

Traceability And Uncertainty: HDL-Cholesterol

Calibrator:	TruCal Lipid (Product Code 1 3570)
Analyte:	HDL-Cholesterol
Method:	HDL-C Immuno FS (Product Code 1 3521)
Reference material:	NIST SRM 1951b Level 2
Literature:	- ISO GUM (1993) Guide to the expression of uncertainty in measurement. ISO, Geneva, Switzerland - EURACHEM Guide (1995) Quantifying uncertainty in analytical measurement. EURACHEM, Teddington, UK
Traceability statement:	Values assigned to the DiaSys TruCal Lipid calibrator (1 3570) for the HDL Cholesterol (HDL-C) assay are traceable to SRM 1951b Level 2 reference material for total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides as provided by National Institute of Standards & Technology (NIST; www.nist.gov/srm). HDL-cholesterol were determined at Centers for Disease Control and Prevention (CDC), using the betaquantification reference method used in the Cholesterol Reference Method Laboratory Network (CRMLN)
Uncertainty:	The total expanded uncertainty is the sum of the uncertainty of the reference material, within-run imprecision of the master calibrator assignment, uncertainty of assigned and measured master calibrator value, and the variability of the value assignment processes used to assign the commercialized product calibrators.
	Calibrator value: 52,2 mg/dL* 1,35 mmol/L*
	Calculated Calibrator Uncertainty: 5,3 % **
	* Approximate value; actual value varies from lot to lot ** Expressed by using a coverage factor 2
Commutability Statement:	The commutability of the DiaSys TruCal Lipid calibrator has been evaluated for serum by calibrator comparison of TruCal Lipid master calibrator against SRM 1951b level 2 calibration. Obtained regression: $Y = 0,976 X + 0,58 \text{ mg/dL}$; $r = 0,99$ TruCal Lipid was judged commutable based on this testing.

A comma is always used in this sheet as decimal separator. Separators for thousands are not used.

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Traceability And Uncertainty: LDL-Cholesterol

Calibrator:	TruCal Lipid (Product Code 1 3570)				
Analyte:	LDL-Cholesterol				
Method:	LDL-C Select FS (Product Code 1 4121)				
Reference material:	NIST SRM 1951b Level 2				
Literature:	1. ISO GUM (1993) Guide to the expression of uncertainty in measurement. ISO, Geneva, Switzerland 2. EURACHEM Guide (1995) Quantifying uncertainty in analytical measurement. EURACHEM, Teddington, UK				
Traceability statement:	Values assigned to the DiaSys TruCal Lipid calibrator (1 3570) for the LDL Cholesterol (HDL-C) assay are traceable to SRM 1951b Level 2 reference material for total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides as provided by National Institute of Standards & Technology (NIST; www.nist.gov/srm). LDL-cholesterol were determined at Centers for Disease Control and Prevention (CDC), using the betaquantification reference method used in the Cholesterol Reference Method Laboratory Network (CRMLN)				
Uncertainty:	The total expanded uncertainty is the sum of the uncertainty of the reference material, within-run imprecision of the master calibrator assignment, uncertainty of assigned and measured master calibrator value, and the variability of the value assignment processes used to assign the commercialized product calibrators. <table border="1"> <tr> <td>Calibrator value:</td><td>116 mg/dL* 3,00 mmol/L*</td></tr> <tr> <td>Calculated Calibrator Uncertainty:</td><td>4,4 % **</td></tr> </table> * Approximate value; actual value varies from lot to lot ** Expressed by using a coverage factor 2	Calibrator value:	116 mg/dL* 3,00 mmol/L*	Calculated Calibrator Uncertainty:	4,4 % **
Calibrator value:	116 mg/dL* 3,00 mmol/L*				
Calculated Calibrator Uncertainty:	4,4 % **				
Commutability Statement:	The commutability of the DiaSys TruCal Lipid calibrator has been evaluated for serum by calibrator comparison of TruCal Lipid master calibrator against SRM 1951b level 2 calibration. Obtained regression: $Y = 0,988 X - 0,274 \text{ mg/dL}$; $r = 0,99$ TruCal Lipid was judged commutable based on this testing.				

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Traceability And Uncertainty: Phospholipids

Calibrator:	TruCal Lipid (Product Code 1 3570)
Analyte:	Phospholipids
Method:	Phospholipids FS (Product Code 1 5741)
Reference material:	Gravimetric master calibrator prepared out of 1,2-Dioleoyl-sn-glycero-3-phosphocholin
Reference method:	None recognized reference method available
Literature:	1. ISO GUM (1993) Guide to the expression of uncertainty in measurement. ISO, Geneva, Switzerland 2. EURACHEM Guide (1995) Quantifying uncertainty in analytical measurement. EURACHEM, Teddington, UK
Traceability statement:	Values assigned to the DiaSys TruCal Lipid calibrator (1 3570) for the Phospholipids assay method are not traceable to a higher order reference material as none is available. Purified 1,2-Dioleoyl-sn-glycero-3-phosphocholin is used to gravimetrically prepare the aqueous based master calibrator.
Uncertainty:	The total expanded uncertainty is the sum of the uncertainty of the reference material, within-run imprecision of the master calibrator assignment and the variability of the value assignment processes used to assign the commercialized product calibrators.
	Calibrator value: 2,87 mmol/L* 222 mg/dL*
	Calculated Calibrator Uncertainty: 1,4 % **
	* Approximate values; actual value varies from lot to lot ** Expressed by using a coverage factor 2
Commutability statement:	To date DiaSys is not aware of recognized reference methods for this analyte. Therefore no commutability studies against reference methods have been done. Commutability against aqueous based Phospholipids standard has been demonstrated. Obtained regression: $Y_{\text{Hitachi 911}}$ $= 1,034 X - 0023 \text{ mmol/L; } r = 0,9989$ $Y_{\text{BM 6010}}$ $= 1,022 X - 0,00 \text{ mmol/L; } r = 1,0000$

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Traceability And Uncertainty: NEFA

Calibrator:	TruCal Lipid (Product Code 1 3570)
Analyte:	NEFA (Non-esterified-fatty-acids)
Method:	NEFA FS (Product Code 1 5781)
Reference material:	Gravimetric master calibrator prepared out of Sodium oleate
Reference method:	None recognized reference method available
Literature:	1. ISO GUM (1993) Guide to the expression of uncertainty in measurement. ISO, Geneva, Switzerland 2. EURACHEM Guide (1995) Quantifying uncertainty in analytical measurement. EURACHEM, Teddington, UK
Traceability statement:	Values assigned to the DiaSys TruCal Lipid calibrator (1 3570) for the NEFA assay method are not traceable to a higher order reference material as none is available. Purified Sodium oleate is used to gravimetrically prepare the aqueous based master calibrator.
Uncertainty:	The total expanded uncertainty is the sum of the uncertainty of the reference material, within-run imprecision of the master calibrator assignment and the variability of the value assignment processes used to assign the commercialized product calibrators.
	Calibrator value:0,90 mmol/L*25,4 mg/dL*
	Calculated Calibrator Uncertainty:2,2 % **
	* Approximate values; actual value varies from lot to lot ** Expressed by using a coverage factor 2
Commutability statement:	To date DiaSys is not aware of recognized reference methods for this analyte. Therefore no commutability studies against reference methods have been done. Commutability against aqueous based NEFA standard have been demonstrated. Obtained regression: $Y_{\text{Hitachi 911}} = 1,009 X - 0,004 \text{ mmol/L}; r = 0,9999$ $Y_{\text{BM 6010}} = 1,001 X + 0,000 \text{ mmol/L}; r = 1,0000$

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