

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:	<ol style="list-style-type: none"> 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:	<p>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)</p>				
Uncertainty:	<p>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.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Calibrator value:</td> <td>52,2 mg/dL* 1,35 mmol/L*</td> </tr> <tr> <td>Calculated Calibrator Uncertainty:</td> <td>5,3 % **</td> </tr> </table> <p>* Approximate value; actual value varies from lot to lot ** Expressed by using a coverage factor 2</p>	Calibrator value:	52,2 mg/dL* 1,35 mmol/L*	Calculated Calibrator Uncertainty:	5,3 % **
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Calculated Calibrator Uncertainty:	5,3 % **				
Commutability Statement:	<p>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.</p>				

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:	<ol style="list-style-type: none"> 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:	<p>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).</p> <p>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)</p>
Uncertainty:	<p>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.</p>
	<p>Calibrator value: 116 mg/dL* 3,00 mmol/L*</p>
	<p>Calculated Calibrator Uncertainty: 4,4 % **</p>
	<p>* Approximate value; actual value varies from lot to lot ** Expressed by using a coverage factor 2</p>
Commutability Statement:	<p>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.</p> <p>Obtained regression: $Y = 0,988 X - 0,274 \text{ mg/dL}$; $r = 0,99$</p> <p>TruCal Lipid was judged commutable based on this testing.</p>

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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:	<ol style="list-style-type: none"> 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:	<p>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.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Calibrator value:</td> <td style="width: 35%;">2,87 mmol/L*</td> <td style="width: 35%;">222 mg/dL*</td> </tr> <tr> <td>Calculated Calibrator Uncertainty:</td> <td colspan="2">1,4 % **</td> </tr> <tr> <td colspan="3">* Approximate values; actual value varies from lot to lot</td> </tr> <tr> <td colspan="3">** Expressed by using a coverage factor 2</td> </tr> </table>	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		
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:	<p>To date DiaSys is not aware of recognized reference methods for this analyte. Therefore no commutability studies against reference methods have been done.</p> <p>Commutability against aqueous based Phospholipids standard has been demonstrated.</p> <p>Obtained regression:</p> $Y_{\text{Hitachi 911}} = 1,034 X - 0023 \text{ mmol/L}; r = 0,9989$ $Y_{\text{BM 6010}} = 1,022 X - 0,00 \text{ mmol/L}; r = 1,0000$												

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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:	<ol style="list-style-type: none"> 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.						
	<table style="width: 100%; border: none;"> <tr> <td style="width: 30%;">Calibrator value:</td> <td style="width: 35%;">0,90 mmol/L*</td> <td style="width: 35%;">25,4 mg/dL*</td> </tr> <tr> <td>Calculated Calibrator Uncertainty:</td> <td colspan="2">2,2 % **</td> </tr> </table>	Calibrator value:	0,90 mmol/L*	25,4 mg/dL*	Calculated Calibrator Uncertainty:	2,2 % **	
	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:	<p>To date DiaSys is not aware of recognized reference methods for this analyte. Therefore no commutability studies against reference methods have been done.</p> <p>Commutability against aqueous based NEFA standard have been demonstrated.</p> <p>Obtained regression:</p> <p>$Y_{\text{Hitachi 911}} = 1,009 X - 0,004 \text{ mmol/L}; r = 0,9999$</p> <p>$Y_{\text{BM 6010}} = 1,001 X + 0,000 \text{ mmol/L}; r = 1,0000$</p>						

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