Traceability and Uncertainty of DiaSys assay systems

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
ALAT[22] (GPT)[23]	ALAT (GPT) FS (IFCC[2] mod.) + Pyridoxal-5-Phosphate FS	1 2701 2 5010	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	89,3	± 1,79 2,01 %
	ALAT (GPT) FS (IFCC[2] mod.) (without Pyridoxal-5-Phosphate)	1 2701	TruCal U	5 9100	Molar extinction coefficient 340 nm	U/L	88,0	± 1,53 1,74 %
	ALAT (GPT) FSC (IFCC[2] mod.) + Pyridoxal-5-Phosphate FS (Concentrated reagent)	2 2705 2 5010	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	88,0	± 2,21 2,51 %
Albumin	Albumin FS (BCG - Bromcresol green method)	1 0220	TruCal U	5 9100	ERM[9]-DA470	g/dL	4,71	± 0,19 4,14 %
			Albumin Standard FS	1 0200	CRM[1] 470	g/dL	5,00	± 0,125 2,50 %
	Albumin FSC (BCG - Bromcresol green method; Concentrated reagent)	2 0250	TruCal U	5 9100	ERM[9]-DA470	g/dL	4,64	± 0,11 2,29 %
Albumin in Urine (Microalbumin)	Albumin in Urine/CSF FS (Microalbumin) (Immunoturbidimetric method)	1 0242	TruCal Albumin U/CSF (Urine application)	1 9300	ERM[9]-DA470k/IFCC[2]	mg/L	Level 1: 11,4 Level 2: 22,2 Level 3: 44,2 Level 4: 147 Level 5: 305	± 0,4 3,43 % ± 0,8 3,42 % ± 1,5 3,43 % ± 5,0 3,42 % ± 10,5 3,43 %
			TruCal Protein (serum application) Lot 13496 – 13500 TruCal Protein high (serum application) Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 5,01 Level 2: 10,0 Level 3: 20,0 Level 4: 40,1 Level 5: 80,1 High: 80,1	± 0,17 3,47 % ± 0,34 3,40 % ± 0,67 3,35 % ± 1,34 3,36 % ± 2,70 3,37 % ± 2,68 3,35 %
Alkaline phosphatase	Alkaline phophatase FS DGKC[5] (DGKC recommended procedure)	1 0401	TruCal U	5 9100	Molar extinction coefficient according to DGKC[5] recommendation	U/L	500	± 24,3 4,86 %
	Alkaline phophatase FS IFCC[2] 37 ℃ (IFCC recommended procedure)	1 0441	TruCal U	5 9100	Molar extinction coefficient at 405 nm according to IFCC[2] recommendation	U/L	244	± 14,5 5,93 %
α-Amylase	α-Amylase CC FS (EPS-G7[24] method)	1 0501	TruCal U	5 9100	Original formulation IFCC[2] 2000 (Molar extinction coefficient 405 nm)	U/L	199	± 9,5 4,76 %
Antistreptolysin O	Antistreptolysin O FS (Particle-enhanced Immunoturbidimetric method)	1 7012	TruCal ASO	1 7010	Commercially available Siemens N Rheumatology Standard SL, calibrated against First International Standard for ASL[7]	IU/mL	Level 1: 50,0 Level 2: 100 Level 3: 200 Level 4: 400 Level 5: 700	± < 4 < 8 % ± < 8 < 8 % ± <16 < 8 % ± < 32 < 8 % ± < 56 < 8 %
Apolipoprotein A1	Apolipoprotein A1 FS (Immunoturbidimetric method)	1 7102	TruCal A1 Lot 12755 - 12757	1 7100	IFCC[2] SP1-01 reference standard (WHO[3]-IRP[13] October 1992)	mg/dL	Level 1: 40,2 Level 2: 125 Level 3: 274	± 3,0 7,45 % ± 7,2 5,74 % ± 15,6 5,71 %
			TruCal HDL/LDL Lot 12098	1 3520	IFCC[2] SP1-01 reference standard (WHO[3]-IRP[13] October 1992)	mg/dL	180	± 5,4 3,04 %
Apolipoprotein B	Apolipoprotein B FS (Immunoturbidimetric method)	1 7112	TruCal Apo B Lot 13788 - 13790	1 7110	IFCC[2] SP3-07 reference standard	mg/dL	Level 1: 37,7 Level 2: 111 Level 3: 265	± 4,2 11,1 % ± 5,6 5,00 % ± 13,8 5,20 %

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
ASAT[25] (GOT[26])	ASAT (GOT) FS (IFCC[2] mod.) + Pyridoxal-5-Phosphate FS	1 2601 2 5010	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	98,7	± 1,99 2,02 %
	ASAT (GOT) FS (IFCC[2] mod.) (without Pyridoxal-5-Phosphate)	1 2701	TruCal U	5 9100	Molar extinction coefficient 340 nm	U/L	90,1	± 1,78 1,98 %
	ASAT (GOT) FSC (IFCC[2] mod.) + Pyridoxal-5-Phosphate FS (Concentrated reagent)	2 2605 2 5010	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	95,7	± 3,03 3,17 %
ATP	ATP Hexokinase FS	1 6201	ATP Standard FS	1 6200	Primary ATP Standard > 99 %; Molar extinction coefficient of NADH[45]	µmol/L	100	± 0,015 1,55 %
Bicarbonate / CO_2	Bicarbonate FS (Enzymatic test using PEPC[27] and a stable NADH[45] analog)	1 0950	Bicarbonate Standard FS	1 0950	Primary Standard based on Sodium carbonate > 99 %	mmol/L	30	± 0,500 1,67 %
Total Bile Acids	Bile acids (Colorimetric endpoint method)	1 2212	Bile acids standard Lot 9163	-	Primary Standard	µmol/L	35	± 0,45 1,29 %
Bilirubin, Direct	Bilirubin Auto Direct FS (DCA[28] method)	1 0821	TruCal U	5 9100	Jendrassik-Grof (Molar extinction coefficient 546 nm)	mg/dL	1,67	± 0,04 2,29 %
Bilirubin, Total	Bilirubin Auto Total FS (DCA[28] method)	1 0811	TruCal U	5 9100	SRM[4] 916	mg/dL	3,38	± 0,07 2,16 %
	Bilirubin Jendrassik-Grof FS	1 0849	Calculation factor	-	Molar extinction coefficient 546 nm	mg/dL	-	± -
Calcium	Calcium AS FS (Arsenazo III method)	1 1130	TruCal U	5 9100	Atomic Absorbtion Spectrometry (AAS)	mg/dL	12,1	± 0,15 1,21 %
			Calcium Standard FS	1 1100	Titrisol $CaCl_2$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[8]	mg/dL	10	± 0,230 2,30 %
	Calcium CPC FS (CPC - Cresolphthalein Complexone method)	1 1121	TruCal U	5 9100	Atomic Absorbtion Spectrometry (AAS)	mg/dL	12,5	± 0,12 0,97 %
			Calcium Standard FS	1 1100	Titrisol $CaCl_2$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[8]	mg/dL	10	± 0,230 2,30 %
	Calcium CPC FSC (CPC - Cresolphthalein Complexone method; concentrated reagent)	2 1145	TruCal U	5 9100	Atomic Absorbtion Spectrometry (AAS)	mg/dL	11,6	± 0,10 0,88 %
			Calcium Standard FS	1 1100	Titrisol $CaCl_2$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[8]	mg/dL	10	± 0,230 2,30 %
	Calcium P FS (Phosphonazo III method)	1 1181	TruCal U	5 9100	Atomic Absorbtion Spectrometry (AAS)	mg/dL	12,4	± 0,20 1,63 %
			Calcium Standard FS	1 1100	Titrisol $CaCl_2$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[8]	mg/dL	10	± 0,230 2,30 %
Chloride	Chloride FS (Thiocyanate method)	1 1200	TruCal U	5 9100	Reference method Coulometry	mmol/L	105	± 1,3 1,28 %
			Chloride Standard FS	1 1200	Titrisol NaCl +/- 0,2 %; traceable to NIST[6] – SRM[4] 999	mmol/L	100	± 1,50 1,50 %
	Chloride 21 FS (Colorimetric method)	-	TruCal E	-	Under development	mmol/L	pending	± pending

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
Cholesterol	Cholesterol FS 5 minute endpoint version (CHOD-PAP[29] Trinder reaction)	1 1350	TruCal U	5 9100	GC-IDMS[10]	mg/dL	146[21]	± 1,76[21] 1,21 %
			Cholesterol Standard FS	1 1300	GC-IDMS[10]	mg/dL	200	± 3,00 1,50 %
	Cholesterol FS 10 minute endpoint version (CHOD-PAP[29] Trinder reaction)	1 1300	TruCal U	5 9100	GC-IDMS[10]	mg/dL	146	± 1,76 1,21 %
			Cholesterol Standard FS	1 1300	GC-IDMS[10]	mg/dL	200	± 3,00 1,50 %
	Cholesterol FSC (CHOD-PAP[29] Trinder reaction; Concentrated reagent)	2 1300	TruCal U	5 9100	GC-IDMS[10]	mg/dL	141	± 1,47 1,04 %
	Free cholesterol FS (CHOD-PAP[29] Trinder reaction)	1 1360	TruCal U	5 9100	GC-IDMS[10]	mg/dL	28,0	± 0,94 3,36 %
Cholinesterase	Cholinesterase FS (BTC[30] method; Optimized DGKC[5] formulation)	1 1401	TruCal U	5 9100	Original formulation DGKC[5] 1992 (Molar extinction coefficient 405 nm)	U/L	6482	± 429 6,62 %
Complement C3c	Complement C3c FS (Immunoturbidimetric method)	1 1802	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 18,8 Level 2: 37,5 Level 3: 75,0 Level 4: 150 Level 5: 300 High: 300	± 0,77 4,12 % ± 1,51 4,02 % ± 3,01 4,02 % ± 6,03 4,02 % ± 12,1 4,02 % ± 12,1 4,02 %
Complement C4	Complement C4 FS (Immunoturbidimetric method)	1 1812	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 6,18 Level 2: 12,4 Level 3: 24,7 Level 4: 49,4 Level 5: 98,8 High: 98,8	± 0,27 4,45 % ± 0,54 4,38 % ± 1,08 4,37 % ± 2,16 4,37 % ± 4,32 4,37 % ± 4,31 4,37 %
Creatine Kinase (CK)	CK-NAC FS (DGKC[5] / IFCC[2] recommended procedure)	1 1601	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	241	± 8,50 3,53 %
CK-MB	CK-MB FS (Based on IFCC[2] recommended procedure, immunoinhibition method using mAK[31])	1 1641	TruCal U	5 9100	DiaSys master calibrator related to ERM[9] - AD455 / IFCC	U/L	90,3	± 6,55 %
	CK-MB FS (Based on DGKC[5] / IFCC[2] recommended procedure, immunoinhibition method using pAK[32])	1 1651	TruCal U	5 9100	Molar extinction coefficient according to IFCC[2] recommendation at 340 nm	U/L	100	± 2,66 2,67 %
Creatinine	Creatinine FS (Jaffe method with compensation)	1 1711	TruCal U	5 9100	GC-IDMS[10]	mg/dL	4,50	± 0,096 2,12 %
	Creatinine FS (Jaffe method without compensation)	1 1711	TruCal U	5 9100	GC-IDMS[10]	mg/dL	3,98	± 0,075 1,90 %
			Creatinine Standard FS	1 1700	GC-IDMS[10]	mg/dL	2,00	± 0,05 2,50 %
	Creatinine FSC (Jaffe method with compensation; Concentrated reagent)	2 1739	TruCal U	5 9100	GC-IDMS[10]	mg/dL	4,25	± 0,05 1,18 %
	Creatinine PAP FS (Enzymatic PAP[33] method)	1 1759	TruCal U	5 9100	GC-IDMS[10]	mg/dL	4,13	± 0,06 1,40 %
			Creatinine Standard FS	1 1700	NIST[6] SRM[4] 967	mg/dL	2,00	± 0,05 2,52 %

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
C-reactive Protein	CRP FS (Immunoturbidimetric method)	1 7002	TruCal CRP TruCal CRP high TruCal CRP 150	1 7000	ERM[9] DA472 / IFCC	mg/L	Level 1: 9,83 Level 2: 19,7 Level 3: 53,1 Level 4: 143 Level 5: 282 CRP high: 460 CRP 150: 143	± 0,58 5,87 % ± 1,11 5,62 % ± 2,97 5,59 % ± 8,03 5,61 % ± 15,8 5,60 % ± 28,2 6,13 % ± 8,03 5,61 %
	CRP U-hs (Particle-enhanced Immunoturbidimetric method)	1 7045	TruCal CRP U (Universal application)	1 7040	ERM[9]-DA470	mg/L	Level 1: 8,45 Level 2: 20,45 Level 3: 100 Level 4: 200 Level 5: 350	± 0,7 7,88 % ± 1,6 7,86 % ± 7,9 7,92 % ± 15,6 7,81 % ± 27,3 7,80 %
			TruCal CRP hs (High sensitive application)	1 7080	ERM[9]-DA470	mg/L	Level 1: 0,50 Level 2: 2,45 Level 3: 8,45 Level 4: 12,45 Level 5: 20,45	± 0,045 9,02 % ± 0,19 7,73 % ± 0,63 7,44 % ± 0,92 7,41 % ± 1,51 7,40 %
Cystatin C	Cystatin C FS (Particle-enhanced Immunoturbidimetric method)	1 7158	TruCal Cystatin C	1 7158	ERM[9] - AD471 / IFCC			±
D-Dimer	D-Dimer FS (Particle-enhanced Immunoturbidimetric method)	1 7268	TruCal D-Dimer	1 7260	Clinical characterized patient samples for deep vein thrombosis of the leg	FEU/mL	7,51	± 0,59 7,92 %
Ethanol	Ethanol FS (Enzymatic endpoint method)	1 0881	Ethanol Standard FS 0.5 mg/mL	1 0890	GC[11]	mg/mL	0,5	± 0,21 %
			Ethanol Standard FS 1.0 mg/mL	1 0910	GC[11]	mg/mL	1,0	± 0,21 %
			Ethanol Standard FS 2.0 mg/mL	1 0920	GC[11]	mg/mL	2,0	± 0,21 %
			Ethanol Standard FS 3.0 mg/mL	1 0930	GC[11]	mg/mL	3,0	± 0,21 %
			Ethanol Standard FS 4.0 mg/mL	1 0940	GC[11]	mg/mL	4,0	± 0,21 %
Ferritin	Ferritin FS (Particle-enhanced Immunoturbidimetric method)	1 7059	TruCal Ferritin	1 7050	WHO[3] International Standard Ferritin, NIBSC[19] code: 94/572	mg/L	Level 1: 118 Level 2: 238 Level 3: 611 Level 4: 1138	± 1,18 1,00 % ± 2,42 1,02 % ± 4,65 0,76 % ± 15,0 1,32 %
Glycerol	Free glycerol FS (GPO[34] method – Trinder reaction)	1 5730	Triglyceride Standard FS (with additional value for glycerol)	1 5700	GC-IDMS[10]	mg/dL	20,6	± 0,55 2,68 %
Gamma-GT	Gamma-GT FS (Szasz mod./IFCC[2] stand.) (kinetic photometric test according to Szasz / Persijn)	1 2801	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 405 nm)	U/L	104	± 1,62 1,56 %
	Gamma-GT FSC (Szasz mod./IFCC[2] stand.) (kinetic photometric test according to Szasz / Persijn; concentrated reagent)	2 2805	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 405 nm)	U/L	102	± 0,83 0,82 %
GLDH	GLDH FS DGKC[5] (DGKC[5] recommended procedure)	1 2411	TruCal U	5 9100	Molar extinction coefficient according to DGKC[5] recommendation at 340 nm	U/L	31,2	± 3,37 10,80 %

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
Glucose	Glucose Gluc-DH FS (Glucose Dehydrogenase method)	1 2531	TruCal U	5 9100	GC-IDMS[10]	mg/dL	180	± 1,7 0,95
			Glucose Standard FS	1 2500	Primary Standard (Glucose 99,5 %)	mg/dL	100	± 1,20 1,20 %
	Glucose Gluc-DH FSC (Glucose Dehydrogenase method; concentrated reagent)	2 2539	TruCal U	5 9100	GC-IDMS[10]	mg/dL	180	± 2,2 1,22 %
	Glucose GOD FS 5 minute endpoint version (GOD-PAP[35] method – Trinder reaction)	1 2550	TruCal U	5 9100	GC-IDMS[10]	mg/dL	180[21]	± 1,7[21] 0,95 %
			Glucose Standard FS	1 2500	Primary Standard (Glucose 99,5 %)	mg/dL	100	± 1,20 1,20 %
	Glucose GOD FS 10 minute endpoint version (GOD-PAP[35] method – Trinder reaction)	1 2500	TruCal U	5 9100	GC-IDMS[10]	mg/dL	180	± 1,7 0,95 %
			Glucose Standard FS	1 2500	Primary Standard (Glucose 99,5 %)	mg/dL	100	± 1,20 1,20 %
	Glucose Hexokinase FS (Hexokinase method)	1 2511	TruCal U	5 9100	GC-IDMS[10]	mg/dL	180	± 1,7 0,92 %
			Glucose Standard FS	1 2500	Primary Standard (Glucose 99,5 %)	mg/dL	100	± 1,20 1,20 %
HbA1c	One HbA1c FS (Particle-enhanced Immunoturbidimetric method) 3 component reagent	1 3329	TruCal HbA1c liquid Lot 13095 - 13098	1 3320	IFCC[2] Reference Method	mmol/mol	Level 1: 34,7 Level 2: 60,1 Level 3: 105 Level 4: 151	± 3,07 % ± 2,89 % ± 2,84 % ± 2,99 %
	One HbA1c FS (Particle-enhanced Immunoturbidimetric method) 2 component reagent	1 3329	TruCal HbA1c liquid Lot 13095 - 13098	1 3320	IFCC[2] Reference Method	mmol/mol	Level 1: 31,6 Level 2: 61,0 Level 3: 104 Level 4: 151	± 3,45 % ± 3,13 % ± 3,08 % ± 3,25 %
	One HbA1c FS (Particle-enhanced Immunoturbidimetric method) 3 component reagent on Inovastar	1 3329	TruCal HbA1c liquid Lot 14350 - 14353	1 3320	NGSP[41] European Reference Laboratory ESRL#7	%	Level 1: 4,7 Level 2: 7,34 Level 3: 11,9 Level 4: 14,6	± - ± - ± - ± -
			IFCC[2] Reference calibrators, supplied by the IFCC[2] network; Monitoring Programme 2010)	-	-	mmol HbA1c/ mol Hb	at 30 at 60 at 90 CV[42] r[43]	5,2 6,9 8,5 4,09 0,9951
α-HBDH	α-HBDH FS (DGKC[5] recommended procedure)	1 3201	TruCal U	5 9100	Molar extinction coefficient according to DGKC[5] recommendation at 340 nm	U/L	210	± 8,37 3,98 %
HDL[44]-Cholesterol	HDL-C Immuno FS (Direct immunoinhibithion method)	1 3521	TruCal HDL/LDL Lot 11974	1 3520	NIST[6] SRM[4] 1951b Level 2	mg/dL	53,8	± 1,6 3,05 %
			TruCal Lipid	1 3570	NIST[6] SRM[4] 1951b Level 2	mg/dL	pending	± pending
Hydroybutyrate	β-Hydroxybutyrate FS (Enzymatic endpoint method)	1 3701	TruCal U	5 9100	Primary Reference Material, R-(-)3-Hydroxybutyric acid > 99 %	mmol/L	1,02	± 0,03 3,03 %
			β-Hydroxybutyrate Standard FS	1 3700	Primary Reference Material, R-(-)3-Hydroxybutyric acid > 99 %	mmol/L	1,00	± 0,02 1,50 %
Hemoglobin	Hemoglobin FS (Photometric endpoint method using potassium cyanide)	2 2549	Calculation factor	-	Calculation factor	g/dL	-	± -
Homocysteine	Homocysteine FS (Enzymatic cycling method)	1 3409	TruCal Homocysteine	1 3400	SRM[4] 1955	µmol/L	Level 2: 6,0 Level 3: 26,0	± 11,00 % ± 10,66 %

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
Immunoglobulin A	Immunoglobulin A FS (Immunoturbidimetric method)	1 7202	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 58,3 Level 2: 117 Level 3: 233 Level 4: 467 Level 5: 933 High: 933	± 1,89 3,24 % ± 3,38 2,90 % ± 6,65 2,85 % ± 13,1 2,81 % ± 26,5 2,84 % ± 26,2 2,81 %
Immunoglobulin E	Immunoglobulin E FS (Particle-enhanced Immunoturbidimetric method)	1 7239	TruCal IgE	1 7230	WHO[3] Reference material IRP[13] 75/502	IU/mL	Level 1: 50 Level 2: 100 Level 3: 200 Level 4: 500 Level 5: 1000	± 3,81 ± 5,23 ± 10,9 ± 11,7 ± 16,4
Immunoglobulin G	Immunoglobulin G FS (Immunoturbidimetric method)	1 7212	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 178 Level 2: 357 Level 3: 713 Level 4: 1427 Level 5: 2853 High: 2853	± 15,1 8,46 % ± 30,0 8,42 % ± 60,0 8,42 % ± 120 8,42 % ± 240 8,41 % ± 240 8,42 %
Immunoglobulin M	Immunoglobulin M FS (Immunoturbidimetric method)	1 7220	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 51,7 Level 2: 103 Level 3: 207 Level 4: 414 Level 5: 827 High: 827	± 2,78 5,38 % ± 5,36 5,19 % ± 10,6 5,15 % ± 21,2 5,14 % ± 42,5 5,14 % ± 42,5 5,14 %
Iron	Iron FS Ferene	1 1911	TruCal U	5 9100	Titrisol $FeCl_3$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[12]	µg/dL	203	± 7,6 3,74 %
			Iron Standard FS	1 1900	Titrisol $FeCl_3$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[12]	µg/dL	100	± 2,00 2,00 %
Lactate	Lactate FS (LDH[36] UV endpoint method)	1 4001	TruCal U	5 9100	Primary standard Lithium L-lactate, molar extinction coefficient 340 nm	mg/dL	28,4	± 1,49 5,24 %
LDH[36]	LDH FS DGKC[5] (DGKC reccommended procedure)	1 4201	TruCal U	5 9100	Molar extinction coefficient according to DGKC[5] recommendation at 340 nm	U/L	411	± 30,6 7,44 %
	LDH FS IFCC[2] (IFCC[2] recommended procedure)	1 4211	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	245	± 4,61 1,88 %
	LDH FSC IFCC[2] (IFCC[2] recommended procedure; Concentrated reagent)	2 4269	TruCal U	5 9100	Original formulation IFCC[2] (Molar extinction coefficient 340 nm)	U/L	242	± 2,20 0,91 %
LDL[37]-Cholesterol	LDL-C Select FS (Selective direct method)	1 4121	TruCal HDL/LDL Lot 11974	1 3520	NIST[6] SRM[4] 1951b Level 2	mg/dL	102	± 2,5 2,49 %
			TruCal Lipid	1 3570	NIST[6] SRM[4] 1951b Level 2	mg/dL	pending	± pending
Lipase	Lipase DC FS (Direct colorimetric method)	1 4321	TruCal U	5 9100	Molar extinction coefficient according to Roche[14] procedure	U/L	91,4	± 2,68 2,93 %
Lithium	Lithium FS (Enzymatic method)	1 4341	TruCal E	-	Under development	mmol/L	pending	± pending

Traceability and Uncertainty of DiaSys assay systems

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
Lipoprotein (a)	Lp(a) 21 FS (Particle-enhanced Immunoturbidimetric method)	1 7139	TruCal Lp(a) 21	1 7140	WHO[3]/IFCC[2] reference material SRM[4] 2B (PRM[15] IFCC[2] Standard)	nmol/L	Level 1: 12,7 Level 2: 27,0 Level 3: 62,8 Level 4: 135 Level 5: 192	± 0,61 4,80 % ± 1,22 4,53 % ± 2,80 4,46 % ± 5,98 4,44 % ± 8,6 4,45 %
					Immuno LEIA® Lp(a) Reference Standard Human[20]	mg/dL	Level 1: 5,99 Level 2: 14,4 Level 3: 41,7 Level 4: 90,0 Level 5: 127	± 0,51 8,60 % ± 1,18 8,19 % ± 3,38 8,11 % ± 7,29 8,10 % ± 10,3 8,10 %
Magnesium	Magnesium XL FS (Xylidyl blue method)	1 4610	TruCal U	5 9100	AAS[16]	mg/dL	3,78	± 0,14 3,67 %
			Magnesium Standard FS	1 4600	Titrisol $MgCl_2$ +/- 0,2 %; traceable to NIST[6]-SRM[4] 682[17]	mg/dL	2,00	± 0,070 3,50 %
Myoglobin	Myoglobin FS (Particle-enhanced Immunoturbidimetric method)	1 7098	TruCal Myoglobin	1 7030	Commercially available Siemens[18] N Myoglobin Standard (human), calibrated against an internal reference preparation	µg/L	Level 1: 65,0 Level 2: 130 Level 3: 260 Level 4: 520	± 2,8 4,35 % ± 7,1 5,45 % ± 14,7 5,65 % ± 19,8 3,80 %
Non-esterified fatty acids (NEFA)	NEFA FS (Trinder method)	1 5781	NEFA Standard FS	1 5780	Primary Standard (Sodium oleate > 98,9 %)	mmol/L	1,00	± 0,02 1,50 %
			TruCal Lipid	1 3570	Primary Standard (Sodium oleate > 98,9 %)	mmol/L	pending	± pending
Pancreatic Amylase	Pancreatic amylase CC FS (EPS-G7[24] method; immunoinhibition of salivary amylase)	1 0551	TruCal U	5 9100	Molar extinction coefficient 405 nm	U/L	128	± 6,9 5,38 %
Phosphorus	Phosphate FS (Molybdate method)	1 5211	TruCal U	5 9100	Phosphate standard solution Merck 1.19898.0500; traceable to NIST[6]-SRM[4] 723d	mg/dL	5,44	± 0,16 3,03 %
			Phosphate Standard FS	1 5210	Phosphate standard solution Merck 1.19898.0500; traceable to NIST[6]-SRM[4] 723b	mg/dL	5,00	± 0,056 1,13 %
Phospholipids	Phospholipids FS (Enzymatic colorimetric method)	1 5741	Phospholipids Standard FS	1 5780	Primary Standard (1,2-Dielaidoyl-sn-glycero-3-phosphocholine > 99 %)	mg/dL	4,00	± 0,14 3,60 %
			TruCal Lipid	1 3570	Primary Standard (1,2-Dielaidoyl-sn-glycero-3-phosphocholine > 99 %	mg/dL	pending	± pending
Potassium	Potassium FS (Enzymatic method)	-	TruCal E	-	Under development	mmol/L	pending	± pending
Prealbumin	Prealbumin FS (Immunoturbidimetric method)	1 0292	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 7,31 Level 2: 14,6 Level 3: 29,3 Level 4: 58,5 Level 5: 117 High: 117	± 0,60 8,25 % ± 1,20 8,20 % ± 2,40 8,20 % ± 4,79 8,19 % ± 9,6 8,19 % ± 9,6 8,19 %

Analyte	DiaSys Product	Product Code	Calibrator	Product Code	Reference	Unit	Value	Uncertainty
Rheumatic factor	Rheumatic factor FS (Immunoturbidimetric method)	1 7022	TruCal RF Lot 13985-13989	1 7020	WHO[3] reference reagent NIBSC W 1066	IU/mL	Level 1: 25,0 Level 2: 50,0 Level 3: 100 Level 4: 250 Level 5: 500	± 1,5 5,93 % ± 2,8 5,60 % ± 4,6 4,56 % ± 9,8 3,93 % ± 21,5 4,31 %
Sodium	Sodium FS (Phosphonazo III colorimetric method)	-	TruCal E	-	Under development	mmol/L	pending	± pending
Total Protein	Total protein FS (Biuret method with sample blank)	1 2311	TruCal U	5 9100	Biuret method with sample blank	g/dL	76,1	± 0,76 1,00 %
			Total protein Standard FS	1 2300	SRM[4] 927c (diluted Albumin)	g/dL	5,00	± 0,100 2,00 %
	Total protein FSC (Biuret method with sample blank; Concentrated reagent)	2 2329	TruCal U	5 9100	Biuret method with sample blank	g/dL	75,0	± 0,72 0,96 %
Total Protein in Urine/CSF	Total protein UC FS (Photometric method using pyrogallol red)	1 0210	Total protein UC Standard FS	1 0260	SRM[4] 927c (diluted Albumin)	mg/L	1300	± 35,0 2,70 %
Transferrin	Transferrin FS (Immunoturbidimetric method)	1 7252	TruCal Protein Lot 13496 – 13500 TruCal Protein high Lot 13360	5 9200	ERM[9]-DA470k/IFCC[2]	mg/dL	Level 1: 44,4 Level 2: 88,9 Level 3: 178 Level 4: 356 Level 5: 711 High: 711	± 1,55 3,49 % ± 3,04 3,42 % ± 6,08 3,42 % ± 12,2 3,43 % ± 24,4 3,43 % ± 24,2 3,41 %
Triglycerides	Triglycerides FS 5 minute endpoint version (GPO[34] method – Trinder reaction)	1 5760	TruCal U	5 9100	GC-IDMS[10]	mg/dL	144[21]	± 2,3[21] 1,60 %
			Triglyceride Standard FS	1 5700	GC-IDMS[10]	mg/dL	200	± 2,60 1,30 %
	Triglycerides FS 10 minute endpoint version (GPO[34] method – Trinder reaction)	1 5710	TruCal U	5 9100	GC-IDMS[10]	mg/dL	144	± 2,3 1,60 %
			Triglyceride Standard FS	1 5700	GC-IDMS[10]	mg/dL	200	± 2,60 1,30 %
	Triglycerides FSC (GPO[34] method – Trinder reaction; concentrated reagent)	2 5770	TruCal U	5 9100	GC-IDMS[10]	mg/dL	143	± 1,7 1,19 %
Unsaturated iron binding capacity (UIBC)	UIBC FS (Ferene method)	1 1921	TruCal UIBC	1 1920	Iron: SRM[4] 682; Transferrin: ERM[9]-DA470k/IFCC[2]	µg/dL	199	± 10,8 7,06 %
Urea	Urea FS (Urease-GLDH[38] kinetic method)	1 3101	TruCal U	5 9100	SRM[4] 909b Level 1	mg/dL	98,1	± 4,25 4,33 %
			Urea Standard FS	1 3100	Primary Standard, Urea 99,6 %	mg/dL	50,0	± 0,750 1,50 %
	Urea FSC (Urease-GLDH[38] kinetic method; Concentrated reagent)	2 3105	TruCal U	5 9100	SRM[4] 909b Level 1	mg/dL	95,8	± 3,94 4,12 %
	Urea CT FS (Colorimetric endpoint method; Berthelot)	1 3115	TruCal U	5 9100	SRM[4] 909b Level 1	mg/dL	95,6	± 4,67 4,88 %
			Urea Standard FS	1 3100	Primary Standard, Urea 99,6 %	mg/dL	50,0	± 0,750 1,50 %
Uric acid	Uric acid FS TBHBA (Uricase – TBHBA[39] method)	1 3021	TruCal U	5 9100	GC-IDMS[10]	mg/dL	5,39	± 0,05 0,89 %
			Uric acid Standard FS	1 3000	GC-IDMS[10]	mg/dL	6,00	± 0,078 1,30 %
	Uric acid FS TOOS (Uricase – TOOS[40] method)	1 3001	TruCal U	5 9100	GC-IDMS[10]	mg/dL	5,34	± 0,06 1,06 %
			Uric acid Standard FS	1 3000	GC-IDMS[10]	mg/dL	6,00	± 0,078 1,30 %

Glossary

[1]	**C**ertified **R**eference **M**aterial
[2]	**I**nternational **F**ederation of **C**linical **C**hemistry
[3]	**W**orld **H**ealth **O**rganization
[4]	**S**tandard **R**eference **M**aterial
[5]	**D**eutsche **G**esellschaft für **K**linische **C**hemie - German Society for Clinical Chemistry and Laboratory Medicine
[6]	**N**ational **I**nstitute of **S**tandards and **T**echnology; www.nist.gov/srm
[7]	The First International Standard for Anti-Streptolysin-O, Human, was established in 1959 (J. Spaun, M.W. Bentzon, S. Olesen Larsen & L. F. Hewitt; International Standard for Antispreptolysin-O; Bulletin WHO 1961, 24, 271-279). The standard was in two forms: freeze-dried ampoules containing 2160 IU (code: ASO); vials of a solution containing 10 IU/ml (code: AST). Due to limited stocks, as an interim measure, some of the 2160 IU freeze-dried stock has been reconstituted and filled at approximately 10 IU/ ml as reagent code: 97/662. This is the only anti-streptolysin-O, Human, reagent currently available from reference institute NIBSC. The solution contains approximately 10 IU/ml but has not yet been calibrated against the International Standard. Assigned content of vial valid at time of production – no information on long term stability. Due to the unsuitable concentration for standardization of DiaSys Antispreptolysin O assay and unclear stability for existing reference material NIBSC 97/662 DiaSys using Siemens N Rheumatology Standard SL for standardization procedure.
[8]	The concentration of the reference material Titrisol Ca Cl2 is verified by complexometric titration with Titriplex III. The molarity of the used Tritriplex III solution is verified by complexometric titration with an Zinc solution. The Zinc solution is traceable on an Zinc primary titer substance. The primary titer substance is directly traceable to SRM 682 (High-Purity Zinc).
[9]	**E**uropean **R**eference **M**aterial, European Commission – Joint Research Centre, Institute for Reference Materials and Measurements (IRMM), Retieseweg 111, B - 2440 Geel (Belgium); www.erm-crm.org
[10]	**G**as-**C**hromatography-**I**sotope **D**ilution **S**pectrometry
[11]	**G**as-**C**hromatography
[12]	The concentration of the reference material Titrisol $FeCl_3$ is verified by complexometric titration with Titriplex III. The molarity of the used Tritriplex III solution is verified by complexometric titration with an Zinc solution. The Zinc solution is traceable on an Zinc primary titer substance. The primary titer substance is directly traceable to SRM[4] 682 (High-Purity Zinc).
[13]	**I**nternational **R**eference **P**reparation
[14]	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim/Germany; www.roche.com
[15]	**P**rimary **R**eference **M**aterial
[16]	**A**tomic **A**bsorbtion **S**pectrometry
[17]	The concentration of the reference material Titrisol $MgCl_2$ is verified by complexometric titration with Titriplex III. The molarity of the used Tritriplex III solution is verified by complexometric titration with a Zinc solution. The Zinc solution is traceable on a Zinc primary titer substance. The primary titer substance is directly traceable to SRM[4] 682 (High-Purity Zinc).
[18]	Siemens Healthcare Diagnostics Products GmbH, Emil-von-Behring-Str. 76, 35041 Marburg/Germany; www.siemens.com/diagnostics
[19]	**N**ational **I**nstitute for **B**iological **S**tandards and **C**ontrol, Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG, United Kingdom;www.nibsc.ac.uk
[20]	Immuno LEIA® Lp(a) Reference Standard Human; Calibration serum for use in quantitative immunological determination of human Lp(a) with immuno LEIA® Lp(a) Reagent Kit. LEIA®, Reg. TM: Technoclone GmbH 1230 Vienna Austria
[21]	Uncertainty calculation based on 10 min reagent
[22]	**Al**anine **A**mino **T**ransferase
[23]	**G**lutamic **P**yruvic **T**ransaminase
[24]	4,6-**e**thylidene-(**G7**)-**p**-nitrophenyl-(G1)-α- D-maltoheptao**s**ide
[25]	**As**partate **A**mino¬**t**ransferase
[26]	**G**lutamic **O**xalacetic **T**ransaminase
[27]	**P**hospho**e**nol**p**yruvate **c**arboxylase
[28]	2,4-**Di**chloro**a**niline
[29]	**Ch**olesterin**o**xi**d**ase **P**eroxidase 4-**A**minoanti**p**yrine

Glossary

[30]	**But**yrylthio**c**holine
[31]	Monoclonal antibodies (German: **M**onoklonale **A**nti**k**örper)
[32]	Polyclonal antibodies (German: **P**olyklonale **A**nti**k**örper)
[33]	**P**eroxidase 4-**A**minoanti**p**yrine
[34]	**G**lycerol-3-**p**hosphate-**o**xidase
[35]	**G**lucose**o**xi**d**ase **P**eroxidase 4-**A**minoanti**p**yrine
[36]	**L**actate **deh**ydrogenase
[37]	**L**ow **d**ensity **l**ipoproteins
[38]	**Gl**utamate **deh**ydrogenase
[39]	2,4,6-**T**ri**b**romo-3-**h**ydroxy**be**nzoic **a**cid
[40]	N-Ethyl-N-(Hydroxy-3-sulfopropyl)-m-Toluidin
[41]	**N**ational **G**lycohemoglobin **S**tandardization **P**rogram
[42]	Reproducibility, **c**oeeficient of **v**ariation
[43]	Linearity, correlation coefficient
[44]	**H**igh **d**ensity **l**ipoproteins
[45]	reduced **N**icotinamide **a**denine **d**inucleotide

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