Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8636 Accredited to ISO 15189:2012

East Kent Hospitals University Foundation NHS Trust

Issue No: 008 Issue date: 24 February 2021

Clinical Biochemistry and

Immunology

East Kent Hospitals University

Foundation Trust

William Harvey Hospital

Kennington Road

Willesborough

Ashford

United Kingdom TN24 0LZ

Contact: Dr Sally Stock

Telephone: +44 (0)1233 616025

Website: http://www.ekhuft.nhs.uk/pathology

E-Mail: sally.stock@nhs.net

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code	
Address William Harvey Hospital Kennington Road Willesborough Ashford TN24 0LZ	Local contact Dr Sally Stock sally.stock@nhs.net	Biochemistry Immunology	A	

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Address Queen Elizabeth the Queen Mother Hospital	Local contact	Biochemistry	В
St Peters Road Margate CT9 4AN	Dr Sally Stock sally.stock@nhs.net		
Address Kent & Canterbury Hospital Ethelbert Road	Local contact	Biochemistry	С
Canterbury CT1 3NG	Dr Sally Stock sally.stock@nhs.net		

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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	Biochemistry examination activities for the purpose of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	A A B, C
	Quantitative determination of:	ADDOLL ALCINICECT C4000	В, О
Serum	Albumin	Abbott Architect Colorimetry using BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Alkaline phosphatase	Abbott Architect, Enzymatic BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	A, B, C
Serum	Alphafetoprotein (non Downs)	Abbott Architect, Immunoassay BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	В
Serum	Alanine transaminase (ALT)	Abbott Architect, Enzymatic BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
plasma (EDTA)	Ammonia	Abbott Architect, Enzymatic BIO-NO-216, BIO-LP-620d, BIO-LP-591, BIO NO 227, BIOEX-046, BIO-WI-001 BIO LP 590a BIO LP 590b BIO LP590c BIO LP 590d	A, B, C

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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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	A B, C
	Quantitative determination of:	Abbott Architect C4000	В, О
Serum	Amylase	Abbott Architect Enzymatic, using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Angiotensin Converting Enzyme (ACE)	ABX Pentra 400, Enzymatic using SOP BIO-LP-114, BIO-WI-053	С
Serum	Antibiotics (GentamIcin)	Abbott Architect, Immunoassay using SOP BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	A, B, C
Serum	Antibiotics (Tobramycin)	Abbott Architect, Immunoassay using SOP BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	В
Serum	Antibiotics (Vancomycin)	Abbott Architect, Immunoassay using SOP BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	A, B, C
Serum	Antibiotics (Amikacin)	Abbott Architect, Immunoassay using SOP BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	В
Serum	Aspartate transaminase (AST)	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001	А
Serum	Bicarbonate	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO 590d	A, B, C

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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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	A B, C
	Quantitative determination of:		, -
Serum	Bile acids	Abbott Architect enzymatic cycling colorimetric methodology using thio-NAD BIO LP 590a, BIO NO 406	С
Serum	Bilirubin (Total)	Abbott Architect Diazo reaction using SOP BIO-LP-620d, BIO-LP- 591, BIO-NO-227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Bilirubin (Conjugated)	Abbott Architect Vanadate oxidation Method using SOP BIO-LP-620d, BIO-LP-591, BIO-NO-227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d BIO LP 818	A, B, C
plasma (EDTA)	Brain natriuretic peptide (BNP)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001	A
Serum	CA 125	Abbott Architect Immunoassay, using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A
Serum	CA 19-9	Abbott Architect Immunoassay BIO-LP-620d, BIO-LP-591, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d, BIO LP 818	В

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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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Serum	CA 153	Abbott Architect Immunoassay, using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	В
	Quantitative determination of:		
Serum	Caeruloplasmin	Abbott Architect immunoturbimetry BIO LP 590a	С
Serum	Calcium	Abbott Architect Colorimetry, using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Carbamazepine	Abbott Architect Fluorescence Polarisation Immunoassay using SOP BIO-LP- 620d, BIO-LP-591, BIO NO 227, 001 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	С
Serum	Carcinoembryonic antigen (CEA)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 004 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	В
Serum	Chloride	Abbott Architect Ion selective electrode using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 005 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	А В, С
	Quantitative determination of:		
Serum	Cholesterol (total)	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 006 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Cholesterol (HDL)	Abbott Architect Direct/Enzymatic using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 007 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Blood (EDTA)	Ciclosporin	Sciex liquid chromatography-mass spectrometry (LC-MS) using the Chromsystems MassTox Immunosuppressant methodology BIO LP 830, BIO LP 831	С
Serum	Creatine Kinase CK	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 009 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Cortisol	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 011 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	А В, С
Serum	Quantitative determination of: C-Reactive Protein (CRP)	Abbott Architect Immunoturbimetric using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 011 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Creatinine	Abbott Architect, Enzymatic, particle enhanced turbidmetric inhibition. using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 012 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Copper	Abbott Architect Colorimetry using BIO-NO-005, BIO-NO-332, BIO-LP-621, BIO-NO-038, BIO-LP-620d, BIO-NO-406, BLS-NO-054, DIR-NO-Q010, BIO LP 817	С
Serum	Cystatin C	Abbott Architect Particle-enhanced turbidimetric immunoassay using BIO-LP-431, BIO-LP-590a, BIO LP 590b BIO LP 590c BIO LP 590d	С
Serum	Digoxin	Abbott Architect particle enhanced turbimetric inhibition assay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 013 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	А
Plasma	Ethanol	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 014 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	А В, С
Serum	Ferritin	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 015 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Follicle stimulating hormone (FSH)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 016	А
Serum	Folate	Abbott Architect Immunoassay BIO-LP-620d, BIO-LP-591, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	A, B, C
Serum	Gamma Glutamyl Transferase (GGT)	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 017 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Plasma	Glucose	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 018 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A,B,C
Serum	Growth Hormone	IDS-iSYS Immunoassay using SOP BIO-LP-709, BIO-NO-038, BIO- NO-332, BIO-NO-282, BIO-LP-621	А
Blood (EDTA)	HbA1c	HPLC Cation Exchange using Tosoh G11 BIO-LP-838	А

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	А В, С
Serum	HCG (Non Downs)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 021 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Insulin like growth factor –1 (IGF1)	IDS-iSYS Immunoassay using SOP BIO-LP-709, BIO-NO-038, BIO- NO-332, BIO-NO-282, BIO-LP-621	A
Serum	Iron	Abbott Architect Colorimetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 024 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Plasma	Lactate	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 025 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	LDH	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 026 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Luteinising hormone (LH)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 027	A
Serum	Lithium	Abbott Architect Colorimetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227,	А
Serum	Macroprolactin	028 Abbott Architect PEG precipitation using SOP BIO-LP-349	A

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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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Quantitative determination of:	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	А В, С
Serum	Magnesium	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 030 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Oestradiol	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 031	A
Serum, Urine	Osmolality	The advanced Micro-Osmometer Model 3320 Freezing point depression using SOP BIO-LP-333	A, B, C
Serum	Paracetamol	Abbott Architect Enzymatic fluorescence polarisation using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 034 BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Phenobarbitone	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 036	С
Serum	Phenytoin	Abbott Architect Enzyme Immunoassay using SOP BIO-LP- 620d, BIO-LP-591, BIO NO 227, 037, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A
Serum	Phosphate	Abbott Architect Colorimetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 038, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B,C

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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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Quantitative determination of:	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	A B, C
Serum	Potassium	Abbott Architect Ion Selective electrode using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, , 039, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Procalcitonin	Abbott architect chemiluminescence microparticle immunoassay. BIO-LP-592	A
Serum	Progesterone	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 041	A
Serum	Prolactin	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 042	A
Serum	Prostate specific antigen (PSA) (Total)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 043	A
plasma (EDTA)	Parathyroid hormone (PTH)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 044	A
Serum	Rheumatoid factor	Immunoturbidimetry by Abbott Architect c1600 using SOP BIO- LP-591	A
Serum	Salicylate	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 045, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Blood (EDTA)	Sirolimus	Sciex liquid chromatography-mass spectrometry (LC-MS) using the Chromsystems MassTox Immunosuppressant methodology BIO LP 830, BIO LP 831	С

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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 (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	A B, C
	Quantitative determination of:	ADDOLL ATCHILECT C4000	В, С
Serum	Sodium	Abbott Architect Ion Selective electrode (indirect) using SOP BIO- LP-620d, BIO-LP-591, BIO NO 227, 047, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Sodium Valproate	Abbott Architect particle enhanced turbidimetric inhibition immunoassay using BIO-LP-620d, BIO-NO-406, BIO-NO-038, BIO-NO-284, BLS-NO-054, BIO-NO-045, DIR-NO-Q010	
Serum	T3 (free)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 048, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A
Serum	T4 (Free)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 049, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A,B,C
Serum	Thyroid peroxidase antibody (TPO)	Abbott architect chemiluminescence microparticle immunoassay BIO-LP-620, BIO-LP-592	A
Serum	Thyroglobulin	Abbott architect ci4100 chemiluminescence microparticle immunoassay using SOP BIO – LP-590a	С

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Serum	Thyroglobulin antibodies	Abbott architect ci4100 chemiluminescence microparticle immunoassay using SOP BIO – LP-590a	С
Blood (EDTA)	Tacrolimus (FK 506)	Sciex liquid chromatography-mass spectrometry (LC-MS) using the Chromsystems MassTox Immunosuppressant methodology BIO LP 830, BIO LP 831	С
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000	A B, C
	Quantitative determination of:	Abbott Architect c4000	B, C
Serum	Testosterone	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 051	A
Serum	Theophylline	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 052	A
Serum (cont'd)	Total Protein	Abbott Architect Colorimetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 053, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Transferrin	Abbott Architect Immunoturbidmetric using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 054, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Serum	Triglyceride	Abbott Architect enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	A, B, C

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measured/Range of measurement	Equipment/Techniques used	Location Code
Troponin I	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 056, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Thyroid stimulating hormone (TSH)	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227 057, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Quantitative determination of:	Abbott Architect c16000 Abbott Architect c4000	A B, C
Urea	Abbott Architect Enymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 058, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A,B,C
Uric Acid	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP- 591, BIO NO 227, 059, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A,B,C
Vitamin B12	Abbott Architect Immunoassay using BIO-LP-620d, BIO-LP-591, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP 590d	A, B, C
Vitamin D	Abbott architect chemiluminescence microparticle immunoassay using SOP BIO-LP- 592	A
	Troponin I Thyroid stimulating hormone (TSH) Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Quantitative determination of: Urea Uric Acid Vitamin B12	Troponin I Troponin I Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 056, BIO LP 590a BIO LP 590a BIO LP 590c BIO LP590d Thyroid stimulating hormone (TSH) Thyroid stimulating hormone (TSH) Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Urea Biochemistry examination of: Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-590a BIO LP 590c BIO LP 590c BIO LP590d In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c16000 Abbott Architect Enymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 058, BIO LP 590a BIO LP 590a BIO LP 590c BIO LP590d Uric Acid Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 059, BIO LP 590c BIO LP590d Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 059, BIO LP 590c BIO LP590d Abbott Architect Immunoassay using BIO-LP-620d, BIO-LP-591, BIO LP 590a BIO LP 590c BIO LP 590

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Quantitative determination of:	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	A B, C
Urine	Albumin (Microalbumin)	Abbott Architect Immunoturbimetric Assay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001	A
Urine	Amylase	Abbott Architect Enzymatic Assay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001	С
Urine	Calcium	Abbott Architect Colorimetry Assay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001	С
Urine	Chloride	Abbott Architect Ion selective electrode using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Urine	Cortisol (UFC)	Abbott Architect Immuoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	А
Urine	Creatinine	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Urine	Magnesium	Abbott Architect Colorimetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	С

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) Quantitative determination of:	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Abbott Architect c16000 Abbott Architect c4000	А В, С
Urine	Phosphate	Abbott Architect Colorimetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	С
Urine	Potassium	Abbott Architect Ion selective electrode using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Urine	Protein (total)	Abbott Architect Turbidmetry using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Urine	Sodium	Abbott Architect Ion selective electrode using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	A, B, C
Urine	Uric acid	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	С
Urine	Urea	Abbott Architect Enzymatic using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 001, BIO LP 590a BIO LP 590b BIO LP 590c BIO LP590d	С

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
CSF	Glucose Protein	Abbott Architect Turbidimetric using SOP BIO LP 591	Α
CSF	Xanthochromia	UVIKON xs Spectrophotometry Using SOP BIO-LP-365	А
Urine	Noradrenaline Adrenaline	Dionex UltiMate 3000 HPLC Systems using SOP LP BIO 381	Α
Urine	Dopamine	Dionex UltiMate 3000 HPLC Systems using SOP LP BIO 381	Α
Urine	Citrate	ABX Pentra 400 Enzymatic using SOP BIO-LP-115, BIO-WI-051	С
Urine	5' Hydroxyindolacetic acid (5HIAA)	Dionex UltiMate 3000 HPLC systems by HPLC using SOP BIO-NO-038, BIO-LP-621, BIO- NO-332, BIO-LP-807, BIO-NO-138, BIO-FO-205, BLS-NO-054, DIR- NO-Q010	A
Urine	Oxalate	ABX Pentra 400 Enzymatic using SOP BIO-LP-110, BIO-WI-050	С
Urine	Porphobilinogen	RECIPE Gel Column Separation Uvikon XS Spectrophotometer using SOP BIO LP 840	Α
Urine	Pregnancy Test (HCG) Qualitative	Siemens Clinitek Status chromatographic immunoassay using SOP BIO LP 815	A

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Sweat	Chloride	Sherwood M926S Mk2 Chloride meter Coulometry, using SOP LP BIO 366	С
	Calculated parameters	Abbott Architect c16000 Abbott Architect c4000	A B,C
Serum	eGFR Serum adjusted calcium LDL Non-HDL cholesterol Total cholesterol/HDL ratio Serum globulins Transferrin saturation index (TSAT)		A, B, C
Urine	BJP:creatinine ratio	Sebia Hydrasys Immunofixation using SOP BIO-LP-245	А
	24 hour urine catechoamines (adrenaline, noradrenaline, dopamine) 24 hour urine 5-HIAA Microalbumin Excretion Rate	Dionex UltiMate 3000 HPLC Systems using SOP LP BIO 381	A

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
	Calculated parameters cont'd:	Abbott Architect c16000 Abbott Architect c4000	
Urine	Urine albumin:creatinine ratio Urine protein:creatinine ratio 24 hour urine protein 24 hour urine calcium 24 hour urine creatinine 24 hour urine magnesium 24 hour urine phosphate 24 hour urine urea 24 hour urine urate 24 hour urine sodium 24 hour urine potassium Calcium clearance ratio		A A,B,C C A,B,C C C C C C C C A,B,C C A,B,C
Serum	Bioactive monomeric prolactin	Abbott Architect Immunoassay using SOP BIO-LP-620d, BIO-LP-591, BIO NO 227, 042	A
Urine	24 hour urine oxalate 24 hour urine citrate	ABX Pentra 400 Enzymatic using SOP BIO-LP-110, BIO-WI-050	С
Urine	24 hour urine cortisol	Abbott Architect Immunoassay using SOP BIO-LP-620d	А
Serum/ascites fluid	Serum albumin ascites gradient (SAAG)	Beckman Immage, nephelometry (fluid) and Abbott Architect c16000 (serum) using SOPs LP-BIO-591 BIO-LP-618g, BIO-LP-160b, , BIO-LP-160c, BIO-LP-162	A

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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Ascitic fluid	Albumin (serum ascitic gradient)	Beckman Immage, nephelometry BIO-LP-618g, BIO-LP-160b, , BIO- LP-160c, BIO-LP-162	А
Serum	Alkaline phosphatase isoenzymes	Sebia Hydrasys 2 gel electrophoresis with wheat germ lectin inhibition BIO-LP-246	А
Serum	ANCA	ASP1200 slide processor, Fluorescence microscope Immunofluorescence using SOP BIO-LP-171, BIO-LP-189, BIO-LP- 192, BIO LP 174	A
Serum	ANA	ASP1200 processor# Fluorescence microscope Immunofluorescence using SOP BIO-LP-170, BIO-LP-189, BIO-LP- 192	A
Serum	Anticyclic citrullinated proteins (CCP)	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-195, BIO-LP-277, BIO-LP-	А
Serum	Antiendomysial Abs serum	275, BIO-LP-276 ASP1200 slide processor, Fluorescence microscope Immunofluorescence using SOP BIO-LP-177, BIO-LP-189, BIO-LP- 192, BIO LP 174	A
Serum	AntiGBM Abs serum	Phadia Immunocap 250 using EIA methodology BIO LP 176	А
Serum	Anti neuronal antibodies	ASP1200 slide processor, Fluorescence microscope Immunofluorescence using BIO- LP-833, BIO-LP-189 and BIO LP 174	A

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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Serum	Autoimmune screen/titre on multiblock	ASP1200 slide processor, Fluorescence microscope Immunofluorescence using SOP BIO-LP-179, BIO-LP-189, BIO-LP- 192, BIO LP 174	A
Serum	C3 quantitation	Beckman Immage nephelometry using SOP BIO-LP-160a, BIO-LP-160b, BIO-LP-160d, BIO-LP-160c, BIO-LP-162	A
Serum	C4 quantitation	Beckman Immage nephelometry using SOP BIO-LP-160a, BIO-LP- 160b, BIO-LP-160d, BIO-LP-160c, BIO-LP-162	А
Serum	ds DNAab	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-172, BIO-LP-277, BIO-LP- 275, BIO-LP-276	A
Serum	ENA antibody screen	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-185, BIO-LP-277, BIO-LP- 275, BIO-LP-276	A
Serum	Haptoglobin	Beckman Immage nephelometry using SOP BIO-LP-160a, BIO-LP-160b, BIO-LP-160d, BIO-LP-160c, BIO-LP-162	A
Serum	Immunoglobulins (Igs) IgA, IgG, IgM	Beckman Immage nephelometry using SOP BIO-LP-160a, BIO-LP- 160b, BIO-LP-160d, BIO-LP-160c, BIO-LP-162	A

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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Serum	Intrinsic factor abs	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-182, BIO-LP-277, BIO-LP- 275, BIO-LP-276	A
Serum	Pemphigus/oid Ab serum	ASP120 slide processor, Fluorescence microscope Immunofluorescence using SOP BIO-LP-180, BIO-LP-189, BIO-LP- 192, BIO LP 174	А
Serum	Rheumatoid factor	Beckman Immage nephelometry using SOP BIO-LP-160a, BIO-LP-160b, BIO-LP-160d, BIO-LP-160c, BIO-LP-162	A
Serum	Serum paraprotein quantitation	Sebia Capillarys 3 electrophoresis TERA BIO LP 240	A
Serum	Serum paraprotein typing/immunofixation	Sebia Capillarys 3 electrophoresis TERA (immunotype), Hydrasys 2 Gel electrophoresis immunofixation using SOP BIO-LP-258, BIO-LP- 243, BIO-LP-803	А
Serum/plasma	Cryoglobulins	Incubator/fridge and visual examination, plus Sebia Hydrasys immunofixation and Beckman Immgae nephelometry if positive using BIO LP 251, BIO LP 244, BIO LP 243	A
Serum	Serum protein electrophoresis	Sebia Capillarys 3 electrophoresis TERA BIO LP 240	A

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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Serum	Specific IgG to Aspergillus fumigatus	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-822, BIO-LP-277, BIO-LP- 275, BIO-LP-276	A
Serum	Total IgE	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-274, BIO-LP-277, BIO-LP- 275, BIO-LP-276	А
Serum	c1 penicillin c2 penicillin c5 ampicillin c6 amoxycillin d1 house dust mite e1 cat e3 horse e5 dog e6 guinea pig e81 sheep e82 rabbit e84 hamster e87 rat e209 gerbil ex71 feather mix ex72 cage bird mix f1 egg white f2 cow's milk f3 cod f4 wheat f5 rye F6 barley f7 oat F201 pecan nut f202 cashew nut	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-274, BIO-LP-277, BIO-LP-275, BIO-LP-276	A

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HUMAN BODY FLUIDS	Immunology examination	In-house documented procedures	
(cont'd)	activities for the purpose of	using manual methods or analysers	
(55111 4)	clinical diagnosis (cont'd)	in conjunction with manufacturers'	
	<u>omnoar aragineolo (sent a)</u>	instructions as specified:	
Serum	Specific IgE (cont'd)	Phadia Immunocap 250 analyser	Α
		Enzyme immunoassay using SOP	
	f8 maize (sweetcorn)	BIO-LP-274, BIO-LP-277, BIO-LP-	
	f9 rice	275, BIO-LP-276	
	f10 sesame seed		
	f11 buckwheat		
	f12 pea		
	f13 peanut		
	f14 soya		
	f15 white bean		
	f17 hazel nut		
	f18 brazil nut		
	f20 almond		
	f23 crab		
	f24 shrimp f25 tomato		
	f26 pork		
	f27 beef		
	f31 carrot		
	f33 orange		
	f35 potato		
	f36 coconut		
	f37 mussel		
	f40 tuna		
	f41 salmon		
	f44 strawberry		
	f45 yeast		
	f47 garlic		
	f48 onion		
	f49 apple		
	f81 cheddar cheese		
	f82 mould cheese		
	f83 chicken f84 kiwi		
	f85 celery		
	f87 melon		
	f91 mango		
	f92 banana		
	f93 chocolate		
	f94 pear		
	f95 peach		
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Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Specific IgE (cont'd) f253 pine nut f255 plum f256 walnut f259 grape f279 chilli pepper f309 chickpea f329 watermelon f343 raspberry f345 macadamia nut f416 omega-5 gliadin f423 rAra h 2 peanut fx1 nut mix fx2 fish mix fx3 grain mix fx5 food mix gx3 grass pollen mix i1 bee venom i3 wasp venom i175 hornet k82 latex m3 aspergillus mx2 mould mix tx8 tree pollen mix wx3 weed pollen mix wx03 rape pollen f96 avocado f203 pistachio nut f208 lemon f210 pineapple f212 mushroom f218 sweet pepper r221 coffee f235 lentil f242 cherry f244 cucumber	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-274, BIO-LP-277, BIO-LP-275, BIO-LP-276	A
	activities for the purpose of clinical diagnosis (cont'd) Specific IgE (cont'd) f253 pine nut f255 plum f256 walnut f259 grape f279 chilli pepper f309 chickpea f329 watermelon f343 raspberry f345 macadamia nut f416 omega-5 gliadin f423 rAra h 2 peanut fx1 nut mix fx2 fish mix fx3 grain mix fx5 food mix gx3 grass pollen mix i1 bee venom i3 wasp venom i175 hornet k82 latex m3 aspergillus mx2 mould mix tx8 tree pollen mix wx3 weed pollen mix wx3 weed pollen f96 avocado f203 pistachio nut f208 lemon f210 pineapple f212 mushroom f218 sweet pepper r221 coffee f235 lentil f242 cherry	activities for the purpose of clinical diagnosis (cont'd) Specific IgE (cont'd) F253 pine nut f256 walnut f259 grape f279 chilli pepper f309 chickpea f329 watermelon f343 raspberry f345 macadamia nut f416 omega-5 gliadin f423 rAra h 2 peanut fx1 nut mix fx2 fish mix fx3 grain mix fx5 food mix gx3 grass pollen mix i1 bee venom i3 wasp venom i175 hornet k82 latex m3 aspergillus mx2 mould mix xx3 weed pollen mix wx3 weed pollen f96 avocado f203 pistachio nut f208 lemon f210 pineapple f212 mushroom f218 sweet pepper r221 coffee f235 lentil f242 cherry

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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:			
Serum	IgA and IgG tissue transglutaminase antibodies	Phadia Immunocap 250 analyser Enzyme immunoassay using SOP BIO-LP-191, BIO-LP-277, BIO-LP- 275, BIO-LP-276	A		
Urine	Urine paraprotein typing/immunofixation	Sebia Hydrasys Gel electrophoresis using SOP LP-BIO- 243	А		
Urine	Urine Bence Jones Protein detection	Sebia Hydrasys Immunofixation using SOP BIO-LP-245	А		
Serum	α1-antitrypsin	Beckman Immage nephelometry Using SOP BIO-LP-160a, BIO-LP- 160b, BIO-LP-160d, BIO-LP-160c, BIO-LP-162	A		
Urine	Urine paraprotein quantitation	Sebia Hydrasys Gel electrophoresis using SOP BIO-LP- 245, BIO-LP-257	А		
END					

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