


# 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>Preventx Limited</h3> <p>Issue No: 001    Issue date: 22 November 2019</p>	
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<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
<p><b>HUMAN BODY FLUIDS</b></p> <p>Urine (male &amp; female) and vulvo-vaginal swabs Rectal swabs Pharyngeal swabs</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>Serum</p>	<p><u>Molecular Biology Tests</u></p> <p>Detection of <i>Chlamydia trachomatis</i> chromosomal and plasmid DNA including the Swedish variant strain and all 15 major serovars</p> <p>Screening for <i>Neisseria gonorrhoeae</i> DNA including wild-type and variant within the DR-9 sequence region</p> <p>Detection of <i>Neisseria gonorrhoeae</i> target DNA (opa, porA)</p> <p><u>Serology tests</u></p> <p>Detection of HIV 1 and 2 antibodies and HIV1 p24 antigen</p>	<p>Documented In-House Methods</p> <p>Roche Cobas 6800 Analyser (dual testing platform) for both the preparation and amplification of DNA for the provision of the result to healthcare professionals Documented in-house methods – PRO-10</p> <p>Roche MagNA Pure Compact preparation workstation and the Roche Cobas z 480 thermocycler amplification equipment for the provision of the result to healthcare professionals Documented in-house methods – PRO-10</p> <p>PRO-10 using Roche HIV Duo assay on the Roche Cobas e801 electrochemiluminescence analyser for screening purposes for the provision of the result to healthcare professionals</p>



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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)	Serology tests (cont'd)	Documented In-House Methods
Serum	Detection of <i>Treponema pallidum</i> (Syphilis) antibody	PRO-10 using Roche Cobas e801 electrochemiluminescence analyser for screening purposes for the provision of the result to healthcare professionals
Serum	Non-Treponemal Syphilis confirmatory testing	PRO-10 using manual RPR card test - RPR Reditest Biokit with in-house documented procedures
Serum	Treponemal Syphilis confirmatory testing	PRO-10 using manual Syphagen TPHA assay from Biokit
Serum	Detection of Hepatitis B surface antigen II	PRO-10 using Roche Cobas e801 electrochemiluminescence analyser for screening purposes for the provision of the result to healthcare professionals
Serum	Detection of Hepatitis B core antibody II	PRO-10 using Roche Cobas e801 electrochemiluminescence analyser for screening purposes for the provision of the result to healthcare professionals
Serum	Detection of Hepatitis C antibody II	PRO-10 using Roche Cobas e801 electrochemiluminescence analyser for screening purposes for the provision of the result to healthcare professionals
END		