

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



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### Public Health England, An Executive Agency of the Department of Health

Issue No: 001 Issue date: 15 August 2018

Virus Reference Laboratory  
61 Colindale Avenue  
London  
NW9 5EQ

Contact: Anna Garrido  
Tel: +44 (0) 20 8327 6155  
E-Mail: [anna.garrido@phe.gov.uk](mailto:anna.garrido@phe.gov.uk)  
Website: [www.gov.uk/phe](http://www.gov.uk/phe)

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#### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES  EDTA plasma, serum          Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)	<u>Virology examination activities for the purposes of clinical diagnosis</u>  Hepatitis C Virus DAA genotypic resistance	In-house documented procedures based on manufacturer's instructions  <b>Sequencing</b> Method: in-house (V7048)  Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions)  Amplification: Bio-RAD Dyad DNA engine thermal cycler  PCR Product purification: Thermo Fisher ExoSAP  Quantification of amplicons: Thermo Fisher Nanodrop ND-1000  Data analysis: ReCall (Sequencher used as backup if ReCall is unavailable)  Interpretation: Geno2Pheno (web service provided by Max Planck Institut)



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<p><b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b></p> <p>Tissue culture isolate, swab in VTM</p> <p>EDTA plasma, serum,</p> <p>Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Herpes Simplex Virus 1 &amp; 2 Phenotypic Drug resistance</p> <p>Human Immunodeficiency Virus type 1 (HIV-1) genotypic resistance</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Plaque reduction</b></p> <p>Method: Cell culture and plaque counting (in-house, V5756)</p> <p>Cells: commercial (Vero, ECACC)</p> <p>Culture system: CO2 incubator (Thermo Fisher Heracell 150i)</p> <p>Class II microbiological safety cabinet</p> <p><b>Sequencing</b></p> <p>Methods: in-house (V5746, V5814)</p> <p>Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions)</p> <p>Amplification: Bio-RAD Dyad DNA engine thermal cycler</p> <p>PCR Product purification: Thermo Fisher ExoSAP</p> <p>Quantification of amplicons: Thermo Fisher Nanodrop ND-1000</p> <p>Data analysis: ReCall (Sequencher used as backup if ReCall is unavailable)</p> <p>Interpretation: Stanford HIV drug resistance database</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
EDTA whole blood, plasma, serum	HIV-1 proviral tropism	Method: in-house (V6790)  Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions)  Amplification: Bio-RAD Dyad DNA engine thermal cyclers  PCR Product purification: Thermo Fisher ExoSAP  Quantification of amplicons: Thermo Fisher Nanodrop ND-1000  Data analysis: ReCall (Sequencher used as backup if ReCall is unavailable)  Interpretation: Geno2Pheno (web service provided by Max Planck Institut)
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Serum, plasma	Hepatitis A genotyping/phylogenetics	<b>Sequencing</b> 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)  Amplification: Bio-RAD Dyad DNA engine thermal cyclers  PCR product purification: Illustra GFX columns, centrifuge  Analysis: DNASTar/Seqman  Genotyping: MegAlign
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		



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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
Oral fluids	Hepatitis A anti HAV- IgG	<b>Manual EIA</b> In-house method using Fortress HAV anti-IgM kit (V7146) Specimen processing: centrifuge Assay processing: waterbath (Grant W28), EIA plate washer (Tecan Columbus Pro), EIA plate reader (Biotek EL-808)
Oral fluids	Hepatitis A anti HAV- IgM	<b>Manual EIA</b> In-house method using Fortress HAV anti-IgM kit (V7147) Specimen processing: centrifuge Assay processing: waterbath (Grant W28), EIA plate washer (Tecan Columbus Pro), EIA plate reader (Biotek EL-808)
Serum, plasma	Hepatitis B Virus sequencing- Pre-core/BCP mutation screen	<b>Sequencing</b> Method: in-house (V7046, V7039) 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) Amplification: Bio-RAD Dyad DNA engine thermal cycler PCR product purification: Illustra GFX columns, centrifuge Analysis: DNASTar/Seqman/MegAlign Mutation determination: BioEdit
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		



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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	Hepatitis B Virus sequencing - surface mutation screen	<b>Sequencing</b> Method: in-house (V7046, V7039) 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) Amplification: Bio-RAD Dyad DNA engine thermal cyclers PCR product purification: Illustra GFX columns, centrifuge  Analysis: DNASTar/Seqman/MegAlign Mutation determination: BioEdit
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Serum, plasma	Hepatitis B Virus sequencing-resistance screen	<b>Sequencing</b> Method: in-house (V7046, V7039) 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) Amplification: Bio-RAD Dyad DNA engine thermal cyclers PCR product purification: Illustra GFX columns, centrifuge  Analysis: DNASTar/Seqman/MegAlign Mutation determination: BioEdit
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		



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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	Hepatitis B Virus sequencing - genotyping/phylogenetics	<b>Sequencing</b> Method: in-house (V7046, V7039) 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) Amplification: Bio-RAD Dyad DNA engine thermal cycler PCR product purification: Illustra GFX columns, centrifuge  Analysis: DNASTar/Seqman  Genotyping: MegAlign
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Serum, plasma	Hepatitis C Virus genotyping/phylogenetics	<b>Sequencing.</b> Method: in-house (V7072) 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 C-1000 thermal cycler PCR product purification: Illustra GFX columns, centrifuge  Analysis/genotyping: DNASTar
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		



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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	Hepatitis Delta Virus RNA	<b>Real-time PCR.</b> Method: in-house (V7216)  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)  Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Life Technologies TaqMan PCR reagents (SuperScript III Platinum One-Step qRT-PCR Kit)  Analysis: ABi 7500 software
Serum, plasma, faeces	Hepatitis E Virus RNA	<b>Real-time PCR.</b> 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)  Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Qiagen Quantitect probe RT-PCR kit reagents  Analysis: ABi 7500 software



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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, faeces	Hepatitis E Virus genotyping/phylogenetics	<b>Sequencing</b> Method: in-house (V7056) 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) Amplification: Bio-RAD Dyad DNA engine thermal cycler PCR product purification: Illustra GFX columns, centrifuge  Analysis: DNASTar/Seqman  Genotyping: MegAlign
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Serum, plasma	Anti-HBc	<b>Manual EIA. (V7152)</b> Commercial reagents (Murex anti-HBc (total) EIA, 8G21-01) Assay processing: dry incubator (Abbott Commander) or water bath (Grant W28), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)
Dried Blood Spot (DBS)	HBsAg	<b>Manual EIA.</b> In-house, using Murex HBsAg EIA v3 reagents (V5734)  Assay processing: incubator (Stuart SI19 or Binder BD 23), plate washer (Biotek ELx50), plate reader (Biotek EL-808)





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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
Dried Blood Spot (DBS)	Confirmation HBsAg	<b>Manual EIA. In-house</b> , using Murex HBsAg EIA v3 reagents (V5735)  Assay processing: incubator (Stuart SI19 or Binder BD 23), plate washer (Biotek ELx50), plate reader (Biotek EL-808)
Faeces	Adenovirus (enteric) DNA	<b>Real-time PCR (In-house)</b>  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 (V6895)  PCR: Applied Biosystems ABI fast 7500 real time thermal cycler with (V6771)  Invitrogen platinum qPCR super mix UDG



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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
Faeces	Astrovirus RNA	<p><b>Real-time PCR (in-house).</b></p> <p>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)</p> <p>Amplification:</p> <p>Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V6895)</p> <p>PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with</p> <p>Invitrogen platinum qPCR super mix UDG</p>
Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy	Enterovirus RNA	<p><b>Real-time PCR (in-house).</b></p> <p>Nucleic acid extraction: Qiasymphony using Qiasymphony mini virus kit V7201, with in-house addition of internal control (as per manufacturer's instructions)</p> <p>Amplification:</p> <p>PCR: (V7199) Applied Biosystems ABi fast 7500 real time thermal cycler with</p> <p>Invitrogen platinum qPCR super mix UDG</p>
Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy	Enterovirus virus culture	<p><b>Viral culture.</b></p> <p>CL3 laboratory, MSC1/III or MSCIII, 37°C CO<sub>2</sub> incubator New Brunswick Galaxy 170 S (V6905, V7135, V5345)</p>



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<p><b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b></p> <p>Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy</p> <p>Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)</p> <p>Faeces</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Enterovirus Genotyping</p> <p>Norovirus RNA</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Sequencing. In house assay</b></p> <p>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 (V5342)</p> <p>Data analysis: Bionumerics version 6.1 by Applied Maths Genotyping: Enterovirus Typing Tool version 1.0 by RIVM and Blastn suite by NCBI</p> <p><b>Real-time PCR (in-house).</b></p> <p>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)</p> <p>Amplification:</p> <p>Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V6895)</p> <p>PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with</p> <p>Invitrogen platinum qPCR super mix UDG</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
Faeces	Norovirus genotyping	<p><b>Sequencing. In-House Assay</b></p> <p><b>QIAGEN QIASYMPHONY</b> 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)</p> <p>Data analysis: Bionumerics version 6.1 by Applied Maths Genotyping: Norovirus Typing Tool version 2.0 by RIVM and Blastn suite by NCBI</p>
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy*	Poliovirus RNA	<p><b>PCR/sequencing.</b> CL3 laboratory, MSCII/III or MSCIII.</p> <p><b>Real time PCR.</b> Automated nucleic acid extraction platform (V7201), reverse transcription (V6895) Applied Biosystem ABI 2720 thermal cycler. Real-time PCR machine Applied Biosystems 7500 TaqMan (V6909)</p> <p><b>Block-based PCR.</b> Thermal cycler, electrophoresis equipment, sequencing facilities (V5342)</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
Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy*	Poliovirus genotyping	<b>PCR/sequencing.</b> CL3 laboratory, MSCI/III or MSCIII.  <b>Real time PCR.</b> Automated nucleic acid extraction platform QiaSymphony (V6860), reverse transcription (V6895) Applied Biosystem ABI 2720 thermal cycler. Real-time PCR machine Applied Biosystems 7500 TaqMan (V6909).
Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy*	Poliovirus virus culture	<b>Viral culture.</b> CL3 laboratory, MSCIII, 37°C CO <sub>2</sub> incubator, Thermo Scientific, Heracell, 150i (V6905, V7158), centrifuge Eppendorf 5810R
Serum or clotted blood	Poliovirus Antibody	<b>Microneutralisation assay.</b> (V5355) CL3 laboratory, MSCIII, 37°C CO <sub>2</sub> incubator Thermo Scientific, Heracell, 150i
Faeces	Rotavirus	<b>Real-time PCR (in-house).</b>  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 (V6895)  PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with  Invitrogen platinum qPCR super mix UDG



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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
Faeces	Rotavirus genotyping	<p><b>Sequencing. In-House Assay</b></p> <p><b>QIAGEN QIASYMPHONY</b> 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)</p> <p>Data analysis: Bionumerics version 6.1 by Applied Maths</p> <p>Genotyping: Blastn suite by NCBI</p>
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Faeces	Sapovirus DNA	<p><b>Real-time PCR (in-house).</b></p> <p>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)</p> <p>Amplification:</p> <p>Reverse transcription on the Applied Biosystem ABI 2720 thermal cycler and life technology master mix and RT enzyme (V6895)</p> <p>PCR: (V6771) Applied Biosystems ABi fast 7500 real time thermal cycler with</p> <p>Invitrogen platinum qPCR super mix UDG</p>



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<p><b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b></p> <p>Viral isolates, faeces, throat swabs, CSF, EDTA-blood, tissue biopsy</p> <p>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</p> <p>Genital and oral swabs, liquid based cytology, tissue biopsy, urine</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Enterovirus EV-D68</p> <p>Visualisation and identification of virus particles</p> <p>Human Papillomavirus Genotyping</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Real-time PCR (in-house).</b></p> <p>Nucleic acid extraction: Qiasymphony, with Qiasymphony mini virus kit V7201, with in-house addition of internal control (as per manufacturer's instructions)</p> <p>Amplification: Applied Biosystems ABI fast 7500 real time thermal cycler V7119 with Applied Biosystem Taqman fast virus 1 step mastermix</p> <p><b>Electron microscopy:</b> In house procedure JEOL JEM-1400, 120kV high-contrast transmission electron microscope fitted with an AMT XR60 digital camera. Direct visualisation and negative staining (V5310). <b>Sample preparation:</b> V5317, V5318, V7149, V6977, V5319, V5320 <b>Grid preparation:</b> Cressington 208C, high vacuum carbon coater (V5315, V5314)</p> <p>In house method <b>Genotyping:</b> 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)</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
Serum, plasma, DBS, swab	Indirect HPV virus-like particle binding	<b>In house method</b> Plate reader (PerkinElmer Gloxmax Multi Detection Plate Reader), plate washer (TECAN Hydroflex), incubator (Genlab LTD MINI/50/55/VIS) (V7092)
Paired serum, CSF	Herpes simplex virus type specific (1&2) intrathecal antibody testing.	<b>Manual EIA.</b> Microbiological safety cabinet class 1 or 2, 37 +/- 2°C incubator, Denley plate washer now replaced with thermos scientific/well wash (Cox scientific Ltd), QUALICOOL Room temperature incubator, Labsystem iEMS plate reader (V6993) Focus Diagnostics HerpeSelect® 1 ELISA IgG assay
Paired serum, CSF	Herpes simplex virus intrathecal antibody.	<b>EIA.</b> Microbiological safety cabinet class 1 or 2, Shake n stack 37 +/- 2°C incubator, Denley plate washer now replaced with thermos scientific/well wash (Cox scientific Ltd))  <b>Automated:</b> Siemens BEP3 analyser, Siemens EIA (V6864) Kit based assay: Siemens Enzygnost anti-Herpes simplex virus IgG





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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
CSF, serum, plasma, whole blood	Human Herpesvirus 6 integration studies	<p><b>Real time PCR.</b> ABI TaqMan 7000 real time PCR system thermal cycler (V5888)</p> <p><b>Block-based PCR. Biorad C1000 touch</b> Thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system (V5797)</p> <p><b>Nucleic acid extraction.</b> Microbiological safety cabinet class 1 or 2, Biomerieux Easy mag extractor (V6805)</p> <p><b>Manual Nucleic acid extraction for inhibitory samples</b> Microbiological safety cabinet class 1 or 2, centrifuge, (V5783)</p> <p><i>In house assay</i></p>
Tissues, EDTA whole blood, serum, plasma, oral fluid, vesicle fluid, CSF	Actin control PCR	<p><b>Real time PCR:</b> ABI TaqMan 7500 Fast real time PCR System thermal cycler (V5889)</p>
CSF, serum, plasma, whole blood	Human Herpesvirus 6 genotyping	<p><b>Sequencing.</b> Pyromark ID Pyrosequencer (V6792)</p> <p><i>In house assay</i></p>
CSF, serum, plasma, whole blood	Human Herpesvirus 7 DNA	<p><b>Block-based PCR.</b> Block based Biorad C1000 touch thermal cycler, E-gel apparatus, Gel Doc (V7217)</p> <p><b>Nucleic acid extraction.</b> Microbiological safety cabinet class 1 or 2, Biomerieux Easy mag extractor (V6805)</p> <p><b>Manual Nucleic acid extraction for inhibitory samples</b> Microbiological safety cabinet class 1 or 2, centrifuge, (V5783)</p> <p><i>In House assay</i></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
Serum or plasma	Measles IgG / IgM	<p><b>EIA.</b> <b>Manual:</b> (V6865)</p> <p>Assay processing: Room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Commercial kit: Siemens BEP3 analyser. Enzygnost Anti Measles IgG (Siemens) Enzygnost Anti measles IgM (Siemens) (V6865)</p>
Serum, plasma, oral fluids	Measles IgG / IgM	<p><b>EIA.</b> Commercial kit: Microimmune Measles IgM capture EIA (Clin-Tech Ltd) Microimmune Measles IgG Capture EIA (Clin-Tech Ltd) (V5660)</p> <p><b>Manual:</b> Assay processing: Room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser.</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
Serum, plasma	Measles IgG immunity screening	<p><b>EIA.</b> Commercial kit: Enzygnost Anti Measles IgG (Siemens) (V6864)</p> <p><b>Manual:</b> Assay processing: Room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser Enzygnost Anti Measles IgG (Siemens) (V6864)</p>
Serum, plasma	Measles IgG avidity	<p><b>EIA.</b> (V6884), Labsystem iEMS plate reader, thermos scientific/well wash (Cox scientific Ltd), QUALICOOL Room temperature incubator Kit based assay: Measles IgG avidity using Euroimmun kit</p>
Paired serum, CSF	Measles Intrathecal antibody	<p><b>EIA.</b> Microbiological safety cabinet class 1 or 2, Shake n stack 37 +/- 2°C incubator, Denley plate washer no longer in use replaced with thermos scientific/well wash (Cox scientific Ltd) <b>Automated:</b> Siemens BEP3 analyser (V6864) Kit based assay: Siemens Enzygnost anti measles virus IgG</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
Oral fluid, mouth swab, throat swab, nasopharyngeal aspirate	Measles RNA	<p><b>Method: Real time PCR</b> (in house)</p> <p><b>Nucleic acid extraction.</b> Nucleic acid extraction: BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions) (V6805)</p> <p>Amplification: Applied Biosystems ABI Prism 7500 Fast real time thermal cycler with Life Technologies TaqMan PCR reagents (SuperScript III Platinum One-Step qRT-PCR Kit) (V7117)</p> <p><b>Manual Nucleic acid extraction for inhibitory samples and tissues</b> (V5783, V5615)</p> <p><b>Block-based PCR.</b></p> <p>Conventional Biorad C1000 touch thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system (V6980)</p>
Oral fluid, mouth swab, throat swab, nasopharyngeal aspirate, CSF, urine, EDTA whole blood. Tissue samples by prior arrangement	Measles genotyping	<p>Data analysis: Bionumerics version 6.1, produced by Applied Maths</p> <p>Genotyping: Maximum Similarity, reference strains defined by WHO</p>
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		
Serum, plasma	Measles plaque reduction neutralisation assay	<p><b>Tissue culture.</b> Microbiological safety cabinet class 2, Lamina flow cabinet, 37 +/- 2°C CO2 incubator (Thermo Scientific HERAccl 150i), 37 +/- 2°C room or incubator (New Brunswick Scientific Innova CO-48), inverted microscope (Olympus CK Tokyo), liquid nitrogen storage facility.</p> <p>Plaque reduction neutralisation test (PRNT) (V6928)</p> <p><i>In house assay</i></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
Serum, plasma, oral fluid	Mumps IgG / IgM	<p><b>EIA.</b> <b>Manual:</b> Commercial kit: Microimmune Mumps IgM capture EIA (Clin-Tech Ltd) Microimmune Mumps IgG Capture EIA (Clin-Tech Ltd) (<i>IgM: V5658</i>) (<i>IgG: V5631</i>) Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser. Commercial kit: Microimmune Mumps IgM capture EIA (Clin-Tech Ltd) Microimmune Mumps IgG Capture EIA (Clin-Tech Ltd) (<i>IgM: V5658</i>) (<i>IgG: V5631</i>)</p>
Serum, plasma	Mumps IgG / IgM	<p><b>EIA.</b> Commercial kit: Enzygnost Anti Parotitis virus/IgG (Siemens) Enzygnost Anti Parotitis virus/IgM (Siemens)(V6565)</p> <p><b>Manual:</b> Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser.</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
Serum, plasma	Mumps IgG Immunity screening	<p><b>EIA.</b> Commercial kit: Enzygnost Anti Parotitis virus/IgG (Siemens)(V6864)</p> <p><b>Manual:</b> 37 +/- 2°C incubator, room temperature incubator, Biotec washer and plate reader Commercial kit: Enzygnost Anti Parotitis virus/IgG (Siemens)(V6864) Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser</p>
Oral fluid, throat swab, nasopharyngeal aspirate	Mumps RNA	<p><b>Real time PCR</b> (in-house).</p> <p><b>Nucleic acid extraction. Method:</b> <i>in-house real time PCR</i> Nucleic acid extraction (V6805): BioMérieux EasyMag automated platform, with NucliSENS extraction reagents (as per manufacturer's instructions)</p> <p>Amplification: Applied Biosystems ABi Prism 7500 Fast real time thermal cycler with Life Technologies TaqMan PCR reagents (SuperScript III Platinum One-Step qRT-PCR Kit) V7151</p> <p><b>Manual Nucleic acid extraction tissues</b> Microbiological safety cabinet class 1 or 2, centrifuge, (V5783, V5615)</p>



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<p><b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b></p> <p>Oral fluid, throat swab, nasopharyngeal aspirate, urine, CSF</p> <p>Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)</p> <p>Serum, plasma</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Mumps PCR for genotyping</p> <p>Parvovirus IgG/IgM</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Block-based PCR.</b></p> <p>Conventional Biorad C1000 touch thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system (V5645)</p> <p>Data analysis: Bionumerics version 6.1, produced by Applied Maths</p> <p>Genotyping: Maximum Similarity, reference strains defined by WHO</p> <p><b>EIA.</b></p> <p>Commercial kit: -Parvovirus B19 IgG EIA (Biotrin) -Parvovirus B19 IgM EIA (Biotrin) (IgM: V5690) (IgG: V5606)</p> <p><b>Manual:</b></p> <p>Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser (V6825)</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
Serum, plasma, amniotic fluid, frozen placenta tissue, frozen foetal tissue	Parvovirus DNA	<b>Real time PCR.</b> Roche Lightcycler 2.0 real time thermal cycler (V5679) <b>Extraction Roche MagNA Pure LC extractor Microbiological safety cabinet class 1 or 2, (V6992)</b> <b>Manual Nucleic acid extraction for inhibitory samples and tissues</b> Microbiological safety cabinet class 1 or 2, centrifuge, (V5783, V5615) <i>In house assay</i>
Serum, plasma, amniotic fluid, frozen placenta tissue, frozen foetal tissue	Parvovirus genotyping	<b>Sequencing.</b> Pyromark ID Pyrosequencer (V5774) <i>In house assay</i>
CSF, serum	Polyomavirus JC serology	<b>Haemagglutination Inhibition.</b> Microbiological safety cabinet class 1 or 2, centrifuge, fridge or +4 cold room (V7090) <i>In house assay</i>
CSF, urine, tissue, serum or plasma, EDTA whole blood	Polyomavirus JC DNA	<b>Real time PCR.</b> ABI TaqMan 7500 Fast real time PCR System thermal cycler (V7095) <b>Extraction Roche MagNA Pure LC extractor Microbiological safety cabinet class 1 or 2, (V6992)</b> <b>Manual Nucleic acid extraction for inhibitory samples and tissues</b> Microbiological safety cabinet class 1 or 2, centrifuge, (V5783, V5615) <i>Altona RealStar real-time PCR</i>





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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	Polyomavirus JC Intrathecal antibody	<b>Haemagglutination Inhibition.</b> Microbiological safety cabinet class 1 or 2, centrifuge, fridge or +4 cold room (V7090) <i>In house assay</i>
Serum, plasma, oral fluid	Rubella IgM	<b>Manual EIA.</b> Microimmune Rubella IgM capture EIA (Clin-Tech Ltd) (V5632).  Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)
Serum, plasma.	Rubella IgM	<b>Method: EIA</b>  <b>Commercial kit:</b> Enzygnost anti-rubella virus IgM (Siemens) (V6865) <b>Manual EIA:</b> Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808) <b>Automated:</b> Siemens BEP3 analyser (V6825)



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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. Dried blood spots by prior arrangement	Rubella IgG antibody status	<p><b>Method: EIA</b></p> <p>Commercial kit: Enzygnost anti-rubella virus IgG (Siemens) (V6864)</p> <p><b>Manual:</b> Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser (V6825)</p>
Serum, plasma	Rubella IgG avidity testing	<p><b>EIA.</b> 37 +/- 2°C incubator, room temperature incubator, thermos scientific/well wash (Cox scientific Ltd) , Labsystem iEMS plate reader (V6884)</p> <p>Kit based assay: Rubella IgG avidity using Euroimmun kit</p>
Serum/CSF pairs	Rubella intrathecal antibody	<p><b>EIA.</b> Microbiological safety cabinet class 1 or 2, 37 +/- 2°C incubator, thermos scientific/well wash (Cox scientific Ltd)</p> <p><b>Automated:</b> Siemens BEP3 analyser (V6864) Kit based assay: Siemens Enzygnost anti Rubella virus IgG</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum, plasma, oral fluid, throat swab</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>Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Rubella RNA</p> <p>Rubella genotyping</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p>PCR (in house)</p> <p><b>Nucleic acid extraction.</b></p> <p><i>Method: in-house real time PCR V7120</i></p> <p>Nucleic acid extraction: BioMérieux EasyMag automated platform (v6805), with NucliSENS extraction reagents (as per manufacturer's instructions)</p> <p>Amplification: Applied Biosystems ABI Prism 7500 Fast real time thermal cycler with Life Technologies TaqMan PCR reagents (SuperScript III Platinum One-Step qRT-PCR Kit) V7120</p> <p><b>Block-based PCR.</b></p> <p>Conventional Biorad C1000 touch thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system (V7122)</p> <p>Data analysis: Bionumerics version 6.1, produced by Applied Maths</p> <p>Genotyping: Maximum Similarity, reference strains defined by WHO</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
Serum, plasma	Varicella zoster IgG	<b>EIA.</b> <b>Manual:</b> 37 +/- 2°C incubator, room temperature incubator, thermos scientific/well wash (Cox scientific Ltd) , Labsystem iEMS plate reader <b>Automated:</b> Siemens BEP3 analyser (V5599)  Kit based- Binding site VaccZyme™ VZV glycoprotein IgG low level EIA
Paired serum, CSF	Varicella zoster intrathecal antibody	<b>EIA.</b> Microbiological safety cabinet class 1 or 2, 37 +/- 2°C incubator, thermos scientific/well wash (Cox scientific Ltd)  <b>Automated:</b> Siemens BEP3 analyser (V6864)  Kit based assay: Siemens Enzygnost anti Varicella zoster virus IgG
Serum, plasma	Varicella zoster IgG avidity	<b>EIA.</b> 37 +/- 2°C incubator, room temperature incubator, thermos scientific/well wash (Cox scientific Ltd) , Labsystem iEMS plate reader (V6884)  Kit based assay: Varicella zoster IgG avidity using Euroimmun kit
Serum, plasma	Varicella zoster IgM	<b>EIA.</b> <b>Manual:</b> Room temperature incubator, 37 +/- 2°C incubator, thermos scientific/well wash (Cox scientific Ltd) plate washer, Labsystem iEMS plate reader <b>Automated:</b> Siemens BEP3 analyser (V6865)  Kit based assay: Siemens (formerly Dade Behring) Enzygnost ELISAS Anti VZV/IgM



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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
Vesicle fluid, oral fluid	Varicella zoster DNA	<p><b>Real time PCR.</b> ABI TaqMan 7500 Fast real time PCR System thermal cycler (V7031)</p> <p><b>Nucleic acid extraction.</b> Microbiological safety cabinet class 1 or 2, Biomerieux Easy mag extractor (V6805)</p> <p><b>Manual Nucleic acid extraction for inhibitory samples</b> Microbiological safety cabinet class 1 or 2, centrifuge, (V5783) <i>In house assay</i></p>
Vesicle fluid, oral fluid	VZV-4 markers for differentiation of vaccine and wild-type VZV	<p><b>Block-based PCR.</b> Conventional Biorad C1000 touch thermal cycler, Invitrogen mother E-base E-gel apparatus, Biorad Gel Doc XR+ imaging system (V7124) <i>In house assay</i></p>
Oral fluids, dried blood spots	Total IgG	<p><b>EIA in house (V5790)</b> <b>Manual</b></p> <p>Assay processing: dry incubator (Abbott Commander) and room temperature incubator (LMS), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated:</b> Siemens BEP3 analyser V6825</p> <p>Total human IgG coated plates (Clin-Tech Ltd)</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
Paired serum/CSF	Intrathecal Total IgG	<b>EIA.</b> Microbiological safety cabinet class 1 or 2, 37 +/- 2°C incubator, thermos scientific/well wash (Cox scientific Ltd) plate washer Labsystem iEMS plate reader <b>Automated:</b> Siemens BEP3 analyser (V5790) <i>In house assay</i>
Paired serum/CSF	Albumin determination	<b>Radial immunodiffusion.</b> Microbiological safety cabinet class 1 or 2, room temperature incubator, Binding Site DIGITAL RID plate reader (V7069) Kit based: binding site
CSF, serum, plasma, EDTA whole blood, oral fluids, amniotic fluid, urine, oral swabs, throat swabs, vesicle fluids	SBCMV internal control PCR	<b>Real time PCR.</b> ABI TaqMan real time thermal cycler, <b>SBCMV</b> PCR (V5695) Generation of SBCMV RNA transcripts (V5379)
Respiratory secretions, nose swab, throat swab, tissue culture fluid	Adenovirus detection/sequencing	<b>Real-time PCR (in house assay).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, Rotor-Gene Q real-time thermal cycler (V6921) <b>Block-based PCR (in house assay).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, agarose gel tank/Invitrogen E-gel, block-based thermal cycler DNA Engine Tetrad 2 or PCR Max Alpha Cycler (V5376)
Respiratory secretions, nose and throat swabs	Human Coronavirus RNA	<b>Real-time PCR (in house assay).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, Qiagen Rotor Gene Q thermal cycler (V6985)



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 secretions, including lower respiratory tract secretions e.g. sputum/BAL and upper tract respiratory secretions e.g. nose and throat swabs	Coronavirus MERS-CoV RNA detection/confirmation	<b>Real-time RT-PCR (in house assay).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, ABI TaqMan 7500 Fast Thermal Cycler (V6991)
Respiratory secretions, nose and throat swabs	Seasonal Influenza RNA	<b>Real-time PCR (in house assay).</b> BioMérieux NucliSENS easyMAG or Roche MagNA Pure 96 automated nucleic acid extraction platform. Block-based thermal cycler reverse transcription (in house method) using DNA Engine Tetrad 2 or PCR Max Alpha Cycler ABI ViiA 7 or Quantstudio 7 flex real-time thermal cycler (V7193)
Respiratory secretions, nose and throat swabs, tissue culture fluid	Influenza strain typing	<b>Haemagglutination inhibition</b> by reference ferret serum antibody. ( <b>In house assay</b> ). Can be performed manually or automated. (V5397)
Paired serum	Influenza antibody response	<b>Haemagglutination inhibition</b> on paired patient sera. <b>Manual</b> <b>Automated</b> Liquid handler (FluidX Xrd-384, and Biomek NXp), using in-house reagents (erythrocyte suspension, influenza virus) (V5403).
Respiratory secretions, nose and throat swabs, tissue culture fluid	Influenza phenotypic drug resistance	<b>Neuraminidase Enzyme Inhibition.</b> BMG Labtech microplate reader (Fluorescence) (or similar), generic 37°C incubator/hot room, generic plate shaker; in house-enzyme inhibition assay (V6815)



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<b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b>	<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	Influenza genotypic drug resistance	<b>PCR and pyrosequencing.</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform., block-based thermal cycler DNA Engine Tetrad 2 or PCR Max Alpha Cyclor Qiagen Pyrosequencer ID96/Q24MDx/Q48autoprep, Qiagen Vacu-prep. In house assay (V6777/V6778/V7132/V7160)
Respiratory sample in lysis buffer, respiratory secretions, nose and throat swabs, tissue culture fluid	Avian influenza confirmation of H5, H7 or H9 subtype virus	<b>Real-time PCR (in house assays).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform. ABI TaqMan 7500 Fast thermal cycler, Qiagen Rotor-Gene Q thermal cycler (V7080, V7081, V5394, V7082, V708, V7019)
Paired serum	Avian Influenza antibody response	<b>Haemagglutination inhibition/Microneutralisation</b> (in house assays) <b>Manual</b> <b>Automated.</b> Liquid handlers (FluidX Xrd-384, Perkin Elmer Janus and Biomek NXp), using in-house reagents (erythrocyte suspension, influenza virus, MDCK cells) (V5429, V5403, V5463).
Respiratory secretions, nose and throat swabs	Parainfluenza RNA	<b>Multiplex PCR – real-time (in house assay);</b> BioMérieux NucliSENS easyMAG or Roche MagNA Pure 96 automated nucleic acid extraction platform, thermal cycler Qiagen Rotor Gene Q, (V5481)





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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 secretions, nose and throat swabs	Respiratory Syncytial Virus/Human Metapneumovirus RNA	<b>Real-time PCR (in house assay).</b> RSV A, RSV B, hMPV A and hMPV B. BioMérieux NucliSENS easyMAG or Roche MagNA Pure 99 automated nucleic acid extraction platform. Block-based thermal cycler reverse transcription using DNA Engine Tetrad 2 or PCR Max Alpha Cycler., Qiagen Rotor-Gene Q thermal cycler (V5381)
Respiratory secretions, nose and throat swabs	Rhinovirus RNA	<b>Real-time PCR (in house assay).</b> BioMérieux NucliSENS easyMAG or Roche MagNA Pure 96 automated nucleic acid extraction platform. Qiagen Rotor Gene Q thermal cycler (V5446)
Respiratory sample in lysis buffer, respiratory secretions, nose and throat swabs, tissue culture fluid	Influenza HA genetic characterisation	<b>Block-based PCR and sequencing (in house methods).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, Block-based thermal cycler DNA Engine Tetrad 2, agarose gel tank/Invitrogen E-Gel, (V6959, V6987, V6988)
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		Analysis and Interpretation: Data analysis: Mega: BioEdit:Bionumerics version 6.1, produced by Applied Maths



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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	Influenza genome sequencing	<b>Block-based PCR and sequencing (in house methods).</b> BioMérieux NucliSENS easyMAG automated nucleic acid extraction platform, Block-based thermal cycler DNA Engine Tetrad 2, agarose gel tank/Invitrogen E-Gel, (V7103, V7115)
Sequence data derived from MiSeq sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		Analysis and interpretation: Data analysis: Mega: BioEdit: Bionumerics version 6.1, produced by Applied Maths
Serum, plasma	Anti-HAV IgG/IgM	<b>Automated CMIA.</b> Architect HAVAb-IgG (Abbott Laboratories) Architect HAVAb-IgM (Abbott Laboratories) (V5733)
Serum, plasma	HBsAg	<b>Automated CMIA.</b> Architect HBsAg (Abbott Laboratories) (V5733)
Serum, plasma	HBsAg quantification	<b>Automated CMIA.</b> 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 (cont'd)</u>	In-house documented procedures based on manufacturer's instructions
Serum, plasma	HBsAg neutralisation	<b>Manual EIA.</b> Biotek plate washer, Biotek plate reader (V5729)  <b>Manual EIA.</b> Biotek plate washer, Biotek plate reader Murex HBsAg Confirmatory version 3 (DiaSorin) (V5729)
Serum, plasma	HBeAg	<b>Automated CMIA.</b> Architect HBe (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBc	<b>Automated CMIA.</b> Architect HBc II (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBc IgM	<b>Automated CMIA.</b> Architect anti-HBc IgM (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBs	<b>Automated CMIA.</b> Architect anti-HBs (Abbott Laboratories) (V5733)
Serum, plasma	Anti-HBe	<b>Automated EIA.</b> Abbott Architect (V5733)  <b>Automated CMIA.</b> Abbott Architect Architect Anti-HBe (Abbott Laboratories) (V5733)



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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 plasma, serum	HBV DNA viral load	<b>Real-time PCR.</b> Method: 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
EDTA plasma, serum	HCV antibody confirmation	<b>Manual EIA.</b> Commercial kit: -Ortho HCV 3.0 ELISA (Ortho) V5020 -Monolisa anti-HCV PLUS version 3 (BioRad) V5035  Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)
EDTA plasma, serum	HCV viral load	<b>Real-time PCR.</b> Method: in-house (V5763)  Nucleic acid extraction: Qiasymphony NA automated platform, with DSP virus/pathogen mini kit reagents (as per manufacturer's instructions, with in-house addition of internal control) V6860  Amplification/quantification: Applied Biosystems ABi Prism 7500 real time thermal cycler with Life Technologies TaqMan PCR reagents (SuperScript III Platinum One-Step qRT-PCR Kit)  Analysis: ABi 7500 software



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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 plasma, serum	HCV enhanced sensitivity viral load	<b>Real time PCR</b> (in house). ABI 7500 Taqman thermal cycler (V5763)
EDTA plasma, serum	HCV genotyping (NS5B sequencing)	Method: in-house PCR (V5099) Nucleic acid extraction: Roche MP96 automated platform, with MagNApure 96 DNA Viral Nucleic Acid Small Volume kit reagents (as per manufacturer's instruction) Amplification: Bio-RAD C-1000 thermal cycler PCR product purification: Illustra GFX columns, centrifuge
Sequence data derived from Sanger sequencing carried out by PHE Genomic Service and Development Unit (GSDU)		Analysis/genotyping: DNASTar (V7072)
Serum, plasma	Hepatitis Delta Virus Anti-HDV IgG	<b>Manual EIA.</b> Commercial kit: DiaSorin anti-HDV (DiaSorin) (V5023) Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)
Serum, plasma	Hepatitis Delta Virus Anti-HDV IgM	<b>Manual EIA.</b> Commercial Kit: DiaSorin IgM anti-HDV (DiaSorin) (V5025) Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)



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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	Hepatitis E Virus Anti-HEV IgG	<b>Manual EIA.</b> Commercial kit: Fortress Hepatitis E Virus IgG ELISA (V5901)  Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)
Serum, plasma	Hepatitis E Virus Anti-HEV IgM	<b>Manual EIA.</b> Commercial kit: Fortress Hepatitis E Virus IgM ELISA (V6769)  Assay processing: dry incubator (Abbott Commander), 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 (cont'd)</u></p> <p>HIV-1/HIV-2 antibody screen/confirmation/typing</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Antibody screen/confirmation</b> Commercial kit: -Enzygnost HIV Integral (Siemens) -Murex HIV Ag/Ab Combination (DiaSorin) (V5084, V5083) <b>Manual EIA.</b> Assay processing: dry incubator (Abbott Commander) or water bath (Grant W28), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><i>HIV1 &amp;2 Typing Assay</i> <i>Method: EIA (in-house) (V7148)</i></p> <p>Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>HIV Western Blot</b> Commercial Kit: HIV-1 Genelabs WB</p> <p>Manual set up: (V5110)</p> <p><i>Automated set up: (V5110 and V7207) using autoblot</i> <i>Bands read visually compared with kit insert reading chart</i></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	<b>Real-time PCR.</b> Method: in-house (V5762 for LTR/Pol PCR and V7180 for gag/int PCR)  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
EDTA plasma, serum	HIV-1 RNA qualitative PCR	<b>Real-time PCR.</b> Method: in-house  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
Serum, plasma	HIV-1 p24 antigen with neutralisation	<b>Manual EIA.</b> Commercial kit: Genscreen HIV-1 p24 antigen EIA (BioRad) (V5018) Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50)





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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	Human T-lymphotropic virus (HTLV)	<b>Real-time PCR.</b> Method: 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)
Serum, plasma	HTLV-I/II antibody screen/confirmation/typing	<b>Automated CMIA.</b> Architect HTLV I/II (Abbott Laboratories) (V5733) <b>HTLV Western Blot</b>  <b>For typing and confirmation purpose</b>  Commercial assay: Genelabs Diagnostics HTLV Blot 2.4  <i>Manual Set up (V5120)</i>  <i>Automated set up (V5120 and V7207)</i> Using Autoblot V7207 Bands read visually compared with kit insert reading chart



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<p><b>HUMAN BODY FLUIDS AND TISSUES (cont'd)</b></p> <p>Unseparated blood on EDTA. Other specimens by arrangement (EDTA/serum sample, tissue, pleural fluid)</p> <p>Serum, plasma</p> <p>Serum, plasma</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Human Herpesvirus 8 quantitation</p> <p>detection of total antibody to <i>Treponema pallidum</i></p> <p>Treponemal IgM</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Real-time PCR.</b> Method: 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>Commercial kit: Syphilis Captia Enzyme Immunoassay (EIA) II (Trinity Biotech)</p> <p><b>Manual EIA: (V7213)</b></p> <p>Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated using DS2: (V7218 and V7213)</b></p> <p>Commercial kit: RecomWell Treponemal IgM EIA (Microgen)</p> <p><b>Manual EIA: (V7214)</b></p> <p>Assay processing: dry incubator (Abbott Commander), EIA plate washer (Tecan Columbus or Biotek ELx50), plate reader (Biotek EL-808)</p> <p><b>Automated using DS2: (V7218 and V7214)</b></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
Serum, plasma	Detection of total antibodies to <i>Treponema pallidum</i> in human serum and CSF	<b>Manual method</b> Commercial kit: Serodia-TPPA (Fujirebio Inc.) <i>Treponema pallidum</i> particle agglutination (TPPA) Assay  Method: Manual assay V7212 Room incubation
Serum, plasma	Rapid Plasma Reagin	V7215, previously G6748 <b>Manual method</b> , room incubation Axis-Shield Rapid Plasma Reagin (RPR)
Serum, plasma	Detection of Antibodies to <i>Treponema</i>	<b>Method: EIA</b> Automated Autoblot analyser (V7207) Commercial kit: INNO-LIA Syphilis Score (Innogenetics)
Swab from genital, rectal or oral ulcer	Real Time PCR Assay for Detection of Organisms Responsible for Genital Ulcerative Diseases (GUD) <i>T. pallidum</i> /HSV 1& 2 / <i>H. ducreyi</i> DNA	Multiplex PCR V7276 (in house) <b>Real-time PCR.</b> Method: in-house (V7276)  Nucleic acid extraction: Roche compact NA automated platform (BRD0084), with MagNAPure compact (as per manufacturer's instructions, with in-house addition of internal control)  Amplification: Life technology PCR mix and Taq polymerase  Analysis: Qiagen Rotagene software



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swab from genital, rectal or oral ulcer</p> <p>Rectal, urethral or genital swab, lymph node aspirate, ulcer swab, residual specimen from unprocessed NAAT swab, fresh dry swab</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Differentiation of HSV1 and II for confirmation of positive HSV in GUD PCR</p> <p>Multiplex Real-Time PCR Assay for the detection of <i>Chlamydia Trachomatis</i> &amp; LGV Serovars directly from clinical specimens</p>	<p>In-house documented procedures based on manufacturer's instructions</p> <p><b>Real-time PCR.</b> Method: Real time Taqman (BRD0273)</p> <p>Commercial kit: Qiagen Artus HSV1/2 PCR kit and Rotagene detection V7276</p> <p>Nucleic acid extraction: Roche compact NA automated platform (BRD0084), with MagNApure compact (as per manufacturer's instructions, with in-house addition of internal control)</p> <p><b>Real-time PCR.</b> Method: 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		