

Notice

Document Reference: NOT/QMS/2/3



Royal United Hospitals Bath
NHS Foundation Trust

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TITLE:	Extension to scope & unaccredited tests
ACTIVE DATE:	12/09/2024

RUH 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 they remain 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 (ETS) from UKAS. The following tests are currently in/or require this process to be undertaken:

Biochemistry

Assay	Reason not accredited
Faecal Elastase	New assay
Faecal Calprotectin	ETS required
Serum Protein Electrophoresis & Immunotyping	ETS required
Cryoglobulins	Addition to scope of accreditation

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Haematology

Assay	Reason not accredited
Antithrombin 3	ETS required
Blood films	ETS required
DOACs	ETS required
Factor Assays	ETS required
Haemoglobinopathy Screen	ETS required
HBA1c	ETS required
Heparin Assays	ETS required
Lupus anticoagulants	ETS required
Malaria ICT	Change in manufacturer of ICT strip
Mixing studies	ETS required
Protein C	ETS required
Protein S	ETS required
Ricof	ETS required
VWF ag	ETS required

Histology

Assay	Reason not accredited
Arginase	Validation in progress
DOG1	Recently validated
Glypican 3	Validation in progress
HepPAR1	Validation in progress
HSV1	Recently validated
Trep. Pallidum	Recently validated
BAP-1	Validated – Using research use only antibody

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Immunology

Assay	Reason not accredited
anti-B2-GP1 (IgG & IgM) - ELISA	ETS required – post receipt of MES equipment

Please refer to our UKAS [schedule of accreditation](#) for a list of accredited activities.