


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>Synnovis Analytics LLP</b>  <b>Issue No: 015 Issue date: 25 June 2025</b>	
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<b>Testing performed at the above address only</b>		

### DETAIL OF ACCREDITATION

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



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
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</u> (cont'd)	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</u> (cont'd)	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 $\beta$ -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</u> (cont'd)	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 antigen Hepatitis B core total 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  <i>Toxoplasma</i> IgG	bioMérieux Vidas PC LP-VIR-VIDAS bioMérieux Vidas PC logbook LP-VIR-CMVSER CMV Serology  LP-VIR-TOXSER Toxoplasma Serology



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HUMAN BODY FLUIDS (cont'd)	<u>Serological examinations for investigation for immunity and markers of infectious disease</u> (cont'd)	In-house documented methods following manufacturers' instructions
Blood	Detection of:	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-EVOSER and LP-VIR-SEROLRGNT (Preparation, Storage and Tracking of Serology Reagents)
	Hepatitis B core antibody	LP-VIR-HBVSER Hepatitis B Serology
	Hepatitis C antibodies/antigen	LP-VIR-HCVSER Hepatitis C Serology
	HTLV I/II antibodies	LP-VIR-HTLVSER HTLV Serology
Blood	Detection of:	Tecan (as above)
	CMV IgG	LP-VIR-CMVSER CMV Serology
	Toxoplasma IgG	LP-VIR-TOXSER Toxoplasma Serology
	Aspergillus Galactomannan Ag	Mycology SOP for antigen detection LP-VIR-ASPEIA
Serum	Treponema specific antibodies	Uisng Launch ASI TPHA Kit LP-VIR-TREPSE Syphilis serology



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HUMAN TISSUES AND FLUIDS  Nucleic Acids extracted in-house  Urine CSF EDTA whole blood          Serum from Clotted blood Plasma from EDTA whole blood Faeces	<u>Molecular examinations for investigation for markers of infectious disease</u>  Investigation for markers of infectious disease  Quantitative detection of:  BK virus DNA          Hepatitis E virus RNA	In-house documented methods following manufacturers' instructions          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   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





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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Nucleic Acids extracted in-house</p> <p>EDTA Blood Genital Swabs Eye swabs Skin swabs Rectal swabs Throat swabs Paraffin-embedded tissue Tissue Biopsies CSF</p>	<p><u>Molecular examinations for investigation for markers of infectious disease (cont'd)</u></p> <p>Qualitative detection of:</p> <p>HSV type 1 and 2 DNA VZV DNA</p>	<p>In-house documented methods following manufacturers' instructions</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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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular examinations for investigation for markers of infectious disease</u> (cont'd)	In-house documented methods following manufacturers' instructions
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	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, S	LP-VIR-NCov2019
Samples collected by a Provider accredited to ISO 15189:2012 or ISO/IEC 17025:2017		
Skin swab set (pooled nose, throat, groin and axilla) collected into MWE Transwabs	Detection of <i>Candida auris</i> DNA	KingFisher Flex Extraction using the MagMAX CORE NA Purification Kit Life Technologies QuantStudio 7 Flex Real-time PCR  LP-VIR-CANDIDPCR
<u>Whole Blood</u> <u>Serum</u> <u>Plasma</u>	<u>Detection and quantitation of:</u> <u>Hepatitis B virus DNA</u> <u>Hepatitis C virus RNA</u> <u>HIV RNA</u>	<u>Abbott Alinity-m analyser real-time PCR method (LP-VIR-Alinity)</u>
<u>Dried blood spot</u>	Detection of: Hepatitis C virus RNA	
END		