


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 UKAS MEDICAL 8640 Accredited to ISO 15189:2012	Synnovis Analytics LLP Issue No: 014 Issue date: 28 November 2024	
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	Testing performed at the above address only	

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUES AND FLUIDS</p> <p>Aspirates Cellular & fluid material contained on swabs, catheter tips, pacing wires and intra-uterine contraceptive devices Fluids Heart valve/vegetation Lymph node aspirate Pus Renal / Bladder stone Tissues Samples from sterile sites Genital samples Semen</p> <p>Aspirates Corneal scrapes Aqueous & vitreous tap Cerebrospinal fluid (CSF) Fluids Tissues</p> <p>Urine</p>	<p><u>Microbiological examinations for the purpose of clinical diagnosis</u></p> <p><u>General Bacteriology/Microbiology</u></p> <p>Isolation of clinically significant bacteria and fungi</p> <p>Detection, identification & quantification of: White blood cells Differential WBC count (CSF) Red blood cells Bacterial cells Yeast cells and fungal hyphae</p> <p>Isolation of clinically significant bacteria and fungi</p>	<p>In-house documented procedures following current UK Standards for Microbiological Investigations (SMLs) and incorporating relevant manufacturers' instructions</p> <p>Manual culture using: IIM-SOP-Processing Specialist Specimens IIM-SOP-Reading Specialist Specimens</p> <p>Staining and microscopic examination using: IIM-SOP-Processing Specialist Specimens IIM-SOP- Specialist Area CAP Fluids</p> <p>Manual culture using: IIM-SOP- Urine Methods IIM-SOP Urines Plate Reading</p>



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Urine	Detection, identification & quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells	Automated urinalysis, Image capture and recognition using: IIM-SOP-Sedimax operation and: A.Menarini Diagnostics SediMAX Manual microscopy using: IIM-SOP- Urine Methods
Blood Bone marrow	Isolation of clinically significant bacteria and fungi	Automated culture using: IIM-BD BACTEC FX: Use & Maintenance IIM-SOP-Blood Culture Processing and Reading Bench IIM-SOP-Auramine and ZN staining and: Becton Dickinson BACTEC FX followed by manual subculture, identification & susceptibility testing as listed below
Expressed breast milk	Sterility check	Manual culture: IIM-SOP-Processing Specialist Specimens IIM-SOP-Reading Specialist Specimens
Cellular and fluid material contained on swabs from nose, throat & groin/perineum	Screening for: Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) <i>Candida auris</i>	Manual culture using: IIM-SOP-Resistance Screening
Cellular and fluid material contained on rectal & throat swabs	Screening for Gentamicin-resistant Enterobacteriaceae	Manual culture using: IIM-SOP-Resistance Screening
Cellular and fluid material contained on rectal swabs	Screening for Vancomycin-resistant Enterococci (VRE)	Manual culture using: IIM-SOP-Resistance Screening
Cellular and fluid material contained on rectal swabs	Screening for Carbapenamase-resistant organisms	Manual culture using: IIM-SOP-Resistance Screening



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Faeces	Isolation of bacterial enteric pathogens: <i>Clostridium difficile</i> <i>Escherichia coli</i> O157 <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Yersinia</i> spp. <i>Pleisiomonas</i> sp.	Manual culture using: IIM-SOP-Faeces Processing IIM-SOP-Faeces Bench Reading
Faeces Blood	Isolation of <i>Campylobacter</i> spp.	Manual culture using: IIM-SOP- Faeces Bench Reading
Bronchoalveolar lavage (BAL) Bronchial aspirate, brushings & washings Cellular and fluid material contained on swabs Endotracheal tube specimen Nasopharyngeal aspirate (NPA) Sputum	Isolation of clinically significant bacteria and fungi	Manual culture using: IIM-SOP-Processing of Respiratory Samples IIM-SOP-Respiratory Plate Reading
Cellular and fluid material contained on swabs	Isolation of <i>Bordetella</i> spp.	Manual culture using: IIM-SOP-Swabs Bench Reading
Bacterial & fungal isolates cultured in-house from the above	Identification/ Biological classification	Manual and/or automated identification using: Bruker Maldi-ToF IIM-SOP- Operation of the Bruker Sirius Biotyper (MALDI-TOF) BioMérieux Vitek IIM-SOP-VITEK2 Operation and: Bruker Sirius Biotyper BioMérieux Vitek2 Manual biochemical/enzymatic & staining/microscopic methods



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Bacterial isolates cultured in-house from the above	Antibiotic susceptibility testing	Disc diffusion & gradient minimum inhibitory concentration determination using current EUCAST methodology & interpretive breakpoints: IIM-SOP-EUCAST Antimicrobial susceptibility testing Automated using: IIM-SOP-VITEK 2 Operation and: BioMérieux Vitek2
Yeast isolates cultured in-house from the above	Antifungal susceptibility testing	Automated using: IIM-SOP-VITEK 2 Operation and: BioMérieux Vitek2
Faeces	Detection of DNA from enteric pathogens: <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>E. coli</i> O157 <i>Campylobacter</i> spp.	Realtime PCR using: IIM-SOP-BD Max and: Becton Dickinson BD Max System
Faeces	Detection of ova, cysts & parasites (OCP)	Unstained and iodine stained direct microscopic examination Formol-ether faecal concentration and microscopic examination using: IIM-SOP Parasite Methods
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Auramine phenol staining and fluorescence microscopy using: IIM-SOP-Parasite Methods
Clear adhesive tape slides	Detection of <i>Enterobius vermicularis</i> larvae and ova	Microscopic examination using: IIM-SOP- Parasite Methods



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Bile Duodenal aspirates Jejunal aspirates	Detection of OCP including: <i>Strongyloides stercoralis</i> larvae <i>Giardia lamblia</i> trophozoites <i>Cryptosporidium</i> oocysts <i>Cyclospora cayetanensis</i> oocysts <i>Cystoisospora belli</i> oocysts	Microscopic examination using: IIM-SOP- Parasite Methods
Female genital tract swabs	Microscopic diagnosis of bacterial vaginitis Detection of <i>Trichomonas vaginalis</i>	Gram stained microscopic examination using: IIM-SOP-Processing Swabs
Urine	Detection of: <i>Legionella pneumophila</i> serotype 1 antigen <i>Streptococcus pneumoniae</i> soluble antigen	Membrane immunochromatographic assay using: IIM-SOP-Binax NOW Legionella and Pneumococcal urinary antigens and: Binax NOW kits
Sputum Bronchoalveolar lavage (BAL) Early morning urine (EMU) Pus Fine needle aspirates (FNA) Fluids Tissues	Isolation and presumptive identification of acid alcohol-fast bacilli (AAFB), inc. <i>Mycobacterium</i> spp.	Manual culture using Löwenstein-Jensen (LJ) media and/or automated liquid culture, using: IIM-SOP-MGiT Use and Operations IIM-SOP-Mycobacteria Investigations and: Becton Dickinson BACTEC MGIT 960
Sputum BAL EMU Gastric aspirates Fluids Tissues Pus FNA Cerebrospinal fluid (CSF) Faeces In-house LJ or MGIT cultures	Detection of acid alcohol-fast bacilli (AAFB)	Auramine Phenol staining followed by fluorescence microscopy using: IIM-SOP-Auramine and ZN Staining



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Respiratory samples Early morning urine (EMU) Gastric aspirates Fluids Tissues Pus Fine needle aspirates (FNA) Cerebrospinal fluid (CSF)	Detection of: <i>Mycobacterium tuberculosis</i> DNA Rifampicin-resistance genes	Realtime PCR using: IIM-SOP-Cepheid GeneXpert Assays and: Cepheid GeneXpert
CSF Serum	<i>Cryptococcus</i> Antigen	Manual lateral flow immunochromatographic assay using: IIM-SOP-Cryptococcal Antigen Lateral Flow Assay and: IMMY CrAg LFA



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Respiratory samples	Detection of nucleic acids from: Influenza A Influenza B Respiratory Syncytial Virus	Realtime PCR using: IIM-SOP-Cepheid GeneXpert Assays and: Cepheid GeneXpert
Combined nose & throat swab in VTM, UTM or liquid Amies Medium	Detection of SARS-CoV-2 virus RNA (COVID-19); specific gene sequences E & N2	Realtime PCR using: IIM-SOP-Rapid COVID-19 Testing and: Cepheid GeneXpert & Xpert Xpress SARS-CoV-2 test cartridge



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Faeces	Microbial serology for: <i>Clostridioides</i> (formerly <i>Clostridium</i>) <i>difficile</i> glutamate dehydrogenase (GDH) Antigen <i>C. difficile</i> toxins A & B <i>Helicobacter pylori</i> Antigen	Automated DS2 ELISA using: IIM-SOP Use of the DS2 for CDT and HPylori and: Dynex DS2
Faeces	<i>C. difficile</i> GDH Antigen <i>C. difficile</i> toxins A & B	Membrane immunochromatographic assay using: IIM-SOP-C.difficile Quik check complete immunocard and: Alere C.DIFF QUIK CHEK Complete
Faeces	Detection of <i>C. difficile tcdB</i> gene	Realtime PCR using: IIM-SOP-Use of Cepheid GeneXpert for detection of <i>C. difficile</i> and: Cepheid GeneXpert
Faeces	Detection of Rotavirus Detection of Adenovirus	Antigen detection by lateral flow using: IIV-SOP-RIDA Quick Rota Adeno



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Combined nose & throat swabs* in Virus Transport Medium (VTM), Universal Transport Medium (UTM) or liquid Amies Medium Nasopharyngeal aspirate (NPA) Bronchoalveolar lavage (BAL)* Post-mortem lung swab Induced Sputum	<u>Molecular</u> Detection of respiratory pathogen nucleic acids: Influenza A&B Rhinovirus Respiratory syncytial virus (RSV) Human metapneumovirus (hMPV) Parainfluenza 1, 2, 3, & 4 Adenoviruses Enteroviruses <i>Mycoplasma pneumonia</i> <i>Bordetella</i> spp. SARS-CoV-2 virus RNA (COVID-19); specific gene sequences Orf1a & Orf8 (*marked samples only)	Nucleic acid extraction and multiplex tandem PCR using: IIV-SOP-Qiagen QIAasymphony Operations & Maintenance IIV-SOP-Operation of the Aus Diagnostics High Plex System IIV-SOP-Aus Diagnostics Respiratory 24-well assay and: QIAasymphony AusDiagnostics High Plex System
Bronchoalveolar lavage (BAL) Non-Directed BAL Induced sputum	<i>Legionella pneumophila</i> <i>Legionella longbeachae</i> <i>Mycoplasma pneumonia</i> <i>Chlamydophila pneumonia</i> <i>Chlamydophila psittaci</i> <i>Bordetella</i> (<i>B. pertussis</i> & <i>B. holmesii</i>) <i>Pneumocystis jiroveci</i>	



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Cellular & fluid material contained on Nose/Throat swab Bronchoalveolar lavage (BAL)	Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV)	Manual nucleic acid extraction followed by Real Time PCR using: IIV-SOP-Manual extraction IIV-SOP-Altona MERS-CoV RT-PCR assay and: Altona MERS-CoV assay ABI Fast 7500 Nucleic acid extraction and real-time PCR amplification using: IIV-SOP-QIAasymphony SP (Qiagen) Operations & Maintenance Guide IIV-SOP-QIAasymphony Extraction Procedure IIV-SOP-ABI 7500 Operation and Maintenance and: QIAasymphony ABI 7500 Real-Time Instrument
Faeces Vomit	Molecular detection of: Norovirus	IIV-SOP-Norovirus Realtime PCR Realtime PCR using: Abbott Alinity m and IIV-SOP-Abbott Alinity m Assays
Plasma	HIV Viral Load Hepatitis B Viral Load Hepatitis C Viral Load	



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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 UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions
Whole blood	CMV Viral Load EBV Viral Load	Automated nucleic acid extraction followed by Real Time PCR using: IIV-SOP-Operation of QIAgility IIV-SOP-QIAsymphony SP (Qiagen) Operations & Maintenance Guide IIV-SOP-QIAsymphony Extraction Procedure IIV-SOP-CMV R-GENE IIV-SOP-EMV R-GENE IIV-SOP-BKV R-GENE and: QIAgility QIAsymphony BioMérieux R-GENE assays ABI Fast 7500
Whole Blood Urine	BK Viral Load	
Cerebrospinal fluid (CFS) Urine Bronco alveolar lavage (BAL) Nasopharyngeal aspirate (NPA) Eye swab/Vitreous humour	CMV EBV	Automated nucleic acid extraction followed by Real Time PCR using: IIV-SOP-Operation of QIAgility IIV-SOP-CMV R-GENE IIV-SOP-EMV R-GENE and: QIAgility QIAsymphony BioMérieux R-GENE assays ABI Fast 7500
Lesion swabs Genital swabs Cerebrospinal fluid (CSF)	HSV-1 & 2 <i>Treponema pallidum</i>	IIV-SOP-HSV Syphilis Qualitative real-time PCR



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Throat swab Eye swab/Vitreous humour Bronco alveolar lavage Nasopharyngeal aspirate Faeces Plasma	Adenovirus	Nucleic acid extraction and real-time PCR amplification (as above) IIV-SOP-Qualitative Adenovirus real-time
Cerebrospinal fluid (CSF) Throat swab Nasal swab Bronco alveolar lavage Nasopharyngeal aspirate Faeces Skin swabs Mucosal swabs	Viral Meningitis panel: Enterovirus Parechovirus	IIV-SOP IIV-SOP-Qualitative Enteroparechovirus real-time PCR
Cerebrospinal fluid (CSF) Skin swabs Mucosal swabs Lesion swabs Eye swab/Vitreous humour	HSV-1 & 2 VZV	IIV-SOP-HSV-1 & 2 Qualitative real-time PCR IIV-SOP-VZV Qualitative real-time PCR
Cerebrospinal fluid (CSF) Vitreous Humour Plasma	JC virus	IIV-SOP-Qualitative JC and Toxoplasma gondii real-time PCR Assay
Cerebrospinal fluid (CSF) Plasma Serum Eye swab/Vitreous humour	<i>Toxoplasma gondii</i>	IIV-SOP-Toxoplasma gondii real-time PCR Assay
Plasma Serum Amniotic Fluid	Parvovirus B19	IIV-SOP-Qualitative parvovirus B19 real time PCR



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Urine Cellular and fluid material contained on self-collected swabs: Rectal Genital Urethral Ulcer 3in1	Detection of <i>C. trachomatis</i> LGV-specific DNA	Automated Nucleic acid extraction and 5Plex real-time PCR using: IIV-SOP-QIA Symphony SP (Qiagen) Operations & Maintenance Guide IIV-SOP-QIA Symphony Extraction Procedure IIV-SOP-Rotor-gene Q Real-time PCR System Operations and Maintenance IIV-SOP-LGV PCR QIA Symphony Rotor-gene Q Target capture and transcription mediated amplification (TMA): IIV-SOP-Gen-Probe Panther Operation & Maintenance IIV-SOP-Hologic Aptima Assays and: Hologic Gen-Probe Panther system
Urine Cellular and fluid material contained in cervical, eye, high-vaginal, rectal and throat swabs	Detection of ribosomal RNA from: <i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> <i>N. gonorrhoeae</i> (confirmation)	IIV-SOP-Hologic Aptima Assays
Urine Cellular and fluid material contained on cervical, high-vaginal &, rectal swabs	Detection of ribosomal RNA from: <i>Trichomonas vaginalis</i> <i>Mycoplasma genitalium</i>	IIV-SOP Hologic Aptima Assays



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Skin Hair Nail Mucous membranes Subcutaneous biopsies Clear adhesive tape strips	Isolation & identification of fungal pathogens Identification of: Filamentous moulds Yeasts Causative organisms of: Erythrasma Pitted keratolysis Pityriasis versicolor	Manual bright-field & Calcofluor-stained fluorescence microscopy using: DMM-SOP-6 DMM-LI-12 DMM-LI-32 DMM-LI-17 and: Leica DMLS & DMRB microscopes
Skin Hair Nail Mucous membranes Subcutaneous biopsies Cellular material contained on swabs & brushes	Isolation and identification of: Filamentous moulds (dermatophytes & non-dermatophytes) Yeasts	Manual culture and macroscopic analysis using: DMM-SOP-7 DMM-LI-06 DMM-LI-07 DMM-LI-08 DMM-LI-09 DMM-LI-22 DMM-LI-14 DMM-LI-21 DMM-LI-29 DMM-LI-30 DMM-LI-33
Fungal cultures isolated from sample types listed above	Identification of: Filamentous moulds (dermatophytes & non-dermatophytes) Yeasts	Manual bright-field microscopy using SOPs listed above for culture and: Leica DMLS & DMRB & Nikon Alphadot YS microscopes

END