Certificate of Analysis

Product Type: USP-EP System Suitability/Verification or Standard Solution

Catalogue Number: A-4767-500

USP Reagent Water (Rw)

Lot Number :	A-3231501-47
Certified Value :	TOC ≤ 0.100mg/L C
Expanded Uncertainty:	*U*= ± 0.007mg/L Carbon
Reference Value:	0.025mg/L Carbon ±*U*
Source Material :	N/A
Certificate Issue Date:	20 Nov 2015
Expiration Date:	14 Jan 2016

Intended Use: This Certified Reference Material (CRM) is intended for use in calibration and testing of a Total Organic Carbon Analyser as a low level TOC water. This water is used to prepare Altus Science reference materials. The expanded uncertainty value (U) applies to both parameters.

Description: One unit of Altus Science TOC Calibration standard consists of a 500ml solution produced from ultrapure, filtered, deionised water with an initial total organic carbon (TOC) no greater than 0.100 mg/L carbon, and having a conductivity no greater than 0.058 µS/cm (at point of production). This CRM is made in accordance with the USP/EP requirements for Reagent Water Rw[1]. These solutions are stored and shipped in scrupulously cleaned 500ml HDPE bottles.

Instructions for Use: These CRMs should be stored in the original shipping container and refrigerated at 5 ± 4 °C upon receipt. Bottles should remain tightly closed between uses. Avoid contaminating open containers. The certified values and stated uncertainties will be valid through the date listed on the bottle.

Period of Validity: The certified values are monitored and purchasers will be notified of any significant changes resulting in recertification or withdrawal of this certified reference material during the period of validity of this certificate. The 500ml ready to use standards are intended for single use only. The validity period is invalid once opened or used.

Homogeneity Assessment: Homogeneity was assessed in accordance with ISO Guide 35[2]. Completed units were sampled using a random sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA (Homogeneity Uncertainty Contribution = $\sqrt{u_{bb}^2}$). Heterogeneity was not detected under the conditions of the ANOVA.

Uncertainty Statement: Uncertainty values in this document are expressed as Expanded Uncertainty. The reported Expanded Uncertainty is based on a standard uncertainty multiplied by a coverage factor *k*= 2 providing a confidence level of95%. The components of combined standard uncertainty include the uncertainties due to characterisation, homogeneity, long term stability, and short term stability (transport) as appropriate. Uncertainty is calculated using TOC or TIC measurement.

The Expanded Uncertainty applies to the product as supplied[2,3].

Certified Value: Is determined under **double-accreditation** in accordance with **ISO/IEC 17025** [4] and also **ISO Guide 34** [5]. The Certified Value is the actual "made-to" concentration confirmed by Altus Science. TOC analytical verification and acceptance criteria are set for quality acceptance of this product.

Method of Preparation: This material was prepared and certified by Altus Science. Blanks consist of ultrapure, filtered, deionised water with an initial TOC no greater than 0.100 mg/L C, and having a conductivity no greater than 0.058 µS/cm at point of production.

Quality Standard Documentation: Altus Science are Accredited by the United Kingdom Accreditation Service (UKAS) to ISO 17025:2005 as a Testing Laboratory, and ISO Guide 34:2009 for CRM manufacture. Contents of Certificates and Labels comply with the requirements of ISO Guide 31:2000 [6].

Certifying Officer: G Roscoe Mr. Graham Roscoe

References:
1) US Pharmacopeia 37-NF 31, General Chapter USP Total Organic Carbon <643>, (USP Convention, USA, 2012) - If applicable
2) ISO Guide 35:2006(E), Reference materials-General and Statistical Principles.
3) ISO/IEC Guide 98-3:2008, Uncertainty of Measurement – Part 3: Guide to the Expression of Uncertainty in Measurement (GUM:1995).
4) ISO/IEC 17025:2005(E), General Requirements for the Competence of Testing and Calibration Laboratories.
5) ISO Guide 34:2009(E), General Requirements for Competence of Reference Material Producers.
6) ISO Guide 31:2000(E), Reference Materials - Contents of Certificates and Labels.

This certificate is issued in accordance with the laboratory accreditation requirements to ISO 17025:2005 of the United Kingdom Accreditation Service (UKAS). UKAS is one of the signatories to the Multilateral Agreement of the European co-operation for Accreditation (EA) as well as the International Laboratory Accreditation (ILAC) Arrangement for the mutual recognition of calibration certificates issued by accredited laboratories. This certificate may NOT be reproduced other than in full, except with the written approval of Altus Science Limited.

UKAS TESTING 8020 UKAS REFERENCE MATERIALS 8020

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