

 UK Health Security Agency	Severn Pathology				 North Bristol NHS Trust
	SOP Name	Extension to Scope of Accredited Activity			
	SOP Number	IS/QST004 (GP/PQFM/2)	Version	2.1	
	Authoriser	Deborah Williams	Date	31.04.26	

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 defined in the relevant UKAS schedule.

N.B. Accreditation applies solely to the sample types specified therein for each method. Sample types not validated by the manufacturer or laboratory fall outside the accredited scope however, testing may be undertaken where there is a clinical need. Contact the relevant clinical team.

Amendments to the laboratory's accredited scope may be required periodically, for example to incorporate new tests or changes to existing methodologies. In such instances, the department will apply to UKAS for an Extension to Scope. The following tests are currently undergoing this process.

Activity	Sample type	Comments
Reporting of TPLA syphilis confirmation assay	Serum/plasma	ETS assessed and recommended for accreditation
Hepatitis IgG & IgM	Serum/plasma	ETS assessed and recommended for accreditation
<i>Mycoplasma genitalium</i> NAAT	Genital samples	ETS assessed and recommended for accreditation
<i>Trichomonas vaginalis</i> NAAT	Endocervical & vaginal swabs	ETS assessed and recommended for accreditation
VZ IgG HT	Serum/plasma	ETS assessed and recommended for accreditation
Flu A/Flu B/RSV/SCV2 – RES4 assay	Nose & throat swabs	ETS assessed and recommended for accreditation
CSF bacterial, viral & fungal targets	CSF	ETS assessed and recommended for accreditation subject to clearance of findings
HIV viral load	Serum	ETS assessed and recommended for accreditation
HBV viral load	Serum/plasma	ETS assessed and recommended for accreditation
HCV viral load	Serum/plasma	ETS assessed and recommended for accreditation
Blood cultures	Blood	ETS assessed and recommended for accreditation
MSSA screening	Nose, groin & wound swabs	ETS assessed and recommended for accreditation
Wound swab culture	Wound swabs	ETS assessed and recommended for accreditation
Enteric bacterial, viral & parasitic targets	Faeces N.B Formed stool samples are not validated for this test	ETS assessed and recommended for accreditation subject to clearance of findings

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The following methods are undergoing further development to strengthen monitoring processes before an application for an extension to scope can be submitted; however, they remain subject to the same quality management system as methods currently within the laboratory's accredited scope.

Activity	Sample type	Comments
Aspergillus specific PCR	EDTA blood, serum, BAL	Not accredited at present. Monitored via the laboratory quality management system
Candida specific PCR	EDTA blood, serum, BAL	Not accredited at present. Monitored via the laboratory quality management system
Mucorales specific PCR	EDTA blood, serum, BAL	Not accredited at present. Monitored via the laboratory quality management system
Panfungal PCR	Pericardial fluid, tissue	Not accredited at present. Monitored via the laboratory quality management system
Pneumocystis specific PCR	EDTA blood, serum, BAL	Not accredited at present. Monitored via the laboratory quality management system