

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9338</p> <p>Accredited to ISO 15189:2022</p>	<p>Nuffield Health</p> <p>Issue No: 013 Issue date: 24 April 2026</p>	
	<p>Pathology Department Nuffield Warwickshire Hospital The Chase Leamington Spa Warwick CV32 6RW</p>	<p>Contact: Steve Rickard/Claire Smith Tel: +44 (0) 1372 569328/+44 (0) 1392 712992 Fax: +44 (0) 01926 436334 Email: Steve.Rickard@nuffieldhealth.com / Claire.Smith@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>Pathology Department Nuffield Warwickshire Hospital The Chase Leamington Spa Warwick CV32 6RW</p> <p style="text-align: right;">Local contact Amrik Singh</p>	<p>Haematology Blood Transfusion Coagulation Chemistry Histopathology Gynaecological Cytology Diagnostic Cytology Microbiology Specimen Reception</p>	A1
<p>Pathology Department Leicester Hospital Scraptoft Lane Leicester LE5 1HY</p> <p style="text-align: right;">As above</p>	<p>Haematology Specimen Reception Blood Issue Fridge</p>	A2
<p>Pathology Department Exeter Nuffield Health Hospital Wonford Road Exeter United Kingdom EX2 4UG</p> <p style="text-align: right;">Local contact Contact: Kate Huish 01392 262138</p>	<p>Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Issue Fridge</p>	B1
<p>Pathology Department Plymouth Nuffield Health Hospital Derriford Road Plymouth United Kingdom PL6 8BG</p> <p style="text-align: right;">As above</p>	<p>Haematology Chemistry Specimen Receipt</p>	B2
<p>Pathology Department Taunton Nuffield Health Hospital Staplergrove Elm Taunton Somerset United Kingdom TA2 6AN</p> <p style="text-align: right;">As above</p>	<p>Haematology Specimen Reception</p>	B3



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Location details	Activity	Location code
<p>Pathology Department Wessex Nuffield Hospital Winchester Road Chandler's Ford Eastleigh United Kingdom SO53 1FF</p> <p style="text-align: right;">Local contact Lisa Bartlett Tel: +44 (0)2380 258407</p>	<p>Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Issue Fridge Histology Fluid Cytology</p>	C1
<p>Nuffield Health Brighton Hospital Warren Road Brighton Sussex BN2 6DX</p> <p style="text-align: right;">Local contact Philip Matthews +44 (0)1273 627005</p>	<p>Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Issue Fridge</p>	D1
<p>Nuffield Health Tunbridge Wells Hospital Kings wood Road Tunbridge Wells Kent TN13 3LU</p> <p style="text-align: right;">As above</p>	<p>Clinical Biochemistry Haematology Histology Non-gynae Cytology</p>	D2
<p>Nuffield Health - Wolverhampton Hospital Wood Road Tettenhall WV6 8LE</p> <p style="text-align: right;">Local contact Nonn Parry Tel: 01902793280</p>	<p>Clinical Chemistry Haematology Blood Transfusion Coagulation Immunology</p>	E1
<p>Nuffield Health - The Grosvenor Hospital Wrexham Road Chester CH4 7QP</p> <p style="text-align: right;">As above</p>	<p>Clinical Chemistry Haematology Coagulation Blood Issue Fridge</p>	E2
<p>Nuffield Health - Shrewsbury Hospital Longden Road Shrewsbury SY3 9DP</p> <p style="text-align: right;">As above</p>	<p>Clinical Chemistry Haematology</p>	E3
<p>Nuffield Health - North Staffordshire Hospital Clayton Road Newcastle-Under-Lyme ST5 4DB</p> <p style="text-align: right;">As above</p>	<p>Clinical Chemistry Haematology Blood Issue Fridge</p>	E4



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Location details	Activity	Location code
Pathology Department The Nuffield Manor Hospital Oxford Beech Road Headington OX3 7RP Local contact Penny Bess Tel: 01865 307595	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Issue Fridge Histology	F1
Cheltenham Nuffield Hospital Hatherley Lane Cheltenham GL51 6SY Local contact Michelle Wyatt Tel: 01242 246516	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Issue Fridge	G1
Pathology Department Nuffield Brentwood Hospital Shenfield Road Brentwood CM15 8EH Local contact Cathryn Mills Tel: 01277 695662	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Issue Fridge Phlebotomy	H1
Pathology Department Nuffield Cambridge Hospital 4 Trumpington Road Cambridge CB28AF As above	Clinical Biochemistry Haematology	H2
Pathology Department Nuffield Health Nuffield Ipswich Hospital Foxhall Road Ipswich IP4 5SW As above	Clinical Biochemistry Haematology	H3
Pathology Department Nuffield Health Leeds 2 Leighton Street Leeds LS1 3EB Local contact Mirriam Ngala Tel: 01133 882352	Haematology Blood Transfusion Coagulation Chemistry Histopathology Microbiology Blood Issue Fridge	I1



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Location details	Activity	Location code
Pathology Department York Nuffield Hospital Haxby Road York West Yorkshire YO31 8TA	As above Haematology Chemistry Specimen Reception Blood Issue Fridge	I2
Pathology Department Guildford Nuffield Hospital Stirling Road Guildford GU2 7RF	Local contact Stephen Kifordu Tel: 01483 540471 Haematology Blood Transfusion Coagulation Chemistry Microbiology	J1
Pathology Department Newcastle Nuffield Hospital Clayton Road Jesmond Newcastle-Upon-Tyne NE2 1JP	Local contact Paula Hope Tel: 0191 2125295 Clinical Biochemistry Haematology Blood Transfusion Blood Issue Fridge	K1
The Pathology Department Nuffield Health Glasgow Hospital 25 Beaconsfield Road Glasgow G12 0PJ	As above Coagulation Chemistry Haematology Histopathology Microbiology Specimen Reception	K2
Pathology Department The Holly Private Hospital High Road Buckhurst Hill Essex IG9 5HX	Local contact Maria DeMatos Tel: 020 8936 1204 Clinical Biochemistry Haematology Blood Transfusion	L1
Pathology Department Parkside Hospital 53 Parkside Wimbledon SW19 5NX	Local contact Kelly Warwick Tel: 020 8971 8022 Clinical Biochemistry Haematology Blood Transfusion	M1



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
Pathology Department Derby Hospital Rykneld Road Derby DE23 4SN	Local contact Amrik Singh Specimen Reception Blood Issue Fridge	A3
Theatres Nuffield Warwickshire Hospital The Chase Leamington Spa Warwick CV32 6RW	As above Blood Issue Fridge No testing occurs at this location	A4
Theatres Leicester Nuffield Hospital Scraptoft Lane Leicester LE5 1HY	As above Blood Issue Fridge No testing occurs at this location	A5
Theatres Derby Nuffield Hospital Rykneld Road Derby DE23 4SN	As above Blood Issue Fridge No testing occurs at this location	A6
Theatres Area Exeter Nuffield Health Hospital Wonford Road Exeter United Kingdom EX2 4UG	As above 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	As above Blood Issue Fridge No testing occurs on this site, blood storage only	B5
Theatres Area Taunton Nuffield Health Hospital Staplegrave Elm Taunton Somerset United Kingdom TA2 6AN	As above Blood Issue Fridge No testing occurs on this site, blood storage only	B6



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Location details	Activity	Location code
Chichester Hospital 78 Broyle Road Chichester PO19 6WB	Local contact As above Specimen reception only	C2
Theatres Area Wessex Nuffield Hospital Winchester Road Chandler's Ford	As above Blood Issue Fridge No testing occurs on this site, blood storage only	C3
Theatres Area Bournemouth Nuffield Hospital Bournemouth United Kingdom	As above Blood Issue Fridge No testing occurs on this site, blood storage only	C4
Theatres Area Chichester Nuffield Hospital Chichester United Kingdom	As above Blood Issue Fridge No testing occurs on this site, blood storage only	C5
Pathology Department Bournemouth Nuffield Hospital 67 Lansdowne Road Bournemouth United Kingdom BH1 1RW	As above Specimen Reception Blood Fridge	C6
Theatres Area Nuffield Health Brighton Hospital Warren Road Brighton Sussex BN2 6DX	As above Blood Issue Fridge No testing occurs on this site, blood storage only	D3
Nuffield Health Hayward's Heath Hospital Burrell Road Hayward's Heath Sussex RH16 1UD	As above Specimen Reception Blood Fridge	D4
Theatres Area Nuffield Health Tunbridge Wells Hospital Kings wood Road Tunbridge Wells Kent TN13 3LU	As above Blood Issue Fridge No testing occurs on this site, blood storage only	D5



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Location details	Activity	Location code
Theatres Area Nuffield Health Hayward's Heath Hospital Burrell Road Hayward's Heath Sussex RH16 1UD Local contact As above	Blood Issue Fridge No testing occurs on this site, blood storage only	D6
Theatres Area Nuffield Health - Wolverhampton Hospital Wood Road Tettenhall WV6 8LE As above	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 As above	Blood Issue Fridge No testing occurs on this site, blood storage only	E6
Theatres Area Nuffield Health - Shrewsbury Hospital Longden Road Shrewsbury SY3 9DP As above	Blood Issue Fridge No testing occurs on this site, blood storage only	E7
Theatres Area Nuffield Health - North Staffordshire Hospital Clayton Road Newcastle-Under-Lyme ST5 4DB As above	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 As above	Blood Issue Fridge No testing occurs on this site, blood storage only	F2
The Vale Hospital Hensol Castle Park Hensol Vale of Glamorgan CF72 8JX As above	Specimen Reception,	G2



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Location details	Activity	Location code
Theatres Area Cheltenham Nuffield Hospital Hatherley Lane Cheltenham GL51 6SY Local contact 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 As above	Blood Issue Fridge No testing occurs on this site, blood storage only	H4
Theatres Area Nuffield Cambridge Hospital 4 Trumpington Road Cambridge CB28AF As above	Blood Issue Fridge No testing occurs on this site, blood storage only	H5
Theatres Area Nuffield Health Nuffield Ipswich Hospital Foxhall Road Ipswich IP4 5SW As above	Blood Issue Fridge No testing occurs on this site, blood storage only	H6
Theatres Nuffield Health Leeds 2 Leighton Street Leeds LS1 3EB As above	Blood Issue Fridge No testing occurs at this location	I3



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Location details	Activity	Location code
Theatres York Nuffield Hospital Haxby Road York West Yorkshire YO31 8TA	Local contact As above Blood Issue Fridge No testing occurs at this location	I4
Pathology Department Woking Nuffield Hospital Shores Road Woking GU21 4BY	As above Specimen Reception	J2
Theatres Guildford Nuffield Hospital Stirling Road Guildford GU2 7RF	As above Blood Issue Fridge No testing occurs at this location	J3
Theatres Woking Nuffield Hospital Shores Road Woking GU21 4BY	As above Blood Issue Fridge No testing occurs at this location	J4
Pathology Department Tees Nuffield Hospital Junction Road Norton Stockton on Tees TS20 1PX	As above Specimen Reception	K3
Theatres The Pathology Department Nuffield Health Glasgow Hospital 25 Beaconsfield Road Glasgow G12 0PJ	As above Blood Issue Fridge No testing occurs at this location	K4
Theatres Area Newcastle Nuffield Hospital Clayton Road Jesmond	As above Blood Issue Fridges No testing occurs at this site, blood storage only	K5



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Location details	Activity	Location code
Ward Tees Hospital Junction Road Norton Stockton on Tees Local contact As above	Blood Issue Fridges only No testing occurs at this location, blood storage only	K6
Pathology Department Parkside Hospital 53 Parkside Wimbledon SW19 5NX		M2
Satellite Area Parkside Hospital 53 Parkside Wimbledon SW19 5NX		M3
Pathology Department The Holly Private Hospital High Road Buckhurst Hill Essex IG9 5HX		L2
Theatres Area The Holly Private Hospital High Road Buckhurst Hill Essex IG9 5HX		L3
Nuffield Brentwood Hospital Shenfield Road Brentwood CM15 8EH Local contact Cathryn Mills Tel: 01277 695662	Phlebotomy – venous collection of blood BR-PATH-SR-SOP 182	H4



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Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	<u>Haematology examination activities for the purpose of clinical diagnosis</u>		
EDTA anticoagulated whole blood	WBC	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	RBC	Sysmex XN-550 DC Impedance with hydrodynamic focusing SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	HGB	Sysmex XN-550 Cyanide-free SLS Spectrophotometry SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	HCT	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	MCV	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	MCH	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	MCHC	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
EDTA anticoagulated whole blood	RDW-CV	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	PLT	Sysmex XN-550 DC Impedance with hydrodynamic focusing SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	NEUT	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	LYMPH	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	MONO	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	EOS	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1
EDTA anticoagulated whole blood	BASO	Sysmex XN-550 Fluorescence Flow Cytometry/ Light Scatter SOP PATH HA SOP 5 SOP TH PATH HA SOP 62	A1, A2, B1, B2, B3 L1



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
EDTA anticoagulated whole blood	WBC	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	RBC	Sysmex XN1000 DC Impedance with hydrodynamic focusing PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	HGB	Sysmex XN1000 Cyanide-free SLS Spectrophotometry PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	HCT	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	MCV	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	MCH	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	MCHC	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	RDW-CV	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
EDTA anticoagulated whole blood	PLT	Sysmex XN1000 DC Impedance with hydrodynamic focusing PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	NEUT	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	LYMPH	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	MONO	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	EOS	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	BASO	Sysmex XN1000 Fluorescence Flow Cytometry/ Light Scatter PA PATH HA SOP 5.1	M1
EDTA anticoagulated whole blood	WBC	Sysmex Pochi using Impedance (DC detection) SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	RBC	Sysmex Pochi using Impedance (DC detection) SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	HGB	Sysmex Pochi using Photometric (Cyanide-free SLS method) SOP PATH D1.2 POCT 4.04	G1, H3, K2



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>		
EDTA anticoagulated whole blood	HCT	Sysmex Pochi using calculation SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	MCV	Sysmex Pochi using calculation SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	MCH	Sysmex Pochi using calculation SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	MCHC	Sysmex Pochi using calculation SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	RDW-CV	Sysmex Pochi using calculation SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	NEUT	Sysmex Pochi using Impedance (DC detection) and size discrimination SOP PATH D1.2 POCT 4.04	G1, H3, K2
EDTA anticoagulated whole blood	LYMPH	Sysmex Pochi using Impedance (DC detection) and size discrimination SOP PATH D1.2 POCT 4.04	G1, H3, K2
Blood	Assessment for cell typing and morphology	Manual SOP – WA-PATH F2 HA 3.35 Blood film preparation, examination of blood films and counting by microscopy	A1
Blood	Differential cell count and cell morphology (detection of abnormalities)	Using manual microscopy Blood Film Preparation & examination EX-PATH HA SOP 29	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. Manual SOP – SO_PATH F2 HA3.26 Blood film preparation, examination of blood films and manual differential by microscopy	A1 C1, E1, H1



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology 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:	
Whole blood	Morphological examination of peripheral blood films: Red cell/white cell/platelets abnormalities	Hematek stainer using Modified Wright's stain and light microscopy PA PATH F2 HA 3.53	M1
Whole blood	Morphological examination of peripheral blood films: Red cell/white cell/platelets abnormalities	Hematek stainer using Romanowsky stain and light microscopy TH PATH HA SOP 30 TH PATH HA SOP 36	L1
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
		Manual SOP – CH_PATH SOP 29 Blood film preparation, examination of blood films and manual differential by microscopy. Stained using Hemaclor Romanowsky stain	G1
		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 HA SOP 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 SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Erythrocyte Sedimentation Rate (ESR) Sedimentation (mm/hr)	Westergren Method Greiner Vacuette manual method SOP WA-PATH F2HA SOP 33 3.30-1 SOP SO-PATH F2 HA3.30	A1, B1, D2, F1, I1, J1
	Erythrocyte Sedimentation Rate (ESR) Sedimentation (mm/hr)	Westergren Method PATH-HA-SOP-33	H1
EDTA anticoagulated whole blood	Erythrocyte Sedimentation Rate (ESR) Sedimentation (mm/hr)	Modified Westergren Method Diesse Mini-Ves automated sedimentation rate EX-PATH F2.1 HA3.1	D1
EDTA anticoagulated whole blood	Erythrocyte Sedimentation Rate (ESR) Sedimentation (mm/hr)	Starstedt S-Sedivette System Westergren Method TH PATH HA SOP 33	L1
EDTA anticoagulated whole blood	Erythrocyte Sedimentation Rate (ESR) Sedimentation (mm/hr)	Vescube 30 Touch Modified Westergren Method <u>SOP-PA PATH HA SOP 33</u>	M1
Plasma	Prothrombin Time (PT) Activated	Sysmex CA660 Coagulometer using Optical Scattered-Light Detection SOP PA PATH HA SOP 61 <u>SOP TH PATH HA SOP 28</u>	A1, B1, C1, E1, F1, I1, J1, L1
Plasma	Partial Thromboplastin Time (APTT)	Sysmex CA660 Coagulometer using Optical Scattered-Light Detection SOP PA PATH HA SOP 61 <u>SOP TH PATH HA SOP 28</u>	A1, B1, C1, E1, F1, I1, J1, L1



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Plasma	INR	Sysmex CA660 Coagulometer using Optical Scattered-Light Detection SOP PATH F2 HA4.01; 02HA SOP 61	A1, B1, C1, E1, F1, I1, J1
Plasma	D-DIMER	Sysmex CA660 Coagulometer using Latex-Enhanced Turbidimetric Immunoassay SOP PATH F2 HA4.01; 02HA SOP 61	A1, B1, C1, E1, F1, I1, J1
Blood	PT APTT	Sysmex CA50 Coagulometer PATH F2 HA4.10 Operation of the Sysmex CA50 Coagulometer	D1, D2, G1
Plasma	Prothrombin Time (PT) Activated	Sysmex CS2000i Coagulometer using Optical Scattered-Light Detection PA PATH HA SOP 61	M1
Plasma	Partial Thromboplastin Time (APTT)	Sysmex CS2000i Coagulometer using Optical Scattered-Light Detection PA PATH HA SOP 61	M1
Plasma	D-DIMER	Sysmex CS2000i Coagulometer using Latex-Enhanced Turbidimetric Immunoassay PA PATH HA SOP 61	M1
Plasma	Fibrinogen	Sysmex CS2000i Coagulometer using Optical Scattered-Light Detection PA PATH HA SOP 61	M1
Blood	Infectious Mononucleosis	Oxoid Latex Agglutination Kit SOP WA PATH F2 HA3.38	A1
	Infectious Mononucleosis	ClearView IM II Agglutination Kit SOP WA PATH F2 HA3.38	H1



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood, serum	Infectious mononucleosis	ClearView IM II Agglutination Kit TH PATH HA SOP 61	L1
Whole blood	Sickle cell solubility	Streck Sickledex kit qualitative solubility test SOP PATH F2 HA3.39	A1, F1
Blood	Determination of plasma viscosity	SOP WA- PATH F2 HA4.24 using Benson Viscometer	A1
	<u>Blood Transfusion activities for the purpose of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Whole Blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Bio-Rad IH-500 analyser using Column Agglutination Technology (Gel Card Method) PATH BT SOP 119	A1, B1, C1, D1, E1, F1, G1, H1, I1, J1, K1
Whole Blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Manual methods using, incubator, card centrifuge. Using corresponding antisera or gel card PATH BT SOP 123	A1, B1, C1, D1, E1, F1, G1, H1, I1, J1, K1



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Anticoagulated venous blood, plasma	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Bio-Rad IH-500 analyser using Column Agglutination Technology (Gel Card Method) PATH BT SOP 119	M1
Anticoagulated venous blood, plasma	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Manual methods using, incubator, card centrifuge and corresponding antisera or gel card PATH BT SOP 123	M1
Whole Blood (EDTA)	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Manual methods using Ortho Workstation and Ortho Biovue method – column agglutination technology SOP LP-TH-PATH-BT02	L1
Whole Blood	Antibody Screen by detection of antibodies to: K, k(Cellano)	Bio-Rad IH-500 analyser using Column Agglutination Technology (Gel Card Method) PATH BT SOP 119	A1



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Whole Blood	Antibody Screen by detection of antibodies to: Rh- C,c,D,E,e K, k(Cellano) Anti-C,Cw,c,D,Ee Kell System Anti-K, k(Cellano) Lewis System Anti-Le ^a , Le ^b Lutheran System Anti-Lu ^a , Lu ^b P System Anti-P1	Bio-Rad IH-500 analyser using manufacturer's 3 cell panel and manufacturer's 3 cell panel with enzyme added PATH BT SOP 119	B1, C1, D1, E1, F1, G1, H1, I1, J1, K1
Whole blood, plasma	Antibody Screen by detection of antibodies to: Anti-C,Cw,c,D,Ee Anti-K	Bio-Rad IH-500 and using Bio-Rad ID-System gel cassette cards PATH BT SOP 119	M1
Whole blood, plasma	Antibody Screen by detection of antibodies to: Anti-C,Cw,c,D,Ee Anti-K	Manual method using BIORAD ID-System gel cassette cards <u>PATH BT SOP 123</u>	M1
Blood	Antibody titration: ABO Anti-A Anti-A1 Anti-B	SOP PATH F2 BT SOP 1193.39 Use of the IH- 500 Analyser Or SOP PATH F2 BT SOP 1233. 51 Manual Blood Transfusion Procedures using, incubator, card centrifuge Using manufacturer's 3 cell panel and Manufacturer's 3 cell panel with enzyme added	B1, C1, D1, E1, G1, H1, I1, J1, K1



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Antibody confirmation: ABO Anti-A Anti-A1 Anti-B Rhesus-Rh Anti-C,Cw,c,D,Ee Kell System Anti-K, k(cellano) Lewis System Anti-Le ^a , Le ^b Lutheran System Anti-Lu ^a , Lu ^b P System Anti-P1	Manual Blood Transfusion Procedures using IH-500 centrifuge, incubator, card centrifuge Using manufacturer's 11 cell panel and manufacturer's 11 cell panel with enzyme added SOP PATH F2 BT3. 51	B1, C1, D1, E1, G1, I1, J1, K1
Plasma	Compatibility testing: Serological crossmatch – serological compatibility testing between donor red cell antigens and patient plasma	Manual Blood Transfusion Procedures PATH BT SOP 123	B1, C1, D1, E1, F1, G1, H1, I1, J1, K1
Whole blood, plasma	Compatibility testing: Serological crossmatch – serological compatibility testing between donor red cell antigens and patient plasma	Automated method using Bio-Rad IH500 and Bio-Rad ID-System gel cassette cards. PATH BT SOP 123	M1
		Manual method using Bio-Rad ID-System gel cassette cards PATH BT SOP 123	M1
Whole blood (EDTA)	Compatibility testing: Serological crossmatch – serological compatibility testing between donor red cell antigens and patient plasma	Manual methods using Ortho Biovue method – column agglutination technology TH PATH BT SOP 46	L1



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)		
Serum	Corrected Calcium LDL-Cholesterol Non-HDL Cholesterol EGFR Total Binding Iron Capacity	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C6000/C501 Analyser and photometry, ISE, colourimetry, spectroscopy and turbidimetry. By calculation	A1 A1 A1 A1 A1
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, colourimetry, spectroscopy and turbidimetry	A1 A1 A1 A1 A1 A1 A1
Serum Urine	Glucose Microalbumin	SOP PATH F2 BC 4.03, PATH F2 BC4.05 using the Roche C6000/C501 Analyser and photometry, ISE, colourimetry, spectroscopy and turbidimetry.	A1 A1
Plasma / serum	PSA FPSA CEA	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



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	SOP PATH BC4.08 SOP PATH F2 BC4.10 using the Roche e411 Analyser and chemiluminescence	
Plasma / serum (cont'd)	CA125		C1, D1, E1, H1, I1, J1
	B12		C1, E1, I1
	Folate		C1, E1, I1
	Ferritin		C1, E1, I1
	TSH		C1, D1, E1, H1, I1
	FT4		C1, D1, E1, H1, I1,
	FT3		C1, E1,
	C199		D1, H1, I1, J1
	C153		D1, H1, I1, J1
	AFP		H1, J1
	Troponin T		J1
	LH		E1, H1, I1
	E2		I1
	Progesterone	I1	



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	SOP PATH BC4.08 SOP PATH F2 BC4.10 using the Roche e411 Analyser and chemiluminescence	
Plasma / serum (cont'd)	FSH		H1, I1
	Prolactin		I1
	Testosterone		D1, H1, I1
	HCG		H1
	SHBG		D1
	LDH		E1
	Oestradiol		E1
	βHCG		E1
	E2		H1
	PSA/FPSA ratio	By calculation	H1
Serum	FT3	Roche e411 by immunoassay SOP PATH BC SOP 6	K1
Serum	FT4		K1
Serum	TSH		K1
Serum	PSA		K1
Serum	CA125		K1
Serum	CA153		K1
Serum	CEA		K1
Serum	CA199		K1



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>		
Serum	Urea	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Sodium		B1, C1, D1, D2, E1, H1, H2, F1, G1, I1, J1, K1, K2
	Potassium	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	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



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>		
Serum (cont'd)	ALT	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	ALP	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	Amylase	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	AST	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2



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



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



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



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry 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:	
Serum (cont'd)	Urate	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	B1, C1, D1, D2, E1, F1, G1, H1, H2, I1, J1, K1, K2
	eGFR	By MDRD calculation.	B1, C1, F1, G1, H1, I1, J1, K1
	LDL Cholesterol		B1, D1, D2, F1, H2, I1, K1
	Non-HDL Cholesterol		B1
	24hr Urine Excretion		B1
	Globulins		B1, F1
	AKI		G1
Urine	Amylase Glucose Magnesium Uric Acid Phosphate Calcium	Roche C311 Analyser and photometry, ISE, colourimetry, spectroscopy, and turbidimetry SOP PATH F2 BC 4.03, PATH F2 BC4.05	H1 H1 H1 H1 H1 H1, H2



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry 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:	
Urine	Microalbumin: Creatine Ratio Protein: Creatinine Ratio	By Calculation	A1 A1
Serum	Protein	ORTHO VITROS XT 7600 Chemilluminescence. PA-PATH-BC-SOP-6	A1 M1
Serum	AFP B-HCG CA15-3 CA19-9 CA 125 CEA Cortisol FSH LH Oestrodiol Progesterone Prolactin PSA FT3 & FT4 Testosterone Troponin I TSH	ORTHO VITROS XT 7600 Dry slide technique detected by potentiometric electrometry. PA-PATH-BC-SOP-6	M1
	Potassium Sodium		



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry 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:	
Serum (cont'd)	Albumin Alkaline Phosphatase ALT Amylase AST Calcium Cholesterol CPK CRP Creatinine Gamma GT Gentamicin Glucose Iron LDH Magnesium Phosphate Total Bilirubin Total Protein Triglycerides Urea Uric acid	ORTHO VITROS XT 7600 Dry slide technique detected by reflectometry, CM/RT and IR slides. PA-PATH-BC-SOP-6 PA-PATH-BC-SOP-23	M1
Serum	High Density Lipoprotein Globulin	By calculation	M1
Serum	Low Density Lipoprotein (LDL)	By calculation	M1



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry 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:	
Serum	B12 Ferritin	Ortho VITROS XT 7600 Chemiluminescence PA-PATH-BC-SOP-6 PA-PATH-BC-SOP-23	M1
	Total Iron Binding Capacity (TIBC)	Slide reflectometry SOP PH-LAB-CHEM-13 PA-PATH-BC-SOP-6 PA-PATH-BC-SOP-23	
	Folate Vitamin D	Ortho VITROS XT 7600 Immunoassay PA-PATH-BC-SOP-6 PA-PATH-BC-SOP-23	M1
	Rheumatoid Factor (RhF)	Ortho Vitros 7600 Microtip Method SOP PH-LAB-CHEM-13 PA-PATH-BC-SOP-23	M1
Serum	NT-proBNP	Ortho VITROS XT 7600 Immunoassay PA PATH BC SOP 23	M1
Serum	Albumin Bun/Urea Calcium Cholesterol HDL Glucose Phosphate Total Bilirubin Total Protein Triglycerides Uric acid	OrthoVitros 5600 Dry Slide Technology_Colorimetric method TH PATH BC SOP 23	L1



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry 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:	
Serum (cont'd)	Alkaline phosphatase Alanine transaminase Amylase Aspartate aminotransferase Creatine Kinase Creatinine GGT LDH	OrthoVitros 5600 Dry Slide Technology Multi-point rate method TH PATH BC SOP 23	L1
Serum	Potassium Sodium	OrthoVitros 5600 Dry Slide Technology Potentiometric method TH PATH BC SOP 23	L1
Serum	CRP	OrthoVitros 5600 Dry Slide Technology Fixed-point immune-rate method TH PATH BC SOP 23	L1
Serum	eGFR	By calculation	L1
Whole Blood (EDTA)	HbA1c	Ortho VITROS XT 7600 Microwell Method <u>PA PATH BC SOP 23</u>	M1
Blood	Detection of HbA1c	SOP WA PATH F2 BC3.14 HbA1C via Sebia Capillary Flex 2 Electrophoresis	A1



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HUMAN BODY SAMPLES (cont'd)	<u>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	Total IgE	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 TISSUE AND FLUIDS	<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	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: PATH MB SOP 23	A1, I1, J1, K2
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



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HUMAN BODY TISSUE AND 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 β -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
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	Detection of Carbapenamase Resistant Organisms (CROs)	Manual Culture using Chromogenic/Selective agar and SOP-WA PATH F2 MB3.92	A1



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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
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, J1
Skin, hair, nails	Isolation of clinically significant fungi	SOP WA-PATH F2 MB 3.71 Manual culture and microscopy;	A1
Serum	<u>Serology activities for the purposes of clinical diagnosis</u> Detection of: 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	In house documented procedures based on equipment manuals and standard methods as specified below 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>HUMAN BODY TISSUE AND FLUIDS (cont'd)</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 Histocore ArcadiaH, Leica Histocore ArcadiaC</p> <p>Microtomy SOP: WA-PATH F2 HS3.08 Leica Histocare Multicut and 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>A1 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>SOP 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>C1, I1</p> <p>C1</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</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 (cont'd)</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>TU PATH-HS 4.76 Sectioning wax blocks using the Rotary Microtome</p>	D2, K2
	<p>Routine staining for identification of basophilic and eosinophilic structures</p>	<p>Routine FFPE H & E staining Haematoxylin and Eosin stain Automated: Leica Autostainer XL SOP: WA-PATH D1 HS4.72 Leica XL Staining machine.</p>	A1
		<p>Routine Haematoxylin and Eosin (H&E) staining Automated using Leica Autostainer XL- SOP OX-PATH F2-HS-3.56</p>	F1
		<p>Routine Haematoxylin and Eosin (H&E) staining Automated using Leica Autostainer XL- SOP GL- PATH-HIS-SOP-1</p>	K2



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological Examination activities for the purposes of clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic examination:	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides.	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant: Macroscopic and Microscopic examination:	
	Acid Mucins	Manual tinctorial stains	A1
	Elastin	Alcian Blue - WA-PATH F2 HS3.39 Using Alcian Blue/ PAS staining and SOP TU-PATH-F2 HS 3.52	A1, D2, F1,
	Helicobacter	Millers Elastic Van Geison (EVG)- WA-PATH F2 HS3.52	A1, C1
	Fungi	Modified Giemsa - WA-PATH F2 HS3.59	A1, C1
	Melanin	Grocott - WA-PATH F2 HS3.55	A1
	Mucins / glycogen	Masson Fontana WA-PATH F2 HS3.51	A1
	Mucins/Glycogen	Alcian Blue Periodic Acid Schiff (ABPAS) - WA-PATH F2 HS3.54	A1, I1
	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, I1
	Ferric Iron	Perl's Iron Stain - WA-PATH F2 HS3.41	A1; C1



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological Examination activities for the purposes of clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic examination:	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant: Manual Tinctorial Stains	
	Helicobacter pylori	Modified Giemsa – EVG - OX-PATH-F2 HS3.61	F1
	Reticulin	Silver Stain - WA-PATH F2 HS3.40	A1
	Mast Cells	Toluidine Blue - WA-PATH F2 HS3.61	A1
	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;
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	<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 III – SOP: WA-PATH D1 HS4.76 Bond-III Immunohistochemistry Stainer	A1
	Cytokeratin – classification of tumours of epithelial origin	AE1/AE3	A1
	Follicular lymphoma. Various B and T cell lymphoproliferative diseases	Bcl2	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 (cont'd)</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis (cont'd)</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Leica Bond III Immunostainer– SOP: WA-PATH D1 HS4.76 Bond-III Immunohistochemistry Stainer</p>	
	Classification of B cell lymphomas, follicular lymphomas and Burkitts lymphoma	Bcl6	A1
	Identification of epithelial cells	BEREP4	A1
	Mucin-like glycoproteins – variety of tumours, classification of adenocarcinomas.	CA125	A1
	Smooth muscle cells Normal and neoplastic mesothelial cells	CALRETININ	A1
	Tumour marker – gastrointestinal, lung, breast	CK18/8	A1
	ID of Burkitts' lymphoma, follicular lymphoma, ALL and renal carcinoma (clear cell)	CD10	A1
	Ewing's sarcoma marker	CD117	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	



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	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
	Thymocytes and T helper cells – identifying anaplastic T-Cell lymphoma	CD4	A1
	T Lymphocytes, myeloid lineage cells	CD43	A1
	ID of B and T cell malignancies	CD5	A1
	Identification of NK cells, neural / neuroendocrine tissue, carcinoid	CD56	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	



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	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
	Identification of epithelial tumours, and may be useful in identifying cholangiocellular carcinomas	CK19	A1
	Normal and abnormal gastric and intestinal epithelium, urothelium and Merkel cells	CK20	A1
	Differentiation between squamous cell carcinoma and adenocarcinoma	CK5 (CK5/6)	A1
	Glandular and transitional epithelial cells	CK7	A1
	Identification of mantle cell lymphomas	CYCLIN D1	A1
	Identification of lymphatic invasion	D2-40	A1
Smooth and striated muscle cells, mesothelial cells, identification of rhabdomyosarcomas, leiomyomas and mesotheliomas	DESMIN	A1	



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	Differential diagnosis of gastrointestinal stromal tumours	DOG 1	A1
	E-cadherin-positive cells in normal and neoplastic tissues	E-CAD	A1
	Epithelial cells	EMA	A1
	Estrogen receptor α-positive cells	ER	A1
		GCDFP15	A1
	Classification of melanomas and melanocytic lesions; metastatic amelanotic melanomas	HMB45	A1
	High grade invasive urothelial carcinoma from prostate cancer	HMWCK	A1
	Alpha Inhibin Expression	INHIBIN	A1
	Plasma cells and related lymphoid cells	KAPPA	A1
<p>Ki-67 expressing neoplastic cells:</p> <ul style="list-style-type: none"> • soft-tissue sarcoma, prostatic adenocarcinoma, and breast carcinoma 	KI67	A1	



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	<p>Plasma cells and related lymphoid cells containing lambda light chains</p>	LAMBDA	A1
	<p>Melanocytes and identification of melanomas, adrenocortical carcinomas</p>	MELAN A	A1
	<p>Epithelial tissues</p>	MNF116	A1
	<p>MUM1-expressing B cells in, activated T cells, and a wide spectrum of related haematolymphoid neoplasms</p>	MUM-1	A1
	<p>Normal and neoplastic cells of neuronal and neuroendocrine origin</p>	NSE	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>Identification of seminomas and desmoplastic small round cell tumors and identification of germ cell tumours</p>	PLAP	A1



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		<p>Automated equipment Leica Bond III immunostainer – SOP: WA-PATH D1 HS4.76 Bond-III Immunohistochemistry Stainer</p>	A1
	<p>Progesterone receptor in human breast carcinomas</p>	PR	A1
	<p>Prostatic epithelium and 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
	<p>Classification of breast tumours</p>	SMM	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>	SYNAPTOPHYSIN	A1
<p>Thyroid transcription factor-1 in normal and malignant cells</p>	TTF-1	A1	
<p>Cells of mesenchymal origin in normal and neoplastic tissues, and is of value in tumour diagnosis</p>	VIMENTIN	A1	



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Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)		Automated equipment Leica Bond III immunostainer – SOP: WA-PATH D1 HS4.76 Bond-III Immunohistochemistry Stainer	
	Classification of Will's tumour, malignant mesothelioma and serous ovarian adenocarcinoma	WT1	A1
Slides prepared in house from the sample types listed above.	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In house procedures: WA-PATH-F2 HS3.04	A1
	<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	C1
		Sample preparation using WA-PATH F2 CY3.24 Systemic Cytology Preparation Procedures WA-PATH F2 HS3.24 Non-Gynae Cytology Preparation Procedures	A1
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



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Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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
END			