


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 7568</p> <p>Accredited to ISO 15189:2022</p>	<h3>Preventx Limited</h3> <p>Issue No: 009    Issue date: 27 February 2025</p>	
	<p>Preventx Limited MBP 4 &amp; 5 Meadowhall Business Park Carbrook Hall Road Sheffield S9 2EQ</p>	<p>Contact: Carly Lattimore Tel: +44 (0) 770 634 4557 E-Mail: carly.lattimore@preventx.com Website: www.preventx.com</p>
<p><b>Testing performed at the above address only</b></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 Tests</u>	Documented In-House Methods
Urine (male & female) and vulvo-vaginal swabs Rectal swabs Pharyngeal swabs	Detection of <i>Chlamydia trachomatis</i> (CT) chromosomal and plasmid DNA including the Swedish variant strain and all 15 major serovars	Roche Cobas 6800/8800 analyser (dual testing platform) SOP-03
Urine and Vaginal Swabs	Screening for <i>Neisseria gonorrhoeae</i> (NG) DNA including wild-type and variant within the DR-9 sequence region	
Urine and Vaginal Swabs	Direct detection of <i>Trichomonas vaginalis</i> (TV) and <i>Mycoplasma genitalium</i> (MG)	Roche Cobas 6800/8800 analyser/TV/MG assay - real-time polymerase chain reaction (PCR) SOP-03
Urine stabilised in PCR media Vulvo-vaginal swabs stabilised in PCR media Rectal swabs stabilised in PCR media Pharyngeal swabs stabilised in PCR media	Detection of <i>Neisseria gonorrhoeae</i> target DNA (opa, porA)	Roche MagNA Pure Compact preparation workstation and the Roche Cobas z 480 thermocycler amplification equipment SOP-06
Urine, pharyngeal / vaginal / rectal swabs	Detection of <i>Neisseria gonorrhoeae</i> target DNA (16S rRNA, porA)	Maxwell RSC48 (extraction platform) and the GeneProof amplification kit on the Roche Light cycler SOP-21
Serum	HCV RNA	Roche Cobas 6800/8800 analyser (dual testing platform) SOP-03
Urine sample, Vaginal / Pharyngeal / Rectal swab	Detection of <i>Neisseria gonorrhoeae</i> DNA (piv recombinant gene)	Roche Cobas 6800/8800 Omni channel analyser SOP-03



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HUMAN BODY FLUIDS (cont'd)	<u>Serology tests</u>	
Serum	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	<i>Treponema pallidum</i> 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		