


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9863</p> <p>Accredited to ISO 15189:2012</p>	<h3>Viapath Analytics LLP</h3> <p>Issue No: 007 Issue date: 13 September 2021</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS</p> <p>Fluids Tissues Cellular & fluid material contained on swabs & other materials from:</p> <p>Genital tract</p> <p>Faeces</p> <p>Wound & tissue</p> <p>Respiratory tract</p>	<p><u>Microbiological examinations for the purpose of clinical diagnosis</u></p> <p>Isolation of microorganisms of clinical significance</p>	<p>In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions</p> <p>Manual inoculation and culture using in-house procedures:</p> <p>LP-MIC-GENITAL Investigation of genital tract and associated specimens</p> <p>LP-MIC-FAECES Investigation of faecal samples</p> <p>LP-MIC-WOUNDS Investigation of wound and related samples</p> <p>LP-MIC-RESPS Investigation of respiratory samples</p>



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Fluids		LP-MIC-FLUIDS Investigation of fluids
Urine		LP-MIC-URINES Investigation of urine
Hair, nail, skin	Isolation and presumptive identification of fungi of clinical significance	LP-MIC-MYCOLOGY Mycology
Fluids	White blood cells (quantification & differentiation) Microorganisms	Gram & differential staining followed by Microscopy LP-MIC-FLUIDS Investigation of fluids



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Yeast cells & fungal hyphae Granular, hyaline & cellular casts	Manual microscopy LP-MIC-URINES Investigation of urine
Whole blood	Isolation of microorganisms of clinical significance	Automated liquid culture using: bioMérieux BacT/Alert followed by manual subculture
Granulocytes Stem cells	Sterility check of final product	LP-MIC-BC Investigation of blood cultures using the bioMérieux BacT/Alert
Fluids Tissues Cellular and fluid material contained on swabs	Isolation of: Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Gentamicin & Carbapenem-Resistant Gram-negative rods (CRE) Vancomycin-Resistant Enterococci (VRE) <i>Candida auris</i>	Manual inoculation and culture using LP-MIC-SCREEN Screening of patients for healthcare associated infections
Bacterial & fungal isolates cultured in-house from the above	Identification/ Biological classification	Automated using: bioMérieux Vitek 2 bioMérieux Vitek Compact LP-MIC-VITEK VITEK bioMérieux Vitek MS MalDI-TOF LP-MIC-VITEKMS Vitek MS operation Manual biochemical/enzymatic & staining/microscopic methods LP-MIC-BASICMETH Principles of basic methods



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Bacterial & yeast isolates cultured in-house from the above	Antimicrobial susceptibility testing (AST)	EUCAST methodology & interpretive breakpoints using: Manual disc diffusion Gradient MIC LP-MIC-MIC MIC Methods Automated using bioMérieux Vitek 2 & Vitek Compact LP-MIC-VITEK LP-MIC-BASICMETH
Blood	Detection of β -D-Glucan	Manual ELISA using: Fungitell kit LP-MIC-BDG Mycology SOP for antigen detection
Serum Cerebrospinal fluid (CSF)	Detection of Cryptococcal antigen	IMMY Latex assay LP-MIC-CRAG Cryptococcal Antigen Detection
Faeces	Detection of: <i>Clostridium difficile</i> toxins A & B <i>C. difficile</i> glutamate dehydrogenase (GDH) <i>Helicobacter pylori</i> antigen	Automated ELISA using: DS2 LP-MIC-DS2 DS2 Instrument Guide LP-MIC-FAECES Investigation of faecal samples
Faeces	Detection of <i>C. difficile</i> tcdB gene	LAMP PCR using: <i>illumigene</i> LP-MIC-ILLUMISOP Loop amp CD toxin B gene LP-MIC-FAECES Investigation of faecal samples
Urine	<i>Legionella pneumophila</i> serogroup 1 antigen	Membrane immunochromatographic assay using: Biotest kit LP-MIC-URINES Investigation of urine



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Faeces	Detection of ova, cysts & parasites (OCP)	Unstained and iodine stained direct microscopy and/or Formol-ether faecal concentration followed by microscopy LP-MIC-FAECES Investigation of faecal samples
Clear adhesive tape slides Perianal swab	Detection of <i>Enterobius vermicularis</i> larvae and ova	Microscopy LP-MIC-FAECES Investigation of faecal samples
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Auramine phenol staining and fluorescence microscopy and/or Ziehl-Neelsen staining and microscopy M.SOP11 Investigation of faecal samples
Genital samples	Detection of <i>Trichomonas vaginalis</i> ova	Microscopy LP-MIC-GENITAL Investigation of genital tract and associated specimens
Urine	Detection of <i>Schistosoma haematobium</i> ova	Microscopy LP-MIC-URINES Investigation of urine
Respiratory samples Fluids	Detection of Acid-Alcohol Fast Bacilli	Auramine phenol staining and fluorescent microscopy Ziehl-Neelsen staining and light microscopy LP-MIC-AFB



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HUMAN BODY FLUIDS	<u>Serological examinations for investigation for immunity and markers of infectious disease</u>	In-house documented methods following manufacturers' instructions
Blood	Detection of: Hepatitis A IgM & IgG Hepatitis B surface antibody (quantitative) Hepatitis B surface antigen Hepatitis B core IgM Hepatitis B core total antibody Hepatitis B e antigen Hepatitis B e antibody Hepatitis C antibodies HIV 1+2 antigen/antibodies HTLV I/II antibodies CMV IgG Syphilis Total antibody	Abbott Architect i2000SR LP-VIR-ARCH Architect logbook LP-VIR-HAVSER Hepatitis A Serology LP-VIR-HBVSER Hepatitis B Serology LP-VIR-HCV Hepatitis C Serology LP-VIR-HIVSER Serology LP-VIR-HTLVSERHTLV Serology LP-VIR-CMVSER Serology LP-VIR-TREPSERSyphilis Serology
Blood	Detection of: CMV IgG EBV IgM EBV IgG HIV 1+2 antigen/antibodies HIV p24 antigen Rubella IgM Rubella IgG <i>Toxoplasma</i> IgG	bioMérieux Vidas PC LP-VIR-VIDAS bioMérieux Vidas PC logbook LP-VIR-CMVSER CMV Serology LP-VIR-EBVSER EBV Serology LP-VIR-HIVSER HIV Serology LP-VIR-MMRSER MMR Serology LP-VIR-TOXSER Toxoplasma Serology



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Blood	Detection of: Hepatitis B surface antibody (quantitative) Hepatitis B core antibody Hepatitis C antibodies/antigen HTLV I/II antibodies	Sample aliquoting using: Tecan Freedom EVO 200 LP-VIR-EVOALIQ Automated assay setup and processing using Tecan Freedom EVO 100 + 200 with Enzyme Immune Assays LP-VIR-EVO SER and LP-VIR-SEROLRGNT (Preparation, Storage and Tracking of Serology Reagents) LP-VIR-HBV SER Hepatitis B Serology LP-VIR-HCV SER Hepatitis C Serology LP-VIR-HTLV SER HTLV Serology



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood</p>	<p><u>Serological examinations for investigation for immunity and markers of infectious disease (cont'd)</u></p> <p>Detection of:</p> <p>CMV IgG CMV IgM Measles IgG Mumps IgG Rubella IgG Parvovirus IgM Parvovirus IgG EBV IgM EBV IgG HSV 1 + 2 IgG <i>Toxoplasma</i> IgG</p> <p>VZV IgG</p> <p><i>Aspergillus</i> Galactomannan Ag</p> <p>Hepatitis B surface antigen*</p> <p>HIV 1&2 Antibody & HIV-1 p24 Antigen*</p> <p>Syphilis Total antibody*</p>	<p>In-house documented methods following manufacturers' instructions</p> <p>Tecan (as above)</p> <p>LP-VIR-CMVSER CMV Serology</p> <p>LP-VIR-MMRSER MMR Serology</p> <p>LP-VIR-PARVOSER Parvovirus Serology</p> <p>LP-VIR-EBVSER EBV Serology</p> <p>LP-VIR-HSVSER HSV Serology</p> <p>LP-VIR-TOXSER <i>Toxoplasma</i> Serology</p> <p>LP-VIR-VZVSER VZV Serology</p> <p>Mycology SOP for antigen detection LP-VIR-ASPEIA</p> <p>Documented-in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening programme as defined in the July 2018 'Infectious Diseases in Pregnancy Screening: laboratory QA evidence requirements (targets marked*)</p> <p>Tecan (as above)</p> <p>LP-VIR-HBVSER Hepatitis B Serology</p> <p>LP-VIR-HIVSER HIV Serology</p> <p>LP-VIR-TREPSER Syphilis Serology</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examinations for investigation for immunity and markers of infectious disease (cont'd)</u>	In-house documented methods following manufacturers' instructions
Blood	Antistreptolysin-O	Manual latex agglutination Werfen Rheumajet ASO LP-VIR-STREP SER Streptococcal serology
Blood	<i>Treponema pallidum</i> IgM	Manual EIA Trinity Biotech CAPITA Syphilis TA LP-VIR-TREP SER Syphilis Serology
Blood	Rheumatoid Factor	Manual latex Dade-Behring RapiTex LP-VIR-RF Detection of Rheumatoid factor
Blood	HIV 1+2 typing	Auto-LIA LP-VIR-HIV SER HIV Serology



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HUMAN TISSUES AND FLUIDS	<p><u>Molecular examinations for investigation for markers of infectious disease</u></p> <p>Investigation for markers of infectious disease</p>	In-house documented methods following manufacturers' instructions
<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Nucleic Acids extracted in-house</p> <p>Urine CSF EDTA whole blood</p> <p>Serum from Clotted blood Plasma from EDTA whole blood Faeces</p>	<p><u>Molecular examinations for investigation for markers of infectious disease (cont'd)</u></p> <p>Quantitative detection of:</p> <p>BK virus DNA</p> <p>Hepatitis E virus RNA</p>	<p>In-house documented methods following manufacturers' instructions</p> <p>LP-VIR-BK BK PCR Nucleic Acid extraction using Qiagen EZ1 Advanced, Qiagen EZ1 Advanced XL, Qiagen Biorobot EZ1 Qiagen EZ1 Biorobot system LP-VIR-EZ1 Sample transfer using: QiAgility LP-VIR-QIAGILITY or Qiagen Universal Biorobot LP-VIR-UNIVERSAL PCR Screening using: Qiagen Rotorgene</p> <p>LP-VIR-HEVPCR HEV RNA Quantitative PCR Nucleic Acid extraction using Qiagen EZ1 Advanced, Qiagen EZ1 Advanced XL, Qiagen Biorobot EZ1 Qiagen EZ1 Biorobot system LP-VIR-EZ1 Sample transfer using: Qiagen QiAgility LP-VIR-QIAGILITY PCR using: Qiagen RotorGene</p>



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<p>Nucleic Acids extracted in-house</p> <p>EDTA whole blood Genital Swabs Eye swabs Skin swabs Rectal swabs Throat swabs Paraffin-embedded tissue Tissue Biopsies CSF</p>	<p>Qualitative detection of:</p> <p>Enterovirus RNA Parechovirus RNA</p>	<p>LP-VIR-ENTPARPCR Enterovirus and Parechovirus Multiplex Rotorgene Assay Nucleic Acid extraction using Qiagen EZ1 Advanced, Qiagen EZ1 Advanced XL, Qiagen Biorobot EZ1 Qiagen EZ1 Biorobot system LP-VIR-EZ1 Sample transfer using: Qiagen QiAgility LP-VIR-QIAGILITY and Qiagen Universal Biorobot LP-VIR-UNIVERSAL PCR using: Qiagen RotorGene</p>
<p>EDTA Blood Genital Swabs Eye swabs Skin swabs Rectal swabs Throat swabs Paraffin-embedded tissue Tissue Biopsies CSF</p>	<p>HSV type 1 and 2 DNA VZV DNA</p>	<p>LP-VIR-HSVZPCR HSV and VZV Multiplex RotorGene Assay Nucleic Acid extraction using Qiagen Qiagen EZ1 Advanced, Qiagen EZ1 Advanced XL, Qiagen Biorobot EZ1 Qiagen EZ1 Biorobot system LP-VIR-EZ1 Sample transfer using: Qiagen QiAgility LP-VIR-QIAGILITY and Qiagen Universal Biorobot LP-VIR-UNIVERSAL</p>



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Combined nose & throat swab in virus transport medium	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, N2	Real-Time PCR using Cepheid GeneXpert Xpert Xpress SARS-CoV-2 assay LP-VIR-XpertSARS
Combined nose & throat swab in virus transport medium	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, S	TECAN EVO 200 sample transfer Tecan EVO 100 & 150 reagent preparation KingFisher Flex nucleic acid extraction Life Technologies Quantstudio7 & ViiA7 Real-Time PCR Altona Diagnostics RealStarSARS-CoV-2 RT-PCR Kit LP-VIR-NCov2019
Combined nose & throat swab in virus transport medium Samples collected by a Provider accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and/or who is listed on the DHSC Approved List for General Population testing	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, S for: General Population testing	LP-VIR-NCov2019 and: DHSC minimum standards for private providers of COVID-19 General Population testing
END		