

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8844

Accredited to
ISO 15189: 2022

NHS Fife

Issue No: 014

Issue date: 26 March 2025

Microbiology Department
Laboratory Medicine
North Laboratory
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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Microbiology Department Laboratory Medicine North Laboratory Victoria Hospital Hayfield Road Kirkcaldy KY2 5AG	Local contact Stephen McGlashan Tel: +44 1592 48095 E-Mail: stephen.mcglashan@nhs.scot	Microbiology Molecular microbiology A
Address Microbiology Department South Laboratory Victoria Hospital Hayfield Road Kirkcaldy KY2 5AG	Local contact Stephen McGlashan Tel: +44 1592 48095 E-Mail: stephen.mcglashan@nhs.scot	Serology B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES/FLUIDS	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate	
CSF	White and red cell enumeration	Culture and Light Microscopy using Kova slides ESOP008 and ESOP 068 Investigation of CSF	A
Genital samples	Detection of <i>Trichomonas vaginalis</i>	Hays criteria with reference to ESOP009 Investigation of genital tract and associated specimens	A
	General isolation and characterisation of micro-organisms of clinical significance	Culture and Light Microscopy of wet preps and Gram stains	
Mouth swabs		ESOP012 Investigation of mouth swabs	A
Nasal samples		ESOP013 Investigation of nasal samples	A
Throat swabs		ESOP015 Investigation of throat swabs	A
Bronchoalveolar lavage, Sputum and associated specimens		ESOP016 Investigation of Bronchoalveolar lavage, sputum and associated specimens	A
Tissues and biopsies		ESOP017 Investigation of tissues and biopsies	A
		ESOP221 Orthopaedic implants or prosthetic joints associated with infection samples	A



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Bone	General isolation and characterisation of micro-organisms of clinical significance (cont'd)	Culture and Light Microscopy of wet preps and Gram stains ESOP020 Investigation of bone and soft tissue associated with osteomyelitis	A
Ear swabs and associated specimens		ESOP023 Investigation of ear swabs and associated specimens	A
Eye swabs and canaliculi pus		ESOP024 Investigation of eye swabs and canalicular pus	A
Skin, and wound swabs, cyst and abscess material		ESOP025 Investigation of swabs, skin and superficial soft tissue infection ESOP 026 investigation of abscesses post operative and deep seated wound infections (pus and exudate) ESOP 028 Investigation intervascular cannular and associated specimens	A
Joint, ascitic, pericardial fluid		ESOP031 Investigation of fluids from normally sterile sites/ESOP 221 Investigation of Orthopaedic implants/prosthetic joint associated infection	A
Intraocular fluids and corneal scrapings		ESOP033 Investigation of intraocular fluids and corneal scrapings	A



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Bile	General isolation and characterisation of micro-organisms of clinical significance (cont'd)	Culture and Light Microscopy of wet preps and Gram stains ESOP027 Investigation of Bile Traditional Culture and Microscopy of wet preps and Gram stains	A
Urine		ESOP 010 Investigation of urine	A
CAPD fluid	White and red cell enumeration	Light Microscopy using Kova slides ESOP030 Investigation of CAPD fluid	A
Nasal, groin, perineum swabs	Identification of MRSA	ESOP032 Investigation of specimens for MRSA screening	A
Sputum	Detection of <i>Mycobacterium tuberculosis</i> complex and detection of Rifampicin resistance genes.	ESOP278. Detection using GeneXpert and MTB/RIF Ultra.	A
Urine	Detection of <i>Legionella pneumophila</i> serogroup 1 urinary antigen	ESOP 189 By the Sofia Legionella Fluorescent Immunoassay. (FIA)	A
Skin, hair and nails	Isolation & identification of fungal pathogens	ESOP072 Investigation of dermatological specimens for superficial mycoses using culture and Lactophenol blue wet mounts	A



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Faeces	Enteric Pathogens	Investigation of faeces for enteric pathogens ESOP021	
Faeces	Helicobacter pylori	Antigen detection by ELISA on DS2 ESOP107 Investigation of Helicobacter pylori	A
Faeces	Qualitative detection of <i>Clostridioides difficile</i> Glutamate dehydrogenase (GDH)	Enzyme immunoassay for the detection of C. difficile glutamate dehydrogenase (GDH) on DS2.	A
Faeces	Toxins A & B	Immunocard Toxin A&B kit. By horizontal flow EIA ESOP196 and ESOP 215	A
Faeces	Detection of <i>Clostridioides difficile</i> Glutamate dehydrogenase and Toxins A&B	ESOP215 Using Techlab C.Diff Quik Chek Complete	A
Blood	Bacterial growth detection	Automated incubation and bacterial growth detection by BD Bactec Fx ESOP 007 -investigation of blood cultures	A
Cultured isolates	Identification of micro-organisms	Automated identification using Vitek 2 and ESOP071 and manual identification tests	A
		MALDI-TOF Identification (VITEK MS) ESOP 255 and 256	A



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Bacterial Isolates	Antimicrobial susceptibility testing	Determination of antimicrobial susceptibility by disc diffusion read manually (ESOP083 and ESOP 079) or on SIRscan i2a 2000, Gradient Mic strip (ESOP080) and Automated broth microdilution using VITEK 2 (ESOP 163). Interpretation of breakpoints and zone sizes based on EUCAST	A
Serum	<u>Serology examination activities for the purpose of clinical diagnosis</u> Antibody/antigen detection for:	Antibody and Antigen detection by electrochemiluminescence immunoassay (ECLIA) on Roche Cobas 8000/e602 ESOP 101 and QMS 696	B
	Anti Hbs Hep B Core Ab Hep BsAg Rubella IgG Syphilis Hepatitis C Ab	ESOP 112 ESOP 102 ESOP 102 ESOP 105 ESOP 104 ESOP 097	
Serum	HIV Dual antigen/antibody detection	Electrochemiluminescence immunoassay ECLIA on Roche Cobas 8000/ e602 BSCORE34	B



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HUMAN BODY TISSUES/FLUIDS	<u>Serology examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate	
Serum	Antibody/antigen detection for: CMV IgM and IgG Measles IgG Hep A IgM and IgG Toxoplasmosis IgG Parvovirus B19 IgM and IgG EBV IgM/EBV IgG/EBNA VZ IgG	Detection by Chemiluminescence immunoassay (CLIA) on Liaison XL ESOP106 ESOP113 ESOP103 & 157 ESOP115 ESOP174 & QMSP698 ESOP173 ESOP116	B
Faeces	Detection of rotavirus	Immunochromatography using the R-BioPharm RIDA@QUICK Rotavirus/Adenovirus Combi test cassette ESOP021	A



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HUMAN BODY TISSUES/FLUIDS	<u>Molecular diagnostic activities for the purpose of clinical diagnosis</u>	In-house documented procedures as referenced and based on United Kingdom Health Security Agency (UKHSA) standards for Microbiology Investigations (SMIs) and manufacturer's instructions as appropriate	A
Urine, Vulvo-vaginal swab, rectal swab, throat swab, eye swab, urethral swab	Detection genito-urinary pathogens	Flexible Scope for targets detected by Qiagen NeuMoDx 96 Molecular System and NeuMoDx real time PCR Assays Flexible scope protocols: ESOP 198 ESOP 266 ESOP 267 Flexible scope limited to the application of these methods for the detection of additional targets listed in QMSR068 Flexible Scope ETS record	
Serum/ plasma	Detection of bloodborne viruses (qualitative and quantitative)	Flexible Scope for targets detected by Qiagen NeuMoDx 96 Molecular System and NeuMoDx real time PCR Assays Flexible scope protocols: ESOP 198 ESOP 266 ESOP 267 Flexible scope limited to the application of these methods for the detection of additional targets listed in QMSR068 Flexible Scope ETS record	A



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Vesicle, lesion and ulcer swabs, fluids and crusts	Detection of:	Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by Artus kits ESOP 257 ESOP 258 ESOP 226	A
Eye swab	Herpes Simplex Virus 1 & 2 Varicella Zoster Virus Detection of:	Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by Artus kits ESOP 257 ESOP 258 ESOP 226	A
Genital swabs	Herpes Simplex Virus 1 & 2 Varicella zoster Adenovirus Detection of Herpes Simplex Virus 1 & 2	Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by Artus Kit ESOP 257 ESOP 258E SOP226	A
Throat swabs Nasopharyngeal swabs using eNaat swabs	Detection of RNA targets of : B-beta coronavirus E gene and S gene	Extraction by Qiagen QIASymphony and detection by Rotor Gene Q by RealStar by Altona diagnostics using RT PCR	A
Eye, throat, and rectal swabs	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i>	Cepheid GeneXpert using the Dual cartridge assay ESOP056	A



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Faeces	Detection of norovirus	Cepheid GeneXpert using the single Xpert Norovirus GI/II cartridge assay ESOP275	A
Nasopharyngeal swab	Detection of SARS-CoV-2, Influenza A/B, and RSV	Cepheid GeneXpert using the 4 plex Xpert SARS-CoV-2, Flu A FluB & RSV cartridge assay ESOP275	A
Nasopharyngeal swab	Detection of SARS-CoV-2, Flu A and Flu B	Detection by single cartridge PCR using the Roche Liat ESOP272	A.B
END			