

List of currently non-accredited tests

Microbiology (8050) Service	Test provided	Tests / process variation
Microbiology	FTD Viral Meningitis assay (Mumps, Parechovirus, VZV, HSV 1&2 and Enterovirus)	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	BD Enteric viral PCR test (Norovirus, Sapovirus, Astrovirus, Rotavirus & adenovirus)	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment. The other 3 virus targets not fully validated to ISO 15189 standard at time of assessment
Microbiology	Bocavirus PCR	Test not fully validated to ISO 15189 standard at time of assessment
Microbiology	Detection of DNA for Pneumocystis jirovecii	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Glactomanan LFA	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	PVL PCR	Change of Platform to ABI prism 7500. Verification has now been completed. Application to reflect new detection platform through ETS, April 2023 UKAS assessment.
Microbiology	Liaison Parvovirus IgG/M on Diasorin Liaison	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Liaison Chlamydia trachomatis IgG on Diasorin Liaison	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Liaison Quantiferon on Diasorin Liaison	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Cepheid GeneXpert SARS-CoV-2 FluA/B and RSV test	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Bosphore SARS CoV-2 PCR assay	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Cepheid GeneXpert SARS CoV-2 PCR assay	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Abbott Alinity SARS CoV-2 PCR assay	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Abbott Alinity Chlamydia and Gonorrhoea PCR assay	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.

Microbiology	Qiasat DX Respiratory panel including SARS CoV-2	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Syphilis RPR (ASI Kit)	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Covid S Antibody assay	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Cepheid GeneXpert carbapenemase detection	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Cepheid GeneXpert MTB/Rif detection	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.
Microbiology	Group B strep enrichment screening for GBS3 clinical trial	Trial organisers suggested not required at the time trial started. 2-year trial, after which if the test is adopted as routine in the laboratory, UKAS accreditation will be sought. Method follows that given by UK HSA.
Microbiology	Testing of heater cooler unit waters for mycobacteria	Outside scope of ISO 15189 as environmental water sample testing. EQA is in place for this via FEPTU. Method follows that recommended by UK HSA. Reports issued with comment about test not being UKAS accredited.
Microbiology	Biomerieux Vidas: CMVG, Toxoplasma G and EBNA/CA IgG	Verification has now been completed. Application to return this to scope through an ETS, April 2023 UKAS assessment.

Combined laboratory (9088) Service	Test provided	Tests / process variation
Biochemistry	CSF-AFP	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	CSR - Cytospin	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	CSF - Ferritin	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	CSF - hCG	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	CSF - Lactate	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	CSF - LDH	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Albumin	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Amylase	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Bilirubin	Test not fully validated to ISO 15189 standard at time of assessment

Biochemistry	Fluid Cholesterol	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Chloride	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Bicarbonate	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Creatinine	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Glucose	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Potassium	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid LDH	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Lipase	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Sodium	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Protein	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Triglyceride	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid Urea	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid AFP	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid CA125	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid CA19-9	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid CEA	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	Fluid hCG	Test not fully validated to ISO 15189 standard at time of assessment
Biochemistry	HbA1C	New equipment, different manufacturer, changed from TOSOH to SEBIA. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Biochemistry	Osmolality	Change in analyser – Vitach 3320 Osmolality now performed using equipment made by a different manufacturer. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Biochemistry	HbA1C	Change in analyser from TOSOH to SEBIA (different manufacturer). New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Biochemistry	AAS Trace Metal Analysis: Trace metals – Zinc Trace metals - Copper	Now performed on the ICPMS – different equipment / manufacturer. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Biochemistry	Sherwood MKII 9265 Chloride	Change in analyser, different manufacturer, change from Sherwood MKII 9265 to ELITech Chlorocheck Chloridometer. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Blood Bank	Feto Maternal Haemorrhage screening: Manual Kleihauer	New test kit in use. Different manufacturer but same methodology. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Coagulation	Lupus Antibody Screening: (DRVVT methodology) Also now includes PTT-LA screening methodology (added 16/04/2020).	Lupus Antibody Screening – DRVVT methodology also now includes PPT-LA screening methodology. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment

Haematology	Bone Marrow Examination	Test not fully validated to ISO 15189 standard at time of assessment.
Haematology	Full Blood Count: Haemoglobin, Haematocrit, Red Cell Count, Nucleated RBC Count, Mean Cell Haemoglobin, Mean Cell Haemoglobin Concentration, Mean Cell Volume, White Cell Count (WBC), Neutrophils, Immature Granulocytes, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelet Count, Mean Platelet Volume, Reticulocyte haemoglobin, equivalent, Reticulocyte.	Test not fully validated to ISO 15189 standard at time of assessment.
Haematology	Bone Marrow Smear preparation and Stain	Test not fully validated to ISO 15189 standard at time of assessment
Haematology	Bone Marrow Smear Cell morphology	Test not fully validated to ISO 15189 standard at time of assessment
Haematology	Sickle Cell Screening	Change in analysers and methodology - from TOSOH HPLC to SEBIA using capillary electrophoresis (in addition to manual screening methods. New test kit, change from Microgen to Clin Tech, same methodology. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment
Haematology	Haemoglobin screening for Thalassaemia and Haemoglobin variants, quantification of HbA2, HbF and HbS	New equipment, different manufacturer, changed from TOSOH to SEBIA. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment
H&I	HLA typing of cadaveric donors (second method): HLA-A, -B and -C.	Change from PCR-SSO to LinkSeq to be run before PCR-SSO - will be dual method. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment
H&I	HLA typing of cadaveric donors (second method): DRB1	Change from PCR-SSP (Was dual method with PCR-SSO), now changed to LinkSeq to be run before PCR-SSO - will be the dual methodology in use. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment
H&I	HLA typing of cadaveric donors (second method): DRB3/4/5 – DQA1	Change from PCR-SSP to LinkSeq to be run before PCR-SSO - will be dual method. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment
H&I	HLA typing of cadaveric donors (second method): DQB1	Change from PCR-SSO to LinkSeq to be run before PCR-SSO - will be dual method. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment
Immunology	Serum Protein electrophoresis: Alpha-1 globulins Alpha-2 globulins	Change in equipment model from Helena V8 to Nexus. New methodology/equipment/kit/manufacture - accreditation is pending UKAS assessment

	Beta globulins Gamma globulins	
Immunology	Serum Free Light Chains: Kappa / Lambda ration Serum Free Kappa Serum Free Lambda IgG Sub-classes: IgG1 subclass IgG2 subclass IgG4 subclass	Change in equipment and methodology from SPA + Binding Site Turbidometer for SFL & subclasses. Different equipment / manufacturer changes from Binding Site to Optilite. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment
Molecular Biology	<u>Haemato-oncology</u> for CML, ALL and some AML: t(9;22) quantifiable minor breakpoint BCR-ABL1	Test not fully validated to ISO15189 standard at this time of assessment.
Molecular Biology	PCR with High Resolution Melt analysis using QuantStudio 6 Flex	Currently sendaway, repatriation for in-house testing. New methodology/equipment/kit/manufacturer - accreditation is pending UKAS assessment

Cellular & Anatomical Pathology (9881) Service	Test provided	Tests / process variation
Neuropathology	Histone H3 K27M mutant	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	I-12F10	Test not fully validated to ISO 15189 standard at time of assessment.
Neuropathology/ Immunocytochemistry	NI-Alpha Synuclein	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-C5-9 (MAC)	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-Caveolin 3	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-HIV	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-MBP	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-MYOTILIN	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-NNM	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-P62	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NI-TDP43	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Immunocytochemistry	NFP	Historical test pending assessment by UKAS, Application to add this to scope through an ETS, DATE tbc, UKAS assessment

Neuropathology/ Immunofluorescence	FITC Immunoglobulins: IgA, IgG, IgM	Historical test pending assessment by UKAS, Application to add this to scope through an ETS, TBC, UKAS assessment
Histopathology/Neuropathology/ Special staining	NS-Mod. Bielschowsky	Test not fully validated to ISO 15189 standard at time of assessment
Histopathology/Neuropathology/ Special staining	NS-Nissl	Test not fully validated to ISO 15189 standard at time of assessment
Histopathology/Neuropathology/ Special staining	NS-Palmgren's	Test not fully validated to ISO 15189 standard at time of assessment
Neuropathology/ Special staining	Same day Method: Melanin/Argentaffin	Historical test pending assessment by UKAS, Application to add this to scope through an ETS, TBC, UKAS assessment
Neuropathology/ Special staining	Elastin fibres	Historical test pending assessment by UKAS, Application to add this to scope through an ETS, TBC, UKAS assessment
Diagnostic Non-Gynae Cytology	Joint fluid crystals	Not diagnostic for this entity. Malignant cells only.
Histopathology/ Immunocytochemistry	BCL2 E17	V/V has now been completed. Application to add this to scope through an ETS, TBC, UKAS assessment.
Histopathology/ Immunocytochemistry	BAP-1	V/V has now been completed. Application to add this to scope through an ETS, TBC, UKAS assessment.
Histopathology/ Immunocytochemistry	MUC 2	V/V has now been completed. Application to add this to scope through an ETS, TBC, UKAS assessment.
Histopathology Immunocytochemistry	SOX10	V/V has now been completed. Application to add this to scope through an ETS, TBC, UKAS assessment.
Histopathology Immunocytochemistry	SOX11	V/V has now been completed. Application to add this to scope through an ETS, TBC, UKAS assessment.
Histopathology Immunocytochemistry	BRAFv600E	V/V has now been completed. Application to add this to scope through an ETS, TBC, UKAS assessment.
Histopathology Immunocytochemistry	CK8/18	Test not fully validated to ISO 15189 standard at time of assessment
Histopathology Immunocytochemistry	TLE protein – TLE1	Test not fully validated to ISO 15189 standard at time of assessment
Diagnostic Non-gynae	Liquid Based Cytology (LBC)	New verified process pending ETS, TBC, UKAS assessment.
Diagnostic Non-gynae	Cytological preparatory techniques	Modernisation of centrifuge equipment to Megafuge 8 and Sample integrity improvement. New verified process pending ETS, TBC, UKAS assessment
Mohs' Clinic [New Service]	Skin from Mohs' Micrographic surgery	New service pending ETS, TBC, UKAS Assessment