

SOP Name SOP Number Authoriser

Severn Pathology

Extension to Scope of Accredited Activity
GP/PQFM/2 Version 1.0
Paul Virgo Date



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	Comments
Treponemal pallidum latex assay (TPLA) – syphilis confirmation assay on the Beckman AU	New test. An application will be submitted to UKAS for extension to scope of accreditation.
Hepatitis IgG & IgM on the Diasorin Liaison XL	Change of assay. An application will be submitted to UKAS for extension to scope of accreditation.
M. genitalium NAAT on the Hologic Panther	New test. An application will be submitted to UKAS for extension to scope of accreditation
Detection of Flu A/Flu B/ RSV/SCV2 - RES4 assay on the Hologic Panther Fusion	Change of assay. An application will be submitted to UKAS for extension to scope of accreditation.
CSF testing for bacterial/viral and fungal targets on the Biomerieux Biofire	New test. An application will be submitted to UKAS for extension to scope of accreditation
Antibody detection of dimorphic fungi	Change of assay. An application will be submitted to UKAS for extension to scope of accreditation.
Panfungal PCR	New test. An application will be submitted to UKAS for extension to scope of accreditation
Aspergillus specific PCR	New test. An application will be submitted to UKAS for extension to scope of accreditation
Candida specific PCR	New test. An application will be submitted to UKAS for extension to scope of accreditation
Mucorales specific PCR	New test. An application will be submitted to UKAS for extension to scope of accreditation
Pneumocystis specific PCR	New test. An application will be submitted to UKAS for extension to scope of accreditation