


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>Acculabs Diagnostics UK Ltd</h3> <p>Issue No: 006 Issue date: 26 August 2021</p>	
	<p>Unit 12 & 14 Wynyard Park Business Village Billingham Teesside TS22 5TB</p>	<p>Contact: Kay Pott Tel: +44 (0)1740 644439 Fax: +44 (0) 1740 661438 E-Mail: kay.pott@acculabsdiagnostics.co.uk Website: www.acculabsdiagnostics.co.uk</p>
<p>Testing performed at the above address (Unit 14) only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Molecular Biology examination activities for the purpose of clinical diagnosis:</u>	Documented In-house methods using analysers specified
Urines, genital, throat and rectal swabs	Detection of all variants of <i>Chlamydia trachomatis</i> cryptic plasmid and genomic DNA	Roche Cobas 4800 multiplex screening system utilising amplification of target DNA by real time PCR and nucleic acid hybridisation. ALD/CLAM/014
Anogenital swabs	Detection of DR-9 specific <i>Neisseria gonorrhoea</i> DNA	Roche Cobas 4800 multiplex screening system- real time PCR and nucleic acid hybridization. ALD/CLAM/014
	<i>Herpes simplex</i> 1 and 2	Roche Cobas 4800 multiplex screening system utilising amplification of target DNA by real time PCR and nucleic acid hybridization ALD/CLAM/17
Urine, vaginal, endocervical, throat and rectal swabs	<i>Neisseria gonorrhoeae</i> confirmation	Cepheid GeneXpert Nucleic Acid Amplification Technique NAAT assay ALD/CLAM/18 V1



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS cont'd	<u>Serology examination activities for the purpose of clinical diagnosis:</u>	Documented In-house methods using analysers and methods specified
Serum/Plasma	Hepatitis B surface antigen (HBsAg)	Roche Cobas e601 using electrochemiluminescence immunoassay SOP ALD/SER/01
Serum/Plasma	Hepatitis B surface antibody (Anti HBs)	
Serum/Plasma	Hepatitis B core antibody (Anti HBc)	
Serum/Plasma	Hepatitis C antibody (Anti HCV)	
Serum/Plasma	Hepatitis A IgM antibody	
Serum/Plasma	Hepatitis A total antibody	
Serum/Plasma (including capillary)	HIV Ag/Ab Combo (Anti HIV1/2 and HIV1p24 Ag)	
Serum/Plasma (including capillary)	Syphilis total antibody	
	Confirmation testing of Syphilis serology:	
Serum/Plasma	Syphilis IgG	Mikrogen Syphilis IgG ELISA ALD/SER/002 Biochrom EZ read Microplate 400 reader ALD/SER/006
Serum/Plasma	Syphilis IgM	Mikrogen Syphilis IgM ELISA ALD/SER/003 Biochrom EZ read Microplate 400 reader ALD/SER/006
Serum/Plasma	<i>Treponema pallidum</i> antibody	New-Bio TPHA haem-agglutination ALD/SER/005
Serum/Plasma	<i>Treponema pallidum</i> antigen	New-Bio Rapid Plasma Reagin kit Manual latex agglutination ALD/SER/004 Interpretation of Syphilis confirmation testing ALD/SER/007



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<p>HUMAN BODY FLUIDS cont'd</p> <p>Combined throat / nasal swabs in viral transport media</p> <p>Samples self-collected or collected by a Provider accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and who is listed on the DHSC Approved Lists for General Population and/or Test to Release (5 and 8 day) testing</p> <p>Saliva</p> <p>Samples self-collected or collected by a Provider accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and who is listed on the DHSC Approved Lists for General Population testing</p>	<p><u>Molecular Biology examination activities for the purpose of clinical diagnosis:</u></p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; N gene, E gene</p> <p>for: General population, Test to Release Day 5, Day 2 and 8 international arrival testing</p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; N gene, E gene</p> <p>for: General population testing</p>	<p>Documented In-house methods using analysers specified</p> <p>VirPath Bead Xtract Viral DNA/RNA Kit and VirPath SARS-CoV-2 Multiplex qRT-PCR Kit. Equipment MGISP-960 SOP ALD COV 01, and Agilent AriaMX SOP ALD COV 02</p> <p>VirPath Bead Xtract Viral DNA/RNA Kit and VirPath SARS-CoV-2 Multiplex qRT-PCR Kit. Equipment MGISP-960 SOP ALD COV 01, and Agilent AriaMX SOP ALD COV 02</p>
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