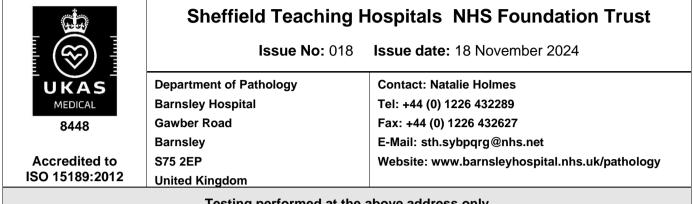
# **Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service** 

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



Testing performed at the above address only

#### Laboratory location:

Location Details	Activity
Department of Pathology	Biochemistry
Gawber Road	Haematology & Blood TransfusionMicrobiology
Barnsley	Cellular pathology sample receipt with subsequent transport and testing at an
S75 2EP	ISO 15189 accredited laboratory.

#### Site activities performed away from the locations listed above:

Location Details	Activity
Mortuary Barnsley Hospital Gawber Road Barnsley S75 2EP	Mortuary Services (body receipt, storage, and release)



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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

# Sheffield Teaching Hospitals NHS Foundation Trust

Issue No: 018 Issue date: 18 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Biochemistry examination activities for the purposes of clinical diagnosis:	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
		Siemens Atellica CH SOP SOP-CB-D-2 by the following methods:
Serum Urine	Albumin	BCG Immunoturbidimetric
Serum	ALP	Enzymatic
Serum	ALT	Enzymatic
Urine	Amphetamine	EMIT
Serum, Urine	Amylase	Enzymatic
Serum	AST	Enzymatic
Urine	Benzodiazepine	EMIT
Serum, Urine	Calcium	Arsenazo III
Urine	Cannabinoids	EMIT
Serum	Carbamazepine	PETINIA
Serum	Cholesterol	Cholesterol Esterase
Serum	Creatine kinase	Enzymatic
Serum, Urine	Chloride	Indirect ISE
Urine	Cocaine	EMIT
Serum	CRP	Latex Agglutination
Serum	Direct Bilirubin	End Point Oxidation
Serum	HDL Cholesterol	Trinder Reaction
Serum Urine	Creatinine	Enzymatic Jaffe

#### DETAIL OF ACCREDITATION



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## **Sheffield Teaching Hospitals NHS Foundation Trust**

Issue No: 018 Issue date: 18 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
		Siemens Atellica CH SOP SOP-CB-D-2 by the following methods:
Serum, Urine	Ethanol	Enzymatic
Serum	Gentamicin	PETINIA
Serum	GGT	Enzymatic
Serum, Plasma (Lithium heparinized, Potassium EDTA, Sodium fluoride/ Potassium oxalate)	Glucose	Hexokinase
Serum	IgA	Immunoturbidimetric
Serum	IgG	Immunoturbidimetric
Serum	IgM	Immunoturbidimetric
Serum	Iron	Ferrozine
Serum	LDH	Enzymatic
Serum	Lithium	Colorimetric End Point
Serum, Urine	Magnesium	Xylidyl Blue
Urine	Methadone	EMIT
Urine	Opiates	EMIT
Serum	Paracetamol	Enzymatic
Serum	Phenytoin	PETINIA
Serum, Urine	Phosphate	Molybdate
Serum, Urine	Potassium	Indirect ISE
Serum	Rheumatoid Factor	Immunoturbidimetric



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## **Sheffield Teaching Hospitals NHS Foundation Trust**

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Testing performed at main address only Type of test/Properties measured/Range of Standard specifications/ Materials/Products tested measurement Equipment/Techniques used HUMAN BODY FLUIDS (cont'd) Biochemistry examination activities for Documented in-house methods the purposes of clinical diagnosis: and manufacturer's operating (cont'd) instructions as specified to support clinical diagnosis: Siemens Atellica CH SOP SOP-CB-D-2 by the following methods: Serum Salicylate Enzymatic Sodium Indirect ISE Serum, Urine Theophylline PETINIA Serum Total Bilirubin Serum Vanadate Oxidation Serum **Total Protein** Biuret Urine, CSF Pyrogallol Red Transferrin Immunoturbidimetric Serum Serum Triglycerides Enzymatic Uric Acid Serum, Urine Enzymatic Serum, Urine Urea Enzymatic Serum Valproate PETINIA



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
		Siemens Atellica IM SOP SOP-CB-D-2 by immunoassay
Serum	AFP	
Serum	Anti-CCP Abs	
Serum	B12	
Serum	CA 125	
Serum	CA 199	
Serum	CEA	
Serum	Cortisol	
Serum	Digoxin	
Serum	Ferritin	
Serum	Folate	
Serum	Free T3	
Serum	Free T4	
Serum	FSH	
Serum	LH	
Plasma (Lithium heparinized, Potassium EDTA, Sodium fluoride/ Potassium oxalate)	NT-ProBNP	
Serum	Oestradiol	
Serum	Progesterone	
Serum	Prolactin	
Serum	PSA	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
		Siemens Atellica IM SOP SOP-CB-D-2 by immunoassay
Serum	PTH	
Serum	SHBG	
Serum	Testosterone	
Serum	Total HCG	
Serum	Troponin I	
Serum	TSH	
Serum	Vit D	
Whole Blood	Ammonia	SOP-CB-MAN-002 PocketChem BA blood ammonia meter (micro- diffusion method with bromocresol green indicator)
Urine	Urinalysis: Protein, Blood, Leucocytes, Nitrite, Glucose, Ketone, pH, Specific Gravity, Urobilinogen, Bilirubin	SOP-CB-MAN-009 Clinitek Status (Multistix 10SG dipsticks)
Urine	Pregnancy Test – Detection of HCG	SOP-CB-POCT-PO13 Siemens Clinitest cartridge on Clinitek Status (chromatographic immunoassay)
Whole Blood	pCO2, sodium, potassium, ionized calcium, chloride	Werfen IL GEM 5000 Cartridge blood gas using electrochemical sensors
	pO2, glucose	SOP-CB-POCT-D-23
	Carbon Monoxide, Carboxyhaemoglobin, Methaemoglobin, Oxyhaemoglobin	



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#### **Sheffield Teaching Hospitals NHS Foundation Trust**

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Whole Blood,	Lactate	Werfen IL GEM 5000 Cartridge blood gas using electrochemical
Whole Blood	рН	sensors SOP-CB-POCT-D-23
Whole Blood (EDTA)	HbA1c	TOSOH G11 HPLC SOP- CB-RC- D-28
Serum, Urine	Osmolality	Advanced Instruments Osmo1 (freezing point depression) SOP CB MAN 006
	Calculation of:	Calculated Tests using Clinisys Winpath
Serum	Osmolar Gap	
Serum	Globulin	
Serum	Adjusted Calcium	
Serum	Cholesterol: HDL ratio	
Serum	LDL	
Serum	Non-HDL cholesterol	
Serum	Iron binding capacity	
Serum	Transferrin	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
	Calculation of:	Calculated Tests using Clinisys Winpath
Urine	24 hour sodium	
Urine	24 hour potassium	
Urine	24 hour chloride	
Urine	24 hour urea	
Urine	24 hour creatinine	
Urine	24 hour calcium	
Urine	Calcium: creatinine ratio	
Urine	Calcium excretion	
Urine	Calcium clearance	
Urine	24 hour phosphate	
Urine	24 hour urate	
Urine	24 hour magnesium	
Urine	24 hour protein	
Urine	Protein: creatinine ratio	
Urine	Urate: creatinine ratio	
Serum	Macroprolactin recovery	
Serum	Estimated Glomerular Filtration Rate (eGFR)	
Serum	Acute Kidney Injury (AKI)	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis:	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Whole Blood (EDTA)	Full blood count: platelets, red blood cells, haemoglobin, haematocrit, MCV, MCH, MCHC, RDW, White cell count, neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, LUCs	Siemens ADVIA2120i analyser flow cytometry and laser light refraction. SOP-HAE-ROU-016
Whole Blood (EDTA)	Blood film assessment and differential count: Metamyelocytes, Myelocytes, Promyelocytes, Blasts, Nucleated RBC	Siemens Hematek 3000 Automated Stainer and manual stains (pH 6.8 Wright Giemsa) Examination by light microscopy SOP-HAE-ROU-D-12 SOP-HAE-ROU-022
Whole Blood (EDTA)	Reticulocytes	Siemens ADVIA2120i analyser flow cytometry and laser light refraction. SOP-HAE-ROU-016 SOP-HAE-ROU-029
Whole Blood (EDTA)	Erythrocyte Sedimentation Rate (automated)	Vitech Starrsed Compact – Westergren method. SOP-HEA-ROU-002
Citrated Plasma	Mixing studies using 50:50 Normal pooled plasma: patient plasma for the investigation of deranged PT &/or APTT results.	SOP-HAE-COAG-D-1 SOP-HAE-COAG-D-23 Immunoturbidometric
Serum/Plasma	Glandular fever - Detection of Infectious mononucleosis antibodies	SOP-HAE-ROU-003 Accusay Mono Immunoassay
Whole Blood (EDTA)	Antigen detection for M. Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale and Plasmodium malariae. Blood film characteristics and morphology for detection of malarial parasite	Apacor CareUS Malaria Kit pH 7.2 Giemsa stain SOP-HAE-ROU-015



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## **Sheffield Teaching Hospitals NHS Foundation Trust**

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Whole Blood (EDTA)	Detection of abnormal haemoglobin (Sickle cell)	SOP-HAE-COAG-D-5 Microgen Tube Test (quantitative method using sodium dithionite)
Citrated Plasma		Stago STA-R Max SOP-HAE-COAG-D-2
	PT/INR PTT Fibrinogen Actin FS APTT	Immunoturbidometric
	D-Dimer	Chromogenic
	Transfusion examination activities for the purposes of clinical diagnosis	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Blood	<ul> <li>Blood Grouping by antigen detection:</li> <li>ABO blood groups.</li> <li>Rhesus blood group antigens: C, c, D, E, e.</li> <li>Kell (K1) blood group antigen.</li> <li>Screen for red cell antibodies and antibody identification.</li> <li>Antibodies include anti-:</li> <li>C<sup>w</sup>, C, c, D, E, e, K, k, Kp(a), Jk(a), Jk(b), Fy(a), Fy(b), Lu(a), M, N, S, s, Le(a), Le(b), P1.</li> <li>Cross matching (compatibility testing of patient's plasma with donor red cells)</li> </ul>	Documented in-house method using Bio-Rad IH-1000 BT analyser, fully automated using Bio-Rad card technology using protocol: SOP-HAE-BB-003 – Use of the IH- 1000 SOP-HAE-BB-012 – Procedure for the identification of atypical red cell antibodies



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# Sheffield Teaching Hospitals NHS Foundation Trust

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Transfusion examination activities for</u> <u>the purposes of clinical diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Blood	<ul> <li>Manual Blood Grouping by antigen detection:</li> <li>ABO blood groups.</li> <li>Rhesus group antigens: C, c, D, E, e.</li> <li>Screen for red cell antibodies and antibody identification.</li> <li>Antibodies include anti-:</li> <li>C<sup>w</sup>, C, c, D, E, e, K, k, Kp(a), Jk(a), Jk(b), Fy(a), Fy(b), Lu(a), M, N, S, s, Le(a), Le(b), P1.</li> <li>Phenotyping by antigen detection.</li> <li>Antigens include: K, Fy(a), Fy(b), S, s, M, N, Jk(a), Jk(b).</li> <li>Cross matching (compatibility testing of patient's plasma with donor red cells)</li> </ul>	Manual procedures using Bio-Rad card technology and Banjo ID- Reader Reader using protocols: SOP-HAE-BB-020 – Manual Card Grouping SOP-HAE-BB-006 – Manual Antibody Screening SOP-HAE-BB-042 – Manual Tube Grouping SOP-HAE-BB-019 – Procedure for the selection and crossmatch of red cells SOP-HAE-BB-012 – Procedure for the identification of atypical red cell antibodies SOP-HAE-BB-013 – Red cell Phenotyping SOP-HAE-BB-021 – Selection and Issue of products for Paeds and Neonates SOP-HAE-BB-D-47 Use of the Banjo ID-Reader



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Transfusion examination activities for</u> <u>the purposes of clinical diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Blood	Quantification of fetal-maternal hemorrhage (Kleihauer Screen)	Guest Medical Kleihauer kit by acid elution followed by microscopy using protocol:
		SOP-HAE-BB-001 – Estimation of FMH by Acid Elution
Blood	Detection of monospecific antiglobulins (Monospecific DAT – manual)	Bio-Rad monospecific direct antiglobulin card technology using protocol:
		SOP-HAE-BB-022 – Direct Antiglobulin Test
		SOP-HAE-BB-D-47 Use of the Banjo ID-Reader
Blood	Detection of monospecific antiglobulins (Monospecific DAT - automated)	Bio-Rad IH-1000 BT analyser, fully automated using Bio-Rad monospecific direct antiglobulin card technology using protocol:
		SOP-HAE-BB-003 – Use of the IH- 1000 SOP-HAE-BB-022 – Direct Antiglobulin Test



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE/FLUIDS	Microbiology examination activities for the purpose of clinical diagnosis	Documented in-house methods and manufacturer's operating instructions for as specified to support clinical diagnosis:
Blood	General isolation and characterisation of micro-organisms of clinical significance	<u>Automated</u> culture using Bact/Alert blood culture system: SOP-MC-BAC-028
Swabs from various body sites, and various body specimens: Wound swabs, swabs from other body sites, sterile ascitic and joint fluids, corneal scrapes, aqueous and vitreous fluids, bronchial alveolar lavage, , small fragments of bone and tissue taken at operation, IV Cannula tips.	General isolation and characterisation of micro-organisms of clinical significance, including antibiotic resistance: Particularly wound swabs, ENT swabs, ophthalmic specimens, fluids, tissues and genital swabs	<u>Manual</u> culture and microscopy (not for genital swabs) SOP-MC-BAC-030/039 SOP-MC-BAC-D-3/D-8/D-9/D-40/
Cerebrospinal fluid (CSF)	Cell enumeration and detection of gram positive and negative bacteria	Manual culture and cell count SOP-MC-BAC-003
Urine	General isolation and characterisation of micro-organisms of clinical significance	Automated microscopy using UF5000: SOP-MC-BAC-D-039 <u>Manual method</u> by microscopy and culture – SOP-MC-BAC-032
Faeces	General isolation and characterisation of gastrointestinal pathogens of clinical significance	Conventional culture using SOP- MC-BAC-029
Faeces, urine	Detection and identification of ova, cysts and parasites	By microscopy using SOP-MC- BAC-D-042



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE/FLUIDS (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions for as specified to support clinical diagnosis:
	Identification and sensitivity of various bacterial and yeast isolates to antibiotics	<u>Manual</u> conventional methods and microscopy using: SOP-MC-BAC-012,019,020,024 <u>Automated</u> Vitek identification cards using MALDI-TOF technology SOP-MC-BAC-D-7
Bacterial isolates from various human samples	Identification of Staphylococcal isolates	Prolex staph latex SOP-MC-BAC-025
Bacterial isolates from various human samples	Identification of <i>Streptococcus</i> pneumoniae	Manual test Latex agglutination Oxoid dry-spot kit SOP-MC-BAC-D-047
Bacterial isolates from various human samples	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Strep grouping kit SOP-MC-BAC-018
Bacterial isolates from various human samples	Identification of Enterobacteriacae and other non-fastidious gram negative bacteria; identification of Corynebacteria and coryne-like organisms; identification of most Neisseria (including Neisseria gonorrhoeae) and Haemophilus spp	API 20E, API Coryne, API NH and slide preparation SOP-MC-BAC-050 SOP-MC-BAC-D-068
Bacterial isolates from various human samples	Detection of Salmonella polyvalent 'O' (PSO) and Salmonella polyvalent 'H' (PSH)	Salmonella agglutination sera SOP-MC-BAC-026
Faeces	Detection of : C.difficile antigen (GDH) C.difficile (Toxin) Rotavirus and Adenovirus antigens	Qualitative immunochromatographic assay – QuikCheck complete (TechLab) SOP-MC-BAC-D-074 SOP-MC- VIR-D-32



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE/FLUIDS (cont'd)	<u>Microbiology examination activities for</u> <u>the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions for as specified to support clinical diagnosis:
Faeces	Detection of: Norovirus	Manual test (lateral flow) SOP-MC-VIR-D-48
Urine	Legionella antigen Strep.pneumoniae antigen	Sofia analyser (Fluorescent EIA) SOP-MC-VIR-019 SOP-MC-VIR-024
Nasal and groin swabs and swabs / specimens from other body sites	Detection of MRSA and MSSA	<u>Manual</u> culture using chromogenic agar plates SOP-MC-BAC-040
Bacterial isolates from various human samples	Determination of sensitivity of various bacterial isolates to antibiotics	Disc testing using disc and E-testin line with EUCAST methods SOP-MC-BAC-033
Bacterial isolates from various human samples	Determination of identification and sensitivity of various bacterial and yeast isolates to antibiotics	Automated MIC using Vitek SOP-MC-BAC-D-7
Nasal and / or throat swabs in VTM or UTM	Detection of:	QIAGEN QIAstat analyser using QIAstat-Dx Respiratory SARS- CoV-2 Panel by PCR SOP-MC-VIR-D-54
	Influenza A	30F-INC-VIK-D-54
	Influenza A, subtype H1N1/pdm09	
	Influenza A subtype H1	
	Influenza A subtype H3	
	Influenza B	
	Coronavirus 229E	
	Coronavirus HKU1	
	Coronavirus NL63	
	Coronavirus OC43	



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Standard specifications/

Equipment/Techniques used

ISO 15189:2012
Testing performed at main address only
Materials/Products tested
Type of test/Properties measured/Range of
measurement
HUMAN BODY TISSUE/FLUIDS
Microbiology examination activities for
the purpose of clinical diagnosis

HUMAN BODY TISSUE/FLUIDS (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods and manufacturer's operating instructions for as specified to support clinical diagnosis:
Nasal and / or throat swabs in VTM or UTM	Detection of:	QIAGEN QIAstat analyser using QIAstat-Dx Respiratory SARS- CoV-2 Panel by PCR SOP-MC-VIR-D-54
	Parainfluenza Virus 1	SOP-INC-VIR-D-54
	Parainfluenza Virus 2	
	Parainfluenza Virus 3	
	Parainfluenza Virus 4	
	Respiratory Syncytial Virus A/B	
	Human Metapneumovirus A/B	
	Adenovirus	
	Bocavirus	
	Rhinovirus/Enterovirus (not differentiated)	
	Legionella pneumophilia	
	Bordetella pertussis	
	Mycoplasma pneumoniae	
	SARS-CoV-2 RNA (COVID-19) E and Orf1ab gene	
Nose and throat swabs in VTM and NPA	Detection of SARS-CoV- 2 Virus RNA (COVID-19) Target Orf1ab gene	Hologic Panther SARS-CoV-2 TMA Assay testing (RT-PCR) using Aptima Fusion SARS-CoV-2 Assay kit



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE/FLUIDS (cont'd)	Serology examination activities for the purpose of clinical diagnosis	Documented in-house methods and manufacturer's operating instructions for as specified to support clinical diagnosis: ** Documented in house methods to meet the requirements of the Infectious Diseases in pregnancy Screening (IDPS) as defined in the July 2018 'NHS Infectious Diseases in Pregnancy Programe: laboratory quality assurance evidence requirements' Siemens Atellica IM by immunoassay SOP SOP-CB-D-2 SOP-MC-VIR-D-39 Antenatal
Blood	Hepatitis A IgM and total antibodies	Screening protocol in Virology
Blood	Hepatitis B surface antibodies	
Blood	Hepatitis B core total antibodies	
Blood	**Hepatitis B surface antigen	
Blood	Hepatitis C IgG antibodies	
Blood	**Syphilis total antibodies	
Blood	**HIV-1 & HIV-2 andibodies / HIV-1 p24 antigen Combo	
Blood	Detection of Procalcitonin Detection of VZ IgG	Mini Vidas <u>Automated</u> Fluorescent EIA SOP- MC-VIR-D-5 SOP-MC-VIR-D- 11,15,16,25,30,31,36,44
END		