EIA. Fortress Hepatitis E Virus IgM ELISA (V6769) EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum, plasma</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>HIV-1/HIV-2 antibody confirmation/typing</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>Antibody confirmation MP Diagnostics HIV Ag/Ab Combo ELISA 4.0 (V7327) -Murex HIV Ag/Ab Combination (DiaSorin) (V5083) Manual EIA.</p> <p>EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise))</p> <p>HIV1 &2 Typing Assay (In house) Method: EIA (V7148)</p> <p>EIA plate washer (Biotek ELx50), plate reader (Tecan Sunrise))</p> <p>HIV Western Blot</p> <p>HIV-1 Genelabs WB</p> <p>Manual set up: (V5110)</p> <p>Automated set up: (V5110 and V7207) using autoblot Bands read visually compared with kit insert reading chart</p>
<p>Serum and Plasma</p>	<p>HIV-1/HIV-2 antibody confirmation/typing</p>	<p>HIV Multisure Rapid Test for typing HIV1 and 2 (V7263)</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
Unseparated blood on EDTA	HIV-1 proviral DNA	Real-time PCR. HIV Proviral DNA (V7180) (V5762) for LTR PCR and V7180 for gag/int PCR Nucleic acid extraction: Qiasymphony NA automated platform (V6860), with DSP virus/pathogen midi kit reagents (as per manufacturer's instructions, with in-house addition of internal control) Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Qiagen QuantiTech Virus RT-PCR mastermix reagents
EDTA plasma, serum	HIV-1 RNA qualitative PCR	Real-time PCR (In house) HIV RNA (V5762) Nucleic acid extraction: Qiasymphony NA automated platform V6860, with DSP virus/pathogen mini kit reagents (as per manufacturer's instructions, with in-house addition of internal control) Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Qiagen QuantiTech Virus RT-PCR mastermix reagents V5762
Unseparated blood on EDTA	Human T-lymphotropic virus (HTLV)	Real-time PCR. (In-house) Nucleic acid extraction: Roche MP96 automated platform (V6838), with MagNAPure 96 DNA Viral Nucleic Acid Mini Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control) Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Qiagen Quantitect master mix (V7155)



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum, plasma</p> <p>Unseparated blood on EDTA. Other specimens by arrangement (EDTA/serum sample, tissue, pleural fluid)</p> <p>Genital swabs in transport media or dry</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>HTLV-I/II antibody confirmation/typing</p> <p>Human Herpesvirus 8 quantitation</p> <p>Detection of Treponema pallidum DNA</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>Automated CMIA. Architect HTLV I/II (Abbott Laboratories) (V5733)</p> <p>HTLV Western Blot</p> <p>For typing and confirmation purpose</p> <p>MP Diagnostics HTLV Blot 2.4</p> <p>Manual Set up (V5120)</p> <p>Automated set up (V5120 and V7207) Using Autoblott 3000 V7207 Bands read visually compared with kit insert reading chart</p> <p>Real-time PCR (In-House) (V5761)</p> <p>Nucleic acid extraction: Roche MP96 automated platform (V6838), with MagNApure 96 DNA Viral Nucleic Acid Mini Volume kit reagents (as per manufacturer's instructions, with in-house addition of internal control)</p> <p>Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Thermo Absolute QPCR ROX master mix V5761</p> <p>Multiplex Real-time PCR. Detection of Treponema pallidum V7338</p> <p>Extraction: Qiagen QiaSymphony Amplification and Quantitation ABI 7500 V6860</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Rectal, urethral or genital swab, ulcer swab, residual specimen from unprocessed NAAT swab, fresh dry swab</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Detection of Chlamydia Trachomatis & LGV Serovars directly from clinical specimens</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>Multiplex Real-time PCR (In house) (V7185)</p> <p>Nucleic acid extraction: Roche MP96 automated platform (V6838), with MagNApure 96 DNA Viral Nucleic Acid large Volume kit reagents (as per manufacturer's instruction)</p> <p>Amplification/quantification: Applied Biosystems ABi Prism 7500 real time with Qiagen Multiplex master mix</p>
END		