

SOP Name Template ref SOP Number Authoriser

Severn Pathology

Extension to Scope of Accredited Activity GP/PQFM/2

IMMQ0111 Ellen Roberts

Version 1.2 Date 18/09/2024



Department of Immunology

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/Test	Sample Type/s	Comments
Anti-MPO/PR3	Serum	ETS platform change from Dynex DS2 QUANTA Lite ELISA to ImmunoCAP 250 ELIA
Anti-GBM	Serum	ETS platform change from Dynex DS2 QUANTA Lite ELISA to ImmunoCAP 250 ELIA
Anti-β2-Glycoprotein 1	Serum	ETS new assay by ImmunoCAP 250 ELiA
Anti-Cardiolipin IgM	Serum	ETS new assay by Dynex DS2 QUANTA Lite ELISA
Neutrophil Function:	Heparinised plasma	ETS reagent change from Phagoburst kit to DHR123 kit,
Oxidative Burst		both on FACSLyric Flow Cytometer.
Alkaline Phosphatase Isoenzymes	Serum	New assay by Sebia Hydrasys 2 Scan Electrophoresis
Oligoclonal Bands	Serum/CSF	New assay by Sebia Hydrasys 2 Scan Electrophoresis
Avian Precipitins	Serum	New assay by ImmunoCAP 250 Allergy
CH50/AP50	Serum	ETS method change from Radial Immunodiffusion (RID) to turbidimetry on the Binding Site Optilite
Alpha-1 Antitrypsin	Serum	ETS method change from Binding Site Optilite to Beckman AU.
β2-microglobulin	Serum	ETS method change from Binding Site Optilite to Beckman AU.
Immunoglobulins (IgG, IGA, IgM)	Serum	ETS method change from Binding Site Optilite to Beckman AU.