

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>9338</p> <p>Accredited to ISO 15189:2012</p>	<h3>Nuffield Health</h3> <p>Issue No: 002    Issue date: 06 July 2020</p>	
	<p><b>Pathology Department</b> Nuffield Warwickshire Hospital The Chase Leamington Spa Warwick CV32 6RW</p>	<p><b>Contact: Richard Heckford</b> Tel: +44 (0) 1926 436344 Fax: +44 (0) 01926 436334 E-Mail: Richard.heckford2@nuffieldhealth.com Website: www.nuffieldhealth.com</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<p><b>Address</b> Pathology Department Nuffield Warwickshire Hospital The Chase Leamington Spa Warwick CV32 6RW</p> <p style="text-align: right;"><b>Local contact</b> Richard Heckford</p>	<p>Haematology Blood Transfusion Coagulation Chemistry Immunology Histopathology Gynaecological Cytology Diagnostic Cytology Microbiology Specimen Reception</p>	A1
<p><b>Address</b> Pathology Department Leicester Hospital Scraptoft Lane Leicester LE5 1HY</p> <p style="text-align: right;">As above</p>	<p>Haematology Specimen Receipt Blood Issue Fridge</p>	A2
<p><b>Address</b> Pathology Department Derby Hospital Rykneld Road Derby DE23 4SN</p> <p style="text-align: right;">As above</p>	<p>Haematology Specimen Receipt Blood Issue Fridge</p>	A3
<p><b>Address</b> Pathology Department Exeter Nuffield Health Hospital Wonford Road Exeter United Kingdom EX2 4UG</p> <p style="text-align: right;"><b>Local contact</b> Contact: Paul Wheatley</p>	<p>Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridge</p>	B1



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Location details	Activity	Location code	
Pathology Department Plymouth Nuffield Health Hospital Derriford Road Plymouth United Kingdom PL6 8BG	Haematology Chemistry Specimen Receipt	B2	
Pathology Department Taunton Nuffield Health Hospital Staplergrove Elm Taunton Somerset United Kingdom TA2 6AN	Haematology Chemistry Specimen Receipt	B3	
Pathology Department Wessex Nuffield Hospital Winchester Road Chandler's Ford Eastleigh United Kingdom SO53 1FF	<b>Local contact</b> Lisa Bartlett Tel: +44 (0)2380 258407	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridge Histology Fluid Cytology	C1
Pathology Department Chichester Nuffield Hospital 78 Broyle Road Chichester West Sussex United Kingdom PO19 6WB	Specimen Reception, Urine Pregnancy testing	C3	
<b>Address</b> Nuffield Health Brighton Hospital Warren Road Brighton Sussex BN2 6DX	<b>Local contact</b> Phil Mathews	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridge	D1
<b>Address</b> Nuffield Health Tunbridge Wells Hospital Kings wood Road Tunbridge Wells Kent TN13 3LU	Clinical Biochemistry Haematology Histology Systemic Cytology Cryotomy	D2	



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Location details	Activity	Location code
Nuffield Health - Wolverhampton Hospital Wood Road Tettenhall WV6 8LE  <b>Local contact</b> Nonn Parry Tel: 01902793280	Clinical Chemistry Haematology Blood Transfusion Coagulation Immunology	E1
Nuffield Health - The Grosvenor Hospital Wrexham Road Chester CH4 7QP	Clinical Chemistry Haematology Coagulation Blood Issue Fridge	E2
Nuffield Health - Shrewsbury Hospital Longden Road Shrewsbury SY3 9DP	Clinical Chemistry Haematology	E3
Nuffield Health - North Staffordshire Hospital Clayton Road Newcastle-Under-Lyme ST5 4DB	Clinical Chemistry Haematology Blood Issue Fridge	E4
Pathology Department The Nuffield Manor Hospital Oxford Beech Road Headington OX3 7RP  <b>Local contact</b> Penny Bess Tel: 01865 307595	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridge Histology	F1
Cheltenham Nuffield Hospital Hatherley Lane Cheltenham GL51 6SY  <b>Local contact</b> Chris Watson	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridge	G1
The Vale Hospital Hensol Castle Park Hensol Vale of Glamorgan CF72 8JX  <b>As above</b>	Specimen Reception, Haematology Chemistry	G2
Pathology Department Nuffield Brentwood Hospital Shenfield Road Brentwood CM15 8EH  Claire Smith Tel: 01277 695662	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridge Phlebotomy	H1



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Location details	Activity	Location code
Pathology Department Nuffield Cambridge Hospital 4 Trumpington Road Cambridge CB28AF	Clinical Biochemistry Haematology	H2
Pathology Department Nuffield Health Nuffield Ipswich Hospital Foxhall Road Ipswich IP4 5SW	Clinical Biochemistry Haematology	H3
<b>Address</b> Pathology Department Nuffield Health Leeds 2 Leighton Street Leeds LS1 3EB	<b>Local contact</b> Mirriam Ngala	Haematology Blood Transfusion Coagulation Chemistry Histopathology Microbiology Specimen Reception I1
<b>Address</b> Pathology Department York Nuffield Hospital Haxby Road York West Yorkshire YO31 8TA	<b>Local contact</b> Mirriam Ngala	Haematology Chemistry Specimen Reception I2
<b>Address</b> Pathology Department Guildford Nuffield Hospital Stirling Road Guildford GU2 7RF	<b>Local contact</b> Stephen Mortlock Tel: 01483 540471	Haematology Blood Transfusion Coagulation Chemistry Microbiology Specimen Reception J1
<b>Address</b> Pathology Department Woking Nuffield Hospital Shores Road Woking GU21 4BY	<b>Local contact</b> As above	Haematology Chemistry Specimen Reception J2



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Location details	Activity	Location code
<p><b>Address</b> Pathology Department Newcastle Nuffield Hospital Clayton Road Jesmond Newcastle-Upon-Tyne NE2 1JP</p> <p><b>Local contact</b> Paula Hope</p>	<p>Clinical Biochemistry Haematology Blood Transfusion Blood Transfusion Issue Fridge</p>	K1
<p><b>Address</b> The Pathology Department Nuffield Health Glasgow Hospital 25 Beaconsfield Road Glasgow G12 0PJ</p> <p><b>Local contact</b> Paula Hope</p>	<p>Haematology Blood Transfusion Coagulation Chemistry Histopathology Microbiology Specimen Reception</p>	K2
<p><b>Address</b> Pathology Department Tees Nuffield Hospital Junction Road Norton Stockton on Tees TS20 1PX</p> <p><b>Local contact</b> Paula Hope</p>	<p>Clinical Biochemistry Haematology Specimen Reception</p>	K3

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

Location details	Activity	Location code
<p>Theatres Nuffield Warwickshire Hospital The Chase Leamington Spa Warwick CV32 6RW</p> <p><b>Local contact</b> Richard Heckford</p>	<p>Blood Issue Fridge No testing occurs at this location</p>	A4
<p>Theatres Leicester Nuffield Hospital Scraptoft Lane Leicester LE5 1HY</p> <p><b>Local contact</b> Richard Heckford</p>	<p>Blood Issue Fridge No testing occurs at this location</p>	A5
<p>Theatres Derby Nuffield Hospital Rykneld Road Derby DE23 4SN</p> <p><b>Local contact</b> Richard Heckford</p>	<p>Blood Issue Fridge No testing occurs at this location</p>	A6



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Location details	Activity	Location code
Theatres Area Exeter Nuffield Health Hospital Wonford Road Exeter United Kingdom EX2 4UG	Blood Issue Fridge No testing occurs on this site, blood storage only	B4
Theatres Area Plymouth Nuffield Health Hospital Derriford Road Plymouth United Kingdom PL6 8BG	Blood Issue Fridge No testing occurs on this site, blood storage only	B5
Theatres Area Taunton Nuffield Health Hospital Staplegrove Elm Taunton Somerset United Kingdom TA2 6AN	Blood Issue Fridge No testing occurs on this site, blood storage only	B6
Theatres Area Wessex Nuffield Hospital Winchester Road Chandler's Ford	Blood Issue Fridge No testing occurs on this site, blood storage only	C3
Theatres Area Bournemouth Nuffield Hospital Bournemouth United Kingdom	Blood Issue Fridge No testing occurs on this site, blood storage only	C4
Theatres Area Chichester Nuffield Hospital Chichester United Kingdom	Blood Issue Fridge No testing occurs on this site, blood storage only	C5
Pathology Department Bournemouth Nuffield Hospital 67 Landsdowne Road Bournemouth United Kingdom BH1 1RW	Specimen Reception Blood Fridge	C6



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Location details	Activity	Location code
Theatres Area Nuffield Health Brighton Hospital Warren Road Brighton Sussex BN2 6DX	Blood Issue Fridge No testing occurs on this site, blood storage only	D3
<b>Address</b> Nuffield Health Hayward's Heath Hospital Burrell Road Hayward's Heath Sussex RH16 1UD	Specimen Reception Blood Fridge	D4
Theatres Area Nuffield Health Tunbridge Wells Hospital Kings wood Road Tunbridge Wells Kent TN13 3LU	Blood Issue Fridge No testing occurs on this site, blood storage only	D5
Theatres Area Nuffield Health Hayward's Heath Hospital Burrell Road Hayward's Heath Sussex RH16 1UD	Blood Issue Fridge No testing occurs on this site, blood storage only	D6
Theatres Area Nuffield Health - Wolverhampton Hospital Wood Road Tettenhall WV6 8LE	Blood Issue Fridge No testing occurs on this site, blood storage only	E5
Theatres Area Nuffield Health - The Grosvenor Hospital Wrexham Road Chester CH4 7QP	Blood Issue Fridge No testing occurs on this site, blood storage only	E6
Theatres Area Nuffield Health - Shrewsbury Hospital Longden Road Shrewsbury SY3 9DP	Blood Issue Fridge No testing occurs on this site, blood storage only	E7



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Location details	Activity	Location code
Theatres Area Nuffield Health - North Staffordshire Hospital Clayton Road Newcastle-Under-Lyme ST5 4DB	Blood Issue Fridge No testing occurs on this site, blood storage only	E8
Theatres Area The Nuffield Manor Hospital Oxford Beech Road Headington OX3 7RP	Blood Issue Fridge No testing occurs on this site, blood storage only	F2
Theatres Area Cheltenham Nuffield Hospital Hatherley Lane Cheltenham GL51 6SY	As above Blood Issue Fridge Blood storage only	G3
Theatres Area & Laboratory Specimen Reception Bristol Nuffield Hospital – The Chesterfield 3 Clifton Hill Clifton Bristol BS8 1BN	As above Blood Issue Fridge Specimen Reception and referral No testing occurs on this site, blood storage only	G4
Theatres Area The Vale Hospital Hensol Castle Park Hensol Vale of Glamorgan CF72 8JX	As above Blood Issue Fridge No testing occurs on this site, blood storage only	G5
Theatres Area Nuffield Brentwood Hospital Shenfield Road Brentwood CM15 8EH	Blood Issue Fridge No testing occurs on this site, blood storage only	H4
Theatres Area Nuffield Cambridge Hospital 4 Trumpington Road Cambridge CB28AF	Blood Issue Fridge No testing occurs on this site, blood storage only	H5





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Location details	Activity	Location code
Theatres Area Nuffield Health Nuffield Ipswich Hospital Foxhall Road Ipswich IP4 5SW	Blood Issue Fridge No testing occurs on this site, blood storage only	H6
Theatres Guildford Nuffield Hospital Stirling Road Guildford GU2 7RF	Local contact As above  Blood Issue Fridge No testing occurs at this location	J3
Theatres Woking Nuffield Hospital Shores Road Woking GU21 4BY	Local contact As above  Blood Issue Fridge No testing occurs at this location	J4
Theatres The Pathology Department Nuffield Health Glasgow Hospital 25 Beaconsfield Road Glasgow G12 0PJ	Blood Issue Fridge No testing occurs at this location	K4
Theatres Area Newcastle Nuffield Hospital Clayton Road Jesmond	Blood Issue Fridges No testing occurs at this site, blood storage only	K5
Ward Tees Hospital Junction Road Norton Stockton on Tees	Blood Issue Fridges only No testing occurs at this location, blood storage only	K6



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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 as specified below:	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Blood Full Blood Count (Hb, RBC, WBC, Hct, MCV, MCH, MCHC, RDW Platelets, Neutrophils, lymphocytes, monocytes, Eosinophils, Basophils)	SOP PATH F2 HA 4.07 Operation of Sysmex XT1800 Analyser and photometry, impedance and light scatter.	A1, H1, I1, K1
Blood	Assessment for cell typing and morphology including enumeration of reticulocytes	Manual SOP – WA-PATH F2 HA 3.31 Blood film preparation, examination of blood films and counting by microscopy and staining with brilliant cresyl blue.	A1,
Blood	Differential cell count and cell morphology (detection of abnormalities)	HO PATH F2 HA3.36 Procedure for Reticulocyte Count New Methylene Blue Film examination by Microscopy	D1, D2
Blood	Differential cell count and cell morphology (detection of abnormalities)	SOPS: Using manual microscopy Blood Film Preparation & examination EX-Path F2 HA3.26	B1, B2, B3
Blood	Assessment for cell typing and morphology including white blood cell differential for enumeration of cell types.	SOP WA PATH F2 HA3.35 Blood film preparation and manual staining with Leishman stain.	A1, F1
		Manual SOP – SO_PATH F2 HA3.26 Blood film preparation, examination of blood films and manual differential by microscopy	C1, E1, H1



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HUMAN BODY FLUIDS as specified below:	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Assessment for cell typing and morphology including white blood cell differential for enumeration of cell types.	Manual Film examination by Microscopy HO PATH F2 HA 3.26 Preparation and Examination of Blood Films and Criteria for making blood films	D1, D2
		Automated Blood Film Preparation Haematek slide Stainer using Haematek stain pack (Modified Wrights stain) OX PATH F2.HA.3.27	F1
		Manual SOP – CH_PATH F2 HA3.26 Blood film preparation, examination of blood films and manual differential by microscopy. Stained using Hemaclor Romanowsky stain.	G1, K3
		Manual SOP –NT_PATH F2 HA3.26 Blood film preparation and staining using the Rapi-Diff II stain kit.	K1
		Manual SOP – GU-PATH F2 HA 3.26 Blood film preparation, examination of blood films and manual differential by microscopy Kit-RAL 555 staining (May Giemsa Grunwald)	J1
		Manual SOP – LE-PATH F2 HA 3.32 Blood film preparation, examination of blood films and manual differential by microscopy Stained using Realstain Quik-diff kit (Modified Giemsa)	I1



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HUMAN BODY FLUIDS as specified below:	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	ESR	SOP WA-PATH F2 3.30-1 Erythrocyte Sedimentation Rate Westergren Method	A1, D2, F1, G1, H1, I1, J1; K3; K1,
		SOP SO-PATH F2 HA3.30 using the BD Seditainer Manual ESR rack	C1, E1, E2, E3, E4, G1, G2
		SOPs: Mini-Ves analyser. ESR using minives EX-PATH F2.1 HA3.1	B1, D1
Blood	PT INR APTT	SOPs PATH F2 HA4.01 and 02 using the Sysmex CA560 Coagulometer and optical density change	A1, C1, E1 J1 I1 H1
	PT APTT D-DIMER INR APTT PT APTT Fibrinogen		
Blood	INR APTT	SOPs PATH F2 HA4.04 Operation of the Sysmex CA660 Coagulometer using Sysmex CA660	B1, F1
	PT APTT	Phototypical clot detection using Sysmex CA50 Coagulometer PATH F2 HA4.10 Operation of the Sysmex CA50 Coagulometer	D1, D2, G1, K3
Blood	Detection of infectious Mononucleosis	SOP WA PATH F2 HA3.38 – Latex Agglutination test -Oxoid Kit	A1
	Detection of infectious Mononucleosis	SOP WA PATH F2 HA3.38 – Latex Agglutination test – Clear View	H1



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HUMAN BODY FLUIDS as specified below:	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Detection of Haemoglobin S	SOP WA PATH F2 HA3.39 – CLIN TECH Kit	A1, F1, H1
Blood	Determination of plasma viscosity	SOP WA- PATH F2 HA4.24 using Benson Viscometer	A1
Blood	Blood Full Blood Count (Hb, RBC, WBC, Hct, MCV, MCH, MCHC, RDW Platelets, Neutrophils, lymphocytes, monocytes, Eosinophils, Basophils)	SOP PATH F2 HA 4.04 Sysmex XS1000i Set up, Start up and Maintenance QC, FBC And photometry, impedance and light scatter	A2, C1, B1, B2, B3, E1, E2, E4 D1, D2, F1, G1, H2, K3; J1
Whole Blood	Full Blood Count ( MCV, Hb, RBC, WBC, Hct, MCV, MCH,MCHC, RDW Platelets, Neutrophils, Lymphocytes, mixed white cells	SOP PATH D1.2 POCT 4.04 Sysmex Pochi using Hydrodynamic focusing Direct Current detection and cumulative pulse height detection	G1, I2, H3, K2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below	
Blood	<b>Blood Grouping/Phenotyping</b>  ABO Rhesus Rh- C,c,D,E,e  Kell Sytem K, K(Cellano)	SOP PATH F2 BT3.39 Use of the Gelstation Analyser using corresponding antisera or gel card  or  SOP PATH F2 BT3.51 Manual Blood Transfusion Procedures using Diamed centrifuge, incubator, card centrifuge. Using corresponding antisera or gel card	A1, B1, C1, D1, E1, F1, G1, H1, I1, J1, K1
Blood	<b>Antibody (screening) investigations:</b>  ABO Anti-A Anti-A1 Anti-B  Rhesus-Rh Anti-C,Cw,c,D,Ee Kell System Anti-K, k(cellano) Lewis System Anti-Lea, Leb Lutheran System Anti-Lua, Lub P System Anti-P1	SOP PATH F2 BT3.39 Use of the Gelstation Analyser  Or  SOP PATH F2 BT3. 51 Manual Blood Transfusion Procedures using Diamed centrifuge, incubator, card centrifuge  Using manufacturer's 3 cell panel and Manufacturer's 3 cell panel with enzyme added	A1, B1, C1, D1, E1, F1, G1, H1, I1, J1, K1



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<p>HUMAN BODY FLUIDS as specified below (cont'd):</p>	<p><u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><b>Antibody confirmation</b></p> <p>ABO Anti-A Anti-A1 Anti-B</p> <p>Rhesus-Rh Anti-C,Cw,c,D,Ee Kell System Anti-K, k(cellano) Lewis System Anti-Le<sup>a</sup>, Le<sup>b</sup> Lutheran System Anti-Lu<sup>a</sup>, Lu<sup>b</sup> P System Anti-P1</p> <p><b>Crossmatching</b> (compatibility testing of patient's plasma with donor red cells)</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified below</p> <p>SOP PATH F2 BT3.39 Use of the Gelstataion Analyser</p> <p>or</p> <p>SOP PATH F2 BT3. 51 Manual Blood Transfusion Procedures using Diamed centrifuge, incubator, card centrifuge</p> <p>Using manufacturer's 11 cell panel and Manufacturer's 11 cell panel with enzyme added</p> <p>SOP PATH F2 BT3.39 Use of the Gelstataion Analyser</p> <p>or</p> <p>SOP PATH F2 BT3.51 Manual Blood Transfusion Procedures</p>	<p>A1, B1, C1, D1, E1, F1, G1; H1, I1, J1, K1</p> <p>A1, B1, C1, D1, E1, F1, G1, H1, I1, J1, K1</p>



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Albumin, ALT, ALP, AST, Total Bilirubin, Creatine Kinase (CK), CRP, Cholesterol, Total GGT, HDL-Cholesterol, Mg, Total protein, Triglyceride, LDH Alpha 1 Antitrypsin C3 C4 Ceruloplasmin IgA IgG IgM Rheumatoid Factor UIBC Iron	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C6000/C501 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	A1 A1
Serum	Corrected Calcium LDL-Cholesterol Non-HDL Cholesterol EGFR Total Binding Iron Capacity	By calculation	A1 A1 A1 A1 A1





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Serum/Urine	Amylase Calcium Creatinine Sodium Potassium Inorganic Phosphate Urea Uric acid	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C6000/C501 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry	A1 A1 A1 A1 A1 A1 A1 A1
Serum Urine	Glucose Microalbumin		A1 A1
Plasma / serum	PSA,  FPSA,  CEA,  CA125,  B12,  Folate,  Ferritin,  TSH,	SOP PATH BC4.08 SOP PATH F2 BC4.10 using the Roche e411 Analyser and chemiluminescence	C1, D1, E1, H1, I1  C1, D1, E1, H1, I1  C1, D1, E1, H1, I1, J1  C1, D1, E1, H1, I1, J1  C1, E1, I1  C1, E1, I1  C1, E1, I1, C1, D1, E1, H1, I1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
	FT4,	SOP PATH BC4.08 SOP PATH F2 BC4.10 using the Roche e411 Analyser and chemiluminescence	C1, D1, E1, H1, I1,
	FT3		C1, E1, D1, H1,
	C199		I1, J1
	C153		D1, H1, I1, J1
	AFP		H1, J1
	Troponin T		J1
	LH		E1, H1, I1, J2
	E2		I1, J2
	Progesterone		I1, J2
	FSH		H1, I1, J2
	Prolactin		I1, J2
	Testosterone		D1, H1, I1, J2
	HCG		H1, I2
	SHBG		D1, I2
	LDH		E1
	Oestradiol		E1
	βHCG		E1
	E2		H1
	PSA/FPSA ratio	By calculation	H1
Serum		SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	
	Urea,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Sodium	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	B1, C1, D1, D2, E1, H1, H2, F1, G1, I1, J1, K1, K2
	Potassium		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Creatinine,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Albumin,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	ALT,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	ALP,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Amylase,	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	AST,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Total Bilirubin,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Calcium,		B1, C1, D1, D2, E1, F1, G1, J1, K1, K2
	Corrected Calcium		C1
	Chloride,		C1, D1, D2, E1, G1
	Creatine Kinase (CK),		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	CRP,	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Cholesterol,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Glucose,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	GGT,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	HDL-Cholesterol,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	LDL-Cholesterol		B1, C1, D1, D2, E1, F1, G1, I1, J1, K1, K2
	LDH		C1, G1, H1, H2, J1, I1, F1
	Iron		F1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Magnesium	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	B1, C1, D1, D2, E1 F1, G1, I1, H1, H2, J1
	Phosphate,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Total protein		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Triglyceride,		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Urate		B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
Serum	eGFR	By MDRD calculation.	B1, C1, F1, G1, H1, I1, J1, K1, K3



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:  SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	
	Adjusted Calcium	By calculation	B1, D1, D2, E1; F1, G1; H1, I1 K1, K3
	LDL Cholesterol		B1, D1, D2, F1, H2, I1. K1
	HDL-Cholesterol		K3
	Non-HDL Cholesterol		B1
	24hr Urine Excretion		B1
	Globulins		B1, F1
	AKI		G1
Urine	Amylase Glucose Magnesium Uric Acid Phosphate Calcium	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C311 Analyser and photometry, ISE, colorimetry, spectroscopy and turbidimetry.	H1 H1 H1 H1 H1 H1, H2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Urine	8SG Strips (Leucocytes, nitrogen, protein, Ph, blood, specific gravity, ketones, glucose, and HCG)	SOP EXPATH D1.2 POCT 4.08 CLINITEK 50 ANALYSER PATH D1.2 POCT 4.07 Clinitek Status Urine Analyser using CLINITEK Status Urine Analyser and 8SG Strips and HCG	B1, B2, B3, E1, E2, E4, G1, G2
Urine	Detection of $\beta$ hCG. (Pregnancy testing)	SOP SO-PATH F2 HA3.40 using Alere HCG Combo Pregnancy Test Kit and immunochromatography	A1, A2, A3, C3, E1; F1
Serum	Determination of CA15-3 CA19-9 CA125 CEA Testosterone Transferrin SHBG LH Progesterone FSH Prolactin HCG Estradiol Cortisol Serum Folate Ferritin Anti-CCP Vitamin B12 Total Vitamin D FT3 FT4 TSH PSA Total PSA Free	SOP PATH F2 BC3.51 using the Roche C6000/e601 Analyser and Electrochemiluminescence	A1 A1





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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Urine/	Microalbumin: Creatine Ratio Protein: Creatinine Ratio	By Calculation	A1 A1
Blood	Detection of HbA1c	SOP WA PATH F2 BC3.14 HbA1C via Sebia Capillary Flex 2 Electrophoresis	A1
Plasma	Detection of:	SOP PATH D1.2 POCT 4.03 using the Abbott I-Stat	
	pH		A1, E1, E2, E3, E4, H1, H2, H3
	pCO2		A1, E1, E2, E3, E4, H1, H2, H3
	pO2		A1, E1, E2, E3, E4, H1, H2, H3
	TCO2		A1, E1, E2, E3, E4, H1, H2, H3
	Urea		B2, B3, J2, H1, H2, H3, K3



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:  SOP PATH D1.2 POCT 4.03 using the Abbott I-Stat	B2, B3, J2, H1, H2, H3, K3
	Sodium,		
	Potassium,		
	Lactate,		
	Creatinine		
	INR PT		
Serum/Urine	Osmolality	Gonotec Osmomat 030 Freezing point depression – SOP – OX-PATH-F2 BC3.76	F1
Blood	Determination of: Glucose Calcium Total Protein Albumin AST ALP ALT GGT	PATH D1.2 POCT4.05 Abaxis Piccolo PATH F2 POCT3 F26 Piccolo Basic User Guide	H3



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS as specified below (cont'd):	<u>Clinical Immunology examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Serum	Protein electrophoresis and immunotyping	SOP WAPATH F2 BC3.141. Protein Electrophoresis by capillary method using Sebia Flex2	A1
Serum	ANA	SOP Path D1 IM 4.02 Running assays on the EUROIMMUN I-2P Analyser - Immunofluorescence	A1
	ANCA Antibodies		
	Autoantibody Profile		
	Endomysial Antibodies		
Serum	Anti Intrinsic factor antibodies	SOP Path D1 IM 4.02 Running assays on the EUROIMMUN I 2P Analyser ELISA	A1
	Anti Tissue Transglutaminase Antibodies		
	Anti Proteinase 3		
	Anti ENA Profile		
	Anticardiolipin IgG and IgM		
	Antigliadin IgG and IgM		
	Anti ds-DNA		
	Antibodies to Nuclear Antigens		
	Anti-Thyroid Peroxidase		
Serum	Detection of Antineuronal Antibodies	SOP Path F2 IM 3.17 EUROBLLOT - Immunoblot	A1
	Antibodies to Nuclear Antigens		



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Serum	<u>Immunology examination activities for the purposes of clinical diagnosis</u>  Total IgE	In house documented procedures based on equipment manuals and standard methods as specified below:  SOP PATH D1 IM 4.10 Operation of the Phadia 250 Immunology Analyser	E1
	Specific IgE to: Grass Pollens Weed Pollens Tree Pollens Microorganisms Epidermals and animal proteins Mites Venoms Drugs Foods – Fruits and vegetables Foods – Seeds, Legumes and nuts Spices Fish , Shellfish and molluscs Eggs and Fowl Meat Milk Foods – Miscellaneous Mixes	SOP PATH D1 IM 4.10 Operation of the Phadia 250 Immunology Analyser	E1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Microbiological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods, incorporating SMIs, as specified below	
Aspirates Cellular & fluid material contained on swabs, Fluids Pus Samples from sterile sites Tissue	Isolation of clinically significant bacteria and fungi	Manual culture using: SOPs WA-PATH F2 MB 3.05-3.011; 3.013; 3.015	A1
	Isolation of clinically significant bacteria	Manual culture using: GU-PATH F2 MB 3.02- Inoculation of Culture Media GU-PATH F2.1 MB 3.05 – Faeces Microscopy, culture and sensitivities	I1, J1
Urine	Isolation of clinically significant bacteria and fungi	Manual culture using: SOP-WA-PATH F2 MB 3.01	A1
Urine	Isolation of clinically significant bacteria	Manual culture using: GU-PATH F2 MB 3.01-Urine Microscopy and culture	I1, J1
Blood	Isolation of clinically significant bacteria and fungi	Automated culture using: BacT Alert WA-PATH F2 MB3.04	A1, I1, J1
Joint Fluids/Ascitic Fluids	Detection and quantification of red and white cells	Manual culture and microscopy using SOP WA-PATH F2 MB 3.13	A1
Joint Fluids	Examination for crystals	Microscopy using polarising microscope and SOP WA-PATH F2 MB 3.74	A1
Cellular and fluid material contained on nose, throat & groin/perineum swabs	Screening for: Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual culture using: MRSA Screening:	A1, I1, J1, K2



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Microbiological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods, incorporating SMIs, as specified below	
Cellular and fluid material contained on nose, throat & groin/perineum swabs	Screening for: Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA)	Manual culture using MSSA Screening: WA-PATH F2 MB3.97	A1
	Detection of <i>Staphylococcus aureus</i>	GL-PATH F2 MB 3.80 Staph Latex test – Prolab Prolax® Staph Latex Kit	K2
HUMAN BODY FLUIDS (cont'd)	<u>Microbiological activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods, incorporating SMIs, as specified below	
Bacterial & fungi isolates cultured in-house from the above	Antimicrobial sensitivity testing	Automated sensitivity testing using MIC and EUCAST guidelines on the Vitek2 analyser, WA-PATH F2 MB5.93  Or Manual disc diffusion & MIC, WA-PATH F2 MB3.39 Sensitivity Testing – EUCAST Disc Diffusion Method	A1, I1, J1
Bacterial & yeast isolates cultured in-house from the above	Identification of $\beta$ -haemolytic streptococci groups A-D, F and G.	WA-PATH F2 MB 3.30 Streptococcal grouping	A1, I1, J1
Bacterial & yeast isolates cultured in-house from the above	Detection of <i>Staphylococcus aureus</i>	WA-PATH F2 MB 3.97 Staph Latex test – Prolab Test Kit	A1, I1, J1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Microbiological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods, incorporating SMIs, as specified below	
Faeces	C. difficile GDH Antigen C. difficile toxins A & B	SOP WA-PATH F2 MB 3.43 Alere Quickcheck Test Kit - Immunochromatographic	A1
Bacterial & fungal isolates cultured in-house from the above	Identification of bacteria and fungi	Manual biochemical/enzymatic & staining using gram stain /microscopic methods WA-PATH F2 MB3.05	A1, I1, J1
Bacterial & fungal isolates cultured in-house from the above	Identification of bacteria and fungi	Automated Identification of culture isolates using Vitek 2, WA-PATH PATH F2 MB5.93.	A1, I1, J1
Bacterial & fungal isolates cultured in-house from the above	Identification of bacteria and fungi	Manual biochemical identification using API 10s strips WA-PATH F2 MB3.05	A1
Faeces	Isolation of bacterial enteric pathogens: <i>Salmonella</i> sp. <i>Shigella</i> spp. <i>Vibrio</i> spp. <i>Campylobacter</i> spp. <i>Yersinia</i> spp	Manual Culture using: SOP WA-PATH F2 MB 3.14	A1
Faeces	Detection of Carbapenamase Resistant Organisms (CROs)	Manual Culture using Chromogenic/Selective agar and SOP-WA PATH F2 MB3.92	A1
Faeces	Detection of Haemoglobin	SOP WA-PATH F2 MB 3.40 using Hema Screen Test Kit	A1
Faeces	Detection of ova, cysts & parasites (OCP)	SOP WA-PATH F2 MB 3.81- Ova Cysts and Parasite Detection - Unstained and iodine stained direct microscopic examination Parasep concentration and microscopic examination.	A1



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HUMAN BODY FLUIDS as specified below (cont'd):	<u>Microbiological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods, incorporating SMIs, as specified below	
Faeces	Detection of <i>Cryptosporidium</i> oocysts	SOP WA-PATH F2 MB 3.81- Ova Cysts and Parasite Detection and WA-PATH F2 MB 3.37 – Cold Ziehl Neelsen stain	A1
Clear adhesive tape slide	Detection of <i>Enterobius vermicularis</i> larvae and ova	SOP WA-PATH F2 MB 3.81- Ova Cysts and Parasite Detection - Microscopic examination	A1, I1, J1
Skin, hair, nails	Isolation of clinically significant fungi	SOP WA-PATH F2 MB 3.71 Manual culture and microscopy; stained using Calcufluor	A1
HUMAN BODY FLUIDS (cont'd)	<u>Serology activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below	
Serum	Detection of: Hep A Total Antibodies IgG IgM Hep B Surface Antibody Hep B Surface Antigen Hep B core antibody (Total) Hep Be antibody Hep Be antigen Hep C antibody HIV I/II Combi	SOP WA-PATH E2 VR 3.12, WA-PATH E2 VR 3.13, WA-PATH E2 VR3.1 using Roche Cobas 6000	A1
Cervical Smear (PreservCyt Solution)	Detection of HPV	SOP PATH F2 VR4.16 HPV Extraction and sample preparation using the Roche Cobas C4800	A1





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<p><b>HUMAN BODY TISSUE AND FLUIDS</b></p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens</p>	<p><u>Histopathological Examination activities for the purposes of clinical diagnosis.</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Tissue Dissection using SOPs – WA-PATH F2 HS3 04a Specimen Cut-up BMS; WA-PATH F2 HS3.04 Specimen Cut-up Assist; WA-PATH F2 HS3.04 Specimen Cut-up Category A</p> <p>Tissue processing using SOP: WA-PATH F2 HS3.06 and Leica ASP300S processor</p> <p>Embedding SOP: WA-PATH F2 HS3.07 Tissue embedding and Leica EG1150H, Leica EG1150C</p> <p>Microtomy SOP: WA-PATH F2 HS3.08 Leica Histocare Biocut and 2125 RTS Sectioning microtome</p> <p>Microtomy Using Leica RM 2235 Microtome and SOPs OX-PATH-F2-HS3.08 and OX-PATH D1 HS4.69</p>	<p>A1, C1, D2, I1, F1; K2;</p> <p>A1, D2, F1, I1, K2</p> <p>A1, D2; I1, K2</p> <p>A1</p> <p>F1, K2</p>
	<p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis including Identification of basophilic and eosinophilic structures</p>	<p>SO PATH F2 using (Leica processor, Shandon Microtome, Thermo Fisher Printmate Cassette Printer)</p> <p>Staining by Leica Autostainer XL using SOP SO-PATH 3.08 and Haematoxylin and eosin</p> <p>TU PATH-HS 4.78 Use of Shandon Finesse Microtome</p>	<p>C1, I1</p> <p>C1</p> <p>D2, K2</p>



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<p><b>HUMAN BODY TISSUE AND FLUIDS</b></p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens</p>	<p><u>Histopathological Examination activities for the purposes of clinical diagnosis.</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Routine staining for identification of basophilic and eosinophilic structures</p>	<p>Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:</p>	<p>D2</p> <p>A1</p> <p>D2</p> <p>F1</p> <p>K2</p>
		<p>TU PATH-HS 4.76 Sectioning wax blocks using the Rotary Microtome</p>	
		<p>Routine FFPE H &amp; E staining Haematoxylin and Eosin stain Automated: Leica Autostainer XL SOP: WA-PATH D1 HS4.72 Leica XL Staining machine.</p>	
		<p>Haematoxylin and Eosin Staining using the Gemini Staining machine. TU PATH-F2 HS 3.36</p>	
		<p>Routine Haematoxylin and Eosin (H&amp;E) staining Automated using Leica Autostainer XL- SOP OX-PATH F2-HS-3.56</p>	
<p>Staining by Sakura Tissue Tek DRS 2000 automated stainer using SOP GL-PATH 3.36 and Haematoxylin and eosin stain.</p>			



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<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides.</p>	<p><u>Histopathological Examination activities for the purposes of clinical diagnosis.</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p>	
	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<p>Macroscopic and Microscopic examination:</p> <p>Manual tinctorial stains</p>	A1
	Acid Mucins	Alcian Blue - WA-PATH F2 HS3.39 Using Alcian Blue/ PAS staining and SOP TU-PATH-F2 HS 3.52	A1, D2, F1,
	Amyloid	Congo Red Stain - WA-PATH F2 HS3.43	A1, C1
	Elastin	Millers Elastic Van Geison (EVG)- WA-PATH F2 HS3.52	A1, C1
	Helicobacter	Modified Giemsa - WA-PATH F2 HS3.59	A1, C1
	Elastin/collagen/muscle/ RBC	Gram Stain - WA-PATH F2 HS3.46	A1
	Fungi	Grocott - WA-PATH F2 HS3.55	A1
	Melanin	Masson Fontana WA-PATH F2 HS3.51	A1
	Muscle, red blood cells, fibrin, connective tissue	Masson Trichrome - WA-PATH F2 HS3.60	A1
Fibrin	MSB - WA-PATH F2 HS3.42	A1	



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HUMAN BODY TISSUE AND FLUIDS	<u>Histopathological Examination activities for the purposes of clinical diagnosis.</u>	Macroscopic and Microscopic examination:  Documented in house methods incorporating manufacturers' instructions where relevant:  Manual Tinctorial Stains	
	Copper	Orcein - WA-PATH F2 HS3.49	A1; C1, F1
	Mucins / glycogen	Alcian Blue Periodic Acid Schiff (ABPAS) - WA-PATH F2 HS3.54	A1
	Mucins/Glycogen	Diastase Alcian Blue Periodic Acid Schiff (DABPAS) - WA-PATH F2 HS3.62	A1
	Mucins/Glycogen	Diastase Periodic Acid Schiff (DPAS) - WA-PATH F2 HS3.45	A1
	Carbohydrates	Periodic Acid Schiff Reaction (PAS) WA-PATH F2 HS3.44	A1; C1
	Fungi	Periodic Acid Schiff (PAS) - WA-PATH F2 HS3.63	A1
	Ferric Iron	Perl's Iron Stain - WA-PATH F2 HS3.41	A1; C1
	Gram positive and negative organisms	Gram Stain – OX-PATH-F2 HS3.46	F1
	Elastin Fibres	Miller's Stain – EVG - OX-PATH-F2 HS3.65	F1
	Helicobacter pylori	Modified Giemsa – EVG - OX-PATH-F2 HS3.61	F1
Reticulin	Silver Stain - WA-PATH F2 HS3.40	A1	



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HUMAN BODY TISSUE AND FLUIDS  Slides prepared in house as above  Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	<u>Histopathological Examination activities for the purposes of clinical diagnosis.</u>	Macroscopic and Microscopic examination:  Documented in house methods incorporating manufacturers' instructions where relevant:	
	Mast Cells	Toluidine Blue - WA-PATH F2 HS3.61	A1; C1
	Collagen	Weigert's Van Gieson - WA-PATH F2 HS3.38	A1
	M. leprae	Wade Fite (Modified ZN) - WA-PATH F2 HS3.64	A1
	Acid Fast Bacilli	ZN Method - WA-PATH F2 HS3.47	A1; C1; F1
	Morphological assessment and interpretation and diagnosis	Microscopy GL-PATH G1 HS3.12 – Histology Authorisation and Reporting.	K2
	<u>Immunocytochemistry examination for the purposes of clinical diagnosis</u>	Microscopic examination supported by automated staining with positive and negative controls:	
		Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer	A1
	Cytokeratin – classification of tumours of epithelial origin	AE1/AE3	A1, C1
	Cytokeratin (High Molecular Weight)	34BE12	C1
Follicular lymphoma. Various B and T cell lymphoproliferative diseases	Bcl2	A1	



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<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Histopathological Examination activities for the purposes of clinical diagnosis.</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p>	
	<p><u>Immunochemistry examination for the purposes of clinical diagnosis</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer</p>	
	<p>Classification of B cell lymphomas, follicular lymphomas and Burkitts lymphoma</p>	<p>Bcl6</p>	<p>A1</p>
	<p>Identification of epithelial cells</p>	<p>BEREP4</p>	<p>A1</p>
	<p>Identification of B-cells in germinal centres, differentiation of lymphomas</p>	<p>BOB-1</p>	<p>A1</p>
	<p>Mucin-like glycoproteins – variety of tumours, classification of adenocarcinomas.</p>	<p>CA125</p>	<p>A1</p>
	<p>Smooth muscle cells Normal and neoplastic mesothelial cells</p>	<p>CALRETININ</p>	<p>A1</p>
	<p>Tumour marker – gastrointestinal, lung, breast</p>	<p>CK18/8</p>	<p>A1</p>
	<p>ID of Burkitts' lymphoma, follicular lymphoma, ALL and renal carcinoma (clear cell)</p>	<p>CD10</p>	<p>A1</p>
<p>Ewing's sarcoma marker</p>	<p>CD117</p>	<p>A1</p>	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<u>Immunochemistry examination for the purposes of clinical diagnosis</u>	Microscopic examination supported by automated staining with positive and negative controls:	
		Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer	A1
	Transmembrane tyrosine kinase receptors	CD138	A1
	Hodgkin's disease	CD15	A1
	CD1a positive cells in normal and neoplastic tissue	CD1a	A1
	B cells and identification of neoplasms of B cell derivation	CD20	A1
	Follicular dendritic cells and mature B cells, lymphoma	CD21	A1
	B cell activator proteins	CD23	A1
	Classification of T-Cell neoplasms	CD3	A1
	Normal B lymphocytes and malignant lymphomas	CD30	A1
	Activated T and B cells	CD31	A1
	Anaplastic large cell Lymphoma, Reed-Sternberg cells, Hodgkin's	CD34	A1, C1
Thymocytes and T helper cells – identifying anaplastic T-Cell lymphoma	CD4	A1	
T Lymphocytes, myeloid lineage cells	CD43	A1	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<u>Immunochemistry examination for the purposes of clinical diagnosis</u>	Microscopic examination supported by automated staining with positive and negative controls:	
		Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer	A1
	T and B lymphocytes	CD45 (LCA)	A1
	ID of B and T cell malignancies	CD5	A1
	Identification of NK cells, neural / neuroendocrine tissue, carcinoid	CD56	A1
	T Cells, oligodendromas and neuroendocrine tumours	CD57	A1
	Detection of activated platelets, neutrophils and basophils	CD68	A1
	Mononuclear phagocytes	CD79A	A1
	Cytotoxic suppressor T Cells	CD8	A1
	B cells and B Cell neoplasms	CD99	A1
ID of adenocarcinomas and carcinoids of the GI tract	CEA	A1	
Terminally differentiated plasma cells	CDX2	A1	
Prognostic indicator for breast cancer	CHROMOGRANIN A	A1	





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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer</p>	A1
	<p>Identification of epithelial tumours, and may be useful in identifying cholangiocellular carcinomas</p>	CK19	A1
	<p>Normal and abnormal gastric and intestinal epithelium, urothelium and Merkel cells</p>	CK20	A1
	<p>Differentiation between squamous cell carcinoma and adenocarcinoma</p>	CK5 (CK5/6)	A1
	<p>Glandular and transitional epithelial cells</p>	CK7	A1
	<p>Identification of mantle cell lymphomas</p>	CYCLIN D1	A1
	<p>Identification of lymphatic invasion</p>	D2-40	A1
	<p>Labels smooth and striated muscle cells as well as mesothelial cells, identification of rhabdomyosarcomas, leiomyomas and mesotheliomas</p>	DESMIN	A1
	<p>Differential diagnosis of gastrointestinal stromal tumours</p>	DOG 1	A1
<p>E-cadherin-positive cells in normal and neoplastic tissues</p>	E-CAD	A1	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer</p>	A1
	<p>Labels epithelial cells in a wide variety of tissues and is a useful tool for the identification of neoplastic epithelia</p>	EMA	A1, C1
	<p>Labels estrogen receptor <math>\alpha</math>-positive cells and is useful in the assessment of estrogen receptor status in human breast carcinomas</p>	ER	A1
	<p>Expressed in mammary gland and several exocrine tissues</p>	GCDFP15	A1
	<p>Classification of melanomas and melanocytic lesions and also aid in distinguishing metastatic amelanotic melanomas from other poorly differentiated tumours of uncertain origin</p>	HMB45	A1
	<p>Marker for differentiation of high grade invasive urothelial carcinoma from prostate cancer</p>	HMWCK	A1
	<p>Alpha Inhibin Expression</p>	INHIBIN	A1
	<p>Labels plasma cells and related lymphoid cells containing kappa light chains</p>	KAPPA	A1



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer</p>	A1
	<p>Ki-67 antigen in normal and neoplastic cells e.g soft-tissue sarcoma, prostatic adenocarcinoma, and breast carcinoma</p>	<p>KI67</p>	A1
	<p>Haematopoetic and nonhaematopoetic neoplasms through detection of leucocyte common antigen</p>	<p>LCA</p>	C1
	<p>Labels plasma cells and related lymphoid cells containing lambda light chains</p>	<p>LAMBDA</p>	A1
	<p>Labels melanocytes and identification of melanomas, and, if melanoma is ruled out, for adrenocortical carcinomas</p>	<p>MELAN A</p>	A1, C1
	<p>Differential identification of colorectal carcinoma</p>	<p>MLH1</p>	A1
	<p>Epithelial tissues from simple glandular to stratified squamous epithelium and identification of normal and neoplastic cells of epithelial origin</p>	<p>MNF116</p>	A1
	<p>Differential identification of colorectal carcinomas</p>	<p>MSH2</p>	A1
	<p>Differential identification of colorectal carcinomas</p>	<p>MSH6</p>	A1



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	<p>Labels the MUM1 protein, which is expressed in a subset of B cells in the light zone of the germinal centre plasma cells, activated T cells, and a wide spectrum of related haematolymphoid neoplasms</p>	MUM-1	A1
	<p>Labels both normal and neoplastic cells of neuronal and neuroendocrine origin</p>	NSE	A1
	<p>Lymphoid restricted immunoglobulin octamer binding antibody</p>	OCT2	A1
	<p>Tumour suppressor gene</p>	P16	A1
	<p>Identification of p53 in normal and neoplastic tissue</p>	P53	A1
	<p>A basal epithelial cell proliferation regulator, identification of prostate adenocarcinoma as an aid in the differentiation between benign prostate lesions and prostate adenocarcinoma</p>	P63	A1
	<p>B-cell-specific activator protein ID of pro-, pre-, and mature B cells and in the classification of lymphomas</p>	PAX5	A1



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	<p>Prostate needle cores differentiation between HGPIN and adenocarcinoma</p>	PIN 4	A1
	<p>identification of seminomas and desmoplastic small round cell tumors and identification of germ cell tumours</p>	PLAP	A1
	<p>Differential identification of colorectal carcinomas</p>	PMS2	A1
	<p>Labels progesterone receptor in human breast carcinomas</p>	PR	A1
	<p>Prostatic epithelium and is a useful tool for the identification of benign and malignant cells of prostatic origin</p>	PSA	A1
	<p>Identification of S100-positive neoplasms, such as malignant melanoma, Langerhans' histiocytosis, chondroblastoma and schwannoma</p>	S100	A1
	<p>Smooth muscle cells, myofibroblasts and myoepithelial cells, and leiomyosarcomas and pleomorphic adenomas</p>	SMA	A1, C1
	<p>Classification of breast tumours</p>	SMM	A1



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Immunocytochemistry examination for the purposes of clinical diagnosis</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p>	
		<p>Automated equipment Leica Bond Max – SOP: WA-PATH D1 HS4.76 Bond-Max Immunohistochemistry Stainer</p>	A1
	<p>Identification of neuroendocrine neoplasms, including neoplasms of epithelial type, ID of nervous system neoplasms with neuronal differentiation and ID of adrenocortical neoplasm</p>	<p>SYNAPTOPHYSIN</p>	A1
	<p>Thyroid transcription factor-1 in normal and malignant cells</p>	<p>TTF-1</p>	A1
	<p>Cells of mesenchymal origin in normal and neoplastic tissues, and is of value in tumour diagnosis</p>	<p>VIMENTIN</p>	A1
	<p>Classification of Will's tumour, malignant mesothelioma and serous ovarian adenocarcinoma</p>	<p>WT1</p>	A1
<p>Slides prepared in house from the sample types listed above.</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Microscopy (qualitative analysis) In house procedures: WA-PATH-F2 HS3.04</p>	A1, C1



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Diagnostic Cytology examination activities for the purposes of clinical diagnosis</u>	In-House documented procedures based on equipment manuals and standard methods as specified below:	
Fluids and Fine needle aspirates (FNAS)		Sample preparation using WA-PATH F2 CY3.24 Systemic Cytology Preparation Procedures WA-PATH F2 HS3.24 Non-Gynae Cytology Preparation Procedures Using – Cytospin, Hologic T2000	A1, C1
Air dried slides, fixed slides and Thinprep slides	Staining for the purposes of Cell Differentiation	SOP WA PATH F2 CY3.07 and CY3.25 Automated staining: Leica Autostainer XL for Papanicolaou and May Grunwald Giemsa stains	A1, C1
Slides prepared in house from the sample types listed above.	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In house procedures: WA-PATH G1 CY 3.26.	A1, C1
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Gynaecological Cytology examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination: In-House documented procedures based on equipment manuals and standard methods as specified below:	A1
Cervical/vaginal cells (Liquid based Cytology/LBC Sample)	Preparation and screening to identify or exclude cytological abnormalities for the purpose of diagnosis	Specimen processing using Thinprep methodology and Hologic T2000 processor – SOP WA PATH F2 CY1.05	A1
Air dried slides, fixed slides and Thinprep slides	Staining for the purposes of Cell Differentiation	SOP WA PATH F2 CY3.07 Automated staining: Leica Autostainer XL for Papanicolaou stain	A1
Slides prepared in house from the samples listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: SOP WA PATH F2 CY3.09 and WA PATH F2 CY3.10	A1
<b>END</b>			