

Weqas GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE







www.weqas.com



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# Director's Profile

nnette Thomas is a Consultant Clinical Biochemist at Cardiff and Vale University Health Board with over 40 years' experience in Laboratory Medicine, 20 years of which has been as Director of Weqas.

Annette is also the national clinical lead for POCT representing POCT in Welsh Government advisory Committees and chairs the POCT Strategic Board and POCT Co-ordinators Network in Wales.

She is a member of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Task Force on Global Lab Quality (TF-GLQ) and past chair of the Committee on Analytical Quality (C-AQ).

She has previously held posts on the Executive Board of the European Committee for External Quality Assurance Programmes in Laboratory Medicine (EQALM), chair of the All Wales Clinical Biochemistry Group (ACB), chair of the National Clinical Biochemistry and Laboratory Medicine Audit Committee in the UK, a member of the Association of Clinical Biochemistry and Laboratory Medicine Scientific Committee and a member of the Royal College of Pathologists Scientific Advisory Committee on Clinical Biochemistry.







## About Us

stablished in 1968, Weqas is one of the largest External Quality Assessment providers in the UK, with over 50 years of experience in delivering global Quality Assurance Programmes in Laboratory Medicine.

Weqas is a "not for profit" NHS organisation hosted by Cardiff and Vale University Health Board, based in Cardiff, UK.

Weqas provides over 50 EQA Programmes, including external audit, performance analysis and an educational advisory service and employs an expert team of scientists delivering services in Laboratory EQA, Point of Care (POCT) EQA, Reference Measurement service, Internal Quality Control (IQC) Production and Education and Training.

Our programmes are underpinned by commutable, metrological, traceable samples and informative reports. Our range of Webbased reporting options cater for the Laboratory Manager, the Laboratory Scientist and the POCT end user. Our team of experienced Scientists and POCT Co-ordinators provide a unique troubleshooting and problem solving service to our clients.

#### GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE





## Laboratory and Point of Care EQA Services

Supplying to more than 35,000 sites per month, Weqas provides over 50 EQA Programmes. As well as Healthcare pathology laboratories, these services are also provided to independent pharmacies, primary care physicians, occupational health providers, forensic pathology services, veterinary pathology laboratories, clinical trial units and diagnostic companies. Weqas EQA services (4301) are accredited in accordance with the International Standard-General Requirements for Proficiency Testing (ISO/IEC 17043).

#### Third Party Control (IQC)

Weqas also provides independent third party IQC and Quality Control Reference Material (QCRM) for a range of analytes. Targeted at clinically relevant concentrations, these products, along with our other services, provide the necessary tools to achieve compliance to ISO 15189. Unbiased, accurate and independent controls are available for assuring the quality of your test items. Weqas IQC are designed and tailored to your specific requirements by a team of Scientists with over 20 years experience in manufacturing.

Our IQC and Quality Control Reference Material (QCRM) are registered with the UK Medicine and Healthcare products Regulatory Agency (MHRA) and conform to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UKMDR2002).

#### Reference Measurement Services

The Weqas Reference Laboratory is a Joint Committee on Traceability in Laboratory Medicine (JCTLM) listed Reference Measurement Service Provider. JCTLM is a European Network of highly specialist laboratories providing accurate target value assignment of clinical material to assist in the global harmonisation of Pathology results. This is the only laboratory currently in the UK providing this service. Wegas also contributes to Standard reference Material (SRM) value assignment in conjunction with the Joint Research Centre (JRC) . The Reference Laboratory is accredited to the International Standard - General requirements for competence of Calibration and Testing Laboratories (ISO/ IEC 17025) and in accordance with Laboratory medicine – Requirements for the competence of calibration laboratories using reference measurement procedures (ISO/IEC 15195). This service is available to IVD manufacturers, Quality Control manufacturers, EQA providers and Clinical Laboratories.

#### Education and Training

With changing technologies, techniques and patient care delivery models, there is a pressing need to ensure there is a focus within education and training programmes for standardisation of analyses, error reporting, poor performance and laboratory accreditation. Education workshops, e-learning and presentations can be tailored to our clients needs.

#### Benefits

- Accredited to ISO 17043, and 17025 in accordance to 15195.
- Web based interactive EQA programmes.
- 40 years of clinical expertise.
- Reference Measurement Laboratory for traceability.

#### Features

- Wide range of accredited EQA Programmes for Laboratory and Point of Care Diagnostic Medicine.
- Products designed to reflect actual patient samples; endogenous, single donors and pooled donor samples distributed to cover the complete clinical range.
- Liquid stable, commutable, linear, traceable samples designed to cover the cut-off, analytical, pathological and clinical decision levels.
- Reference Measurement Value Assignment for Laboratories, EQA Providers and IVD Manufacturers.

The Weqas team is supported by a Steering Committee which advises the organisers on the overall operation of its programmes, including the frequency of distribution of materials, the types of materials to be distributed, methods of statistical analysis, data presentation, and the desirability of introducing new investigations.

More information on the Steering Committee including members' profiles can be found on our website:

www.weqas.com



## Programmes

eqas is an ISO 17043 accredited proficiency testing provider (number 4301), offering a range of EQA programmes for Laboratory Medicine. Weqas offers a visibly different, high quality, clinical and science-based service to support laboratories in maintaining ISO 15189, underpinned by commutable, metrological, traceable samples and informative reports.

For a complete list of all our EQA Programmes and analytes, please see our Quick Guide on page 38-45.

In a recent article on EQA best practice, the following factors were identified as core factors for laboratories in their choice of EQA provider:

*Factors influen	cing choice of EQA provider - Why Weqas?
Accreditation status	Weqas accredited to ISO 17043.
Clinically relevant distribution frequency	Where EQA is used to assess IVDs, a minimum of 6 distributions p.a. is advisable (BS EN 14136). Apart from rare diseases, Weqas' programmes are bimonthly as a minimum. For core tests, the distribution (or challenge) frequency is monthly.
Clinically relevant range and number of samples	Weqas provides "blinded", commutable samples wherever possible with additional challenging samples and linear panels to assess method linearity, specificity and sensitivity.
Clinically relevant performance specification	Weqas uses Milan Model 2 performance specification whenever appropriate: based on biological variation data.
Programme designed and overseen by appropriately competent professionals	Weqas' Director has over 40 years experience in Laboratory Medicine and is supported by a team of Clinical Scientists and an Independent Scientific Advisory group.
Education	Training and helpline support. Pre-analytical, Analytical and Post-analytical education.
Reporting to Professional body / Regulatory body	Reporting to professional body within the UK, with mechanisms in place for identification and reporting of persistent poor performance issues.
Post-marketing surveillance	Weqas liaises with laboratories, manufacturers, professional bodies, regulatory and competent authorities.
Independent	Weqas is a "not for profit" NHS organisation and is not affiliated to an IVD manufacturer.

\*James D, Ames D, Lopez B, et al. External Quality Assessment : Best practice. J Clin Pathol 2014;67:651.





## Laboratory EQA

## Serum Chemistry

Frequency: Monthly

Samples: 4 (3.0 mL) or 4 (1.0 mL)

Material: Off the clot human serum

**Key features:** Liquid human serum samples requiring no prior preparation. Samples consist of a panel of 8 linearly related samples distributed on a number of occasions over that period which are used to assess both laboratory and method performance, including linearity, bias, within and between batch imprecision. Trueness is also assessed for a number of analytes using high metrological order Reference measurement systems.

Traceable Reference Values provided for electrolytes and metabolites. Includes calculated parameters.

Additional challenging samples distributed to assess diagnostic accuracy near the cut points, method interferences and for educational purposes. Sigma metric scoring based on clinically relevant Milan Model 2 performance specification.

Analyte	Approx. Ra	ange Covered
Sodium	100 - 165	mmol/L
Potassium	1.6 - 8.0	mmol/L
Chloride	73 – 123	mmol/L
Bicarbonate	7 – 28	mmol/L
Urea	1.5 – 25	mmol/L
Creatinine	25 - 600	µmol/L
e-GFR	<15->90	mLs/min/1.73m <sup>2</sup>
Glucose	1.4 – 25	mmol/L
Calcium	1.2 - 3.3	mmol/L
Adjusted Calcium	1.4 - 3.0	mmol/L
Phosphate	0.2 - 2.2	mmol/L
Total Protein	34 - 86	g/L
Albumin	20 - 53	g/L
Calculated Globulin	20-40	g/L
Magnesium	0.2 - 2.0	mmol/L
Urate	100 - 700	µmol/L
Lithium	0.05 - 2.0	mmol/L
Lipase	10-400	IU/L
Osmolality	190 - 390	mOsmo/kg
AST	5 - 300	IU/L IFCC
ALT	5 – 500	IU/L IFCC
ALP	25 - 400	IU/L SCE
СК	20 - 1200	IU/L SCE
Gamma GT	10-400	IU/L SCE
Total Amylase	15 - 800	IU/L
Pancreatic Amylase	20-160	IU/L
LDH	50 - 700	IU/L SCE
Iron	7 – 30	µmol/L
TIBC	28 - 82	µmol/L
Transferrin	1.5 – 3.5	g/L
Transferrin Saturation	22 – 30	%
Gentamicin	1-8	µg/mL

## **HIL Serum Indices**

Frequency: Monthly

Samples: 3 (1.0 mL)

Material: Off the clot human serum

**Key features:** Liquid human serum samples with known concentration of haemoglobin, bilirubin and triglyceride added to assess performance of haemolysis, icteric and lipaemic indices on all major platforms. Caters for both quantitative and qualitative results.

Analyte	Approx. Range Covered		
Semi-Quantitative Haemolysis Index	0 – 3.5 g/L as Hb		
Semi-Quantitative Icterus Index	0 – 500 µmol/L as Total Bilirubin		
Semi-Quantitative Lipaemic Index	0 – 10 mmol/L as Intralipid Triglyceride		
Qualitative Haemolysis Index	Negative to +++ Positive		
Qualitative Icterus Index	Negative to +++ Positive		
Qualitative Lipaemic Index	Negative to +++ Positive		

Analyte	Approx. Ran	ge Covered
Cholesterol	2.5 – 9.5	mmol/L
Triglyceride	0.3 - 7.0	mmol/L
HDL Cholesterol	0.6 – 2.5	mmol/L
LDL Cholesterol	1.0-6.0	mmol/L
Apolipoprotein A1	0.8 - 2.4	g/L
Apolipoprotein B	0.3 - 2.0	g/L
Lipoprotein (a)	5 - 300	nmol/L
Non-HDL Cholesterol	1.5 – 6.5	mmol/L

#### Lipids

Frequency: Monthly **Samples:** 4 (1.0 mL) Material: Off the clot human serum

Key features: Liquid human serum samples requiring no prior preparation. Commutable single or pooled donor samples. Lipid profile includes all routinely monitored analytes and calculated parameters. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision. Trueness is also assessed for a number of analytes using high metrological order Reference measurement systems. IDGCMS and CDC reference values provided for Cholesterol, Triglyceride and HDL. Sigma metric scoring based on clinically relevant Milan Model 2 performance specification.

Analyte	Approx. Ran	ge Covered
Total Bilirubin	30 – 350	µmol/L
Conjugated Bilirubin	10 - 100	µmol/L

#### Bilirubin

Frequency: Monthly **Samples:** 4 (1.0 mL)

Material: Off the clot human serum

Key features: Liquid human serum samples. Panel of samples covering the pathological range for both conjugated and total bilirubin in neonates and adults. Samples assess both laboratory and method performance, including linearity, bias, within and between batch imprecision. Suitable for Laboratory analysers, Blood Gas analysers and POCT devices.

Analyte	Approx. Ran	ige Covered
Salicylate	0-800	mg/L
Paracetamol	0-350	mg/L
Ethanol	0-4500	mg/L
*Ethylene Glycol	0-3000	mg/L
*Methanol	0-2500	mg/L
Whole Blood Ethanol	0-4500	mg/L

#### **ED** Toxicology

Frequency: Monthly

4 (0.5 mL) Whole Blood Ethanol

Material: Off the clot human serum and whole blood

Key features: Liquid human serum samples. Linearly related panel covering the analytical and Toxic pathological range. Samples assess both laboratory and method performance, including linearity, bias, within and between batch imprecision. Challenging samples at clinically relevant cut-off concentrations.

### hsTroponin

Frequency: Monthly

**Samples:** 3 (1.0 mL)

Material: Off the clot human serum

Key features: Includes challenging samples at limits of detection and diagnostic "99th centile" for hs TnT and Tnl. Liquid human serum samples require no pre-analytical preparation. Linearly related panel covering a clinically relevant range.

**Samples:** 4 (1.0 mL)

Analyte **Approx.** Range Covered hsTroponin I (hs-cTnI) 1-300 ng/L hsTroponin T (hs-cTnT) 4-200 ng/L

## Urine Chemistry

#### Frequency: Monthly

Samples: 3 (2.5 mL) + 3 (0.5 mL) acidified

Material: Fresh filtered human urine

**Key features:** Fresh endogenous and spiked urine samples distributed. Separate 1mL acidified samples supplied for Calcium, Magnesium and Phosphate for enhanced stability. Samples assess both laboratory and method performance, including linearity, bias, within and between batch imprecision.

Analyte	Approx. Ran	ge Covered
Sodium	13 - 200	mmol/L
Potassium	9-137	mmol/L
Chloride	13 - 300	mmol/L
Urea	38 - 500	mmol/L
Creatinine	1.0 - 22	mmol/L
Glucose	0-40	mmol/L
Calcium	0.5 – 7.0	mmol/L
Phosphate	6 – 35	mmol/L
Protein	0-2	g/L
Albumin	0-2000	mg/L
Magnesium	0.5 – 8.5	mmol/L
Urate	0.5 - 5.0	mmol/L
Osmolality	100 - 1000	mmol/kg
Total Amylase	0-400	IU/L
Albumin/Creatinine ratio	0 - 200	mg/mmol
Protein/Creatinine ratio	0 - 300	mg/mmol

Analyte	Approx. Ran	ge Covered
Cortisol	60 - 1450	nmol/L
Progesterone	1.0 - 100	nmol/L
Oestradiol	37 - 16000	pmol/L
Testosterone	0.1 - 60	nmol/L
Free Testosterone	0-2	mol/L
SHBG	20-100	nmol/L
FAI	0-150	%
DHEA-S	0 - 100	µmol/L
T4	64 - 280	nmol/L
Т3	1.5 – 12	nmol/L
FT4	8 - 50	pmol/L
FT3	3.0-40	pmol/L
TSH	0.1 - 55	mU/L
LH	2 - 80	IU/L
FSH	0.8 - 100	IU/L
Prolactin	48 - 800	mU/L

Analyte	Approx. Ran	ge Covered
Ferritin	5 – 3500	µg/L
B12	120 - 850	ng/L
Active B12	0-300	pmol/L
Folate	1.2 - 24	µg/L
Iron	4 - 160	µmol/L
TIBC	27 - 90	µmol/L
UIBC	3 - 100	µmol/L
Transferrin	1.6-4	g/L
Transferrin Saturation	10-90	%

## Endocrine

#### Frequency: Monthly

Samples: 4 (1.8 mL)

Material: Off the clot human serum

**Key features:** Liquid human serum samples requiring no prior preparation. Single donor samples are used wherever possible to minimise any matrix effects. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision. Trueness is also assessed for Testosterone, Cortisol and Progesterone using high metrological order Reference measurement systems. Challenging samples are distributed to assess the performance at clinical decision points as well as ongoing programme of interpretative exercises, Macroprolactin and antibody interferences. Includes Calculated parameters.

#### Haematinics

Frequency: Monthly

Samples: 4 (1.0 mL)

Lab EOA

Material: Off the clot human serum

**Key features:** Liquid human serum samples requiring no prior preparation. Commutable, endogenous samples, covering the physiological and pathological range with additional spiked samples to cover "toxic" range for Iron. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision.

Analyte	Approx. Range Covered	
рН	7.0 - 7.7	
H⁺	20 - 100	nmol/L
pCO <sub>2</sub>	2 - 10	kPa
pO <sub>2</sub>	4 – 25	kPa
Actual Bicarbonate (aHCO3)	20 – 30	mmol/L
TCO <sup>2</sup>	15 – 35	mmol/L
Na <sup>+</sup>	115 – 160	mmol/L
K <sup>+</sup>	2 – 6	mmol/L
Cl	76 – 123	mmol/L
Magnesium	0.4 - 1.6	mmol/L
iCa++	0.2 - 1.8	mmol/L
Glucose	1.9 - 23.0	mmol/L
Lactate	0.3 – 6.5	mmol/L
Urea	2.8 - 25.0	mmol/L
Creatinine	30 – 560	µmol/L
Haematocrit (iStat only)	0 – 70	%PCV
Lithium	0.35 - 1.35	mmol/L
SBC (sHCO3)	20 – 30	mmol/L
BE	-5 to +5	
sO <sub>2</sub>	90 - 100	%

Analyte	Approx. Ran	ge Covered
Total Haemoglobin	100 - 190	g/L
Carboxyhaemoglobin	1-32	%
Methaemoglobin	2 – 35	%
Oxyhaemoglobin	35 - 95	%

Analyte	Approx. Ran	ge Covered
NT-Pro BNP	20-4000	ng/L

### **Blood Gas**

Frequency: Monthly

**Samples:** 3 (2.5 mL)

Material: Tonometered protein buffered aqueous solution and whole blood

Key features: Aqueous material minimises the risk of preanalytical error sampling due to its protein foam layer. Wide clinical range covered over the course of the year. iCa++ concentration is suitable for the evaluation of instruments used in the monitoring of patients on citrate anticoagulation for Continuous Renal Replacement Therapy (CRRT). Programme assesses both laboratory and method performance, including bias, within and between batch imprecision. Once a year, tonometered whole blood is distributed. This material has identical oxygen saturation characteristics to fresh whole blood and is used to provide an assessment of accuracy for pO2 (especially at low pO2) and in the evaluation of derived parameters (SBC, BE and Oxygen Saturation). The hemoglobin buffering in this material provides a 10-minute open ampule stability. Both materials are suitable for use for the majority of POCT and Laboratory analysers.

#### Co-oximetry

Frequency: Monthly Samples: 3 (2.0 mL)

Material: Bovine haemolysate solution

**Key features:** Packaged in an easy to use dual-chambered vial that separates the oxyhemoglobin from methemoglobin to enhance stabilty. Material contains the 4 major haemoglobin derivates and unlike dyes has equivalent spectral properties and sensitivity to whole blood. Compatible with all major Co-oximeters. Panel covers clinically relevant ranges. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision.

### NT-Pro BNP

Frequency: Bimonthly

**Samples:** 3 (0.5 mL)

Material: Human Plasma (EDTA / LiHep)

**Key features:** The base material for BNP is human EDTA plasma and for NT-Pro BNP Lithium Heparin plasma to correctly reflect the performance with patient samples. To enhance the range the plasma is spiked with recombinant human BNP-32 and NT-Pro BNP respectively with the addition of Protease inhibitors to improve stability. For BNP the samples are dispatched frozen. Surrogate, clinically appropriate linear panels suitable for both Laboratory and POCT analysers. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision and linearity.

## HbA1c

Frequency: Monthly / Bimonthly

Samples: 3 (0.2 mL) / 2 (0.2 mL) in bimonthly programme

Material: Fresh EDTA whole blood

**Key features:** Fresh EDTA whole blood from individual diabetic patients and healthy volunteers are distributed monthly/ bimonthly. These samples reflect the wide range of HbA1c seen in the screening, diagnosis and monitoring of Diabetes. Challenging samples from patients with known Hb variants are also distributed to assess current practice. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision. Trueness is assessed using the IFCC secondary reference methods with Sigma metric scoring based on clinically relevant Milan Model 1 performance specification. Additional samples are distributed annually as part of the European HbA1c Trial to assess the performance across all countries and all manufacturers. The full report is provided as part of the programme.

### CRP

Frequency: Monthly

**Samples:** 3 (0.5 mL)

Material: Off the clot human serum

**Key features:** Commutable, endogenous samples and samples spiked with a highly purified source of human CRP to provide extended range. Endogenous samples covers high sensitivity (hs) CRP methods for cardiovascular risk assessment and enhanced range panel covers CRP methods used as an inflammatory marker. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision and linearity.

## Porphyrin

Frequency: Quarterly

Samples: 3 (4.2 mL) Urine 3 (1.5 mL) Plasma

Material: Fresh filtered human urine, EDTA plasma, faeces

**Key features:** Covers both Qualitative and Quantitative assays for Porphobilinogen, Total Urine Porphyrin and Plasma Porphyrins. Regular educational exercises include Interpretive comments, Audit and clinical case studies. Reference target value assignment, EDTA plasma patient samples, faecal samples and clinical case interpretation are provided by the Cardiff Porphyria Service. Challenging samples at or near diagnostic cut points distributed. Programme assesses both laboratory and method performance, including bias and within batch imprecision.

Analyte	Approx. Range Covered	
× HbA1c	32 – 85	mmol/mol Hb

\* IFCC and NGSP values assigned by the European Reference Laboratory for Glycohaemoglobin.

Analyte	Approx. Range Covered	
CRP	0-300	mg/L

Analyte	Approx. Range Covered	
Porphobilinogen	0-170	µmol/L
PBG / Creatinine Ratio	0->30	µmol/mmol
Total Urine Porphyrin	0-4000	nmol/L
Quant TUP / Creat Ratio	0->500	nmol/mmol
Plasma porphyrin	8-300	nmol/L
Faecal porphyrin	35 - 700	nmol/g

Analyte	Approx. Range Covered	
Total Bile Acids	5 - 108	µmol/L
Cholic Acid	0-83	µmol/L
Deoxycholic Acid	0 – 25	µmol/L

### **Bile Acids**

Frequency: Monthly Samples: 3 (0.5 mL)

Material: Off the clot human serum

**Key features:** Panel of liquid human serum samples covering an appropriate range for the diagnosis and monitoring of Cholestasis in Pregnancy. Ratio of Bile Acids in the samples reflect both physiological levels and that observed in obstetric cholestasis. ID-GCMS target values available for individual Bile Acids, Cholic acid and Deoxycholic acid. Challenging samples are also distributed to assess specificity of the methods including those containing Chenodeoxycholic acid and Ursodeoxycholic, a dihydroxycholic bile acid used in the treatment of cholestatic disease. Programme assesses laboratory and method performance, including bias, within and between batch imprecision, linearity, trueness and specificity.

Analyte	Approx. Range Covered	
Ammonia	25 – 800 μmol/L	

#### Ammonia

Frequency: Monthly Samples: 3 (0.5 mL) Material: Off the clot human serum

**Key features:** A range of Ammonia samples are distributed covering both normal and pathological levels including those seen in urea cycle defects. Liquid human serum, commutable and compatible with all enzymatic methods assayed on laboratory analysers, dry slide chemistry analysers and POCT devices. Programme assesses laboratory and method performance, including bias, within and between batch imprecision and linearity.

Analyte	Approx. Range Covered	
Homocysteine	5 – 220	µmol/L

#### Homocysteine

Frequency: Bimonthly

Samples: 3 (0.5 mL)

Material: Off the clot human serum

**Key features:** Liquid human serum samples with a range of concentrations found in both inborn errors and cardiovascular risk assessment. Endogenous samples along with a panel of linearly related samples produced from donations from healthy volunteers spiked with homocysteine. The linearly related samples are distributed on a number of occasions over the year to assess both laboratory and method performance, including linearity, bias, within and between batch imprecision.

#### Serum ACE

Frequency: Bimonthly

Samples: 3 (0.5 mL)

Material: Off the clot human serum

**Key feature:** Commutable, single donor patient samples. Each donation is distributed on a number of occasions over the year to assess both laboratory and method performance, including bias, within and between batch imprecision.

### Urine Oxalate & Citrate

Frequency: Monthly

**Samples:** 3 (2.5 mL)

Material: Filtered and acidified human urine

**Key features:** This programme is designed to span the analytical and clinically relevant range for the diagnosis and management of hyperoxaluria and hypocitraturia. The linearly related samples are distributed on a number of occasions over the year to assess both laboratory and method performance, including linearity, bias, within and between batch imprecision.

## **Pregnancy Testing**

Frequency: Bimonthly

**Samples:** 3 (1.0 mL)

**Material:** Filtered urine from pregnant and non-pregnant volunteers, off the clot human serum

**Key features:** Suitable for manual or automated lateral flow methods. Increased volume dispensed into wide neck tubes available for those using lateral flow dip stick assays. Participants can submit both quantitative and qualitative results. Challenging samples at or near lower limits of detection/ Ag excess to assess sensitivity and Hook effect. Programme assess both laboratory and method performance, including, sensitivity, interferences, bias, within and between batch imprecision.

## Renal Calculi<sup>\*</sup>

Frequency: Bimonthly

Samples: 4 (100-150 mg)

Material: Dry powdered chemical or ground human calculi

**Key features:** Ready to use, stable samples, covering common and rare calculi constituents. Qualitative and Quantitative analysis. Suitable for spectroscopy and wet chemistry methods.

Analyte	Approx. Ran	ge Covered
Serum ACE	10 - 110	IU/L

Analyte	Approx. Ran	ge Covered
Oxalate	0.1 - 1.8	mmol/L
Citrate	0.1-8.5	mmol/L

Analyte	Approx. Range Covered
Urine hCG	0-100000 IU/L
Serum hCG	5 – 120 000 IU/L

Analyte	Approx. Range Covered	
Quantitative FIT	2—480 µg Hb/g matrix	

For quantitative tests - Programme assesses both laboratory and method performance, including, sensitivity, bias, within batch imprecision.

## Quantitative Faecal Hb

Frequency: Monthly

#### Samples: 3

Material: Organic material spiked with human whole blood

**Key features:** Material closely mirrors the basic constituents of human faeces. FIT samples are pre loaded into buffered collection tubes specific to each instrument. Covers the pathological and analytical range for quantitative FIT automated analysers. Samples challenging clinically relevant cut-offs for symptomatic testing pathways.

Analyte Approx. Range Cove		ge Covered
Amphetamine	0-3000	µg/L
Amphetamines Group Screen	Qualitative	n/a
Benzodiazepines	0 - 1000	µg/L
Barbiturates	0 - 1000	µg/L
Buprenorphine	0 - 30	µg/L
Cocaine	0 - 1000	μg/L
Cannabis	0-400	µg/L
EDDP	0 - 1000	µg/L
Heroin	0 - 30	µg/L
Ketamine	0-3000	µg/L
MDMA	0-3000	µg/L
Methadone	0 - 1000	μg/L
Methamphetamine (mAMP)	0-3000	µg/L
Opiates (Morphine)	0 - 1000	μg/L
Phencyclidine (PCP)	0 – 75	µg/L
Tricyclic antidepressants (TCA)	0-3000	µg/L

Analyte	Approx. Ran	ge Covered
sFlt-1	60 - 10,000	pg/mL
PIGF	<12-900	pg/mL
sFlt-1/PIGF Ratio	0 - 700	
Pre-Eclampsia Risk	Qualitative In	terpretation

#### Urine Drugs of Abuse

Frequency: Bimonthly

**Samples:** 3 (3.0 mL)

Material: Fresh filtered human urine with 1° and 2° metabolites added

**Key feature:** Samples includes different panels of drug / metabolites. Linear samples cover analytical and clinically relevant ranges including at or near lower limit of detection for qualitative methods. Suitable for qualitative and quantitative results. Traceable, "gravimetric" concentration of metabolite and 1° drug. Programme assesses both laboratory and method performance, including, linearity (recovery to gravimetric), specificity, bias, within and between batch imprecision.

#### Pre-Eclampsia

Frequency: Monthly

Samples: 3 (0.5 mL)

Material: Human EDTA plasma

**Key features:** Samples cover analytical and clinical range for sFlt-1 & PIGF. Post - analytical interpretation of pre-eclampsia risk outcome also assessed. Samples suitable for Lab and POCT instruments. Endogenous samples from patients along with a panel of linearly related samples produced from donations from healthy volunteers spiked with PIGF and sFlt-1. The linearly related samples are distributed on a number of occasions over the year to assess both laboratory and method performance, including linearity, bias, within and between batch imprecision.

## Therapeutic Drug Monitoring (TDM)

Frequency: Monthly

**Samples:** 3 (1.0 mL)

Material: Off the clot human serum

**Key features:** Linear panel with known traceable "gravimetric, weighed in" concentration of drug. Programme assesses both laboratory and method performance, including, sensitivity, specificity, linearity (recovery to gravimetric), bias, within and between batch imprecision.

Analyte	Approx. Ran	ge Covered
Amikacin	0 – 25	mg/L
Carbamazapine	0-12	mg/L
Digoxin	0-3	µg/L
Gentamicin	0-5	mg/L
Lamotrigine	0-24	mg/L
Lithium	0-2.0	mmol/L
Methotrexate	0 - 1.0	µmol/L
Phenobarbital	0-40	mg/L
Phenytoin	0 – 25	mg/L
Teicoplanin	0 - 60	mg/L
Theophylline	0-20	mg/L
Tobramycin	0-10	mg/L
Valproic acid	0-125	mg/L
Vancomycin	0-30	mg/L
Whole Blood Immunosuppre	essants	
- Ciclosporin	0-600	µg/L
- Sirolimus	0-20	µg/L
- Tacrolimus	0 - 15	µg/L

Proca	Ici	iton	in
10000			

Frequency: Monthly

**Samples:** 3 (0.5 mL)

Material: Off the clot human serum

**Key features:** Samples provided to cover range of Procalcitonin concentrations seen in both LRTI and systemic bacterial infection or severe sepsis. Samples suitable for Lab and POCT instruments. Endogenous samples along with a panel of linearly related samples produced from donations from healthy volunteers spiked with procalcitonin. The linearly related samples are distributed on a number of occasions over the year to assess both laboratory and method performance, including linearity, bias, within and between batch imprecision.

### pH Meter

Frequency: Monthly

Samples: 3 (10.0 mL)

Material: Buffered aqueous solutions

**Key features:** Samples are supplied ready to use; no preanalytical preparation required. Suitable for assessing pH Meter performance across a number of laboratory applications e.g clinical applications in urine / fluids and for general laboratory applications for buffers and reagents. Programme assesses both laboratory and meter performance, including, linearity, bias, within and between batch imprecision.

Analyte	Approx. Range Covered
Procalcitonin	0–100 ng/mL

Analyte	Approx. Range Covered
рН	2.0 - 12.0



## Glucose & Ketones

Frequency: Monthly, Bimonthly or Quarterly

**Samples:** 1 (0.5 mL)

Material: Red dyed serum or plasma

Key features: Ready to use liquid samples in sterile dropper vials containing both glucose and ketones. Suitable for all glucose Meters. Sites or individual users can be assessed. POCT Coordinator summary reports. Simple traffic light reports for end users.

	r	na		C
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			9	

Frequency: Bimonthly

**Samples:** 1 (5.0 mL)

Material: Fresh filtered human urine

Key features: Material is commutable with all Urinalysis strips and meters. Both quantitative, semiquantitative and qualitative results accommodated. Qualitative drop down fields on website customised for each instrument / strip. Separate sub-programme for quantitative microalbumin, and Albumin/ creatinine ratio.

Analyte	Approx. Range Covered
Glucose	2.0-30 mmol/L
Ketones	0.6–6 mmol/L

Analyte	Approx. Ran	ge Covered
Glucose	0-60	mmol/L
Ketones	0-20	mmol/L
Protein	0-5	g/L
Haemoglobin (Blood)	0 – 7500	µg/L
Specific Gravity	1.005 - 1.020	
рН	6-8	
Bilirubin	0-50	µmol/L
Urobilinogen	0-200	µmol/L
Leucocytes	0-500	µl esterase/L
Nitrites	0-40	µmol/L
Albumin/Creatinine	0.8 – 78	mg/mmol
Urine Albumin (Microalbumin)	0-200	mg/L
Creatinine	1-22	mmol/L

### **Pregnancy Testing**

Frequency: Bimonthly

**Samples:** 3 (1.0 mL)

Material: Filtered urine from pregnant and non-pregnant volunteers, off the clot human serum

Key features: Suitable for manual or automated lateral flow methods. Increased volume dispensed into wide neck tubes available for those using lateral flow dip stick assays. Participants can submit both quantitative and qualitative results. Challenging samples at or near lower limits of detection/ Ag excess to assesss sensitivity and Hook effect. Programme assess both laboratory and method performance, including, sensitivity, interferences, bias, within and between batch imprecision.

Analyte	Approx. Range Covered
Urine hCG	0-100000 IU/L
Serum hCG	5 – 120 000 IU/L

Analyte	Approx. Ran	ge Covered
Total bilirubin	30 – 350	µmol/L
Conjugated bilirubin	10 - 100	µmol/L

### Bilirubin

Frequency: Monthly Samples: 4 (1.0 mL) Material: Off the clot human serum

**Key features:** Liquid human serum samples. Panel of samples covering the pathological range for both conjugated and total bilirubin in neonates and adults. Samples assess both laboratory and method performance, including linearity, bias, within and between batch imprecision. Suitable for Laboratory analysers, Blood Gas analysers and POCT devices.

Analyte	Approx. Ra	nge Covered
рН	7.0 – 7.7	
H⁺	20 - 100	nmol/L
pCO <sub>2</sub>	2 - 10	kPa
pO <sub>2</sub>	4 - 25	kPa
Actual Bicarbonate (aHCO3)	20 - 30	mmol/L
TCO <sub>2</sub>	15 – 35	mmol/L
Na <sup>+</sup>	115 - 160	mmol/L
K+	2 – 6	mmol/L
Cl	76 – 123	mmol/L
Magnesium	0.4 - 1.6	mmol/L
iCa++	0.2 - 1.8	mmol/L
Glucose	1.9 - 23.0	mmol/L
Lactate	0.3 – 6.5	mmol/L
Urea	2.8 - 25.0	mmol/L
Creatinine	30 - 560	µmol/L
Haematocrit (iStat only)	0 - 70	%PCV
Lithium	0.35 - 1.35	mmol/L
SBC (sHCO3)	20 - 30	mmol/L
BE	-5 to +5	
sO	90 - 100	%

#### **Blood Gas**

Frequency: Bimonthly

Samples: 3 (2.5 mL)

**Material:** Tonometered protein buffered aqueous solution and whole blood

Key features: Aqueous material minimises the risk of preanalytical error sampling due to its protein foam layer. Wide clinical range covered over the course of the year. iCa++ concentration is suitable for the evaluation of instruments used in the monitoring of patients on citrate anticoagulation for Continuous Renal Replacement Therapy (CRRT). Programme assesses both laboratory and method performance, including bias, within and between batch imprecision. Once a year, tonometered whole blood is distributed. This material has identical oxygen saturation characteristics to fresh whole blood and is used to provide an assessment of accuracy for pO2 (especially at low pO2) and in the evaluation of derived parameters (SBC, BE and Oxygen Saturation). The hemoglobin buffering in this material provides a 10-minute open ampule stability. Both materials are suitable for use for the majority of POCT and Laboratory analysers.

Analyte	Approx. Ran	ge Covered
Total Haemoglobin	100 - 190	g/L
Carboxyhaemoglobin	1-32	%
Methaemoglobin	2 – 35	%
Oxyhaemoglobin	35 – 95	%

### Co-oximetry

Frequency: Bimonthly

**Samples:** 3 (2.0 mL)

Material: Bovine haemolysate solution

**Key features:** Packaged in an easy to use dual-chambered vial that separates the oxyhemoglobin from methemoglobin to enhance stabilty. Material contains the 4 major haemoglobin derivates and unlike dyes has equivalent spectral properties and sensitivity to whole blood. Compatible with all major Co-oximeters. Panel covers clinically relevant ranges. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision.

Frequency: Bimonthly

**Samples:** 1 (0.3 mL)

**Material:** Liquid stable biological samples suitable for use on a wide range of devices

**Key features:** Samples are supplied ready to use, no preanalytical preparation is required.

## Fetal Fibronectin

Frequency: Bimonthly

Samples: 2 (0.6 mL)

Material: Synthetic Amniotic Fluid containing purified fFN

**Key features:** Liquid stable samples are supplied ready to use; no pre-analytical preparation is required. Qualitative and Quantitative reporting available, with interpretations based on cut-offs of 50 and 200 ng/mL (EQUiPP study 2014). Linear related panel distributed covering the clinically relevant range. Programme assesses both site and device performance, including bias, within and between batch imprecision and linearity.

#### phIGFBP-1

Frequency: Bimonthly

**Samples:** 2 (1.0 mL)

Material: Synthetic Amniotic Fluid containing semi-purified IGFBP-1

**Key features:** Liquid stable samples are supplied ready to use; no pre-analytical preparation is required. Linear related panel distributed covering the clinically relevant range. Programme assesses both site and device performance, including bias, within and between batch imprecision and linearity.

#### POCT PROM

Frequency: Bimonthly

**Samples:** 2 (1.0 mL)

Material: Synthetic Amniotic fluid containing semi-purified IGFBP-1

**Key features:** Liquid stable samples are supplied ready to use; no pre-analytical preparation is required. Linear related panel distributed covering the clinically relevant range. Programme assesses both site and device performance, including bias, within and between batch imprecision and linearity.

Analyte	Approx. Range Covered
INR	1-4.5 Units

Analyte	Approx. Range Covered	
Quantitative fFN	0–400 ng/ml	
Qualitative fFN	Negative / Positive	

Analyte	Approx. Range Covered	
phIGFBP-1	Negative / Positive	

Analyte	Approx. Range Covered
IGFBP-1	Negative / Positive

Analyte	Approx. Range Covered	
Cholesterol	3.0-8.0	mmol/L
Triglycerides	0.8 - 2.5	mmol/L
HDL	0.6 - 3.0	mmol/L
Glucose	5 – 20	mmol/L

#### POCT Lipids (Healthcheck)

Frequency: Bimonthly Samples: 1 (0.5 mL)

Material: Off the clot human serum & Whole Blood

**Key features:** Patient samples covering normal and pathological ranges. Human serum samples require no preparation, reducing risk of pre-analytical errors. Additional assessment of accuracy using whole blood samples.

#### Haemoglobin

Frequency: Bimonthly

Samples: 2 (1.0 mL)

Material: Purified bovine haemolysate

**Key features:** Ready to use samples in dropper bottles, no need for reconstitution.

Analyte	Approx. Range Covered	
× HbA1c	32 – 85	mmol/mol Hb

**Approx.** Range Covered

38-200 g/L

\* IFCC and NGSP values assigned by the European Reference Laboratory for Glycohaemoglobin.

Analyte

Haemoglobin

#### HbA1c

Frequency: Bimonthly

**Samples:** 2 (0.2 mL)

Material: Fresh EDTA whole blood

**Key features:** Fresh EDTA whole blood from individual diabetic patients and healthy volunteers are distributed monthly / bimonthly. These samples reflect the wide range of HbA1c seen in the screening, diagnosis and monitoring of Diabetes. Challenging samples from patients with known Hb variants are also distributed to assess current practice. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision. Trueness is assessed using the IFCC secondary reference methods with Sigma metric scoring based on clinically relevant Milan Model 1 performance specification. Additional samples are distributed annually as part of the European HbA1c Trial to assess the performance across all countries and all manufacturers. The full report is provided as part of the programme.

Analyte	Approx. Range Covered	
CRP	0 - 150	mg/L

#### POCT CRP

Frequency: Bimonthly Samples: 2 (0.5 mL) Material: Off the clot human serum

**Key features:** Commutable, endogenous samples. Samples targeted at appropriate concentrations for antibiotic stewardship, covering a concentration range of 10 - 150 mg/L. Programme assesses both site and method performance, including bias, within and between batch imprecision and linearity.

### HIV

Frequency: Bimonthly

**Samples:** 3 (0.5 mL)

Material: Off the clot human serum

**Key features:** Samples are prepared with a non-infective source of recombinant HIV markers (p24 Ag, HIV-1 Ab and HIV-2 Ab) to mimic different clinical presentations. Developed for 4th generation assays, the users ability to identify both Abs and Ag are assessed.

### Urine Drugs of Abuse

#### Frequency: Bimonthly

**Samples:** 3 (3.0 mL)

**Material:** Fresh filtered human urine with 1° and 2° metabolites added

**Key feature:** Samples includes different panels of drug / metabolites. Linear samples cover analytical and clinically relevant ranges including at or near lower limit of detection for qualitative methods. Suitable for qualitative and quantitative results. Traceable, "gravimetric" concentration of metabolite and 1° drug. Programme assesses both laboratory and method performance, including, linearity (recovery to gravimetric), specificity, bias, within and between batch imprecision.

Analyte	Approx. Range Covered
p24 Antigen	Negative / Positive
HIV-1 Antibody	Negative / Positive
HIV-2 Antibody	Negative / Positive

Analyte	Approx. Ran	ge Covered
Amphetamine	0-3000	µg/L
Amphetamines Group Screen	Qualitative	n/a
Benzodiazepines	0 - 1000	µg/L
Barbiturates	0 - 1000	µg/L
Buprenorphine	0-30	µg/L
Cocaine	0 - 1000	µg/L
Cannabis	0-400	µg/L
EDDP	0 - 1000	µg/L
Heroin	0-30	µg/L
Ketamine	0-3000	µg/L
MDMA	0-3000	µg/L
Methadone	0 - 1000	µg/L
Methamphetamine (mAMP)	0-3000	µg/L
Opiates (Morphine)	0 - 1000	µg/L
Phencyclidine (PCP)	0 - 75	µg/L
Tricyclic antidepressants (TCA)	0-3000	μg/L

## POCT Respiratory Virus\*

Frequency: Bimonthly

Samples: 2 (1.0 mL)

Material: Buffered material spiked with inactivated virus

**Key features:** Liquid stable samples are supplied ready to use; no pre-analytical preparation is required. Qualitative reporting for SARS-CoV-2 Ag (RNA), Influenza A, Influenza B and RSV available.

Analyte	Approx. Range Covered
SARS-CoV-2 Ag (RNA)	Negative / Positive
Influenza A	Negative / Positive
Influenza B	Negative / Positive
RSV	Negative / Positive

ROTEM / TEM		
Test	Analyte	
Extem	CT (Secs), A5 (mm), A10 (mm), ML (%)	
Fibtem	CT (Secs), A5 (mm), A10 (mm), ML (%)	
Heptem	CT (Secs), A10 (mm)	
Intem	CT (Secs)	

#### TEG

Test	Analyte
CFF	A10, MA (mm)
СК	R (mins), K (mins), MA (mm)
СКН	R (mins), K (mins), MA (mm)
CRT	MA (mm), LY-30

Analyte	yte Approx. Range Co									
Creatinine	50 - 700	µmol/L								
e-GFR	<15->90	mls/min/1.73m2								

## Viscoelastic Haemostasis<sup>\*</sup>

#### Frequency: Quarterly

Samples per set: 2 (3.0 mL)

**Material:** Lyophilised human plasma which may be enriched with unfractionated Heparin

**Methods:** Rotational Thromboelastometry (ROTEM) / Thromboelastometry (TEM) / Thromboelastography (TEG)

**Key features:** Working in collaboration with ECAT. Covers the analytes Extem, Intem, Fibtem, Heptem and Aptem.

#### Creatinine

Frequency: Bimonthly Samples: 3 (0.5 mL) Material: Lysed whole blood

**Key features:** Commutable material for whole blood POCT devices. No pre-analytical preparation is required.

Analyte	Approx. Range Covered								
D-Dimer	100–4000 μg/L FEU								
Qualitative D-Dimer	Negative / Positive								

#### **D-Dimer**

Frequency: Bimonthly

Samples: 3 (1.0 mL)

Material: Endogenous human samples

**Key features:** Samples are supplied ready to use, no preanalytical preparation is required. Quantitative and qualitative reporting available. Programme assesses both laboratory and method performance, including bias, within and between batch imprecision and linearity.

Analyte	Approx	. Range Covered
Troponin T	<10-380	ng/L
Troponin I	<10-1375	ng/L
CK-MB (activity)	0-180	IU/L
CK-MB (mass)	0-60	μg/L
Myoglobin	14 - 500	μg/L

#### **POCT** Cardiac

**Samples:** 3 (0.5 mL)

Material: EDTA Plasma

**Key features:** EDTA plasma samples require no pre-analytical preparation. Linearly related panel covering a clinically relevant range.

# Additional Services

eqas has a wealth of experience in providing quality assurance services for Point of Care users and understands that not all our clients' needs are the same. We therefore offer different levels of service to cater for the unique needs of our clients in Point of Care settings.

Our Fully Managed Service is designed for sites that do not have the support of a local laboratory Point of Care Department for performance oversight. Weqas will perform the tasks that are generally the remit of a Point of Care co-ordinator e.g. Registration of instruments and maintenance of the database on Weqas platforms, result entry, report issue and interpretation, poor performance management. We also offer a 'Data Entry only' service.

A dedicated helpline service provides clients with direct access to experienced personnel who can offer advice on method performance, interpretation and troubleshooting.

#### Features

<ul> <li>Samples individually packaged &amp; shipped directly to each site (Shipping option 1)</li> <li>OR</li> <li>Samples shipped in bulk in a single package to POCT Lead for re-packaging and distribution (Shipping option 2)</li> </ul>
<ul> <li>Individual reports sent to each location</li> <li>Performance reviewed by Weqas</li> <li>Overall summary report sent to POCT Lead with poor performance sites identified</li> <li>Non-returns report sent to POCT Lead</li> <li>Primary care governance leads notified of non-compliand and poor performance issues</li> <li>Repeat samples automatically dispatched free of charge poor performing sites</li> <li>Repeat performance reviewed by Weqas and Primary care governance lead / POCT Lead sent an outcome report fo poor performance sites</li> <li>Troubleshooting advice provided for poor performance</li> </ul>

For a full list of analytes and programmes please see the "Quick Guide" on page 38-45.



## Weqa

URINALYSIS EQA Sample No: Batch: 06031

## Education

eqas has a wealth of experience in delivering training sessions tailored to suit the individual requirements of the customer. Wegas provides web-based e-learning, telephone or face-to-face training. A helpline service is also provided where participants can contact Wegas for advice on their method performance and interpretation of their EQA data. This troubleshooting and educational activity is an important part of the service.

#### Annual Conference

A two day meeting in the form of scientific seminars, management seminars and EQA workshops are organised annually with additional ad hoc workshops. The annual meetings include current hot topics within Laboratory Medicine and provide participants the opportunity to exchange views, to engage with organisers and to discuss problems and strategies. Meetings are approved for CPD by both the IBMS and RCPath. The EQA workshops cover statistical analysis, interpretation of EQA and problem solving through interactive case studies.

#### EQA Workshops

Throughout the year Weqas also host small group EQA Workshops on both Laboratory and POCT programmes. These are aimed at delivering face-to-face training sessions where participants can gain a better understanding of report interpretation and are an excellent opportunity to troubleshoot and discuss any issues.

#### POCT Training

A number of ad hoc POCT Training days are held throughout the year. The sessions provide essential tools for both POCT Co-ordinators and users to support a quality and safe service. Weqas' POCT training packages ensure that users have the correct knowledge, skills and competence in the delivery of POCT. Wegas will work with users and POCT co-ordinators to tailor the training to their needs. These are organised on request and can be delivered at the client's venue.

For more information on workshops or tailored training sessions please visit our website www.wegas.com or email contact@wegas.com.





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## IQC Tailored service

ur third party controls provide accurate, independent, unbiased, quality tools for use as part of your quality assurance process. CE marked Internal Quality Control (IQC) and Quality Control Reference Material (QCRM) can be assayed daily to provide confidence in your analytical testing. Our products are clinically relevant, value-added QC, expertly designed by a team of Clinical and Biomedical Scientists with over 20 years experience in manufacturing. Wegas also has the capability to produce bespoke IQC products tailored to your specific requirements.

#### Examples of PoCT IQC

- Lipid Control Norm is an assayed quality control material which includes Cholesterol, HDL Cholesterol, Triglyceride and Glucose for use in Healthcheck programmes for monitoring the performance of POCT analysers. The material has been assayed using both laboratory and a range of POCT methods.
- Urine hCG Controls for POCT Pregnancy Testing are available as a negative and positive control. Samples are also available near the limit of detection of the methods to aid your competency testing programme.
- POCT Glucose & Ketone Controls are available as liquid stable material at 6 concentrations to cover the analytical range.

#### Examples of Laboratory IQC

- Cardiac Marker IQC is a liquid IQC with Troponin values at or near 99<sup>th</sup> centile "diagnostic cut point".
- A number of Quality Control Reference Materials (QCRM) are available which provide traceability to a higher order method.
- Chemistry QCRM linearity panel are available as a range of up to 8 samples and are suitable for ISO 15189 method verification. These can be customised to your requirements. An example is provided on page 33.
- Bile Acid QCRM is available with ID-GCMS target values and uncertainty of measurement for the individual Bile Acids.
- Endocrine QCRM is provided with ID-LC-MS/MS Reference values and uncertainty of measurement for a number of steroids.
- Ethylene Glycol Linearity Control available at 5 linearly related concentrations.
- Positive and negative controls for guaiac based Faecal Occult Blood tests (FOB).

#### Testosterone / Cortisol Calibrators

The use of Tandem Mass Spectrometry has increased significantly for steroid analysis and is now a routine procedure in some laboratories. Testosterone and Cortisol Tandem MS standards are used as an assayed quality control material for verification of "in house" prepared calibrators to assist laboratories with ISO 15189 compliance. Weqas' standards are prepared and value assigned by the Weqas Reference Measurement Laboratory using traceable material of the highest metrological order. Further information on this material is provided on page 32-33.



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IOC



## Electrolyte Quality Control Reference Material

#### Volume: 3.5 mL

**Material:** Sterile liquid human serum, with an antibiotic added to prolong stability, available at a range of concentrations. Analyte values for Sodium, Potassium, Magnesium, Calcium and Lithium are obtained using a validated FAES / FAAS method traceable to SI units via the use of primary reference material. The assigned values for Chloride are obtained from the ISE method mean values derived from a minimum of 2 distributions of EQA material to all participants of the Serum Chemistry programme.

**Storage:** Stable until the expiration date on the vial label when stored unopened at -20°C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles.

Examples of the concentration of measurands available

		Targe	Target value mmol/L							
Measurand	Level 2	Level 4	Level 6	Level 8						
Sodium mmol/L	111.6	124.0	137.4	151.1	FAES Reference					
Potassium mmol/L	2.65	4.19	5.81	7.52	method					
Magnesium mmol/L	0.62	0.97	1.33	1.69	FAAS Reference					
Calcium mmol/L	1.62	2.07	2.51	2.92	Method					
Lithium mmol/L	0.25	0.74	1.23	1.74						
Chloride mmol/L	81.3	92.1	103.1	114.2	ISE					

#### **Testosterone Quality Control Reference Material**

#### Volume: 1.8 mL

**Material:** Sterile liquid human serum, with an antibiotic added to prolong stability, available at a range of concentrations. The assigned ID-LC-MS/MS target values are provided as a confirmation of accuracy. The Testosterone target values are traceable to SI units via the use of a primary standard and primary reference material.

**Storage:** Stable until the expiration date on the vial label when stored unopened at -20°C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles.

#### Examples of the concentration of measurands available

Examples of the concentration of measurands available

Level	ID-LC-MS/MS Target Value (nmol/L)	Expanded Uncertainty
1	4.49	0.14
2	9.68	0.31
3	15.11	0.48
4	28.93	0.92

#### **Testosterone** Calibrators

#### Volume: 1.0 mL

**Material:** Sterile liquid, charcoal stripped, human serum. The Testosterone target values are traceable to a gravimetrically added certified reference standard. Calibrator values are assigned using a validated ID-LC-MS/MS reference method. Suitable for the calibration of Tandem Mass Spectrometer testosterone methods.

**Storage:** Stable until the expiration date on the vial label when stored unopened at -20°C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles.

Level **ID-LC-MS/MS** Target Expanded Value (nmol/L) Uncertainty 0 0 1 0.50 2 1.76 0.06 3.05 0.10 3 4 7.97 0.25 5 15.13 0.48 6 25.0 0.79 7 40.11 1.27

IOC

## Chemistry Quality Control Reference Material

#### Volume: 3.5 mL

**Material:** Sterile liquid human serum, with an antibiotic added to prolong stability, available at a range of concentrations. Analyte values for Sodium, Potassium, Calcium, Magnesium and Lithium are obtained using a validated FAES / FAAS reference method and traceable to SI units via the use of primary reference material. Values for Creatinine, Uric Acid and Glucose are assigned using a validated ID-GCMS reference method. The assigned values for Chloride are obtained from the ISE method mean values derived from a minimum of 2 distributions of EQA material to all participants of the Serum Chemistry Programme.

**Storage:** Stable until the expiration date on the vial label when stored unopened at -20°C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles (use immediately).

Examples of the concentration of measurands available

		Targe	t value mmol/L		Method
Measurand	Level 2	Level 4	Level 6	Level 8	
Sodium mmol/L	111.6	124.0	137.4	151.1	FAES Reference
Potassium mmol/L	2.65	4.19	5.81	7.52	method
Chloride mmol/L	81.3	92.1	103.1	114.2	ISE
Calcium mmol/L	1.65	2.01	2.37	2.73	FAAS Reference
Magnesium mmol/L	0.66	1.01	1.36	1.72	method
Lithium mmol/L	0.25	0.77	1.28	1.80	
Creatinine µmol/L	108	247	378	513	ID-GCMS
Uric Acid µmol/L	260	371	482	593	
Glucose mmol/L	4.6	10.1	15.6	21.2	

### Cortisol Quality Control Reference Material

#### Volume: 1.8 mL

**Material:** Sterile liquid human serum, with an antibiotic added to prolong stability, available at various concentrations. The assigned ID-LC-MS/MS target values are provided as a confirmation of accuracy.

**Storage:** Stable until the expiration date on the vial label when stored unopened at -20°C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles.

Examples of the concentration of measurands available

Level	ID-LC-MS/MS Target Value (nmol/L)	Expanded Uncertainty
1	227.75	9.3
2	334.54	13.7
3	566.44	23.1
4	1065.45	43.5

#### **Cortisol Calibrators**

#### Volume: 1.0 mL

**Material:** Sterile liquid, charcoal stripped, human serum. The Cortisol target values are traceable to a gravimetrically added certified reference standard. Calibrator values are assigned using validated ID-LC-MS/MS reference method. Suitable for the calibration of Tandem Mass Spectrometer cortisol methods.

**Storage:** Stable until the expiration date on the vial label when stored unopened at -20°C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles.

Examples of the concentration of measurands available

Level	ID-LC-MS/MS Target Value (nmol/L)	Expanded Uncertainty
0	0	-
1	25.49	1.04
2	52.03	2.13
3	93.73	3.83
4	257.37	10.51
5	509.00	20.79
6	940.25	38.41
7	1466.93	59.93
8	2012.89	82.23

## IQC & EQA POCT Hybrid Programmes

#### What are our Hybrid Programmes?

This is a concept where IQC and EQA are combined in one programme.

Our Hybrid services include:

#### The provision of CE-marked IQC material

- Sites are sent IQC samples sufficient for 1 month
- Acceptance values predetermined, appropriate for instrument and clinical utility
   of test
- Materials are delivered to POCT locations, or to other agreed distribution points
- Liquid, stable materials

#### Site enters IQC results into a 3rd party cloud-based system

- Instant feedback provided on pass / fail status
- Complete audit trail of QC activity

#### EQA is incorporated without the need for additional samples or data entry

- IQC data is extracted at defined intervals and assessed
- Weqas generate EQA reports which are emailed to the user / organiser

#### Available Programmes

This combined service is currently available for the following programmes:

- Hybrid Lipid
- Hybrid HbA1c

Further information can be found on www.weqas.com.





## Reference Measurement Service



he Weqas Reference Measurement Laboratory is accredited to the recognised International Standard – General requirements for competence of Calibration and Testing Laboratories (ISO/IEC 17025) and in accordance with Laboratory medicine – Requirements for the competence of calibration laboratories using reference measurement procedures (ISO/IEC 15195).

The Reference Measurement Laboratory offers a range of reference measurement procedures utilising "gold standard" technology, using traceable material of the highest metrological order, with gravimetric preparation of all samples and calibrators. All uncertainty calculations are made according to the Guide to the Expression of Uncertainty in Measurement (GUM).

The laboratory is listed as a Joint Committee on Traceability in Laboratory Medicine (JCTLM) reference measurement provider and regularly participates in the JCTLM RELA surveys for Reference Laboratories. The Head of the Reference Measurement Laboratory, is a member of the JCTLM Reference Measurement Method review teams for metabolites and non-peptide hormones and is the team leader for electrolytes and blood gases.

Traceable reference measurement services underpin the global effort in the harmonisation of laboratory results. This ensures that patients receive the correct diagnosis and treatment independent of the country or hospital they are in. The services are available to all relevant healthcare professionals, including National Metrological Institutes, IVD Manufacturers and EQA organisers.

Analytical Technique	Analyte	Approx. Rang	e Covered	Matrix				
Isotope Dilution Gas Chromatography Mass Spectrometry (ID-GCMS)	Steroids - Progesterone* - Testosterone - Cortisol	1 - 100 1 - 35 100 - 1500	nmol/L nmol/L nmol/L	Serum Serum Serum, Urine				
	Bile Acids - Cholic Acid* - Deoxycholic Acid* - Chenodeoxycholic Acid*	0.1 - 100 0.1 - 100 0.1 - 100	μmol/L μmol/L μmol/L	Serum Serum Serum				
	Creatinine	25 - 600	µmol/L	Serum, Urine				
	Glucose	1 – 25	mmol/L	Serum				
	Uric Acid	0.1-1.2	mmol/L	Serum				
	Cholesterol	1-8	mmol/L	Serum				
	Triglycerides	0.6 - 8	mmol/L	Serum				
Isotope Dilution Liquid Chromatography	Testosterone	1-35	nmol/L	Serum				
Mass Spectrometry (ID-LC-MS/MS)	Cortisol	100 - 1500	nmol/L	Serum, Urine				
Flame Atomic Absorption / Emission	Sodium	105 - 160	mmol/L	Serum				
Spectrometry	Potassium	1.8 - 7.5	mmol/L	Serum				
	Calcium	1.6-4	mmol/L	Serum				
	Magnesium	0.4 - 2	mmol/L	Serum				
	Lithium	0.2 - 2	mmol/L	Serum				
UV / Vis spectrometry	Lactate Dehydrogenase	100 - 500	IU	Calibration materials,				
(IFCC 37°C methods)	Gamma Glutamyl Transferase	20-400	IU	control specimens				
	Aspartate Transaminase	5 - 600	IU	anu serum				
	Alanine Transaminase	5 - 300	IU					

\* Not Accredited

#### Traceability: Certified Reference Material

- Traceable material of the highest metrological order is used for all method calibration where available.
- Suitable matrix matched traceable control material of a higher order is used in all methods, where available, as a confirmation of the traceability and accuracy of each method.

All reference methods are recognised as primary or secondary reference measurement procedures. Where available, methods listed as JCTLM approved reference methods are used. Exact matching isotope dilution used for all Mass Spectrometry methods provides the most accurate method for generating sample results. All samples and calibrators are prepared gravimetrically using traceable weighing equipment as appropriate. Dilution of samples for atomic absorption/emission methods utilises automated equipment, increasing the accuracy of sample preparation. The performance criteria used for all methods conform to currently accepted international criteria for Reference Measurement Procedures.

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# Quick Guide

ur Quick Guide section has been designed to give an 'At A Glance' view of our EQA programmes and the analytes that are covered. The tables on pages 40-44 list all of the analytes covered along the top, the programme they are included in is indicated by a circle in the relevant row.

We have also included an Index on page 45 to help you to quickly navigate to the desired programme. Further information about our programmes and sample dispatch dates can be found on our website: www.weqas.com.





Programmes	Analytes	Adjusted Calcium	Alanine aminotransferase (ALT)	Albumin	Albumin (Urine)	Albumin / Creatinine Ratio	Alkaline phosphatase (ALP)	Amikacin	Ammonia	Amphetamine •	Amylase (Total)	Apolipoprotein A1	Apolipoprotein B	Aspartate Aminotransferase (AST)	Vitamin B12	Barbiturates •	BE	Benzodiazepines •	Bicarbonate (Actual) (aHCO3)	Bicarbonate	Bile Acids (Total)	Bilirubin (Conjugated)	Bilirubin (Total)	Bilirubin (Urine)	Buprenorphine •	Calcium (Total)	Calculated Globulins	Cannabis •	Carbamazepine	Carboxyhaemoglobin
Ammonia			~	~	~	4	~	~		~	4	4	4	4	_															
Rile Acids																														
Biliruhin	- I P																													
Blood Gas	LP																													
Co-oximetry	LP																													
Creatinine	P																													
CRP	LΡ																													
D-Dimer	Р																													
ED Toxicology	1																													
Endocrine	L																													
Fetal Fibronectin	Р																													
Glucose & Ketones	Р																													
Haematinics	L																													
Haemoglobin	Р																													
HbA1c	LΡ																													
HIL Serum Indices	L																													
HIV	Р																													
Homocysteine	L																													
hsTroponin	L																													
INR	Р																													
Lipids	L																													
NT-Pro BNP	L																													
pH Meter	L																													
phIGFBP-1	Р																													
POCT Cardiac	Р																													
POCT Lipids (Healthcheck)	Р																													
POCT PROM	L																													
Porphyrin	Р																													
Pre-Eclampsia	L																													
Procalcitonin	L																													
Quantitative Faecal Hb	L																													
Renal Calculi	L																													
Respiratory Virus	Р																													
Serum ACE	L																													
Serum Chemistry	L		•	•										•						•										
Serum hCG	L																													
Therapeutic Drug Monitoring	L							•																						
Urinalysis	Р																							•						
Urine Chemistry	L																													
Urine Drugs of Abuse	LP																								•					
Urine Oxalate & Citrate	L																													
Urine Pregnancy	Р																													
Viscoelastic Haemostasis	— Р	• Q	ualit	ative	and	Qua	ntita	tive	tests	avai	: ilable	: 2.	<b>L</b> = l	_aboi	: rator	y EQ.	A	<b>P</b> =	POCT	Γ EQ/	4								-	

Programmes	Analytes	HDL Cholesterol	Heroin ●	HIL Serum Indices	HIV	Homocysteine	IGFBP-1	Influenza A	Influenza B	INR	lonized Calcium (iCa++)	Iron	Ketamine ●	Ketones	Lactate	Lactate Dehydrogenase (LDH)	Lamotrigine	LDL Cholesterol	Leucocytes	ĽH	Lipase	Lipoprotein (a)	Lithium	Magnesium	MDMA	Methadone •	Methaemoglobin	Methamphetamine (mAMP) •	Methotrexate	Myoglobin
Ammonia	L																												÷	
Bile Acids	L																													
Bilirubin	LP																													
Blood Gas	LΡ																													
Co-oximetry	LP																													
Creatinine	Р																													
CRP	LP																													
D-Dimer	Р																													
ED Toxicology	L																													
Endocrine	L																													
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Urinalysis	Р													•																
Urine Chemistry	L																													
Urine Drugs of Abuse	LΡ																													
Urine Oxalate & Citrate	L																													
Urine Pregnancy	Р																													
Viscoelastic Haemostasis	Р														:															
		• Q	ualita	ative a	and	Quar	ntitat	ive t	ests a	avai	lable	2.	<b>L</b> = L	abo	rator	y EQ.	A	<b>P</b> =	POC	T EQ.	A									

s DL Cholesterol BNP
NITTIES Non-HDL NT-Pro B
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		IJ	imus		) un	ific (	olim		plar	oster	hhy		amy	•	/ Cre	ТЗ	T4	sferr	sferr	clic /	yceri	onin	onin			بە		pilind	roic	Somy	pelas
Programmes		SHB(	Sirol	s02	Sodi	Spec	Tacro	TCO.	Teico	Testo	Theo	TIBC	Tobr	TUP	TUP	Total	Tota	Trans	Tran	Tricy	Trigly	Trop	Trop	TSH	UIBC	Urat	Urea	Urob	Valpi	Vand	Visco
Ammonia	L																														
Bile Acids	L																														
Bilirubin	LP																														
Blood Gas	LΡ																														
Co-oximetry	LP																														
Creatinine	Р																														
CRP	LP																														
D-Dimer	Р																														
ED Toxicology	L																														
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Serum hCG	L																														
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Urine Chemistry	L																														
Urine Drugs of Abuse	LΡ																														
Urine Oxalate & Citrate	L																														
Urine Pregnancy	Р																														
Viscoelastic Haemostasis	Р																														
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