



Application Report

Calibration and Traceability Version 1

cobas® CRP Test (REF 08024669 190)

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Introduction

Each lot of the **cobas** CRP Test for the **cobas b101** system is factory calibrated and does not require any further calibration activities. The instrument automatically reads in the lot - specific calibration data from the barcode information printed on the **cobas** CRP Test disc, eliminating the need for calibration by the user. Calibration of each disc is performed such that each measurement result can be traced via an unbroken chain to the ERM-DA472/IFCC reference material. How this is achieved is described in this document.

Traceability

The **cobas** CRP Test has been standardized against the higher order ERM-DA472/IFCC reference material. This material has shown traceability to the ERM-DA470 reference material. The value assignment measurements of CRP in ERM-DA470 had been calibrated with the 1st International Standard CRP 85/506, to which values had been assigned by using a pure protein as calibrant. Therefore ERM-DA472 is traceable to the pure protein calibrant, and thus to the SI. Certified values are given in mg/L (see below).

The **cobas b** 101 instrument reports values in mg/L by default or mg/dL if needed.

Certified value and expanded uncertainty for the mass concentration of CRP in ERM-DA472/IFCC:

Certified value [mg/L]	U_{CRM} (k = 2) [mg/L]
41.8	2.5

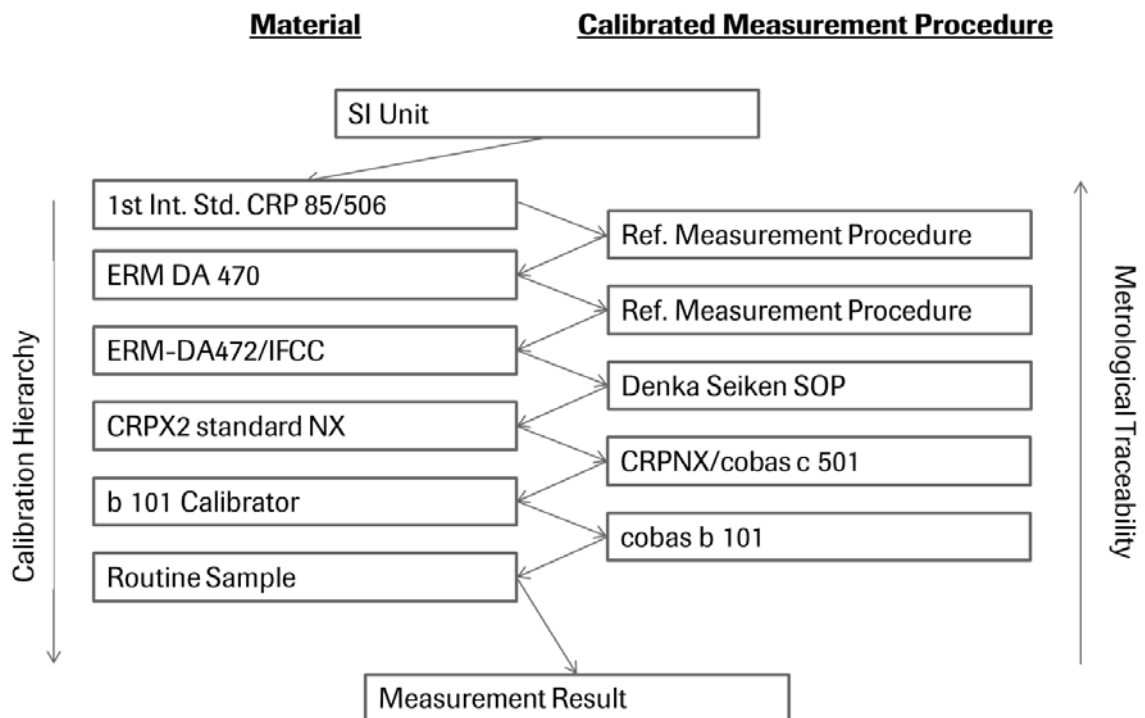
Standardization and Value Assignment Process

The ERM-DA472/IFCC reference material is used by Denka Seiken Co., Ltd. to ultimately assign the value to the CRPX2 standard NX calibrator. The assignment process is regulated by proprietary Standard Operating Procedures (SOPs) and assures an unbroken traceability chain.

CRPX2 standard NX is used to calibrate the CRP-LatexX2 “SEIKEN” NX test on the cobas c 501 instrument.

The so calibrated **cobas c 501** reference system is used to establish the assigned value for the working calibrator (b 101 Calibrator). The working calibrator is based on spiked frozen pooled serum and is used to assign the lot specific calibration data for the **cobas CRP Test** on the **cobas b101** system. The traceability is shown in Figure 1 below:

Figure 1 Traceability cobas CRP Test



Reference Standardization

Calibration of the **cobas c 501** reference system is performed with the CRPX2 standard NX calibrator according to manufacturers instructions. To verify the calibration, several control materials are measured. If measurement results of single measurements are outside the defined tolerance the system is recalibrated (see Table 1 below).

Table 1 Control material used for verification of calibration

Control Material	Samples	Allowed tolerance
CRPX2 standard NX	1.5, 15, 40, 160, 320 mg/L	$\leq \pm 5\%$
IQL and IQH	approx. 9 mg/L IQL and approx. 25 mg/L IQH	$\leq \pm 30\%$ for IQL and $\leq \pm 15\%$ IQH
ERM-DA474	41.2 mg/L	$\leq \pm 5\%$

Working Calibrator Standardization

As working calibrator CRP spiked frozen serum pools are used. 10 different sample pools are used for disc calibration covering the whole measuring range.

To compensate for variance of the reference system value assignment is done as follows:

On 8 days an aliquot of each pool is thawed and measured 3 times.

The mean value of the 8x3 measurements from each pool is assigned to the individual pool.