

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)	CE Status has now been approved and this will be added back to scope for an ETS June 2021 UKAS visit
Microbiology	BD Enteric viral PCR test (Norovirus, Sapovirus, Astrovirus, Rotavirus & adenovirus)	Verification has now been completed for Norovirus. Application to return this to scope through an ETS, June 2021 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, June 2021 UKAS assessment.
Microbiology	Glactomanan LFA	Verification has now been completed. Application to return this to scope through an ETS, June 2021 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, June 2021 UKAS assessment.
Microbiology	Liaison Parvovirus IgG/M on Diasorin Liaison	Verification has now been completed. Application to return this to scope through an ETS, June 2021 UKAS assessment.
Microbiology	Liaison Chlamydia trachomatis IgG on Diasorin Liaison	Verification has now been completed. Application to return this to scope through an ETS, June 2021 UKAS assessment.
Microbiology	Liaison Quantiferon on Diasorin Liaison	Verification has now been completed. Application to add this to scope through an ETS, June 2021 UKAS assessment. Schedule will need amending to reflect new detection platform in June 2021 UKAS visit
Microbiology	Cepheid GeneXpert FluA/B and RSV test	Verification has now been completed. Application to add this to scope through an ETS, June 2021 UKAS assessment.
Microbiology	Elitech Genefinder SARS CoV-2 PCR assay	Verification has now been completed. Application to add this to scope through an ETS, June 2021 UKAS assessment.
Microbiology	Abbott M2000 SARS CoV-2 PCR assay	Verification has now been completed. Application to add this to scope through an ETS, June 2021 UKAS assessment.
Microbiology	Cepheid GeneXpert SARS CoV-2 PCR assay	Verification has now been completed. Application to add this to scope through an ETS, June 2021 UKAS assessment.
Microbiology	Abbott Alinity SARS CoV-2 PCR assay	Verification has now been completed. Application to add this to scope through an ETS, June 2021 UKAS assessment.

Microbiology	Qiasat DX Respiratory panel including SARS CoV-2	New test: Test will not be fully validated to ISO 15189 standard at time of assessment
Microbiology	Syphilis RPR (ASI Kit)	New test: Test will not be fully validated to ISO 15189 standard at time of assessment
Microbiology	Covid S Antibody assay	New test: Test will not be fully validated to ISO 15189 standard at time of 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	Change in analysers and methodology - from TOSOH HPLC to Sebia using capillary electrophoresis. New methodology accreditation is pending UKAS assessment
Coagulation	Lupus Antibody Screening: (DRVVT methodology) Also now includes PTT-LA screening methodology (added 16/04/2020).	Accreditation pending assessment by UKAS for PPT-LA screening methodology.
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 using S-Test kit (Microgen) screening which is still accredited) New methodology accreditation is pending UKAS assessment
Haematology	Haemoglobin screening for Thalassaemia and Haemoglobin variants, quantification of HbA2, HbF and HbS	Change in analysers and methodology - from TOSOH HPLC to Sebia using capillary electrophoresis. New methodology 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

Cellular & Anatomical Pathology (9881) Service	Test provided	Tests / process variation
Histopathology/	CK8/18	Test not fully validated to ISO 15189 standard at time of assessment

Immunocytochemistry	Test provided	Tests / process variation
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
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
Histopathology/Neuropathology/ Special staining Enzyme histochemistry	NS-Warthin/Starry	Test not fully validated to ISO 15189 standard at time of assessment
Diagnostic Non-Gynae Cytology	Joint fluid crystals	Not diagnostic for this entity. Malignant cells only.