


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p>UKAS MEDICAL 7983</p> <p>Accredited to ISO 15189:2012</p>	<p>Nationwide Pathology Limited</p> <p>Issue No: 008 Issue date: 01 August 2022</p>	
	<p>Unit 1 Bitteswell Business Park Ullesthorpe Road Bitteswell Lutterworth LE17 4LR</p>	<p>Contact: Sheryl Dunn Tel: +44 (0)1858 571 322 E-Mail: Enquiries@nationwidepathology.co.uk Website: www.nationwidepathology.co.uk</p>
<p>Testing and sampling performed at the locations specified below.</p>		

Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Address	Local contact		
Unit 1 Bitteswell Business Park Ullesthorpe Road Bitteswell Lutterworth LE17 4LR	Sheryl Dunn	Biochemistry Immunology Haematology COVID-19 molecular testing	A
Customers' sites or premises The customer's sites or premises must be suitable for the sampling undertaken and will be subject of contract review arrangements between the provider and the customer	Sheryl Dunn	Sampling for subsequent COVID-19 molecular testing	B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Biochemistry</u> Quantitative analyses of:	Documented in-house procedures and manufacturer's instructions with specific reference to Atellica Automated System using ISE or Spectrophotometric method	A
Serum/EDTA plasma	Alanine Aminotransferase (ALT)		
Serum/plasma	Albumin		
Serum/EDTA plasma	Alkaline Phosphatase (ALP)		
Blood/ Serum / Plasma	Amylase (AMY)		
Serum/EDTA plasma	Aspartate Aminotransferase (AST)		
Blood/ Serum / Plasma	C Reactive Protein (CRP)		
Serum/plasma	Calcium (CA)		
Serum/heparinised plasma	Chloride (Cl-)		
Serum/plasma	Cholesterol (CHOL)		
Serum/plasma	Enzymatic Creatinine		
Serum/plasma	Creatinine Kinase (CKNAC)		
Blood/ Serum / Plasma	Direct Bilirubin (DBIL)		
Serum/plasma	Gamma Glutamyl Transferase (GGT)		
Sodium fluoride/potassium oxalate plasma	Glucose (GLU)		
Serum/EDTA plasma	HDL Cholesterol Direct		



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry (cont'd)</u> Quantitative analyses of: (cont'd)	Documented in-house procedures and manufacturer's instructions with specific reference to Atellica Automated System using ISE or Spectrophotometric method	A		
Blood/ Serum / Plasma	Immunoglobulin IgA				
Blood/ Serum / Plasma	Immunoglobulin IgG				
Blood/ Serum / Plasma	Immunoglobulin IgM				
Blood/ Serum / Plasma	Inorganic Phosphate (IP)				
Serum/sodium heparin plasma/ lithium/heparin plasma	Iron (FE)				
Serum/ Heparinised Plasma/ EDTA Plasma	Quantitative analyses of: Ferritin (FER)			Documented in-house procedures and manufacturer's instructions with specific reference to Atellica Automated System using Chemiluminescence	A
Serum	Folate				
Serum/ Heparinised Plasma/ EDTA Plasma	Free T4 (FT4)				
Serum	Prostate specific antigen (PSA)				
Serum/ Heparinised Plasma/ EDTA Plasma	TSH3-Ultra (TSH3-UL)				
Serum/EDTA plasma/ lithium-heparin/ sodium-heparin plasma	Vitamin D Total (VitD)				
Serum	Vitamin B 12 (VitB12)				



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry</u> (cont'd)	Documented in-house procedures and manufacturer's instructions with specific reference to the Atellica Automated System using ISE or spectrophotometric method	A
Blood/ Serum / Plasma	Magnesium (MG)		
Serum/heparinised plasma	Potassium (K+)		
Serum/heparinised plasma	Sodium (Na+)		
Serum /lithium Heparin plasma and EDTA plasma	Total Bilirubin (TBI)		
Serum/Plasma (heparinised)	Total Protein (TP)		
Serum/Plasma (heparinised)	Transferrin (TRNF)		
Serum/ Plasma (EDTA)	Triglycerides (TGL)		
Serum/plasma	Urea Nitrogen (BUN)		
Serum/plasma	Uric acid (UA)		
	<u>Immunology</u>	Documented in-house procedures and manufacturer's instructions with specific reference to Atellica Automated System using Chemiluminescence	A
Serum/Plasma	HIV 1 & 2		
	P24ag		
	HAV IgM		
	HAV total		
	Anti HBs		
	HCV		
	HBsAg		
	Rubella IgG		
	Syphilis		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology</u> (cont'd)	Documented in-house procedures and manufacturer's instructions with specific reference to the Atellica Automated System using 2-site sandwich immunoassay and direct chemiluminescent	A
Serum/Plasma	Active-B12 (Holotranscobalamin) (AB12)		
	Anti-Thyroglobulin (Atg)		
	Anti-Thyroid Peroxidase (aTPO)		
	Cortisol (COR)		
	Dehydroepiandrosterone (DHEA-S04)		
	Enhanced Estradiol (EE2)		
	Follicle Stimulating Hormone (FSH)		
	Free Triiodothyronine (FT3)		
	Hepatitis B Core Antigen (aHBCM)		
	Hepatitis B Core Antigen HBc Total (HBcT)		
	Luteinising Hormone (LH)		
	Progesterone (PRGE)		
	Prolactin (PRL)		
	Sex-Hormone Binding Globulin (SHBG)		
	Testosterone (TSTII)		
	Total HCG (THCG)		
	Total Thyroxine (T4)		
	Total Triiodothyronine (T3)		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology</u> (cont'd)		
Serum, plasma	Detection of COV2T	Documented in-house procedures and manufacturer's instructions with specific reference to the Atellica	A
Serum, plasma	Detection of COVG	Documented in-house procedures and manufacturer's instructions with specific reference to the Atellica	A
Heparin whole blood or test specific sample collection tubes	TB specific T cell response	Interferon- gamma release assay using in house documented procedures and manufacturers kit instructions: SOP 058 QuantiFERON-TB Gold Plus using SOP 076 Liaison XL	A
Serum	Measles IgG Mumps IgG Varicella IgG	Documented in house procedures and manufacturer's instructions with specific reference to BioMérieux VIDAS V60	A
Whole Blood	<u>Haematology</u> Basophils (BASO) Concentration (MCHC) Eosinophils (EOSO) Full blood count (FBC) Haematocrit (HCT) Haemoglobin (HB) Lymphocytes (LYMP) Mean Cell Haemoglobin (MCH) Mean Cell Volume (MCV) Mean Cell Volume (MCV) Monocytes (MONO) Neutrophils (NEUT) Red Blood Cells (RBC) White Blood Cells (WBC)	Documented in-house procedures and manufacturer's instructions with specific reference to Siemens Advia 2120 using electrical impedance variation principle, absorbance measurements, spectrophotometry pulse measurements and calculations	A



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HUMAN BODY FLUIDS (cont'd) Whole Blood in EDTA	<u>Immunology</u> (cont'd) HbA1c	Documented in-house procedures and manufacturer's instructions with specific reference to Biorad HB Variant using ion exchange high performance liquid chromatography	A
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab	For: General Population Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods	In-house method based on UKHSA Guidance for COVID-19 Sampling for testing purposes	B



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular virology diagnostic examination activities for the purpose of clinical diagnosis</u>	Following in-house documented procedures	
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab in Viral Transport Medium	Detection of SARS CoV-2 virus RNA (COVID-19) with target gene RdRp	SARS-CoV-2 real-time RT-PCR by Primerdesign nCOV (target gene RdRp) using Seeprep Seegene automated extraction robot (SOP 077) used with the Hain-Brucker NA Extraction kit or manual extraction using the Zymo research Quick DNA/RNA viral magbead kit detection (SOP 080) performed on the Abbott m2000rt thermocycler or the Genesig q16 thermocycler (SOP 078)	A
Serum, plasma	Detection of IgG/IgM for SARS COV-2	Lateral Flow IgG/IgM detection using the NaIVon Minden assay.	A
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab in Viral Transport Medium	Detection of SARS-CoV-2	Thermofisher Taqman Taqpath RT-PCR using the Applied Biosystems QuantStudio 5 on extracts obtained using the Applied Biosystems MAgmax Viral/Pathogen II isolation kit on the Kingfisher Flex	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular virology diagnostic examination activities for the purpose of clinical diagnosis</u>	Following in-house documented procedures	
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab in Viral Transport Medium	Detection of SARS-CoV-2	Inactivated viral media swabs Hamilton Starlet liquid handling systems with thermofisher kingfisher RNA extraction analysers. In conjunction with both the primer design novacyt RNA extraction reagent kit and taqman taqpath extraction reagent kit.	A
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab in Viral Transport Medium	Detection of SARS-CoV-2	Hamilton STAR liquid handling systems with Quantstudio 5 and taqman taqpath reagents.	A
Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) Swab in Viral Transport Medium	Sequencing of day 2 Covid positive PCR samples	Sequencing of Covid positive PCR samples using the Ion Torrent G5 sequencing system.	A
END			