

Accreditation Certificate

Claymon Biomnis Laboratories Ltd

Three Rock Road, Sandyford Industrial Estate, Dublin 18

Medical Testing Laboratory

Registration number: 159MT

is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard **ISO/IEC 15189:2007 2nd Edition**

"Medical laboratories - Particular requirements for quality and competence"


(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)

Date of award of accreditation: **14:02:2005**

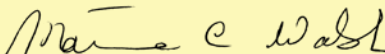
Date of last renewal of accreditation: **18: 11:2009**

Expiry date of this certificate of accreditation: **18: 11:2014**

This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager: 

Dr Adrienne Duff

Chairperson: 

Dr Máire Walsh

Issued on 18 November 2009

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.

The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

Schedule of Accreditation



(Annex to Accreditation Certificate)

Permanent Laboratory:
Category A

CLAYMON BIOMNIS LABORATORIES LTD

Medical Testing Laboratory

Initial Registration Date : 14-February-2005
Postal Address: Three Rock Road
(Address of other locations as they apply) Sandyford Industrial Estate
Dublin 18
Telephone: +353 (1) 2958545
Fax: +353 (1) 2955399
E-mail: info@claymonbiomnis.ie
Website: www.claymon.com
Contact Name: Ms Brid Muimneach
Facilities: Public testing service

Schedule of Accreditation



Permanent Laboratory:
 Category A

THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO/IEC 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

Testing and Calibration Categories:

- Category A:** Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category B:** Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.
- Category C:** Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.
- Category D:** Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using
- (a) portable test equipment
 - (b) a site laboratory
 - (c) a mobile laboratory or
 - (d) equipment from a mobile or site laboratory

Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

Glossary of Terms

Facilities:

- Public calibration/testing service:** Commercial operations which actively seek work from others.
- Conditionally available for public calibration/testing:** Established for another primary purpose but, more commonly than not, is available for outside work.
- Normally not available for public calibration/testing:** Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will on request verify the status and scope.

GENERAL CHEMISTRY INAB CLASSIFICATION NO. 1061

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	POSITIVE CUT OFF	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Cannabis Metabolites	Urine	Olympus AU640	CEDIA	ng/mL	50	Microgenics THC Calibrators	UKNEQAS	D17
Cocaine	Urine	Olympus AU640	CEDIA	ng/mL	300	Microgenics Multi-drug Calibrators	UKNEQAS	D21
Methadone	Urine	Olympus AU640	CEDIA	ng/mL	300	Olympus DAU Methadone Calibrators	UKNEQAS	D11
Opiates	Urine	Olympus AU640	CEDIA	ng/mL	300	Microgenics Multi-drug Calibrators	UKNEQAS	D10
6-Acetyl Morphine	Urine	Olympus AU640	CEDIA	ng/mL	10	Cedia 6-AM Calibrators	UKNEQAS	D14
EDDP	Urine	Olympus AU640	CEDIA	ng/mL	100	Microgenics Multi-drug Calibrators	UKNEQAS	D19
Amphetamines/ Ecstasy	Urine	Olympus AU640	CEDIA	ng/mL	1000	Microgenics Multi-drug Calibrators	UKNEQAS	D18
Benzodiazepines	Urine	Olympus AU640	CEDIA	ng/mL	200	Microgenics Multi-drug Calibrators	UKNEQAS	D24



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Permanent Laboratory:

Category A

GENERAL CHEMISTRY INAB CLASSIFICATION NO. 1061

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	POSITIVE CUT OFF	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Creatinine	Urine	Olympus AU640	CEDIA	mmol/L	<0.4 mmol/L: ? Sample integrity; 0.5 - 2.0: dilute sample; > 2.0: compatible with normally concentrated urine	Microgenics Creatinine Calibrators	UKNEQAS	D34
Sample Check	Urine	Olympus AU640	CEDIA	%	Range 85-105	NaOH	UKNEQAS	D26
pH	Urine	Olympus AU640	CEDIA	pH units	Range 4.7 - 7.8	Microgenics pH Calibrators	UKNEQAS	D20
Ethanol	Urine, Serum, Plasma	Olympus AU640	DRI	mg/dL	10	Microgenics Alcohol Calibrators	UKNEQAS	D35

Note: The Drugs of Abuse Assays (with the exemption of alcohol) are screening tests which provide preliminary positive or negative results.



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Permanent Laboratory:

Category A

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
B 2 Microglobulin	Serum, EDTA, Heparin Plasma	Architect	Microparticle Enzyme Immunoassay	mg/L	1.19-2.42	B2M Master Calibrators	RIQAS	CC90
Cytomegalovirus IgG	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	AU/mL	< 6: Negative >6: Positive	Architect CMV IgG Master Calibrators	UKNEQAS	CC75
Cytomegalovirus IgM	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Index	< 0.85: Negative >1.00: Positive	Architect CMV IgM Calibrators	UKNEQAS	CC83
Hepatitis A IgG/IgM	Serum, Heparin Plasma	Architect	Microparticle Enzyme Immunoassay	Index	Negative	HAVAB Calibrator	UKNEQAS	CC87, CC88
Hepatitis C	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	S/C O	Negative	Architect HepC Calibrator	UKNEQAS	CC74
HIV Ab/Ag Combo	Serum, EDTA Lip Hep Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	S/C O	Negative	Architect HIV Calibrator	UKNEQAS	CC73

GENERAL CHEMISTRY INAB CLASSIFICATION NO. 1061

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Homocysteine	Serum, EDTA, Lip Hep Heparin Plasma	Architect	Microparticle Enzyme Immunoassay	µmol/L	< 15	Homocysteine Cal	UKNEQUAS	CC91
Rubella IgG	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	<5: Negative 5-10: Equivocal >10: Positive	Architect Rubella IgG Calibrator	UKNEQAS	CC76
Rubella IgM	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Index	<1.2: Negative 1.2-1.60: Equivocal ≥1.60: Positive	Architect Rubella IgM Calibrator	UKNEQAS	CC81
Valproic Acid	Serum, EDTA, Heparin Plasma	Architect	Fluorescence Polarisation Immunoassay	µg/mL	50 - 100	Valproic Acid Standard Calibrator	RIQAS	CC 78
Vancomycin	Serum, EDTA, Heparin Plasma	Architect	Fluorescence Polarisation Immunoassay	µg/mL	5 - 10 (Trough) 20 - 40 (Peak)	AxSYM Vancomycin Standard Calibrator	RIQAS	CC 84

GENERAL CHEMISTRY INAB CLASSIFICATION NO. 1061

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Alkaline Phosphatase (ALP)	Serum, Heparin plasma	Architect c8000	AMP buffer not IFCC	U/L	40 - 150	Water	NEQAS/IEQAS	CC03
Alanine AminoTransferase (ALT)	Serum, EDTA, Heparin Plasma	Architect c8000	TRIS buffer without PLP	U/L	0 - 55	Water	NEQAS/IEQAS	CC04
Amylase	Serum, Heparin plasma	Architect c8000	G3 Substrate	U/L	25 - 125	Water	NEQAS/IEQAS	CC05
Aspartate Aminotransferase (AST)	Serum, Heparin (Na or Li) plasma	Architect c8000	TRIS buffer without PLP	U/L	5 - 36	Water	NEQAS/IEQAS	CC06
Cholesterol	Serum, Heparin plasma	Architect c8000	Cholesterol esterase / oxydase	mmol/L	< 5.0	MultiConstituent Calibrator	NEQAS/IEQAS	CC09
Calcium	Serum, Heparin plasma	Architect c8000	Arsenazo III	mmol/L	2.1- 2.6	MultiConstituent Calibrator	NEQAS/IEQAS	CC10
Glucose	Sodium Fluoride	Architect c8000	Hexokinase + G6PD	mmol/L	3.1 - 6.1 (fasting)	MultiConstituent Calibrator	NEQAS/IEQAS	CC11
Creatinine	Serum, EDTA, Heparin Plasma,	Architect c8000	Kinetic Jaffe	µmol/L	Male: 62 - 115 Female: 40 - 90	MultiConstituent Calibrator	NEQAS/IEQAS	CC12
Creatinine	Urine	Architect c8000	Kinetic Jaffe	mmol/24h	Male: 9 - 21 Female: 7 - 14	MultiConstituent Calibrator	NEQAS/IEQAS	CC12
HDL	Serum, EDTA, Heparin Plasma	Architect c8000	Accelerator Selective Detergent	mmol/L	1 - 1.55	HDL Calibrator	NEQAS/IEQAS	CC13
Iron	Serum	Architect c8000	Ferene	µmol/L	Female: 4.6 - 27.9 Male: 5.5 - 25.8	Iron/Magnesium Calibrator	NEQAS/IEQAS	CC14
BNP	Serum	Architect c8000	CMIA	pg/mL	< 100 pg/mL	BNP Calibrator	NEQUAS	CC85

GENERAL CHEMISTRY INAB CLASSIFICATION NO. 1061

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Magnesium	Serum, Heparin plasma	Architect c8000	Arsenazo III	mmol/L	0.65 - 1.10	Iron/Magnesium Calibrator	NEQAS/IEQAS	CC15
Phosphate	Serum, Heparin plasma	Architect c8000	Phosphomolybdate UV	mmol/L	0.80 - 1.56	MultiConstituent Calibrator	NEQAS/IEQAS	CC16
Total Protein	Serum, Heparin (Na or Li) plasma	Architect c8000	Biuret	g/L	64 - 83	MultiConstituent Calibrator	NEQAS/IEQAS	CC17
Urea	Serum, Heparin (Na or Li) plasma	Architect c8000	Kinetic Urease	mmol/L	Female: 2.5 - 7.7 Male: 3.2 - 8.8	MultiConstituent Calibrator	NEQAS/IEQAS	CC18
Uric Acid	Serum, Heparin (Na or Li) plasma	Architect c8000	Endpoint Uricase	µmol/L	Female: 155 - 394 Male: 240 - 520	MultiConstituent Calibrator	NEQAS/IEQAS	CC19
Glycated Haemoglobin (HbA1c)	Whole blood	Architect c8000	Immunoturbidimetric	%	4.8 to 5.9% in non-diabetics, 6 to 8% in controlled diabetics and > 8% in uncontrolled diabetics	MULTIGENT Hemoglobin-A1c	RIQAS	CC29
Albumin	Serum, Heparin plasma	Architect c8000	BCG	g/L	40 - 54	MultiConstituent Calibrator	NEQAS/IEQAS	CC42
LDL	Serum, EDTA, Heparin Plasma	Architect c8000	Measured, Liquid Selective Detergent	mmol/L	<3.4	MULTIGENT LDL Calibrator	NEQAS	CC44
Lipoprotein a (Lp(a))	Serum, EDTA, Heparin Plasma	Architect c8000	Immunoturbidimetric	g/L	<0.3	Quantia Lp(a) Standard	CAP	CC49
Carbon Dioxide (Co ₂)	Serum, Heparin plasma	Architect c8000	PEP Carboxylase	mmol/L	22 - 29	Carbon Dioxide Calibrator	CAP	CC50

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
ImmunoGlobulin E (IgE)	Serum, EDTA, Heparin Plasma	Architect c8000	Immunoturbidimetric	g/L	<100	Quantia IgE Standard	RIQAS	CC47
ImmunoGlobulin M (IgM)	Serum, EDTA, Heparin Plasma	Architect c8000	Immunoturbidimetric	g/L	Female: 0.33 - 2.93 Male: 0.22 - 2.40	Specific Proteins Multiconstituent Calibrator	RIQAS	CC51
ImmunoGlobulin G (IgG)	Serum, EDTA, Heparin Plasma	Architect c8000	Immunoturbidimetric	g/L	Female: 5.52 - 16.31 Male: 5.40 - 18.22	Specific Proteins Multiconstituent Calibrator	RIQAS	CC52
ImmunoGlobulin A (IgA)	Serum, EDTA, Heparin Plasma	Architect c8000	Immunoturbidimetric	g/L	Female: 0.69 - 5.17 Male: 1.01 - 6.45	Specific Proteins Multiconstituent Calibrator	RIQAS	CC53
Unsaturated Iron Binding Capacity (UIBC)	Serum, Heparin plasma	Architect c8000	Ferene	µmol/L	20 - 62	UIBC Liquid Calibrator	CAP	CC54
Transferrin	Serum, EDTA, Heparin Plasma	Architect c8000	Immunoturbidimetric	g/L	Female: 1.73 - 3.60 Male: 1.63- 3.44	Specific Proteins Multiconstituent Calibrator	RIQAS	CC55
Rheumatoid Factor (RF)	Serum	Architect c8000	Immunoturbidimetric	IU/mL	<30	Rheumatoid factor Calibrator	RIQAS	CC56

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Sodium (Na)	Serum, Heparin plasma	Architect c8000	Ion-selective electrode diluted (Indirect)	mmol/L	135 - 145	ICT Reference Solution	NEQAS/IEQAS	CC57
Potassium (K)	Serum, Heparin plasma	Architect c8000	Ion-selective electrode diluted (Indirect)	mmol/L	3.3 - 5.3	ICT Reference Solution	NEQAS/IEQAS	CC57
Chloride (Cl)	Serum, Heparin plasma	Architect c8000	Ion-selective electrode diluted (Indirect)	mmol/L	98 - 107	ICT Reference Solution	NEQAS/IEQAS	CC57
Gamma Glutamyl Transferase	Serum, Heparin (Na or Li) plasma	Architect c8000	L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	U/L	Female: 9 - 36 Male: 12 - 64	Water	NEQAS/IEQAS	CC60
Lactate DeHydrogenase (LDH)	Serum, Heparin (Na or Li) plasma	Architect c8000	Lactate to Pyruvate (NADH)	U/L	125 - 243	Water	NEQAS/IEQAS	CC61
Triglycerides	Serum, Heparin (Na or Li) plasma	Architect c8000	Glycerol Phosphate Oxidase	mmol/l	0.6 - 1.70	MultiConstituent Calibrator	NEQAS/IEQAS	CC62
C Reactive Protein (CRP)	Serum, Heparin (Na or Li) plasma	Architect c8000	Immunoturbidimetric	mg/L	<5	C-Reactive Protein Calibrator	RIQAS/NEQAS	CC63
Microalbumin	Urine	Architect c8000	Immunoturbidimetric	mg/g Creatinine (Spot Collection); mg/24h (24h Collection)	Spot Collection: <30 24h Collection: <30	Microalbumin Calibrator	NEQAS	CC67
Total Bilirubin	Serum, EDTA, Heparin Plasma	Architect c8000	Diazo	µmol/L	3.4 - 21	Bilirubin Calibrator	NEQAS/IEQAS	CC68

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Cortisol	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	nmol/L	Morning: 171 - 800 nmol/L	Cortisol Calibrator	RIQAS	CC07
Luteinising Hormone (LH)	Serum, EDTA plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	mIU/mL	Male: 1.7 - 8.6 Female: 2.4 - 12.6 (Follicular Phase); 14 - 96 (Mid cycle peak); 1.0 - 11.4 (Luteal phase); 7.7 - 59 (Post menopause without HRT)	LH Calibrator	RIQAS	CC08
Progesterone	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	nmol/L	Male: <0.6 Female: 0.6 - 4.7 (Follicular phase); 5.3 - 86 (Luteal phase); 0.3 <2.5 (Post Menopause);	Progesterone Calibrator	RIQAS	CC20

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Testosterone	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	nmol/L	Male: 8 - 30	Testosterone Calibrator	RIQAS	CC21
Free TriiodoThyronine (FT3)	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	pmol/L	2.63 - 5.70	FT3 Calibrator	RIQAS	CC22
Follicle Stimulating Hormone (FSH)	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	mIU/mL	Male: 1.5 - 12.5 Female: 3.5 - 12.5 (Follicular phase); 4.7 - 21.5 (mid cycle peak); 1.7 - 7.7 (Luteal phase); 26 - 135 (Post menopause)	FSH calibrator	RIQAS	CC23
Prolactin	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	µIU/mL	Male: 54 - 381 Female: 25 - 629	Prolactin Calibrator	RIQAS	CC24
Oestradiol	Serum, EDTA, Heparin(Li) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	pmol/L	Male: 40 - 161 Female: 46 - 607 (Follicular phase); 315 - 1828 (Pre Ovulatory peak); 161 - 774 (Luteal phase); < 201 (Post menopause)	Oestradiol Calibrator	RIQAS	CC25

GENERAL CHEMISTRY INAB CLASSIFICATION NO. 1061

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Parathyroid Hormone (PTH)	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	ng/L	15 - 68.3	PTH Calibrator	NEQAS	CC26
Hepatitis B Surface Antigen (Hbs Ag)	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	Negative	HbsAg Calibrator	NEQAS	CC28
Thyrotropine (Thyroid Stimulating Hormone, TSH)	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	μIU/mL	0.270 - 4.200	TSH Calibrator	RIQAS	CC30
Free Thyroxin	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	pmol/L	9 - 19	FT4 Calibrator	RIQAS	CC31
Total Prostate Specific Antigen (Total PSA)	Serum	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	ng/mL	<4	Total PSA Calibrator	NEQAS/RIQAS	CC32
Ferritin	Serum, EDTA, Heparin(Li) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	ng/mL	Male: 22- 275 Female: 5 - 204	Ferritin Calibrator	RIQAS	CC33

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Beta Human Chorionic Gonadotrophin (Beta HCG)	Serum, EDTA, Heparin Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	mIU/mL	<5.0	Beta HCG Calibrator	RIQAS	CC34
Carcinomic Antigen 125 (CA125)	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	< 35	CA125 Calibrator	RIQAS/NEQAS	CC35
Carcinomic Antigen 153 (CA153)	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	<31.3	CA153 Calibrator	RIQAS/NEQAS	CC36
Carcinomic Antigen 199 (CA199)	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	<37	CA199 Calibrator	RIQAS/NEQAS	CC37
CarcinoEmbryonic Antigen (CEA)	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	ng/mL	<5	CEA Calibrator	RIQAS	CC38
Vitamin B12	Serum, EDTA plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	pg/mL	120 - 750	B12 Calibrator	RIQAS/NEQAS	CC39
AlphaFetoProtein (AFP)	Serum, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	0.0 - 6.64	AFP Calibrator	RIQAS	CC40
Syphilis	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Cut Off	Negative	Syphilis TP Calibrator	NEQAS	CC41

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Anti-Thyroglobulin (Anti-Tg)	Serum, EDTA, Heparin(Li) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	IU/mL	<5.61	Anti-Tg Calibrator	CAP	CC45
Anti-Thyroid Peroxidase (Anti-TPO)	Serum, EDTA, Heparin(Li, Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	kiU/L	< 4.11	Anti-TPO Calibrator	NEQAS	CC46
Hepatitis B Surface Antibody (Anti-Hbs)	Serum, EDTA, Heparin(Na) Plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	mIU/mL	Negative: <10 Positive: >10	Anti-Hbs Calibrator	NEQAS	CC48
Folate	Serum, Heparin (Li) plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	ng/mL	2.7 - 34	Folate Calibrator	RIQAS/NEQAS	CC58
Hepatitis B Core Antibody	Serum, Heparin (Li) plasma	Architect i2000	Chemiluminescent Microparticle ImmunoAssay (CMIA)	ng/mL	Negative	Anti-Hbs Calibrator	NEQAS	CC58

HAEMATOLOGY INAB CLASSIFICATION NO. 1030

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
White Cell Count	EDTA WHOLE BLOOD	Advia 120	Flow Cytometry (FC)	X10 ⁹ /L	3.88 - 10.49	Bayer Setpoint	UKNEQAS/IEQAS	H22
Red Cell Count	EDTA WHOLE BLOOD	Advia 120	FC laser optics. Mie's theory	X10 ⁹ /L	F: 3.73-5.02, M: 4.28 - 5.59	Bayer Setpoint	UKNEQAS/IEQAS	H22
Haemoglobin	EDTA WHOLE BLOOD	Advia 120	CyanmethHb colorimetric method	g/dL	F:11.3-15.2; M:13.5-17.2	Bayer Setpoint	UKNEQAS/IEQAS	H22
Haematocrit	EDTA WHOLE BLOOD	Advia 120	Calculated from the RBC & MCV	Ratio	F:0.323-0.462; M:0.381-0.499	Bayer Setpoint	UKNEQAS/IEQAS	H22
Mean Cell Volume	EDTA WHOLE BLOOD	Advia 120	Indirect measurement (mean of the RBC Vol)	fL	83.1-99.1	Bayer Setpoint	UKNEQAS/IEQAS	H22
MCH	EDTA WHOLE BLOOD	Advia 120	Calculation derived from HGB, RBC& MCV	pg	28.3 - 33.9	Bayer Setpoint	UKNEQAS/IEQAS	H22
MCHC	EDTA WHOLE BLOOD	Advia 120	FC laser optics. Utilizing RBC channel/Mie group	g/dL	32.1 - 36.6	Bayer Setpoint	UKNEQAS/IEQAS	H22
Platelet Count	EDTA WHOLE BLOOD	Advia 120	FC laser optics. Utilizing RBC channel/Mie map.	X10 ⁹ /L	164 - 382	Bayer Setpoint	UKNEQAS / IEQAS	H22

HAEMATOLOGY INAB CLASSIFICATION NO. 1030

TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Neutrophil Count	EDTA WHOLE BLOOD	Advia 120	Indirect measurement of WBC by algorigrams/cluster analysis.	$\times 10^9/L$	1.91 - 7.16	Bayer Setpoint	UKNEQAS / IEQAS	H22
Lymphocyte Count	EDTA WHOLE BLOOD	Advia 120	Indirect measurement of WBC by algorigrams/cluster analysis.	$\times 10^9/L$	1.01 - 3.13	Bayer Setpoint	UKNEQAS / IEQAS	H22
Monocyte Count	EDTA WHOLE BLOOD	Advia 120	Indirect measurement of WBC by algorigrams/cluster analysis.	$\times 10^9/L$	0.19- 0.68	Bayer Setpoint	UKNEQAS / IEQAS	H22
Eosinophil Count	EDTA WHOLE BLOOD	Advia 120	Indirect measurement of WBC by algorigrams/cluster analysis.	$\times 10^9/L$	0.05 - 0.51	Bayer Setpoint	UKNEQAS / IEQAS	H22
Basophil Count	EDTA WHOLE BLOOD	Advia 120	Indirect measurement of WBC by algorigrams/cluster analysis.	$\times 10^9/L$	0.02 - 0.15	Bayer Setpoint	UKNEQAS / IEQAS	H22

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TEST NAME	SAMPLE TYPE	ANALYSER	METHOD	UNITS	ADULT REF. RANGE	CALIBRATORS	PROFICIENCY TESTING SCHEME	SOP
Erythrocyte Sedimentation Rate (ESR)	EDTA WHOLE BLOOD	Micro Test 1	Photo-Metric Kinetic Technology	Mm/hr	<50yrs M 0-8 F 0-10 >50yrs M0-12 F 0-15	N/A	IEQAS (Labquality)	H09
Prothrombin Time (PT)	Plasma	CA540	Photo Optical Technology	Sec	10-13	Dade Behring Multi Cal	UKNEQAS	H33
Activated Partial Thromboplastin Time (APTT)	Plasma	CA540	Photo Optical Technology	Sec	22.6-29.6	N/A	UKNEQAS	H34
Fibrinogen	Plasma	CA540	Photo Optical Technology	g/L	1.5-4	Dade Behring SHP*	UKNEQAS	H35
Blood Film & White Cell Differential. Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Leucocytes	Blood Film	Manual	Staining / Microscopy	N/A	N/A	N/A	UKNEQAS / IEQAS	H4

MICROBIOLOGY INAB CLASSIFICATION NO. 1010

TEST	SAMPLE TYPE	ANALYSER	METHOD	CONTROLS USED	PROFICIENCY TESTING SCHEME	SOP
Blood Culture	Blood	Bactec	Bactec Blood Culture Instrument Culture Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	GM54
Fluid Culture	Processing and Interpretation of Sterile Body Fluids excluding blood, CSF, and urine.	Manual	Culture Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM41
Mycology Culture	Hair samples, Nail clippings / scrapings, Skin scrapings	Manual	Culture Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM50
Swabs	Ear swabs, Throat swabs, Eye swabs, Nose swabs	Manual	Culture, Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM47, CM42, CM46, CM43

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TEST	SAMPLE TYPE	ANALYSER	METHOD	CONTROLS USED	PROFICIENCY TESTING SCHEME	SOP
Genital Swabs	Processing and Interpretation of Genital Tract and associated specimens for Candida spp. Bacterial vaginosis & Revelant pathogens	Manual	Culture Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM48
Methicillin Staphylococcus Aureus strains	Swabs Urine Sputum Exudates Body Fluids	Manual	Culture using Chromogenic Agar Sensitivity if Required	Yes ATCC Strain	UKNEQAS	CM54
Tip Culture	Indwelling Cannulae / Catheters	Manual	Culture Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM45 & CM 56
Skin and Wound Cultures	Exudates Pus Swabs	Manual	Culture Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM44

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TEST	SAMPLE TYPE	ANALYSER	METHOD	CONTROLS USED	PROFICIENCY TESTING SCHEME	SOP
Urinalysis	Urine	Advantus	Bayer Clinitek	Bayer Chem Stix	UKNEQAS	GM81
Urine Microcopy Culture	CSU MSU	Manual	Culture Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM38
IUCDs	IUCDs for common pathogens and Actinomyces	Manual	Culture Sensitivity Microscopy (if required)	Yes depending on organisms isolated	UKNEQAS	CM55
Screening for Occult Blood	Faeces	N/A	Immunochromotography	Yes	UKNEQAS	CM52
Sensitivities and Identification	Isolates	Vitek 2 Compact	ID and Susceptibility cards	ATCC Strains as recommended by manufacturer	UKNEQAS	GM69 GM70 CM 34 CM 35