

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



4301

Accredited to
ISO/IEC 17025:2017

Cardiff and Vale University Health Board, operating as WEQAS

Issue No: 005 Issue date: 10 December 2020

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Calibration performed at the above address only

DETAIL OF ACCREDITATION

Measured Quantity Instrument or Gauge	Range	Calibration and Measurement Capability (CMC) Expressed as an Expanded Uncertainty ($k = 2$)	Remarks
Provision of Laboratory Medicine Reference Measurements Services in accordance with the requirements of ISO 15195:2018			Documented In-House Methods in accordance to JCTLM requirements. The JCTLM reference method are included in parenthesis
HUMAN BODY FLUIDS Clinical analysis			
Electrolytes in blood serum:			
Calcium	1.6-4 mmol/L	2.6 %	using Flame Atomic Absorption Spectrometry (FAAS) (NRMeth 20)
Lithium	0.2-2 mmol/l	1.91 %	using FAAS (C1RMP_E11)
Magnesium	0.4-2 mmol/l	1.34 %	using FAAS (C1RMP_E14)
Potassium	1.8-7.5 mmol/l	1.39 %	using Flame Atomic Emission Spectrometry (FAES), (NRMeth 25)
Sodium	105-160 mmol/l	1.14 %	using FAES (NRMeth 24)
Enzymes in blood serum:			
Lactate dehydrogenase	100-500 IU/L	4.4 %	using UV-Vis Spectrometry (IFCC 37°C method) (NRMeth 66)
Gamma Glutamyl Transferase	20-400 IU/L	5.6 %	using UV-Vis Spectrometry(IFCC 37°C method) (NRMeth 69)
Enzymes in blood serum or plasma:			
Aspartate Aminotransferase	5-600 IU/L	2.75 %	using UV-Vis Spectrometry (IFCC 37°C method) (NRMeth 68)
Alanine Aminotransferase	5-300 IU/L	2.75 %	using UV-Vis Spectrometry (IFCC 37°C method) (NRMeth 67)



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Measured Quantity Instrument or Gauge	Range	Calibration and Measurement Capability (CMC) Expressed as an Expanded Uncertainty ($k = 2$)	Remarks
HUMAN BODY FLUIDS Clinical analysis (cont'd)			Documented In-House Methods in accordance to JCTLM requirements. The JCTLM reference method are included in parenthesis (cont'd)
Hormones in blood serum and urine:			
Cortisol	100-1500 nmol/L	2.44 %	using Isotope dilution Gas Chromatography Mass Spectrometry (ID- GCMS), (NRMeth 8)
Cortisol	25 – 2000 nmol/L	2.13 %	Using isotope dilution liquid chromatography tandem mass spectrometry (LC-MS/MS). Method LP-QL3-LC-MS/MSCORT
Hormones in blood serum:			
Testosterone	1-35 nmol/L	4.06 %	using ID-GCMS (NRMeth 60)
Testosterone	0.5 – 40 nmol/L	2.74 %	Using isotope dilution liquid chromatography tandem mass spectrometry (LC-MS/MS). Method LP-QL3-LC-MS/MSTEST
Metabolites and substrates in blood: serum:			
Cholesterol	1-8 mmol/l	3.63 %	using ID-GCMS (NRMeth 2)
Creatinine	25-600 µmol/l	1.24 %	using ID-GCMS (NRMeth 1)
Glucose	1-25 mmol/L	1.72 %	using ID-GCMS (NRMeth 4)
Uric acid	0.1-1.2 mmol/L	3 %	using ID-GCMS (NRMeth 3)
Triglyceride	0.6-8 mmol/L	2.83 %	using ID-GCM (NRMeth 5)
END			



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Appendix - Calibration and Measurement Capabilities

Introduction

The definitive statement of the accreditation status of a calibration laboratory is the Accreditation Certificate and the associated Schedule of Accreditation. This Schedule of Accreditation is a critical document, as it defines the measurement capabilities, ranges and boundaries of the calibration activities for which the organisation holds accreditation.

Calibration and Measurement Capabilities (CMCs)

The capabilities provided by accredited calibration laboratories are described by the Calibration and Measurement Capability (CMC), which expresses the lowest uncertainty of measurement that can be achieved during a calibration. If a particular device under calibration itself contributes significantly to the uncertainty (for example, if it has limited resolution or exhibits significant non-repeatability) then the uncertainty quoted on a calibration certificate will be increased to account for such factors. The CIPM-ILAC definition of the CMC is as follows:

A CMC is a calibration and measurement capability available to customers under normal conditions:

- (a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or
- (b) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement.

The CMC is normally used to describe the uncertainty that appears in an accredited calibration laboratory's schedule of accreditation and is the uncertainty for which the laboratory has been accredited using the procedure that was the subject of assessment. The CMC is calculated according to the procedures given in M3003 and is normally stated as an expanded uncertainty at a coverage probability of 95 %, which usually requires the use of a coverage factor of $k = 2$. An accredited laboratory is not permitted to quote an uncertainty that is smaller than the published CMC in certificates issued under its accreditation.

The CMC may be described using various methods in the Schedule of Accreditation:

As a single value that is valid throughout the range.

As an explicit function of the measurand or of a parameter (see below).

As a range of values. The range is stated such that the customer can make a reasonable estimate of the likely uncertainty at any point within the range.

As a matrix or table where the CMCs depend on the values of the measurand and a further quantity.

In graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the CMC.

Expression of CMCs - symbols and units

In general, only units of the SI and those units recognised for use with the SI are used to express the values of quantities and of the associated CMCs. Nevertheless, other commonly used units may be used where considered appropriate for the intended audience. For example, the term "ppm" (part per million) is frequently used by manufacturers of test and measurement equipment to specify the performance of their products. Terms like this may be used in Schedules of Accreditation where they are in common use and understood by the users of such equipment, providing their use does not introduce any ambiguity in the capability that is being described.

When the CMC is expressed as an explicit function of the measurand or of a parameter, this often comprises a relative term (e.g., percentage) and an absolute term, i.e. one expressed in the same units as those of the measurand. This form of expression is used to describe the capability that can be achieved over a range of values. Some examples are shown below. It should be noted that these expressions are *not* mathematical formulae but are instead written in a commonly used shorthand for expressing uncertainties - therefore, for purposes of clarity, an indication of how they are to be interpreted is also provided below.

DC voltage, 100 mV to 1 V: 0.0025 % + 5.0 μ V

Over the range 100 mV to 1 V, the CMC is 0.0025 %·V + 5.0 μ V, where V is the measured voltage.

Hydraulic pressure, 0.5 MPa to 140 MPa: 0.0036 % + 0.12 ppm/MPa + 4.0 Pa

Over the range 0.5 MPa to 140 MPa, the CMC is 0.0036 %· p + (0.12·10⁻⁶· p ·10⁻⁶) + 4.0 Pa, where p is the measured pressure in Pa.

It should be noted that the percentage symbol (%) simply represents the number 0.01. In cases where the CMC is stated only as a percentage, this is to be interpreted as meaning percentage of the measured value or indication.

Thus, for example, a CMC of 1.5 % means 1.5 · 0.01 · i , where i is the instrument indication.