Schedule of Accreditation

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Hammersmith Medicines Research Limited

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Biochemistry examination activities for the purposes of clinical trials:	Documented in house method based on manufacturer's instructions
Urine	Automated Urinalysis: Blood, Leukocyte esterase, pH, Specific gravity, Bilirubin, Nitrites, Proteins, Ketones, Glucose, Urobilinogen	SLM017: Beckman Coulter iChem VELOCITY using reflective photometry
Urine	Automated Urine Microscopy: White and Red Blood cells	SLM018: Beckman Coulter IQSPRINT using digital imaging and auto-particle recognition
	Biochemistry examination activities for the purposes of clinical trials:	Documented in house method based on manufacturer's instructions using Ortho Vitros XT 7600
EDTA whole blood	HbA1C	MicroTip Endpoint Spectrophotometry SOP: SLM1058
Serum	Alanine aminotransferase	MicroSlide Multiple-point rate SOP: SLM1018
	Albumin	MicroSlide CM SOP:SLM1001
	Albumin/Globulin ratio	Calculation SOP: SLM1001
	Alkaline phosphatase	MicroSlide Multiple-point rate SOP: SLM1019
	Amylase	MicroSlide Two-point rate SOP: SLM1025
	Aspartate aminotransferase	MicroSlide Multiple-point rate SOP: SLM1052

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical trials (cont'd):	Documented in house method based on manufacturer's instructions using Ortho Vitros XT 7600
Serum (cont'd)	Bilirubin total	MicroSlide CM SOP: SLM1003
	Calcium	MicroSlide CM SOP: SLM1004
	Carbon dioxide	MicroSlide Enzymatic endpoint SOP: SML1016
	Chloride (ISE)	MicroSlide PM SOP: SLM1022
	Cholesterol	MicroSlide CM SOP: SLM1005
	C-reactive protein	MicroSlide Fixed-point IR SOP:1017
	Creatine kinase	MicroSlide Multiple-point rate SOP: SLM1020
	Creatinine	MicroSlide Two-point rate SOP: SLM1026
	Direct bilirubin	SOP: SLM1090
	Gamma glutamyl transferase	MicroSlide: Dry slide technology, Multiple-point rate SOP: SLM1021
	Glucose	MicroSlide: CM SOP: SLM1006
	Globulin	Calculation SOP: SLM1010
	Glomerular filtration rate (estimated)	Calculation SOP: SLM1026
	High density lipoprotein	MicroSlide CM SOP: SLM1007
	Immunoglobulin A	MicroTip Blanked endpoint Spectrophotometry SOP:SLM1053
	Immunoglobulin G	MicroTip Blanked endpoint Spectrophotometry SOP:SLM1054
	Immunoglobulin M	MicroTip Blanked endpoint Spectrophotometry SOP:SLM1055

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical trials (cont'd):	Documented in house method based on manufacturer's instructions
		Documented in house method based on manufacturer's instructions using Ortho Vitros XT 7600
Serum (cont'd)	Lactate dehydrogenase	MicroSlide Multiple-point rate SOP: SLM1030
	Lipase	MicroSlide Two-point rate SOP: SLM1028
	Low density lipoprotein (measured)	MicroTip Endpoint Spectrophotometry SOP: SLM1059
	Magnesium	MicroSlide CM SOP: SLM1008
	Phosphate	MicroSlide CM SOP: SLM1009
	Potassium ISE	MicroSlide PM SOP: SLM1023
	Sodium (ISE)	MicroSlide PM SOP: SLM1024
	Total protein	MicroSlide CM SOP: SLM1010
	Triglycerides	MicroSlide CM SOP: SLM1012
	Unconjugated Bilirubin (IBIL)	Calculation SOP: SLM 1003 and SLM1090
	Urea	MicroSlide CM SOP: SLM1013
	Uric acid	MicroSlide CM SOP: SLM1014

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical trials (cont'd):	Documented in house method based on manufacturer's instructions using Ortho Vitros XT 7600
Urine	Creatinine (urine)	MicroSlide Two-point rate SOP: SLM1026
	Creatinine clearance	Calculation SOP: SLM1026
	Microalbumin	MicroTip Blanked endpoint Spectrophotometry SOP: SLM1056
	Total protein (urine)	MicroSlide CM SOP: SLM1011
		Documented in house method based on manufacturer's instructions using IDS iSYS system
Serum	Bone Specific Alkaline Phosphatse (BAP)	Enzymatic Spectrophotometry SOP: SLM704
Serum	Immunoassay:	Documented in house method based on manufacturer's instructions using Ortho Vitros XT 7600
	Beta human chorionic gonadotropin	MicroWell SOP: SLM1100
	C-reactive protein	Immunoturbidity SOP: SLM1066
	Follicular stimulating hormone	MicroWell SOP: SLM1104
	Prolactin	MicroWell SOP: SLM1114
	Testosterone	MicroWell SOP: SLM1116
	Thyroid stimulating hormone	MicroWell SOP: SLM1117
	Thyroxine free	MicroWell SOP: SLM1118
	Triiodothyronine free	MicroWell SOP: SLM1119
	Troponin I	Immunochemiluminometric assay SOP: SLM1120

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Immunoassay (cont'd):	Documented in house method based on manufacturer's instructions using IDS iSYS system
Urine	Intact amino-terminal propeptide of type 1 procollagen (PINP)	Immunochemiluminometric assay SOP: SLM706
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical trials	Documented in house method based on manufacturer's instructions using Beckman Coulter Unicel DxH 800 analyser
WHOLE BLOOD	Quantification of:	
	Full blood count	SLM306:
	White blood cells	Coulter Principle
	White cell differentials	Coulter Principle
	Haematocrit	Calculation
	Haemoglobin	Photometric
	Mean cell Haemoglobin	Calculation
	Mean cell volume	Calculation
	Mean Corpuscular Haemaglobin Concentration (MCHC)	Calculation
	Mean platelet volume	Calculation
	Platelets	Coulter Principle
	Red blood cells	Coulter Principle
	Red blood cell distribution width	Calculation
	Reticulocyte count	SLM307: VCSn Technology

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical trials (cont'd)</u>	Documented in house method based on manufacturer's instructions using Nikon E400 Microscope
	<u>Blood Film Morphology</u>	SOP SLM002: Microscopy
Whole Blood	White cell differential	SOP SLM002: Microscopy
HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purposes of clinical trials</u>	Documented in house method based on manufacturer's instructions using ACL TOP 300
BLOOD (PLASMA)	Quantification of:	
	Prothrombin time and INR	SLM415: Coagulometric
	Activated partial thromboplastin time	SLM417: Chromogenic
	Fibrinogen	SLM418: Coagulometric
HUMAN BODY FLUIDS (cont'd)	<u>Serology examination activities for the purposes of clinical trials</u>	Documented in house method based on manufacturer's instructions
		Documented in house method based on manufacturer's instructions using Ortho Vitros XT 7600
Serum		
	Hepatitis B core antibody	MicroWell SOP: SLM1106
	Hepatitis B surface antibody	MicroWell SOP: SLM1107
	Hepatitis B surface antigen	MicroWell SOP: SLM1108
	Hepatitis C virus antibodies	MicroWell SOP: SLM1109
	HIV screen (HIV1, HIV2 antibody and p24 antigen)	MicroWell SOP: SLM1110

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purposes of clinical trials</u>	
Plasma	Tubercolosis (TB) Interferon gamma	Qiagen QuantiFERON Gold Plus SOP: SLM286
END		