

Pathology Tests Outside Current Scopes of Accreditation: September 2020

UKAS requires that Pathology services accredited to BS EN ISO 15189:2012 make clear to their users if any tests within their repertoire are not included in their scope of accreditation. This is usually due to an extension to scope application and is routine for any significant delay within the laboratory. Any such examinations are listed below with a description of the reason for not being on the published schedule of accreditation.

Where this is the case, services users can have confidence in the results of these tests as the Laboratories will operate them under the same stringent conditions of quality and competence as for accredited tests and will usually be working to achieve accreditation of the tests. The scope of any laboratory's accreditation may be reviewed at the UKAS website via this link and using the reference numbers below:

<https://www.ukas.com/services/accreditation-services/medical-laboratory-accreditation-iso-15189>

8097 Blood Sciences

9929 Histopathology & Cytopathology

8458 Medical Microbiology

8444 Cytogenetics

9839 Haemato-oncology (Immunophenotyping)

20653 Molecular Diagnostics

Departments with Tests Currently Unaccredited:

Department	Test	Plan
Blood Sciences	Biochemistry: Cryoglobulins Chylomicrons	Remain out of scope Remain out of scope
	Thyroglobulin and Anti-thyroglobulin on the Diasorin Liaison XL	ETS to follow
	SARS-CoV-2 PCR test on the Cepheid GeneXpert	ETS to follow
	SARS-CoV-2 IgG antibody test on the Ortho Clinical Diagnostics Vitros 5600	ETS to follow

The ROYAL MARSDEN

	Blood Transfusion: Blood Grouping ABO Confirmation Rh & K Phenotyping DAT Antibody ID	ETS application has been sent to UKAS
Histopathology	All in scope	
Medical Microbiology	Adenovirus, rotavirus, norovirus, measles, and VZV	Extension to scope has been recommended by UKAS (clearances ongoing)
Cytogenetics	All in scope	
Immunophenotyping	All in Scope	
Molecular Diagnostics	New UKAS number, equipment and building work	Initial assessment clearances are with UKAS, accreditation has been recommended.

Referral tests: A number of tests will be referred to other specialist laboratories and not provided onsite. These tests are expected to be UKAS accredited to ISO15189 and this is reviewed annually in all laboratories to verify accreditation status. Any tests referred without accreditation

For further details, please contact Helen Phillips, Pathology Quality Manager:

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