


 UK Health Security Agency	Severn Pathology				 North Bristol NHS Trust
	SOP Name	Extension to Scope of Accredited Activity			
	SOP Number	GP/PQFM/2 IS/QST004	Version	2.0	
	Authoriser	Deborah Williams	Date	31.01.25	

### **Department of Infection Sciences - Extension to Scope of Accreditation**

Severn Pathology will comply with the requirements of all relevant regulatory bodies and is committed to the use of examination procedures that will ensure the acceptable quality of all tests performed and are fit for their intended use.

The accredited scope of activity for the department is given in the UKAS schedule. From time to time, amendments to this scope may be required, examples include addition of new tests or changes to test methodology. In such cases, the department will apply for Extension to Scope from UKAS. The following tests are currently in this process.

Activity	Sample type	Comments
<b>Reporting of <i>Treponema pallidum</i> latex assay (TPLA) syphilis confirmation assay</b>	Serum/plasma	ETS methodology change from manual TPPA to TPLA on Beckman AU
<b>Hepatitis IgG &amp; IgM</b>	Serum/plasma	ETS methodology change from Fortress manual EIA to Diasorin Liaison XL
<b><i>Mycoplasma genitalium</i> NAAT</b>	Genital samples	New test ETS for Hologic Panther
<b><i>Trichomonas vaginalis</i> NAAT</b>	Endocervical & vaginal swabs	New testing location ETS for Hologic Panther at North Bristol Trust
<b>VZ IgG HT</b>	Serum/plasma	ETS methodology change from VZ IgG CLIA to VZ IgG high throughput CLIA on Liaison XL
<b>Flu A/Flu B/RSV/SCV2 – RES4 assay</b>	Nose & throat swabs	ETS methodology change from Hologic Panther to Hologic Panther Fusion
<b>CSF bacterial, viral &amp; fungal targets</b>	CSF	New methodology ETS Biomerieux Biofire (ME panel)
<b>HIV viral load</b>	Serum	New methodology ETS Hologic Aptima on Hologic Panther
<b>HBV viral load</b>	Serum/plasma	New methodology ETS Hologic Aptima on Hologic Panther
<b>HCV viral load</b>	Serum/plasma	New methodology ETS Hologic Aptima on Hologic Panther
<b>Blood cultures</b>	Blood	New testing location ETS for BD Bactec FX at Weston site
<b>MSSA screening</b>	Nose, groin & wound swabs	New methodology ETS Kiestra semi-automated inoculation, incubation and reading
<b>Wound swab culture</b>	Wound swabs	New methodology ETS Kiestra semi-automated inoculation, incubation and reading
<b>Enteric bacterial, viral &amp; parasitic targets</b>	Faeces	New test ETS for SeroSep EntericBio (DX, C. diff, Viral 3)
<b>Aspergillus specific PCR</b>	EDTA blood, serum, BAL	New test ETS commercial PCR
<b>Candida specific PCR</b>	EDTA blood, serum, BAL	New test ETS commercial PCR
<b>Mucorales specific PCR</b>	EDTA blood, serum, BAL	New test ETS commercial PCR

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<b>Panfungal PCR</b>	Pericardial fluid, tissue	New test ETS laboratory developed PCR
<b>Pneumocystis specific PCR</b>	EDTA blood, serum, BAL	New test ETS commercial PCR
<b>Antibody detection of dimorphic fungi (Histoplasma sp., &amp; Coccidioides sp.)</b>	EDTA blood, serum	Change from CFTs to manual IMMY latex agglutination.
<b>Antibody detection of Coccidioides sp.</b>	EDTA blood, serum, CSF	Change from CFTs to manual IMMY lateral flow test (LFT)
<b>Antibody detection of Blastomyces sp. &amp; Coccidioides sp.</b>	EDTA blood, serum	Change from CFTs to manual IMMY EIA