


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 7568</p> <p>Accredited to ISO 15189:2012</p>	<p>Preventx Limited</p> <p>Issue No: 006 Issue date: 09 December 2021</p>	
	<p>Preventx Limited MBP 4 & 5 Meadowhall Business Park Carbrook Hall Road Sheffield S9 2EQ</p>	<p>Contact: Natalie Loeber Tel: +44 (0)333 344 4462 E-Mail: natalie.loeber@preventx.com Website: www.preventx.com</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Urine (male & female) and vulvo-vaginal swabs Rectal swabs Pharyngeal swabs</p>	<p><u>Molecular Biology Tests</u></p> <p>Detection of <i>Chlamydia trachomatis</i> (CT) chromosomal and plasmid DNA including the Swedish variant strain and all 15 major serovars</p> <p>Screening for <i>Neisseria gonorrhoeae</i> (NG) DNA including wild-type and variant within the DR-9 sequence region</p>	<p>Documented In-House Methods</p> <p>Roche Cobas 6800/8800 analyser (dual testing platform) SOP-03</p>
<p>Urine and Vaginal Swabs</p>	<p>Direct detection of <i>Trichomonas vaginalis</i> (TV) and <i>Mycoplasma genitalium</i> (MG)</p>	<p>Roche Cobas 6800/8800 analyser/TV/MG assay - real-time polymerase chain reaction (PCR) SOP-03</p>
<p>Urine stabilised in PCR media Vulvo-vaginal swabs stabilised in PCR media Rectal swabs stabilised in PCR media Pharyngeal swabs stabilised in PCR media</p>	<p>Detection of <i>Neisseria gonorrhoeae</i> target DNA (opa, porA)</p>	<p>Roche MagNA Pure Compact preparation workstation and the Roche Cobas z 480 thermocycler amplification equipment SOP-06</p>
<p>Urine, pharyngeal / vaginal / rectal swabs</p>	<p>Detection of <i>Neisseria gonorrhoeae</i> target DNA (16S rRNA, porA)</p>	<p>Maxwell RSC48 (extraction platform) and the GeneProof amplification kit on the Roche Light cycler SOP-21</p>



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Issue No: 006 **Issue date:** 09 December 2021

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Serum	<u>Serology tests</u> Detection of HIV 1 and 2 antibodies and HIV1 p24 antigen	Roche HIV Duo assay on the Roche Cobas e801 electrochemiluminescence analyser SOP-04
Serum	Detection of <i>Treponema pallidum</i> (Syphilis) antibody (screening)	Roche Cobas e801 electrochemiluminescence analyser SOP-04
Serum	Non-Treponemal Syphilis (reagin) antibodies - confirmatory testing	Manual Rapid Labs RPR (Rapid Plasma Reagin) test kit. SOP-23 RPR
Serum	Treponema pallidum antibodies - confirmatory testing	Manual Rapid Labs TPHA test kit. SOP-22
Serum	Detection of Hepatitis B surface antigen (screening)	Roche Cobas e801 electrochemiluminescence analyser SOP-04
Serum	Detection of Hepatitis B core antibody (screening)	Roche Cobas e801 electrochemiluminescence analyser SOP-04
Serum	Detection of Hepatitis C antibody (screening)	Roche Cobas e801 electrochemiluminescence analyser SOP-04

END