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



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ISO 15189:2012**

**Issue No: 006      Issue date: 24 August 2023**

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**Testing performed at the above address only**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant
Whole Blood	General isolation and characterisation of micro-organisms of clinical significance	Automated culture using : BacT/Alert blood culture system: SOP RWF-MIC-SOP3  Vitek2 automated identification and susceptibility test system: SOP RWF-MIC-SOP80
Swabs,tissues and fluids from various body sites.	Isolation,identification and antimicrobial susceptibility testing of bacterial isolates of clinical significance including manual microscopy when applicable	<u>Manual culture and microscopy.</u> RWF-MIC-SOP34 RWF-MIC-SOP4 RWF-MIC-SOP55 RWF-MIC-SOP32 RWF-MIC-SOP71 RWF-MIC-SOP52 RWF-MIC-SOP51 RWF-MIC-SOP56 RWF-MIC-SOP94 RWF-MIC-SOP54 RWF-MIC-SOP68 RWF-MIC-SOP64 RWF-MIC-SOP92 RWF-MIC-SOP73 RWF-MIC-SOP65 RWF-MIC-SOP50



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant (continued)
Urine	Isolation, identification and antimicrobial susceptibility testing of bacterial isolates of clinical significance and enumeration of blood cells by manual microscopy.	<u>Automated culture</u> using Mast Urisystem RWF-MIC-SOP10  <u>Manual method</u> RWF-MIC-SOP10
Faeces	Culture and isolation of gastrointestinal pathogens	Manual culture RWF-MIC-SOP41
Faeces	Detection of GDH	<u>DS2</u> ELISA (Premier) RWF-MIC-SOP37
	Detection of GDH & C.difficile A & B toxin	<u>Palette tests</u> Immunocard RWF-MIC-SOP37
	Detection of C.difficile gene	<u>PCR</u> Meridian Illumigene RWF-MIC-SOP37
	<u>Parasitology</u>	
Faeces and other samples	Microscopy for endoparasites.	Light Microscopy Faecal parasites RWF-MIC-SOP42
Faeces	Microscopy for ova and cysts including cryptosporidia	Ethyl acetate concentration and auramine phenol stained slides RWF-MIC-SOP42
	<u>Screening Specimens</u>	
Swabs for screening (infection control)	Glycopeptide Resistant Enterococci (GRE) Screening	Manual culture RWF-MIC-SOP33
Swabs for screening (infection control)	Carbapenamase (CPE) screening	Manual culture RWF-MIC-LI141 RWF-MIC-SOP33
Swabs for screening (infection control)	MRSA Screening	RWF-MIC-SOP31



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant (continued)
Urine	Screening for Legionella antigen	Tru Legionella RWF-MIC-SOP10
Urine	Screening for Pneumococcal antigen	Tru Pneumococci RWF-MIC-SOP10
	<u>Mycology</u>	
Skin scrapes, nails & hair	Mycology identification primarily for dermatophytes	Manual culture and UV microscopy RWF-MIC-SOP11
Nasopharyngeal aspirates	Human Respiratory Syncytial Virus (RSV)	RSV Respi-strip RWF-MIC-SOP58
	<u>Molecular</u>	
Sexual health screening	Chlamydia trachomatis and N.gonorrhoeae detection	NAATS using Roche Cobas 4800 RWF-MIC-SOP38
Faeces	PCR screening for enteric pathogens: Salmonella Shigella Campylobacter E.coli 0157	Automated PCR method Enteric Bio gastro panel 2 RWF-MIC-SOP 99
Oropharyngeal, nasopharyngeal swabs and nasopharyngeal aspirates	Detection of SARS-CoV-2 RNA (COVID-19) specific gene sequences, orf1ab and E gene RNA	Launch Anatolia Bosphore novel Coronavirus PCR Detection kit V 2.0 with Perkin Elmer Prepito D and Chemagic 360 extraction instruments, and ThermoFisher ABI 7500 and QuantStudio 5 thermocyclers, RWF-MIC-SOP119



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant (continued)
Oropharyngeal, nasopharyngeal swabs and nasopharyngeal aspirates	Differentiated detection of SARS-CoV-2, Influenza A virus, Influenza B virus and RSV using N and RdRp genes	Bruker Hain FluoroType SARS-CoV-2/Flu/RSV PCR assay with GenoXtract extraction instruments and Fluorocycler XT thermocycler RWF-MIC-SOP119
	<u>Serology</u>	
	Detection of:	<u>Automated serology</u> Dynex DS2 Analyser RWF-MIC-SOP20
Blood ( Serum)	Measles IgG	Virion Serion Measles IgG SOP RWF-MIC-SOP25
Faeces	H.pylori antigen detection	Dynex DS2 analyser Launch HPSa kit RWF-MIC-SOP102
		Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme (IDPS) screening programme as defined in the 'NHS Infectious Diseases in Pregnancy Screening Programme: laboratory quality assurance evidence requirements'.
Blood (Serum)	Detection of:	<u>Automated serology</u> Biomerieux Vidas analyser RWF-MIC-SOP29 Using test kit specified:
	HIV 1&2 Antibody	Vidas HIV duo Ultra RWF-MIC-SOP6
	Hepatitis B Surface Antigen	Vidas HBsAg Ultra RWF-MIC-SOP 9



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HUMAN BODY FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions as relevant (continued)
Blood (Serum) (cont'd)	Detection of: (cont'd)	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme (IDPS) screening programme as defined in the 'NHS Infectious Diseases in Pregnancy Screening Programme: laboratory quality assurance evidence requirements'.
	Hepatitis B core antibody	<u>Automated serology</u> Biomerieux Vidas analyser RWF-MIC-SOP29 Using test kit specified:  Vidas Anti-HBc total 11 RWF-MIC-SOP17
	CMV IgG	Vidas CMV IgG RWF-MIC- 18
	CMV IgM	Vidas CMV IgM RWF-MIC-SOP19
	Hepatitis A IgM	Vidas HAV IgM RWF-MIC-SOP22
	Varicella Zoster (VZV) IgG	Vidas VZV IgG RWF-MIC-SOP13
	Lyme IgG	Vidas Lyme IgG RWF-MIC-SOP24
	Lyme IgM	Vidas Lyme IgM RWF-MIC-SOP24
	Toxoplasma antibody	Vidas Toxo Comp RWF-MIC-SOP28



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Blood (Serum)	Detection of:	<u>Automated serology</u> Abbott Architect analyser RWF-MIC-LI126 Using test kit specified:
	Rubella IgG	ARC Rubella IgG RWF-MIC-SOP30
	Syphilis antibody	ARC syphilis RWF-MIC-SOP 27
	Hepatitis B surface Antigen	ARC HBsAg Qual II RWF-MIC-SOP9
	HIV testing	ARC HIVAg/Ab RWF-MIC-SOP6
	Hepatitis C Ab	ARC Anti-HCV RWF-MIC-SOP23
	Hepatitis B antibody	ARC Anti-HBs & ARC Anti-HBc II RWF-MIC-SOP17
	EBV IgM	ARC EBC IgM RWF-MIC-SOP21
	Hepatitis B Core Antibody	RWF-MIC-SOP15
END		