



S-Monovette® Lithium-Heparin Gel⁺

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Clinical Equivalence on Roche cobas® Analysers

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The clinical equivalence of the S-Monovette® Lithium-Heparin Gel⁺ in comparison to the S-Monovette® lithium heparin gel or S-Monovette® lithium heparin without gel was shown in a study on 57 frequently requested clinical-chemical and immunological parameters in plasma on Roche cobas® analysers. If there are measurement differences between the S-Monovette® Lithium-Heparin Gel⁺ and the reference, these are within the acceptance range. Even after seven days of storage at 2-8 °C, the S-Monovette® Lithium-Heparin Gel⁺ is clearly within the acceptance limits for almost all tested analytes. The deviation of glucose and potassium is slightly higher after 7 days of storage. The S-Monovette® Lithium-Heparin Gel⁺ is thus a blood collection system that absolutely meets the high demands of today's medical laboratory diagnostics and also enables short centrifugation times of up to 4 minutes.

Introduction

Turn-Around-Time (TAT) is an important factor in the laboratory process, especially in emergency diagnostics. An essential component of TAT is the centrifugation time. With the new Sarstedt S-Monovette® Lithium-Heparin (LH) Gel⁺ it is possible to reduce the centrifugation time considerably, e.g. from 10 to 5 minutes at 3000 x g. The time gained accelerates the therapy decision and is, thus, a benefit for patient care. In this study, the S-Monovette® Lithium-Heparin Gel⁺ is compared with the S-Monovette® Lithium-Heparin gel or, respectively, with the S-Monovette® Lithium-Heparin without gel (oG) for 57 frequently requested clinical-chemical and immunological parameters on Roche cobas® analysers. In order to reduce possible influences, the centrifugation conditions are identical for all S-Monovettes. The stability of the analytes was tested over seven days.

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Materials and methods

Venous blood was taken from 30 healthy adult donors. A Safety-Multifly[®] needle 20 G (REF 85.1637.235) was used to collect blood into a neutral S-Monovette[®] 2.7 ml (REF 05.1729.001) as a discard tube using the aspiration technique. Following in random order were an S-Monovette[®] LH Gel⁺ 4.9 ml (REF 04.1954), an S-Monovette[®] LH (oG) 4.9 ml (REF 04.1936) and an S-Monovette[®] LH Gel 4.9 ml (REF 04.1940), all of which were stored standing upright before centrifugation and after mixing overhead. Two S-Monovettes Neutral 9 ml (REF 02.1726.001) were then collected using the vacuum technique. In order to obtain values for parameters outside the measuring range in healthy donors, the S-Monovettes Neutral 9 ml were combined in one container, a control serum added and mixed. An S-Monovette[®] LH Gel⁺, an S-Monovette[®] LH (oG) and an S-Monovette[®] LH Gel 4.9 ml were filled with this blood and mixed (Fig. 1). Only the spiked analytes were measured. Centrifugation was performed no later than 30 minutes after blood collection. All S-Monovettes were centrifuged at 3,000 x g for 10 minutes to exclude the effects of different centrifugation conditions. To achieve a barrier between the plasma and corpuscular blood components, a Seraplas[®] V13 filter (REF 53.419) was subsequently inserted into the S-Monovette[®] LH (oG). Blood was collected on four different days from 15 female and 15 male donors. The S-Monovettes were stored at 2-8 °C, and the parameters in Table 1 were measured within 7 hours (day 0), as well as one day later (day 1) and after seven days (day 7). All measurements were carried out at the same time of day. The measurement was performed on a Roche cobas c702 module or an e602 module and, for two analytes, on a Siemens BN Prospec.

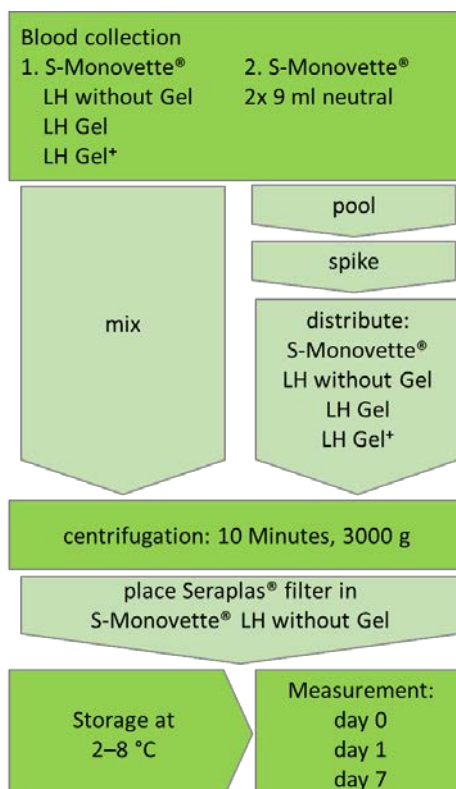


Fig. 1 Study structure for blood collection

Evaluation

The evaluation of the data was based on recommendations of CLSI EP09-A3 2013 [1]. The values measured on day 0 of the S-Monovette® LH Gel⁺ and the reference values (from the S-Monovette® LH Gel or LH without gel) were plotted against each other and a linear regression was calculated according to Passing-Bablok (Fig. 2, red line) [2]. The black dotted line corresponds to the ideal value without deviations. Measurement pairs of which one or both values were outside the measurement range of the respective method were not considered. The deviation in clinically relevant areas and in respect of the median of the measured values was calculated using the obtained straight line equation (Fig. 2, green lines). The diagrams on the stability of the analytes (see appendix) show the median of the deviation, calculated according to the Hodges-Lehman point estimator. The reference is always the data set of day 0 from the respective S-Monovette®. The confidence intervals (95 %) were calculated according to Tukey [3,4].

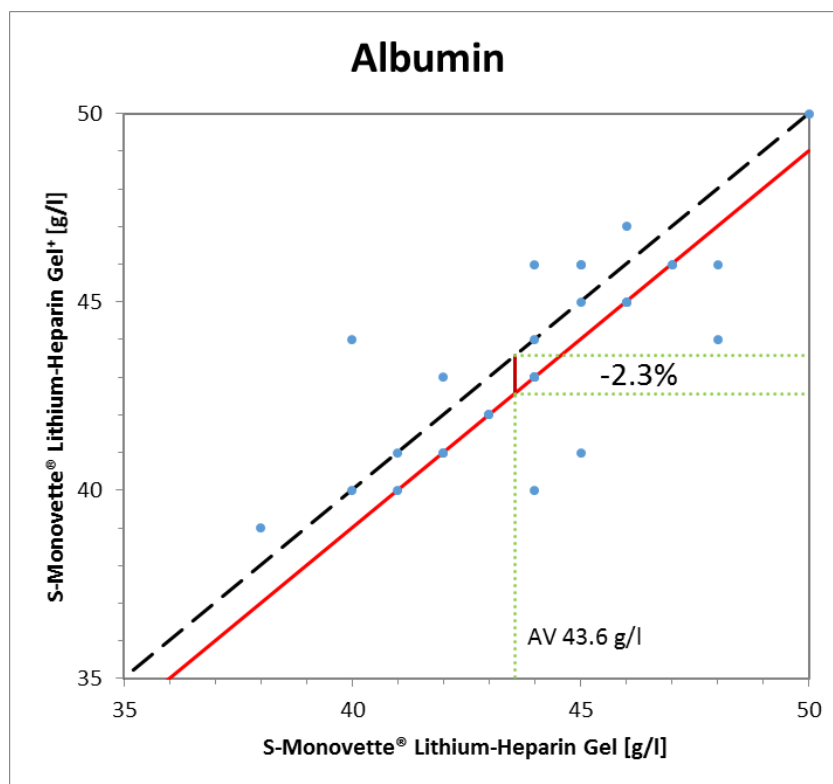


Fig. 2 Evaluation via linear regression using Albumin as an example

Acceptance limits

The percentage acceptance limits were taken from Rili-BÄK (2014, Table B 1a) or Westgard [5]. The absolute acceptance limits were calculated either based on the mean value of the measured values and the percentage acceptance limit, or on the basis of the method error. The extent to which these acceptance limits can be transferred to an institution's in-house laboratory should be assessed individually. The manufacturer accepts no liability to this effect.



Results and discussion

Comparison of S-Monovette® Lithium-Heparin Gel[†] with S-Monovette® Lithium-Heparin without gel

The results of the regression are presented in Table 1. Only in one case, i.e. progesterone, the absolute deviation at one point exceeds the acceptance limit, but the percentage deviation is within the acceptance criteria. For none of the other 57 parameters is the deviation at clinically relevant points or the mean value larger than the acceptance limit. For the C3 complement, troponin T, and immunoglobulin G, the confidence interval of the gradient does not include the value one, or zero, for the axis segment. However, the deviations are all within the acceptance limits. The deviations of the S-Monovette® LH Gel[†] compared to the S-Monovette® LH with Seraplas® filter are therefore clinically irrelevant.



Table 1 Comparison of S-Monovette® Lithium-Heparin Gel⁺ and S-Monovette® Lithium-Heparin oG, values beyond the target range are marked in bold

Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		% Abs	% Abs
						%	Abs		%	Abs		%	Abs		
Albumin ^a	g/L	30	1.000 (0.800; 1.000)	-1.000 (-1.000; 8.200)	35 ¹	-2.9	-1	53 ¹	-1.9	-1	44.1	-2.3	-1	12.5	5.5
AP ^a	U/L	30	1.000 (0.961; 1.000)	-1.000 (-1.000; 2.078)	30 ¹	-3.3	-1	120 ¹	-0.8	-1	61.4	-1.6	-1	11.0	6.7
Estradiol ^b	ng/L	26	1.000 (0.949; 1.019)	0.000 (-0.888; 1.153)	8 ²	0.0	0	498 ²	0.0	0	76.3	0.0	0	22.0	16.8
Bilirubin (direct) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ²	0.0	0.0	0.3 ¹	0.0	0.0	0.3	0.0	0.0	13.0	0.1
Bilirubin (total) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ¹	0.0	0.0	1.2 ¹	0.0	0.0	0.5	0.0	0.0	13.0	0.1
Complement C3 ^c	g/L	30	1.050 (1.000; 1.154)	-0.068 (-0.178; -0.010)	0.90 ¹	-2.6	-0.02	1.80 ¹	1.2	0.02	1.1	-1.1	-0.01	8.4	0.09
Calcium ^a	mmol/L	30	0.900 (0.800; 1.000)	0.231 (0.000; 0.457)	2.15 ¹	0.7	0.02	2.58 ¹	-1.1	-0.03	2.3	0.0	0.00	6.0	0.14
Carbamazepine* ^a	mg/L	29	1.000 (1.000; 1.040)	0.100 (-0.080; 0.100)	4.0 ³	2.5	0.1	10.0 ³	1.0	0.1	7.0	1.4	0.1	12.0	0.9
CHE ^a	kU/L	30	1.000 (0.913; 1.036)	0.000 (-0.288; 0.648)	5.3 ¹	0.0	0.0	12.9 ¹	0.0	0.0	7.8	0.0	0.0	9.8	0.8
Chloride ^a	mmol/L	30	1.000 (0.750; 1.500)	0.000 (-50.000; 25.000)	94 ¹	0.0	0	110 ¹	0.0	0	99.4	0.0	0	4.5	4.5
Cholesterol ^a	mg/dL	30	1.000 (0.961; 1.057)	0.000 (-11.257; 7.533)	40 ²	0.0	0	200 ¹	0.0	0	191.7	0.0	0	7.0	13.4
CK ^a	U/L	30	0.995 (0.979; 1.006)	0.636 (-0.538; 3.009)	40 ²	1.1	0	190 ¹	-0.2	0	169.7	-0.1	0	11.0	18.6
CK-MB* ^a	U/L	29	0.913 (0.750; 1.000)	1.696 (1.000; 3.000)	25 ²	-1.9	0	50 ²	-5.3	-3	12.3	5.1	1	24.1	3.1
Cortisol ^b	µg/L	30	1.015 (0.989; 1.049)	-3.164 (-7.005; 0.424)	62 ¹	-3.6	-2	194 ¹	-0.2	0	121.3	-1.1	-1	16.0	19.3
CRP* ^a	mg/L	28	1.000 (0.987; 1.000)	-0.050 (-0.050; 0.027)	5.0 ²	-1.0	0.0	10.0 ²	-0.5	-0.1	5.8	-0.9	0.0	13.5	0.8
Digoxin* ^a	µg/L	29	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.8 ³	0.0	0.0	2.0 ³	0.0	0.0	1.4	0.0	0.0	14.0	0.2
Iron ^a	µmol/L	30	1.000 (0.972; 1.038)	0.200 (-0.364; 0.760)	5.8 ¹	3.4	0.2	34.5 ¹	0.6	0.2	19.3	1.0	0.2	30.7	6.0
Total Protein ^a	g/L	30	1.000 (0.850; 1.100)	0.000 (-7.500; 10.750)	66 ¹	0.0	0	87 ¹	0.0	0	73.2	0.0	0	6.0	4.8
Ferritin ^b	µg/L	30	1.000 (0.966; 1.045)	1.000 (-1.045; 2.293)	18 ¹	5.6	1	360 ¹	0.3	1	86.6	1.2	1	13.5	12.2
Folate ^b	µg/L	28	1.028 (0.925; 1.118)	0.226 (-0.362; 0.809)	3.9 ¹	8.6	0.3	26.8 ¹	3.6	1.0	7.3	5.9	0.4	39.0	3.0
fT3 ^b	ng/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	2.5 ¹	0.0	0.0	4.4 ¹	0.0	0.0	3.2	0.0	0.0	13.0	0.4



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		% Abs	% Abs
						%	Abs		%	Abs		%	Abs		
ft4 ^b	ng/L	28	1.000 (0.900; 1.139)	-0.100 (-2.024; 1.150)	9.9 ¹	-1.0	-0.1	16.2 ¹	-0.6	-0.1	12.9	-0.8	-0.1	13.0	1.7
FSH ^b	U/L	27	1.000 (0.981; 1.023)	0.000 (-0.062; 0.149)	1.5 ²	0.0	0.0	134.8 ²	0.0	0.0	13.1	0.0	0.0	14.0	1.8
GGT ^a	U/L	30	1.000 (0.944; 1.000)	0.000 (0.000; 1.111)	10 ²	0.0	0	60 ¹	0.0	0	26.9	0.0	0	11.5	3.1
Glucose ^a	mg/dL	30	1.000 (0.930; 1.083)	0.000 (-7.042; 7.744)	74 ¹	0.0	0	109 ¹	0.0	0	92.4	0.0	0	11.0	10.3
GOT (AST) ^a	U/L	30	0.972 (0.818; 1.000)	0.097 (-0.500; 3.909)	5 ²	-0.8	0	35 ¹	-2.5	-1	22.7	-2.3	-1	11.5	3.9
GPT (ALT) ^a	U/L	30	1.000 (0.929; 1.000)	0.000 (0.000; 1.607)	10 ²	0.0	0	45 ¹	0.0	0	25.8	0.0	0	11.5	2.9
Haptoglobin ^a	g/L	29	1.000 (0.975; 1.033)	0.000 (-0.034; 0.017)	0.30 ¹	0.0	0.00	2.00 ¹	0.0	0.00	1.0	0.0	0.00	25.1	0.25
Uric Acid ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	2.3 ¹	0.0	0.0	8.2 ¹	0.0	0.0	5.0	0.0	0.0	7.0	0.4
Urea ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	17 ¹	0.0	0	43 ¹	0.0	0	28.7	0.0	0	10.5	3.0
HCG ^{*b}	U/L	30	0.993 (0.970; 1.006)	-0.079 (-5.318; 7.082)	100.0 ²	-0.8	-0.8	2000.0 ²	-0.7	-13.8	549.3	-0.7	-3.8	14.0	76.6
HDL ^a	mg/dL	30	0.961 (0.929; 1.000)	1.118 (-1.000; 2.964)	40 ¹	-1.1	0	60 ¹	-2.1	-1	59.4	-2.0	-1	11.6	6.8
HS Troponin T ^{*b}	µg/L	30	0.893 (0.857; 0.927)	0.001 (-0.001; 0.003)	0.014 ²	-5.0	-0.001	0.300 ²	-10.4	-0.031	0.1	-10.0	-0.011	21.0	0.039
IgA ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.7 ¹	0.0	0.0	5.0 ¹	0.0	0.0	1.9	0.0	0.0	12.0	0.2
IgG ^a	g/L	30	1.017 (1.000; 1.053)	-0.213 (-0.571; -0.050)	7.0 ¹	-1.3	-0.1	16.0 ¹	0.4	0.1	9.7	-0.5	0.0	10.0	1.0
IgM ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.4 ¹	0.0	0.0	2.8 ¹	0.0	0.0	0.9	0.0	0.0	13.0	0.1
Potassium ^a	mmol/L	30	0.875 (0.714; 1.000)	0.463 (0.000; 1.129)	3.6 ¹	0.3	0.0	4.8 ¹	-2.9	-0.1	4.0	-1.1	0.0	4.5	0.2
Creatinin ^a	mg/dL	30	1.000 (0.941; 1.024)	-0.010 (-0.028; 0.041)	0.50 ¹	-2.0	-0.01	1.20 ¹	-0.8	-0.01	0.9	-1.1	-0.01	11.5	0.10
LDH ^a	U/L	30	0.988 (0.931; 1.065)	8.191 (-2.855; 16.362)	350 ²	1.1	4	248 ¹	2.1	5	155.0	4.1	6	9.0	14.4
LDL ^a	mg/dL	29	1.023 (1.000; 1.056)	-1.351 (-5.556; 1.000)	40 ²	-1.0	0	150 ¹	1.4	2	111.8	1.1	1	11.9	13.4
LH ^b	U/L	30	0.979 (0.957; 1.000)	0.028 (-0.100; 0.109)	1.0 ²	0.7	0.0	95.6 ²	-2.1	-2.0	8.1	-1.8	-0.1	27.9	2.2
Lipase ^a	U/L	30	1.000 (1.000; 1.029)	0.000 (-1.171; 0.000)	13 ¹	0.0	0	60 ¹	0.0	0	35.2	0.0	0	37.9	13.3
Magnesium	mmol/L	30	1.000 (0.909; 1.000)	0.000 (0.000; 0.072)	0.66 ¹	0.0	0.00	1.07 ¹	0.0	0.00	0.8	0.0	0.00	7.5	0.06



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
Sodium ^a	mmol/L	30	1.000 (0.667; 1.000)	0.000 (0.000; 46.500)	135 ¹	0.0	0	145 ¹	0.0	0	140.5	0.0	0	3.0	4.2
p-Amylase ^a	U/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	13 ¹	0.0	0	53 ¹	0.0	0	30.7	0.0	0	17.7	5.4
Phenytoin* ^a	mg/L	29	1.000 (1.000; 1.250)	0.000 (-0.750; 0.000)	10 ³	0.0	0	20 ³	0.0	0	3.1	0.0	0	11.0	0.6
Phosphorous ^a	mmol/L	30	1.000 (0.933; 1.000)	0.000 (0.000; 0.069)	0.81 ¹	0.0	0.00	1.45 ¹	0.0	0.00	1.0	0.0	0.00	9.0	0.09
Procalcitonin* ^b	µg/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.5 ²	0.0	0.0	2.0 ²	0.0	0.0	0.6	0.0	0.0	8.4	0.3
Progesterone ^b	µg/L	6	0.865 (0.800; 1.000)	0.085 (0.000; 0.260)	1.5 ²	-7.8	-0.1	27.0 ²	-13.1	-3.6	3.4	-11.0	-0.4	17.0	0.5
RF* ^c	kU/L	8	1.000 (0.914; 1.182)	-1.000 (-5.364; 1.714)	10 ²	-10.0	-1	15 ²	-6.7	-1	29.9	-3.3	-1	13.5	3.9
Testosterone ^b	µg/L	26	1.000 (0.972; 1.019)	0.000 (-0.004; 0.013)	3.50 ²	0.0	0.00	8.60 ²	0.0	0.00	2.5	0.0	0.00	20.5	0.51
Transferrin ^a	g/L	30	0.953 (0.882; 1.037)	0.097 (-0.132; 0.310)	2.00 ¹	0.1	0.00	3.60 ¹	-2.0	-0.07	2.8	-1.3	-0.04	8.0	0.24
Triglyceride ^a	mg/dL	30	0.984 (0.963; 1.000)	1.858 (0.000; 4.148)	40 ²	3.0	1	200 ¹	-0.7	-1	133.2	-0.2	0	9.0	12.0
TSH ^b	mU/L	30	0.985 (0.965; 1.000)	0.012 (-0.020; 0.047)	0.40 ¹	1.6	0.01	4.20 ¹	-1.2	-0.05	2.0	-0.9	-0.02	13.5	0.27
Valproic Acid* ^a	mg/L	29	0.934 (0.877; 1.033)	4.126 (-4.777; 12.648)	50.0 ³	1.7	0.8	100.0 ³	-2.4	-2.4	114.6	-3.0	-3.4	11.5	18.0
Vancomycin* ^a	mg/L	30	1.000 (0.962; 1.080)	0.000 (-2.040; 0.885)	10 ³	0.0	0	25 ³	0.0	0	32.1	0.0	0	12.0	4.0
Vitamin B12 ^b	ng/L	30	1.006 (0.953; 1.073)	-5.389 (-25.482; 13.188)	191 ¹	-2.2	-4	663 ¹	-0.2	-2	335.6	-1.0	-3	30.0	100.0

*spiked

^a Roche cobas c 702

^b Roche cobas e 602

^c Siemens BN Prospec

¹ Reference range

² Critical value

³ Therapeutic concentration



Comparison of S-Monovette® Lithium-Heparin Gel⁺ with S-Monovette® Lithium-Heparin Gel

The results of the regression are presented in Table 2. For none of the 57 parameters is the deviation at clinically relevant points or the mean value larger than the acceptance limit. For carbamazepine and testosterone, the confidence interval of the gradient does not include the value one or the value zero for the axis segment. However, the deviations are all within the acceptance limits. The deviations of the S-Monovette® LH Gel⁺ compared to the S-Monovette® LH Gel are therefore clinically irrelevant.



Table 2 Comparison of S-Monovette® Lithium-Heparin Gel⁺ and S-Monovette® Lithium-Heparin Gel, values beyond the target range are marked in bold

Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		% Abs	% Abs
						%	Abs		%	Abs		%	Abs		
Albumin ^a	g/L	30	1.000 (1.000; 1.333)	0.000 (-14.833; 0.000)	35 ¹	0.0	0.0	53 ¹	0.0	0.0	43.8	0.0	0.0	12.5	5.5
AP ^a	U/L	30	1.000 (0.976; 1.029)	0.000 (-2.147; 1.226)	30 ¹	0.0	0.0	120 ¹	0.0	0.0	61.1	0.0	0.0	11.0	6.7
Estradiol ^b	ng/L	26	1.019 (1.000; 1.042)	0.484 (-0.500; 1.000)	8 ²	8.3	0.6	498 ²	2.0	10.0	74.8	2.6	1.9	22.0	16.8
Bilirubin (direct) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ²	0.0	0.0	0.3 ¹	0.0	0.0	0.2	0.0	0.0	13.0	0.1
Bilirubin (total) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ¹	0.0	0.0	1.2 ¹	0.0	0.0	0.5	0.0	0.0	13.0	0.1
Complement C3 ^c	g/L	30	1.000 (0.960; 1.107)	-0.010 (-0.126; 0.034)	0.90 ¹	-1.1	-0.01	1.80 ¹	-0.6	-0.01	1.1	-0.9	-0.01	8.4	0.09
Calcium ^a	mmol/L	30	0.938 (0.833; 1.000)	0.147 (0.000; 0.384)	2.15 ¹	0.6	0.01	2.58 ¹	-0.6	-0.01	2.3	0.1	0.00	6.0	0.14
Carbamazepine* ^a	mg/L	29	1.032 (1.000; 1.053)	-0.054 (-0.179; 0.100)	4.0 ³	1.8	0.1	10.0 ³	2.6	0.3	7.1	2.4	0.2	12.0	0.9
CHE ^a	kU/L	30	1.000 (0.933; 1.038)	0.000 (-0.308; 0.490)	5.3 ¹	0.0	0.0	12.9 ¹	0.0	0.0	7.7	0.0	0.0	9.8	0.8
Chloride ^a	mmol/L	30	1.000 (0.750; 1.333)	0.000 (-33.000; 25.000)	94 ¹	0.0	0.0	110 ¹	0.0	0.0	99.4	0.0	0.0	4.5	4.5
Cholesterol ^a	mg/dL	30	1.000 (0.967; 1.020)	0.500 (-3.200; 6.417)	40 ²	1.3	0.5	200 ¹	0.3	0.5	190.5	0.3	0.5	7.0	13.4
CK ^a	U/L	30	0.997 (0.986; 1.000)	0.156 (0.000; 1.449)	40 ²	0.1	0.0	190 ¹	-0.2	-0.4	169.1	-0.2	-0.3	11.0	18.6
CK-MB* ^a	U/L	29	1.000 (0.800; 1.000)	1.000 (1.000; 2.600)	25 ²	4.0	1.0	50 ²	2.0	1.0	12.2	8.2	1.0	24.1	3.1
Cortisol ^b	µg/L	30	1.000 (0.981; 1.042)	0.000 (-4.542; 1.778)	62 ¹	0.0	0.0	194 ¹	0.0	0.0	120.6	0.0	0.0	16.0	19.3
CRP* ^a	mg/L	28	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	5.0 ²	0.0	0.0	10.0 ²	0.0	0.0	5.7	0.0	0.0	13.5	0.8
Digoxin* ^a	µg/L	29	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.8 ³	0.0	0.0	2.0 ³	0.0	0.0	1.4	0.0	0.0	14.0	0.2
Iron ^a	µmol/L	30	1.000 (0.983; 1.025)	0.100 (-0.285; 0.417)	5.8 ¹	1.7	0.1	34.5 ¹	0.3	0.1	19.3	0.5	0.1	30.7	6.0
Total Protein ^a	g/L	30	1.000 (0.944; 1.091)	0.000 (-6.500; 4.028)	66 ¹	0.0	0.0	87 ¹	0.0	0.0	73.0	0.0	0.0	6.0	4.8
Ferritin ^b	µg/L	30	1.000 (0.938; 1.030)	0.000 (-1.242; 3.000)	18 ¹	0.0	0.0	360 ¹	0.0	0.0	87.8	0.0	0.0	13.5	12.2
Folate ^b	µg/L	29	1.000 (0.930; 1.087)	0.100 (-0.709; 0.428)	3.9 ¹	2.6	0.1	26.8 ¹	0.4	0.1	8.1	1.2	0.1	39.0	3.0
fT3 ^b	ng/L	30	1.000 (1.000; 1.059)	0.000 (-0.182; 0.000)	2.5 ¹	0.0	0.0	4.4 ¹	0.0	0.0	3.2	0.0	0.0	13.0	0.4
fT4 ^b	ng/L	28	1.028 (0.958; 1.188)	-0.415 (-2.369; 0.515)	9.9 ¹	-1.4	-0.1	16.2 ¹	0.2	0.0	12.8	-0.5	-0.1	13.0	1.7



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
FSH ^b	U/L	28	1.013 (1.000; 1.034)	-0.010 (-0.141; 0.100)	1.5 ²	0.7	0.0	134.8 ²	1.3	1.8	11.9	1.3	0.1	14.0	1.8
GGT ^a	U/L	30	1.000 (0.955; 1.000)	0.000 (0.000; 0.841)	10 ²	0.0	0.0	60 ¹	0.0	0.0	27.2	0.0	0.0	11.5	3.1
Glucose ^a	mg/dL	30	1.000 (0.949; 1.045)	0.000 (-4.545; 4.679)	74 ¹	0.0	0.0	109 ¹	0.0	0.0	93.4	0.0	0.0	11.0	10.3
GOT (AST) ^a	U/L	30	1.000 (1.000; 1.128)	0.000 (-2.808; 0.000)	5 ²	0.0	0.0	35 ¹	0.0	0.0	22.5	0.0	0.0	11.5	3.9
GPT (ALT) ^a	U/L	30	1.000 (0.980; 1.067)	0.000 (-1.433; 0.441)	10 ²	0.0	0.0	45 ¹	0.0	0.0	25.5	0.0	0.0	11.5	2.9
Haptoglobin ^a	g/L	29	1.000 (0.983; 1.037)	0.000 (-0.041; 0.015)	0.30 ¹	0.0	0.00	2.00 ¹	0.0	0.00	1.0	0.0	0.00	25.1	0.25
Uric Acid ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	2.3 ¹	0.0	0.0	8.2 ¹	0.0	0.0	5.0	0.0	0.0	7.0	0.4
Urea ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	17 ¹	0.0	0.0	43 ¹	0.0	0.0	29.1	0.0	0.0	10.5	3.0
HCG* ^b	U/L	30	0.999 (0.988; 1.015)	2.156 (-3.023; 6.889)	100.0 ²	2.1	2.1	2000.0 ²	0.0	0.3	545.4	0.3	1.7	14.0	76.6
HDL ^a	mg/dL	30	1.000 (0.971; 1.000)	0.000 (0.000; 1.515)	40 ¹	0.0	0.0	60 ¹	0.0	0.0	58.3	0.0	0.0	11.6	6.8
HS Troponin T* ^b	µg/L	30	0.971 (0.886; 1.037)	0.002 (0.000; 0.008)	0.014 ²	14.4	0.002	0.300 ²	-2.1	-0.006	0.1	-0.5	-0.001	21.0	0.039
IgA ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.7 ¹	0.0	0.0	5.0 ¹	0.0	0.0	1.9	0.0	0.0	12.0	0.2
IgG ^a	g/L	30	1.018 (1.000; 1.045)	-0.183 (-0.411; 0.000)	7.0 ¹	-0.8	-0.1	16.0 ¹	0.6	0.1	9.6	-0.1	0.0	10.0	1.0
IgM ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.4 ¹	0.0	0.0	2.8 ¹	0.0	0.0	0.9	0.0	0.0	13.0	0.1
Potassium ^a	mmol/L	30	1.000 (1.000; 1.200)	0.000 (-0.760; 0.000)	3.6 ¹	0.0	0.0	4.8 ¹	0.0	0.0	4.0	0.0	0.0	4.5	0.2
Creatinin ^a	mg/dL	30	1.000 (0.955; 1.036)	0.000 (-0.035; 0.037)	0.50 ¹	0.0	0.00	1.20 ¹	0.0	0.00	0.9	0.0	0.00	11.5	0.10
LDH ^a	U/L	30	1.000 (0.941; 1.053)	2.000 (-5.105; 10.794)	350 ²	0.6	2.0	248 ¹	0.8	2.0	158.1	1.3	2.0	9.0	14.4
LDL ^a	mg/dL	29	1.008 (0.977; 1.035)	-0.500 (-3.316; 3.047)	40 ²	-0.5	-0.2	150 ¹	0.4	0.7	111.7	0.3	0.4	11.9	13.4
LH ^b	U/L	30	1.000 (0.985; 1.000)	0.000 (0.000; 0.051)	1.0 ²	0.0	0.0	95.6 ²	0.0	0.0	8.0	0.0	0.0	27.9	2.2
Lipase ^a	U/L	30	1.000 (1.000; 1.034)	0.000 (-1.069; 0.000)	13 ¹	0.0	0.0	60 ¹	0.0	0.0	35.0	0.0	0.0	37.9	13.3
Magnesium	mmol/L	30	1.000 (1.000; 1.167)	0.000 (-0.138; 0.000)	0.66 ¹	0.0	0.00	1.07 ¹	0.0	0.00	0.8	0.0	0.00	7.5	0.06
Sodium ^a	mmol/L	30	1.286 (1.000; 2.000)	-40.286 (-141.000; 0.000)	135 ¹	-1.3	-1.7	145 ¹	0.8	1.1	140.3	-0.1	-0.2	3.0	4.2



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
p-Amylase ^a	U/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	13 ¹	0.0	0.0	53 ¹	0.0	0.0	30.5	0.0	0.0	17.7	5.4
Phenytoin ^{*a}	mg/L	29	1.000 (1.000; 1.333)	0.000 (-1.000; 0.000)	10 ³	0.0	0.0	20 ³	0.0	0.0	3.2	0.0	0.0	11.0	0.6
Phosphorous ^a	mmol/L	30	0.989 (0.944; 1.000)	0.009 (0.000; 0.055)	0.81 ¹	0.0	0.00	1.45 ¹	-0.5	-0.01	1.0	-0.2	0.00	9.0	0.09
Procalcitonin ^{*b}	µg/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.5 ²	0.0	0.0	2.0 ²	0.0	0.0	0.6	0.0	0.0	8.4	0.3
Progesterone ^b	µg/L	6	0.990 (0.976; 1.056)	0.002 (-0.028; 0.017)	1.5 ²	-0.8	0.0	27.0 ²	-1.0	-0.3	3.1	-0.9	0.0	17.0	0.5
RF ^{*c}	kU/L	8	1.000 (0.955; 1.353)	0.000 (-7.206; 0.909)	10 ²	0.0	0.0	15 ²	0.0	0.0	28.5	0.0	0.0	13.5	3.9
Testosterone ^b	µg/L	26	1.000 (0.986; 1.019)	0.010 (0.006; 0.013)	3.50 ²	0.3	0.01	8.60 ²	0.1	0.01	2.4	0.4	0.01	20.5	0.51
Transferrin ^a	g/L	30	1.012 (0.933; 1.179)	-0.050 (-0.483; 0.159)	2.00 ¹	-1.3	-0.03	3.60 ¹	-0.2	-0.01	2.8	-0.6	-0.02	8.0	0.24
Triglyceride ^a	mg/dL	30	0.994 (0.967; 1.000)	0.719 (0.000; 3.767)	40 ²	1.2	0.5	200 ¹	-0.2	-0.4	132.9	0.0	0.0	9.0	12.0
TSH ^b	mU/L	30	0.991 (0.963; 1.010)	0.008 (-0.025; 0.053)	0.40 ¹	1.2	0.00	4.20 ¹	-0.7	-0.03	2.0	-0.5	-0.01	13.5	0.27
Valproic Acid ^{*a}	mg/L	29	0.964 (0.900; 1.048)	2.489 (-4.690; 8.288)	50.0 ³	1.4	0.7	100.0 ³	-1.1	-1.1	111.9	-1.4	-1.5	11.5	18.0
Vancomycin ^{*a}	mg/L	30	0.950 (0.914; 1.000)	1.050 (0.000; 2.207)	10 ³	5.5	0.6	25 ³	-0.8	-0.2	33.4	-1.9	-0.6	12.0	4.0
Vitamin B12 ^b	ng/L	30	1.013 (0.951; 1.065)	-6.430 (-23.949; 14.863)	191 ¹	-2.1	-4.0	663 ¹	0.3	2.0	333.5	-0.7	-2.2	30.0	100.0

*spiked

^a Roche cobas c 702

^b Roche cobas e 602

^c Siemens BN Prospec

¹ Reference range

² Critical value

³ Therapeutic concentration

Stability of analytes

A follow-up measurement was taken from each S-Monovette® one day and seven days after blood collection. Since there is no clinically relevant difference between the S-Monovette® LH Gel⁺ and the S-Monovette® LH Gel or S-Monovette® LH (oG) with Seraplas® filter on day 0, the S-Monovette® LH Gel⁺ of day 0 was always set as the reference value for stability. While, for GOT and estradiol, the percentage acceptance limits are exceeded in the lower range after one day, the absolute limits are not (Table 3). With FSH, the absolute limit is exceeded at the upper range, but not the percentage limit. For CK-MB, both the absolute and the percentage acceptance limits are exceeded at the mean value. However, it should be noted that CK-MB is an analyte spiked with control serum, as are CRP, HCG, HS troponin T, procalcitonin, RF and all pharmaceutical drugs. The aging behaviour of these parameters therefore corresponds only partly to that of the native analytes.

After seven days, either the absolute or the percentage acceptance limit is exceeded at one point for the following analytes, but not both: cholesterol, GOT, LDH, LDL, phosphorous, progesterone, testosterone and vancomycin (Table 4). In AP, one of the two acceptance limits is exceeded at two points. However, since only one of the two acceptance limits is exceeded, these parameters are stable for seven days. For glucose and potassium, both the absolute and the percentage acceptance limits are exceeded at two out of three points. Stability over seven days is not given for these parameters.

For the analytes estradiol, LDH, LH, procalcitonin, progesterone and vitamin B12 a tolerable deviation is observed after seven days. Guder et. al. indicates a shorter storage stability for these parameters [6]. The time period in which follow-up measurements are possible for certain analytes depends on the process and storage conditions and should be determined individually. Particularly for glucose, the measurement should be carried out without delay. The manufacturer accepts no liability to this effect. For prolonged storage, especially of whole blood, a sample tube with stabilizing additive must be used, e.g. S-Monovette® GlucoEXACT (REF 04.1945.001 or 05.1074.001).



Table 3 Comparison of S-Monovette® Lithium-Heparin Gel⁺ of Day 0 with Day 1, values beyond the target range are marked in bold

Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
Albumin ^a	g/L	30	1.000 (0.800; 1.000)	0.000 (0.000; 9.000)	35 ¹	0.0	0.0	53 ¹	0.0	0.0	43.6	0.0	0.0	12.5	5.5
AP ^a	U/L	30	0.974 (0.940; 1.000)	0.538 (-1.000; 2.640)	30 ¹	-0.8	-0.2	120 ¹	-2.1	-2.5	61.0	-1.7	-1.0	11.0	6.7
Estradiol ^b	ng/L	26	1.000 (0.965; 1.056)	2.000 (-1.694; 3.247)	8 ²	26.3	2.0	498 ²	0.4	2.0	76.3	2.6	2.0	22.0	16.8
Bilirubin (direct) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ²	0.0	0.0	0.3 ¹	0.0	0.0	0.2	0.0	0.0	13.0	0.1
Bilirubin (total) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ¹	0.0	0.0	1.2 ¹	0.0	0.0	0.5	0.0	0.0	13.0	0.1
Complement C3 ^c	g/L	30	1.000 (0.857; 1.129)	0.020 (-0.110; 0.165)	0.90 ¹	2.2	0.02	1.80 ¹	1.1	0.02	1.1	1.8	0.02	8.4	0.09
Calcium ^a	mmol/L	30	1.000 (0.875; 1.214)	-0.020 (-0.509; 0.275)	2.15 ¹	-0.9	-0.02	2.58 ¹	-0.8	-0.02	2.3	-0.9	-0.02	6.0	0.14
Carbamazepine ^{*a}	mg/L	29	1.000 (0.968; 1.067)	0.100 (-0.207; 0.265)	4.0 ³	2.5	0.1	10.0 ³	1.0	0.1	7.2	1.4	0.1	12.0	0.9
CHE ^a	kU/L	30	1.000 (1.000; 1.077)	0.000 (-0.569; 0.000)	5.3 ¹	0.0	0.0	12.9 ¹	0.0	0.0	7.7	0.0	0.0	9.8	0.8
Chloride ^a	mmol/L	30	1.250 (1.000; 2.000)	-24.000 (-99.000; 1.000)	94 ¹	-0.5	-0.5	110 ¹	3.2	3.5	99.5	0.9	0.9	4.5	4.5
Cholesterol ^a	mg/dL	30	1.016 (0.947; 1.077)	-2.871 (-13.538; 8.722)	40 ²	-5.6	-2.2	200 ¹	0.2	0.4	191.1	0.1	0.2	7.0	13.4
CK ^a	U/L	30	0.997 (0.972; 1.002)	-3.182 (-4.201; 0.321)	40 ²	-8.2	-3.3	190 ¹	-2.0	-3.7	169.0	-2.2	-3.7	11.0	18.6
CK-MB ^{*a}	U/L	29	0.866 (0.500; 1.000)	-2.259 (-4.000; 1.500)	25 ²	-22.4	-5.6	50 ²	-17.9	-9.0	12.8	-31.1	-4.0	24.1	3.1
Cortisol ^b	µg/L	30	0.978 (0.938; 1.024)	1.788 (-2.329; 6.000)	62 ¹	0.7	0.4	194 ¹	-1.3	-2.5	120.6	-0.7	-0.9	16.0	19.3
CRP ^{*a}	mg/L	28	1.000 (0.966; 1.000)	0.000 (0.000; 0.093)	5.0 ²	0.0	0.0	10.0 ²	0.0	0.0	5.7	0.0	0.0	13.5	0.8
Digoxin ^{*a}	µg/L	29	1.000 (0.955; 1.000)	0.000 (0.000; 0.050)	0.8 ³	0.0	0.0	2.0 ³	0.0	0.0	1.4	0.0	0.0	14.0	0.2
Iron ^a	µmol/L	30	1.000 (0.991; 1.019)	0.000 (-0.461; 0.142)	5.8 ¹	0.0	0.0	34.5 ¹	0.0	0.0	19.5	0.0	0.0	30.7	6.0
Total Protein ^a	g/L	30	1.000 (0.909; 1.000)	0.000 (0.000; 6.545)	66 ¹	0.0	0.0	87 ¹	0.0	0.0	73.0	0.0	0.0	6.0	4.8
Ferritin ^b	µg/L	30	0.981 (0.950; 1.009)	-0.217 (-1.627; 0.817)	18 ¹	-3.1	-0.6	360 ¹	-1.9	-6.9	90.0	-2.1	-1.9	13.5	12.2
Folate ^b	µg/L	29	1.015 (0.943; 1.136)	-0.198 (-0.897; 0.271)	3.9 ¹	-3.6	-0.1	26.8 ¹	0.8	0.2	8.1	-0.9	-0.1	39.0	3.0
fT3 ^b	ng/L	30	1.000 (0.857; 1.200)	0.000 (-0.660; 0.500)	2.5 ¹	0.0	0.0	4.4 ¹	0.0	0.0	3.2	0.0	0.0	13.0	0.4



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
fT4 ^b	ng/L	28	1.059 (0.913; 1.226)	-0.647 (-2.844; 1.163)	9.9 ¹	-0.7	-0.1	16.2 ¹	1.9	0.3	12.7	0.8	0.1	13.0	1.7
FSH ^b	U/L	28	0.977 (0.965; 1.000)	0.008 (-0.100; 0.068)	1.5 ²	-1.8	0.0	134.8 ²	-2.3	-3.0	12.6	-2.2	-0.3	14.0	1.8
GGT ^a	U/L	30	1.000 (0.929; 1.000)	-0.500 (-0.500; 1.036)	10 ²	-5.0	-0.5	60 ¹	-0.8	-0.5	26.8	-1.9	-0.5	11.5	3.1
Glucose ^a	mg/dL	30	1.000 (1.000; 1.038)	-2.000 (-5.327; -2.000)	74 ¹	-2.7	-2.0	109 ¹	-1.8	-2.0	93.7	-2.1	-2.0	11.0	10.3
GOT (AST) ^a	U/L	30	1.000 (0.974; 1.143)	1.000 (-2.500; 1.359)	5 ²	20.0	1.0	35 ¹	2.9	1.0	22.7	4.4	1.0	11.5	3.9
GPT (ALT) ^a	U/L	30	1.000 (0.909; 1.032)	0.000 (-0.823; 2.000)	10 ²	0.0	0.0	45 ¹	0.0	0.0	25.4	0.0	0.0	11.5	2.9
Haptoglobin ^a	g/L	29	1.000 (0.968; 1.030)	0.000 (-0.021; 0.033)	0.30 ¹	0.0	0.00	2.00 ¹	0.0	0.00	1.0	0.0	0.00	25.1	0.25
Uric Acid ^a	mg/dL	30	1.000 (1.000; 1.063)	0.000 (-0.291; 0.000)	2.3 ¹	0.0	0.0	8.2 ¹	0.0	0.0	5.0	0.0	0.0	7.0	0.4
Urea ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	17 ¹	0.0	0.0	43 ¹	0.0	0.0	29.0	0.0	0.0	10.5	3.0
HCG ^{*b}	U/L	30	0.979 (0.959; 1.003)	-1.187 (-12.133; 4.430)	100.0 ²	-3.3	-3.3	2000.0 ²	-2.2	-43.3	546.9	-2.3	-12.7	14.0	76.6
HDL ^a	mg/dL	30	1.000 (0.980; 1.000)	-1.000 (-1.000; 0.255)	40 ¹	-2.5	-1.0	60 ¹	-1.7	-1.0	58.2	-1.7	-1.0	11.6	6.8
HS Troponin T ^{*b}	µg/L	30	0.988 (0.962; 1.000)	0.002 (0.002; 0.004)	0.014 ²	16.1	0.002	0.300 ²	-0.4	-0.001	0.1	1.2	0.001	21.0	0.039
IgA ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.7 ¹	0.0	0.0	5.0 ¹	0.0	0.0	1.9	0.0	0.0	12.0	0.2
IgG ^a	g/L	30	0.978 (0.956; 1.000)	0.154 (-0.100; 0.379)	7.0 ¹	0.0	0.0	16.0 ¹	-1.2	-0.2	9.7	-0.6	-0.1	10.0	1.0
IgM ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.4 ¹	0.0	0.0	2.8 ¹	0.0	0.0	0.9	0.0	0.0	13.0	0.1
Potassium ^a	mmol/L	30	1.000 (1.000; 1.167)	0.100 (-0.583; 0.100)	3.6 ¹	2.8	0.1	4.8 ¹	2.1	0.1	4.0	2.5	0.1	4.5	0.2
Creatinin ^a	mg/dL	30	1.000 (0.900; 1.045)	0.000 (-0.035; 0.085)	0.50 ¹	0.0	0.00	1.20 ¹	0.0	0.00	0.9	0.0	0.00	11.5	0.10
LDH ^a	U/L	30	0.966 (0.918; 1.022)	4.121 (-4.663; 11.057)	350 ²	-2.2	-7.8	248 ¹	-1.7	-4.3	160.5	-0.8	-1.3	9.0	14.4
LDL ^a	mg/dL	29	1.000 (0.917; 1.070)	1.000 (-5.649; 8.583)	40 ²	2.5	1.0	150 ¹	0.7	1.0	112.4	0.9	1.0	11.9	13.4
LH ^b	U/L	30	0.989 (0.964; 1.000)	-0.146 (-0.200; 0.035)	1.0 ²	-15.6	-0.2	95.6 ²	-1.2	-1.2	8.0	-2.9	-0.2	27.9	2.2
Lipase ^a	U/L	30	1.000 (1.000; 1.040)	0.000 (-0.880; 0.000)	13 ¹	0.0	0.0	60 ¹	0.0	0.0	35.0	0.0	0.0	37.9	13.3
Magnesium	mmol/L	30	1.000 (0.833; 1.000)	0.000 (0.000; 0.143)	0.66 ¹	0.0	0.00	1.07 ¹	0.0	0.00	0.8	0.0	0.00	7.5	0.06



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
Sodium ^a	mmol/L	30	1.000 (0.750; 1.333)	0.500 (-46.167; 35.375)	135 ¹	0.4	0.5	145 ¹	0.3	0.5	140.1	0.4	0.5	3.0	4.2
p-Amylase ^a	U/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	13 ¹	0.0	0.0	53 ¹	0.0	0.0	30.3	0.0	0.0	17.7	5.4
Phenytoin* ^a	mg/L	29	1.000 (0.600; 1.000)	0.000 (0.000; 1.400)	10 ³	0.0	0.0	20 ³	0.0	0.0	3.1	0.0	0.0	11.0	0.6
Phosphorous ^a	mmol/L	30	1.000 (0.950; 1.018)	0.010 (-0.008; 0.057)	0.81 ¹	1.2	0.01	1.45 ¹	0.7	0.01	1.0	1.0	0.01	9.0	0.09
Procalcitonin* ^b	µg/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.5 ²	0.0	0.0	2.0 ²	0.0	0.0	0.6	0.0	0.0	8.4	0.3
Progesterone ^b	µg/L	6	1.000 (0.895; 1.200)	0.000 (-0.350; 0.103)	1.5 ²	0.0	0.0	27.0 ²	0.0	0.0	3.1	0.0	0.0	17.0	0.5
RF* ^c	kU/L	7	1.018 (0.895; 1.091)	-0.228 (-2.273; 2.632)	10 ²	-0.5	-0.1	15 ²	0.2	0.0	31.6	1.0	0.3	13.5	3.9
Testosterone ^b	µg/L	26	1.037 (1.018; 1.051)	-0.002 (-0.023; 0.026)	3.50 ²	3.6	0.13	8.60 ²	3.7	0.32	2.5	3.6	0.09	20.5	0.51
Transferrin ^a	g/L	30	1.016 (0.920; 1.140)	-0.041 (-0.358; 0.215)	2.00 ¹	-0.5	-0.01	3.60 ¹	0.4	0.02	2.8	0.1	0.00	8.0	0.24
Triglyceride ^a	mg/dL	30	0.998 (0.959; 1.021)	0.285 (-1.670; 5.279)	40 ²	0.5	0.2	200 ¹	-0.1	-0.2	133.3	0.0	0.0	9.0	12.0
TSH ^b	mU/L	30	0.965 (0.939; 1.000)	0.047 (-0.010; 0.093)	0.40 ¹	8.3	0.03	4.20 ¹	-2.4	-0.10	2.0	-1.2	-0.02	13.5	0.27
Valproic Acid* ^a	mg/L	29	1.111 (0.959; 1.211)	-10.252 (-18.571; 2.635)	50.0 ³	-9.4	-4.7	100.0 ³	0.9	0.9	111.9	2.0	2.2	11.5	18.0
Vancomycin* ^a	mg/L	30	1.000 (0.875; 1.056)	-1.000 (-3.083; 1.313)	10 ³	-10.0	-1.0	25 ³	-4.0	-1.0	33.2	-3.0	-1.0	12.0	4.0
Vitamin B12 ^b	ng/L	30	1.009 (0.923; 1.079)	-4.771 (-26.016; 25.154)	191 ¹	-1.6	-3.0	663 ¹	0.2	1.5	333.2	-0.5	-1.6	30.0	100.0

*spiked

^a Roche cobas c 702

^b Roche cobas e 602

^c Siemens BN Prospec

¹ Reference range

² Critical value

³ Therapeutic concentration



Table 4 Comparison of S-Monovette® Lithium-Heparin Gel⁺ of Day 0 with Day 7, values beyond the target range are marked in bold

Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
Albumin ^a	g/L	30	1.000 (1.000; 1.400)	1.000 (-16.300; 1.000)	35 ¹	2.9	1.0	53 ¹	1.9	1.0	43.6	2.3	1.0	12.5	5.5
AP ^a	U/L	30	0.932 (0.875; 1.000)	-1.363 (-5.000; 2.313)	30 ¹	-11.3	-3.4	120 ¹	-7.9	-9.5	61.0	-9.0	-5.5	11.0	6.7
Estradiol ^b	ng/L	26	0.981 (0.947; 1.003)	1.394 (0.348; 3.000)	8 ²	16.4	1.2	498 ²	-1.6	-8.2	76.3	-0.1	-0.1	22.0	16.8
Bilirubin (direct) ^a	mg/dL	29	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ²	0.0	0.0	0.3 ¹	0.0	0.0	0.2	0.0	0.0	13.0	0.1
Bilirubin (total) ^a	mg/dL	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.1 ¹	0.0	0.0	1.2 ¹	0.0	0.0	0.5	0.0	0.0	13.0	0.1
Complement C3 ^c	g/L	30	1.047 (0.933; 1.182)	0.005 (-0.133; 0.119)	0.90 ¹	5.3	0.05	1.80 ¹	5.0	0.09	1.1	5.1	0.06	8.4	0.09
Calcium ^a	mmol/L	30	1.000 (0.800; 1.143)	-0.015 (-0.338; 0.457)	2.15 ¹	-0.7	-0.02	2.58 ¹	-0.6	-0.02	2.3	-0.7	-0.02	6.0	0.14
Carbamazepine* ^a	mg/L	29	0.985 (0.948; 1.000)	0.070 (0.000; 0.373)	4.0 ³	0.2	0.0	10.0 ³	-0.8	-0.1	7.2	-0.5	0.0	12.0	0.9
CHE ^a	kU/L	30	1.000 (0.944; 1.056)	0.000 (-0.392; 0.408)	5.3 ¹	0.0	0.0	12.9 ¹	0.0	0.0	7.7	0.0	0.0	9.8	0.8
Chloride ^a	mmol/L	30	1.000 (1.000; 2.000)	-1.000 (-100.000; -1.000)	94 ¹	-1.1	-1.0	110 ¹	-0.9	-1.0	99.5	-1.0	-1.0	4.5	4.5
Cholesterol ^a	mg/dL	30	0.947 (0.918; 0.986)	8.521 (0.521; 13.602)	40 ²	16.0	6.4	200 ¹	-1.1	-2.1	191.1	-0.9	-1.7	7.0	13.4
CK ^a	U/L	30	1.007 (0.989; 1.023)	-3.040 (-4.791; -1.346)	40 ²	-6.9	-2.8	190 ¹	-0.9	-1.8	169.0	-1.1	-1.9	11.0	18.6
CK-MB* ^a	U/L	29	1.000 (0.556; 1.250)	-3.000 (-5.500; 1.000)	25 ²	-12.0	-3.0	50 ²	-6.0	-3.0	12.8	-23.5	-3.0	24.1	3.1
Cortisol ^b	µg/L	30	0.977 (0.954; 1.000)	2.750 (0.000; 5.015)	62 ¹	2.2	1.3	194 ¹	-0.9	-1.7	120.6	0.0	0.0	16.0	19.3
CRP* ^a	mg/L	28	1.000 (0.967; 1.000)	-0.200 (-0.200; -0.037)	5.0 ²	-4.0	-0.2	10.0 ²	-2.0	-0.2	5.7	-3.5	-0.2	13.5	0.8
Digoxin* ^a	µg/L	29	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.8 ³	0.0	0.0	2.0 ³	0.0	0.0	1.4	0.0	0.0	14.0	0.2
Iron ^a	µmol/L	30	0.994 (0.971; 1.015)	-0.301 (-0.645; 0.133)	5.8 ¹	-5.7	-0.3	34.5 ¹	-1.4	-0.5	19.5	-2.1	-0.4	30.7	6.0
Total Protein ^a	g/L	30	1.000 (1.000; 1.000)	-1.000 (-1.000; -1.000)	66 ¹	-1.5	-1.0	87 ¹	-1.1	-1.0	73.0	-1.4	-1.0	6.0	4.8
Ferritin ^b	µg/L	30	0.975 (0.923; 1.023)	0.507 (-1.849; 2.731)	18 ¹	0.3	0.1	360 ¹	-2.4	-8.6	90.0	-2.0	-1.8	13.5	12.2
Folate ^b	µg/L	29	0.929 (0.865; 1.000)	0.255 (-0.300; 0.672)	3.9 ¹	-0.6	0.0	26.8 ¹	-6.2	-1.7	8.1	-4.0	-0.3	39.0	3.0



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		% Abs	% Abs
						%	Abs		%	Abs		%	Abs		
fT3 ^b	ng/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	2.5 ¹	0.0	0.0	4.4 ¹	0.0	0.0	3.2	0.0	0.0	13.0	0.4
fT4 ^b	ng/L	28	1.000 (0.903; 1.178)	0.500 (-1.796; 1.737)	9.9 ¹	5.1	0.5	16.2 ¹	3.1	0.5	12.7	3.9	0.5	13.0	1.7
FSH ^b	U/L	28	1.000 (0.995; 1.028)	0.000 (-0.151; 0.020)	1.5 ²	0.0	0.0	134.8 ²	0.0	0.0	12.6	0.0	0.0	14.0	1.8
GGT ^a	U/L	30	1.000 (0.889; 1.000)	0.000 (0.000; 2.389)	10 ²	0.0	0.0	60 ¹	0.0	0.0	26.8	0.0	0.0	11.5	3.1
Glucose ^a	mg/dL	30	1.029 (0.964; 1.125)	-14.544 (-22.750; -8.218)	74 ¹	-16.7	-12.4	109 ¹	-10.4	-11.3	93.7	-12.6	-11.8	11.0	10.3
GOT (AST) ^a	U/L	30	1.000 (0.905; 1.067)	1.000 (-0.567; 2.762)	5 ²	20.0	1.0	35 ¹	2.9	1.0	22.7	4.4	1.0	11.5	3.9
GPT (ALT) ^a	U/L	30	0.958 (0.885; 1.000)	-0.208 (-1.000; 1.365)	10 ²	-6.3	-0.6	45 ¹	-4.6	-2.1	25.4	-5.0	-1.3	11.5	2.9
Haptoglobin ^a	g/L	29	1.000 (0.970; 1.029)	0.020 (-0.007; 0.043)	0.30 ¹	6.7	0.02	2.00 ¹	1.0	0.02	1.0	1.9	0.02	25.1	0.25
Uric Acid ^a	mg/dL	30	1.000 (0.961; 1.000)	0.000 (0.000; 0.163)	2.3 ¹	0.0	0.0	8.2 ¹	0.0	0.0	5.0	0.0	0.0	7.0	0.4
Urea ^a	mg/dL	30	1.000 (0.964; 1.000)	0.000 (0.000; 0.821)	17 ¹	0.0	0.0	43 ¹	0.0	0.0	29.0	0.0	0.0	10.5	3.0
HCG ^{*b}	U/L	30	0.998 (0.980; 1.025)	-6.579 (-18.323; 3.932)	100.0 ²	-6.8	-6.8	2000.0 ²	-0.5	-10.5	546.9	-1.4	-7.7	14.0	76.6
HDL ^a	mg/dL	30	0.960 (0.935; 1.000)	-1.220 (-3.500; 0.210)	40 ¹	-7.0	-2.8	60 ¹	-6.0	-3.6	58.2	-6.1	-3.5	11.6	6.8
HS Troponin T ^{*b}	µg/L	30	1.000 (0.979; 1.038)	0.003 (0.001; 0.004)	0.014 ²	17.9	0.003	0.300 ²	0.8	0.003	0.1	2.4	0.003	21.0	0.039
IgA ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.7 ¹	0.0	0.0	5.0 ¹	0.0	0.0	1.9	0.0	0.0	12.0	0.2
IgG ^a	g/L	30	0.966 (0.940; 1.000)	0.174 (-0.100; 0.422)	7.0 ¹	-1.0	-0.1	16.0 ¹	-2.4	-0.4	9.7	-1.6	-0.2	10.0	1.0
IgM ^a	g/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.4 ¹	0.0	0.0	2.8 ¹	0.0	0.0	0.9	0.0	0.0	13.0	0.1
Potassium ^a	mmol/L	30	1.500 (1.000; 2.000)	-1.600 (-3.550; 0.400)	3.6 ¹	5.6	0.2	4.8 ¹	16.7	0.8	4.0	10.3	0.4	4.5	0.2
Creatinin ^a	mg/dL	30	0.957 (0.889; 1.000)	0.012 (-0.020; 0.067)	0.50 ¹	-2.0	-0.01	1.20 ¹	-3.4	-0.04	0.9	-3.0	-0.03	11.5	0.10
LDH ^a	U/L	30	1.042 (0.872; 1.315)	3.396 (-39.565; 29.096)	350 ²	5.1	18.0	248 ¹	5.5	13.7	160.5	6.3	10.1	9.0	14.4
LDL ^a	mg/dL	29	0.935 (0.889; 0.975)	9.797 (5.074; 14.222)	40 ²	18.0	7.2	150 ¹	0.0	0.0	112.4	2.2	2.5	11.9	13.4
LH ^b	U/L	30	0.982 (0.957; 1.000)	-0.070 (-0.200; 0.078)	1.0 ²	-8.8	-0.1	95.6 ²	-1.9	-1.8	8.0	-2.7	-0.2	27.9	2.2
Lipase ^a	U/L	30	1.000 (1.000; 1.040)	0.000 (-1.020; 0.000)	13 ¹	0.0	0.0	60 ¹	0.0	0.0	35.0	0.0	0.0	37.9	13.3



Parameter	Unit	n	Gradient (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit	
					Measuring value	Error		Measuring value	Error		Mean value	Error		%	Abs
						%	Abs		%	Abs		%	Abs		
Magnesium	mmol/L	30	0.917 (0.750; 1.083)	0.057 (-0.078; 0.195)	0.66 ¹	0.3	0.00	1.07 ¹	-3.0	-0.03	0.8	-1.4	-0.01	7.5	0.06
Sodium ^a	mmol/L	30	1.000 (0.750; 1.500)	-1.500 (-71.750; 33.500)	135 ¹	-1.1	-1.5	145 ¹	-1.0	-1.5	140.1	-1.1	-1.5	3.0	4.2
p-Amylase ^a	U/L	30	1.000 (0.976; 1.000)	0.000 (0.000; 0.452)	13 ¹	0.0	0.0	53 ¹	0.0	0.0	30.3	0.0	0.0	17.7	5.4
Phenytoin* ^a	mg/L	29	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	10 ³	0.0	0.0	20 ³	0.0	0.0	3.1	0.0	0.0	11.0	0.6
Phosphorous ^a	mmol/L	30	0.933 (0.818; 1.077)	0.128 (-0.017; 0.248)	0.81 ¹	9.1	0.07	1.45 ¹	2.1	0.03	1.0	5.9	0.06	9.0	0.09
Procalcitonin* ^b	µg/L	30	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.5 ²	0.0	0.0	2.0 ²	0.0	0.0	0.6	0.0	0.0	8.4	0.3
Progesterone ^b	µg/L	6	0.960 (0.867; 1.091)	-0.040 (-0.264; 0.093)	1.5 ²	-6.7	-0.1	27.0 ²	-4.1	-1.1	3.1	-5.3	-0.2	17.0	0.5
RF* ^c	kU/L	7	1.000 (0.773; 1.125)	0.000 (-2.875; 5.727)	10 ²	0.0	0.0	15 ²	0.0	0.0	31.4	0.0	0.0	13.5	3.9
Testosterone ^b	µg/L	26	1.064 (1.038; 1.090)	0.035 (0.019; 0.047)	3.50 ²	7.4	0.26	8.60 ²	6.8	0.58	2.5	7.8	0.19	20.5	0.51
Transferrin ^a	g/L	30	1.032 (0.913; 1.194)	-0.020 (-0.434; 0.304)	2.00 ¹	2.2	0.04	3.60 ¹	2.6	0.09	2.8	2.5	0.07	8.0	0.24
Triglyceride ^a	mg/dL	30	0.942 (0.868; 1.028)	4.508 (-4.592; 12.145)	40 ²	5.5	2.2	200 ¹	-3.5	-7.1	133.3	-2.4	-3.2	9.0	12.0
TSH ^b	mU/L	30	1.000 (0.971; 1.023)	-0.020 (-0.060; 0.038)	0.40 ¹	-5.0	-0.02	4.20 ¹	-0.5	-0.02	2.0	-1.0	-0.02	13.5	0.27
Valproic Acid* ^a	mg/L	29	1.025 (0.958; 1.111)	-6.751 (-14.579; 0.367)	50.0 ³	-11.0	-5.5	100.0 ³	-4.2	-4.2	111.9	-3.5	-3.9	11.5	18.0
Vancomycin* ^a	mg/L	30	1.000 (0.857; 1.038)	-2.000 (-2.962; 1.571)	10 ³	-20.0	-2.0	25 ³	-8.0	-2.0	33.2	-6.0	-2.0	12.0	4.0
Vitamin B12 ^b	ng/L	30	1.013 (0.889; 1.107)	-14.772 (-43.821; 22.333)	191 ¹	-6.5	-12.4	663 ¹	-1.0	-6.4	333.2	-3.2	-10.6	30.0	100.0

*spiked

^a Roche cobas c 702

^b Roche cobas e 602

^c Siemens BN Prospec

¹ Reference range

² Critical value

³ Therapeutic concentration

Conclusion

The clinical equivalence of the S-Monovette® Lithium-Heparin Gel⁺ and the S-Monovette® Lithium-Heparin with Seraplas® filter can be successfully demonstrated for 57 clinical-chemical and immunological analytes in plasma on Roche cobas® analyzers. After seven days of storage, the concentration changes of all tested analytes, with the exception of glucose and potassium, are well within the acceptance limits.

For each change in the sample tube, handling, transport and centrifugation conditions and storage, the laboratory should evaluate the manufacturer's data and its own data to ensure that analyses are not falsified and the reference ranges used are valid. The manufacturer accepts to this effect.

Literature

[1] Clinical and Laboratory Standards Institute Dokument EP09-A3 2013

[2] Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. Applications of linear regression procedures for method comparison studies in clinical chemistry, Part I. *J Clin Chem Clin Biochem.* 1983;21(11):709–720

[3] Hollander M, Wolfe DA. *Nonparametric Statistical Methods.* 2nd ed. New York, NY: John Wiley & Sons Inc.; 1999

[4] Harter HL, Owen DB, eds. *Selected Tables in Mathematical Statistics, Volume I,* Providence, RI: American Mathematical Society; 1973

[5] <https://www.westgard.com/biodatabase1.htm>

[6] Guder WG, Zawta B. *Recommendations of the Working group on preanalytical quality of the German United Society for Clinical Chemistry and Laboratory Medicine,* 3rd completely revised edition; 2009



Annex

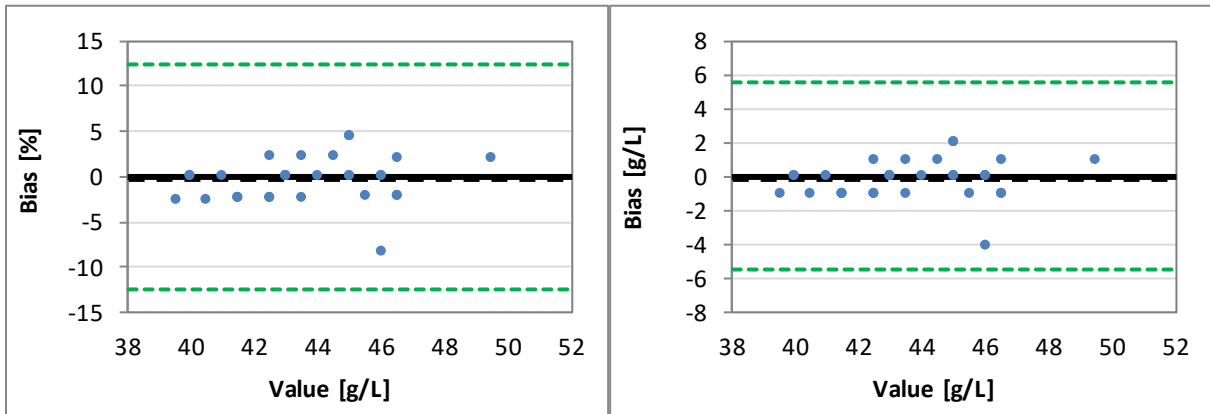
- I. Diagrams
- II. Methods used

I. Diagrams

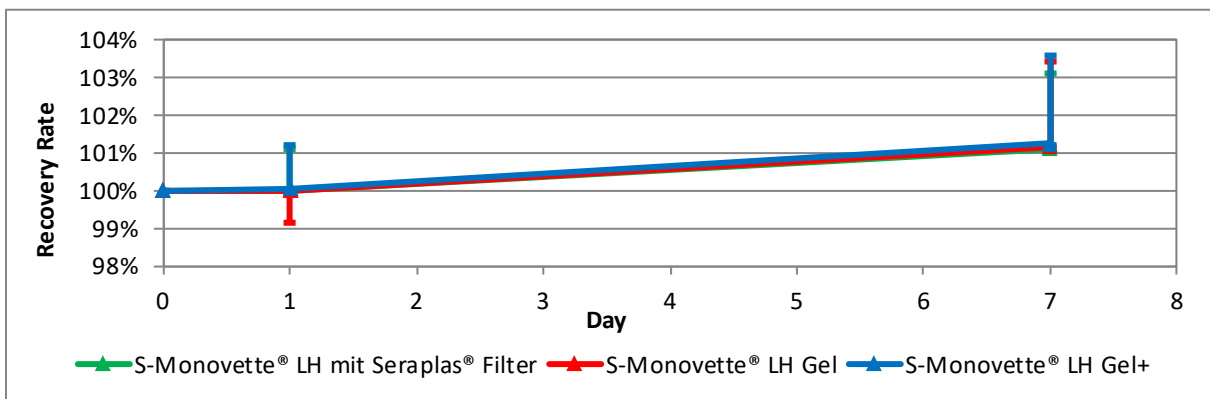
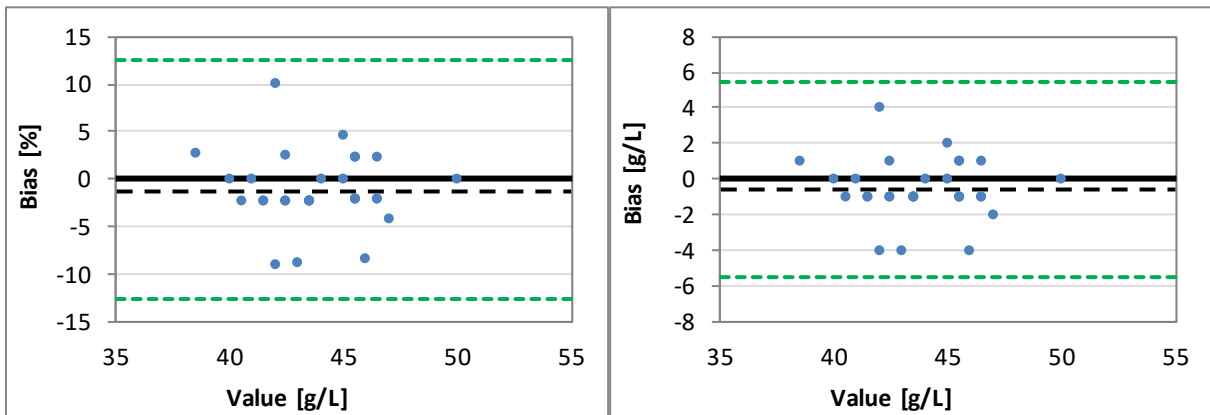
The Bland-Altman diagrams and the Recovery Rates for each parameter are shown.

Albumin

S-Monovette® LH Gel⁺ vs. S-Monovette® LH Gel



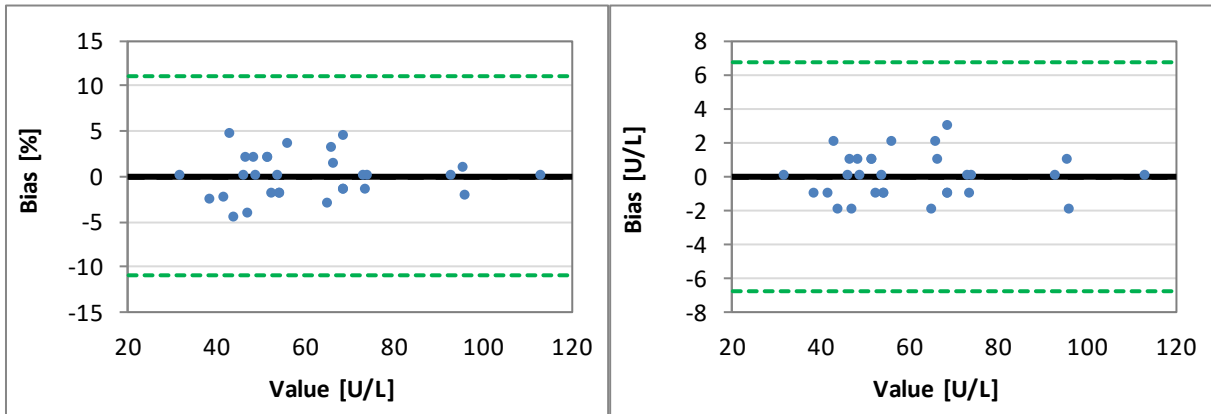
S-Monovette® LH Gel⁺ vs. S-Monovette® LH with Seraplas® Filter



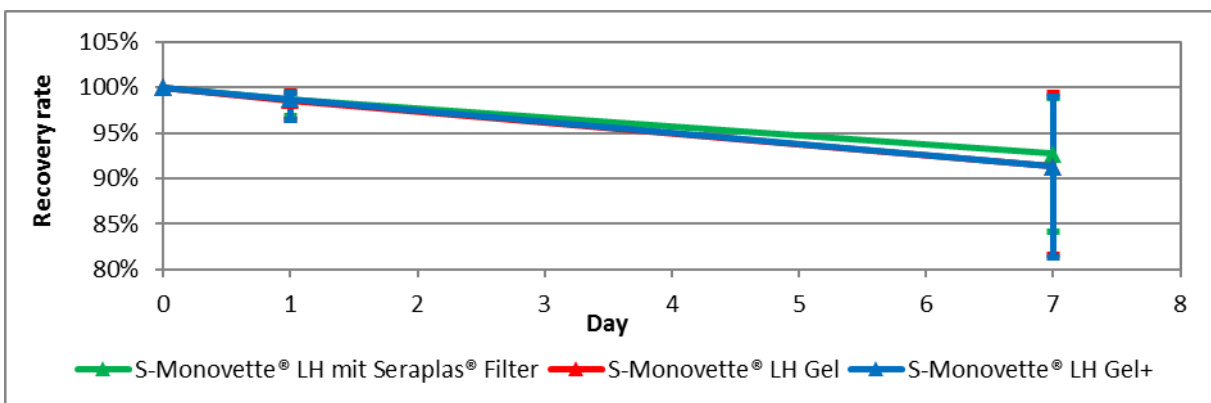
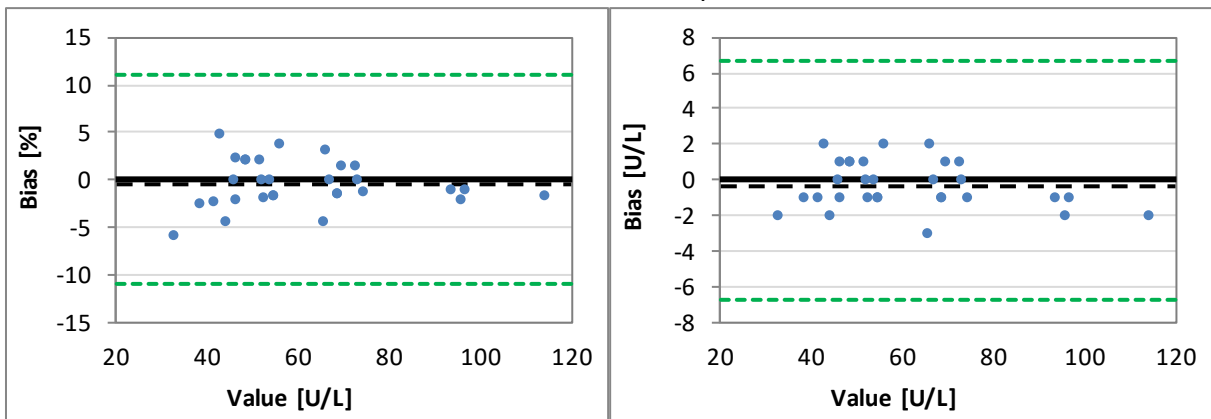


AP

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



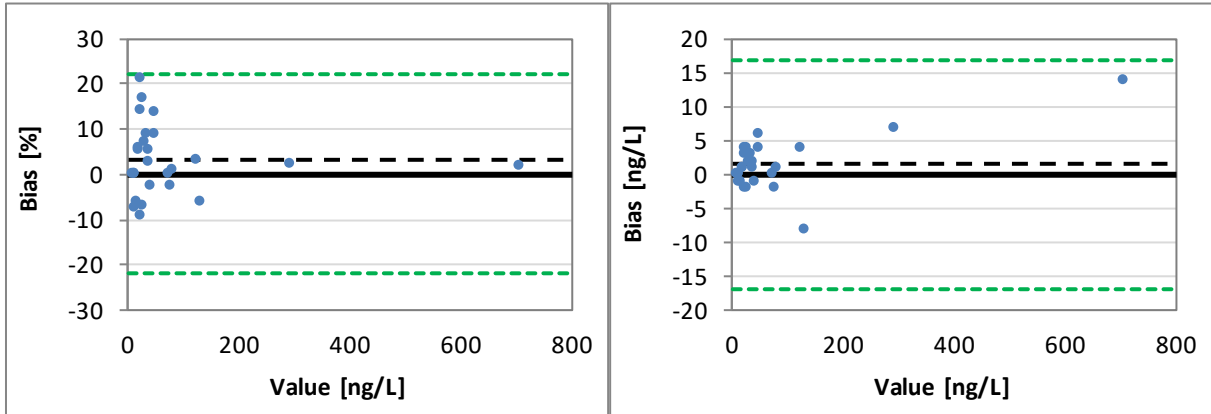
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



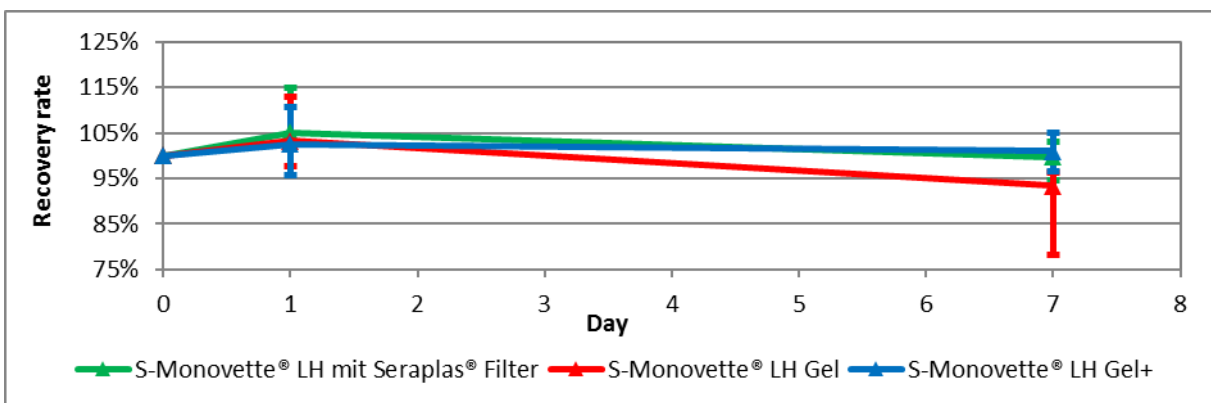
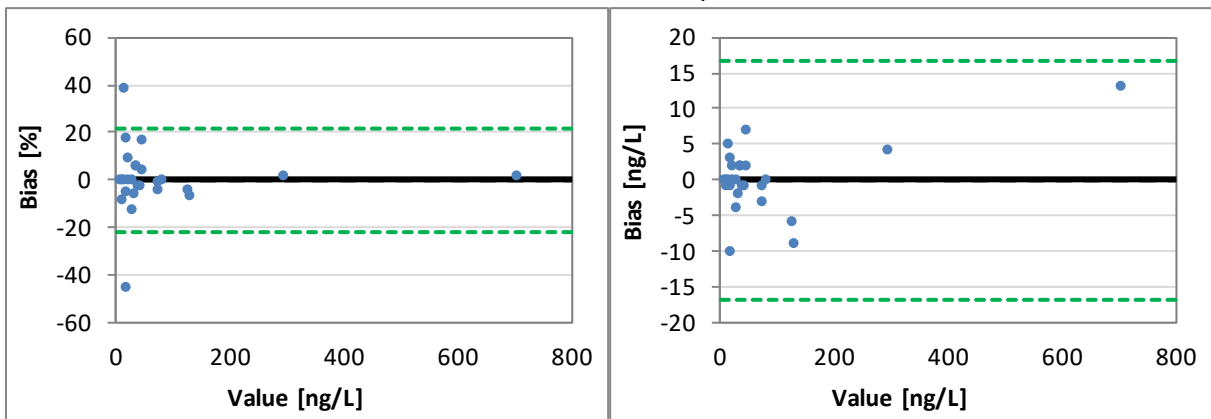


Estradiol

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



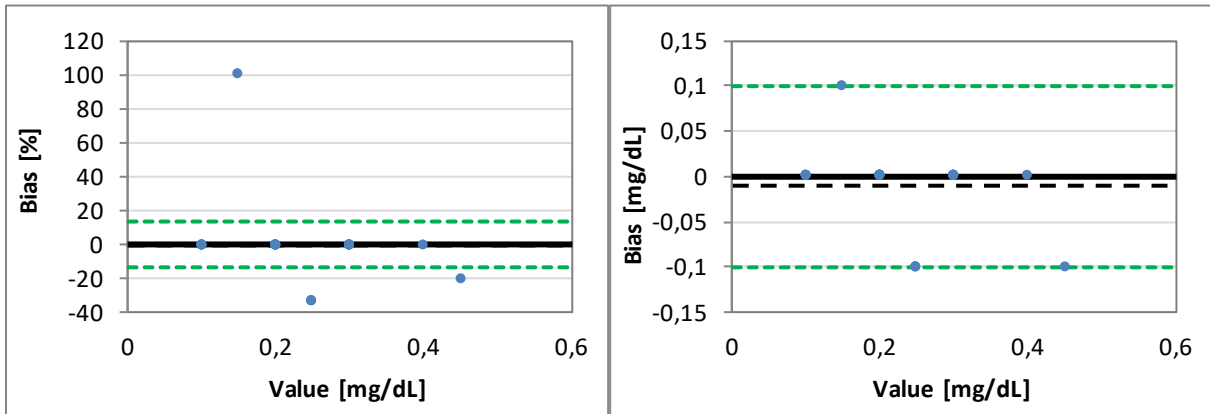
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



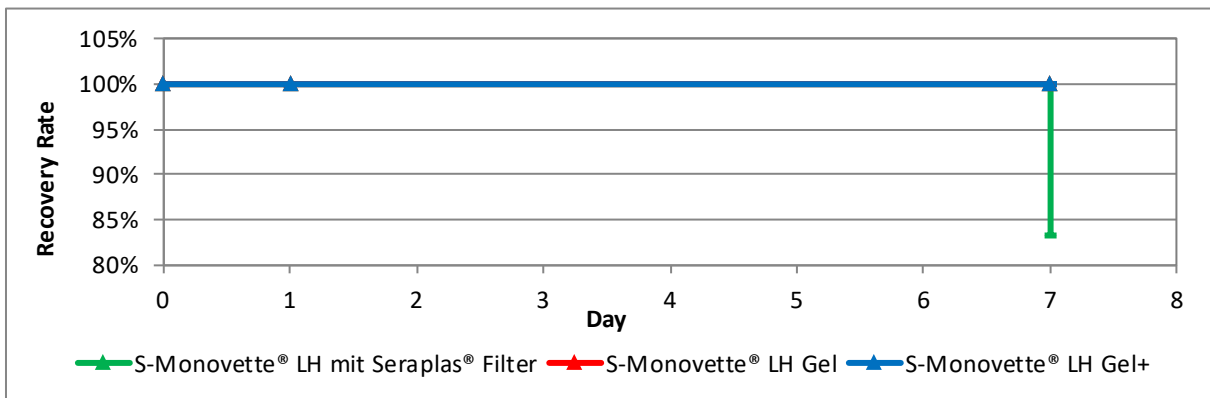
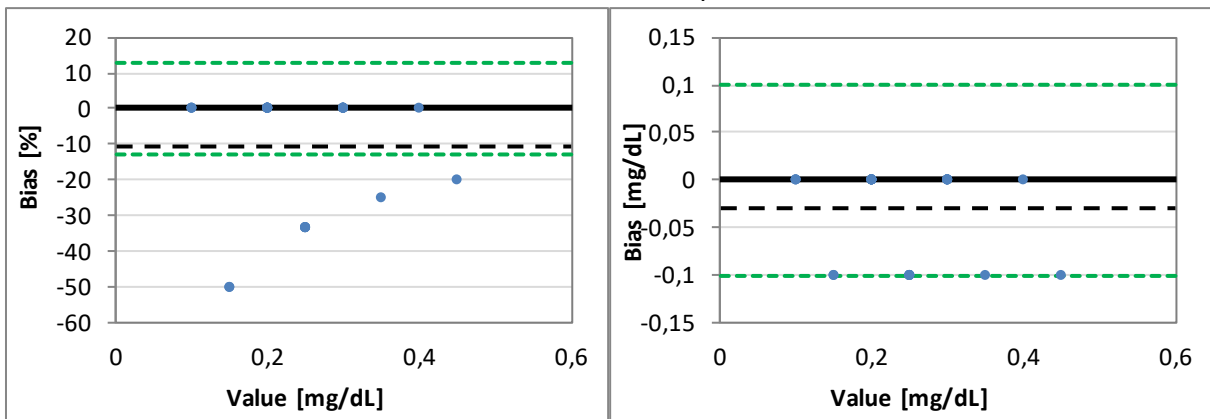


Bilirubin (direct)

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



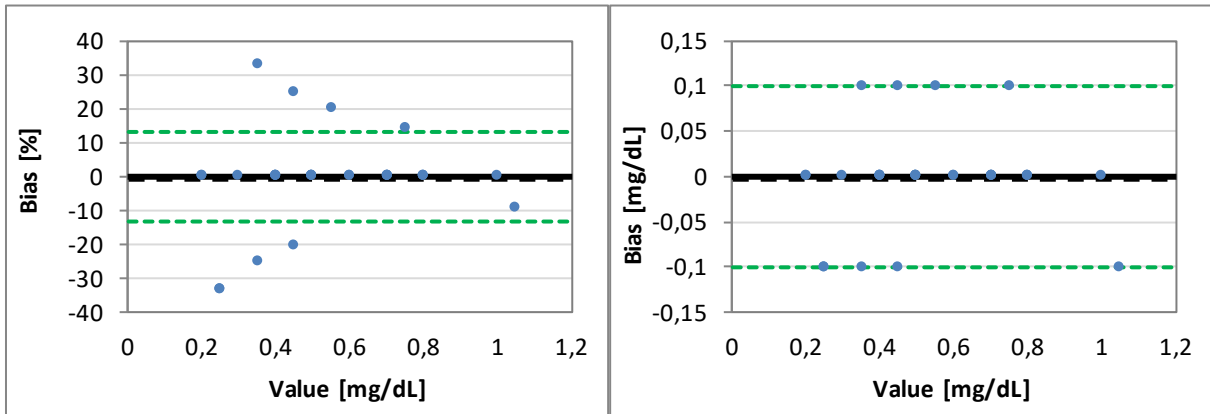
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



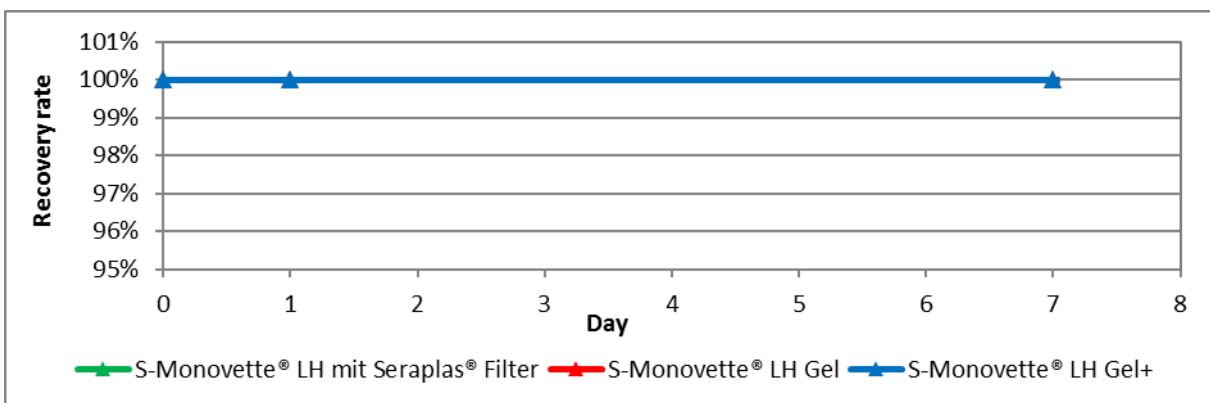
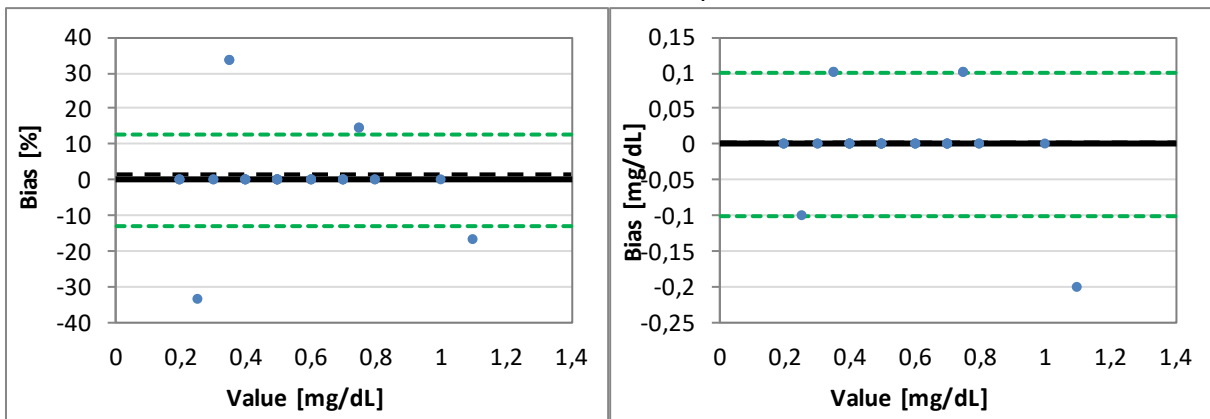


Bilirubin (total)

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

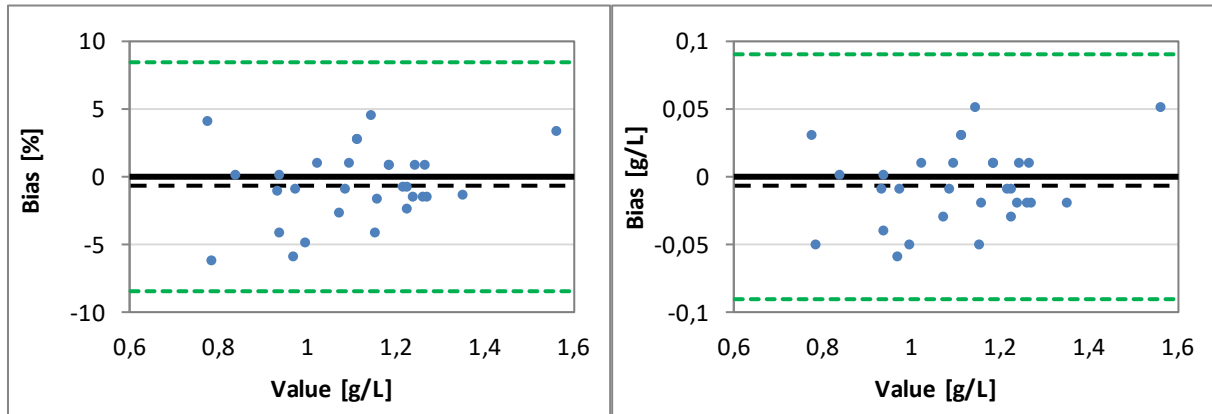


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

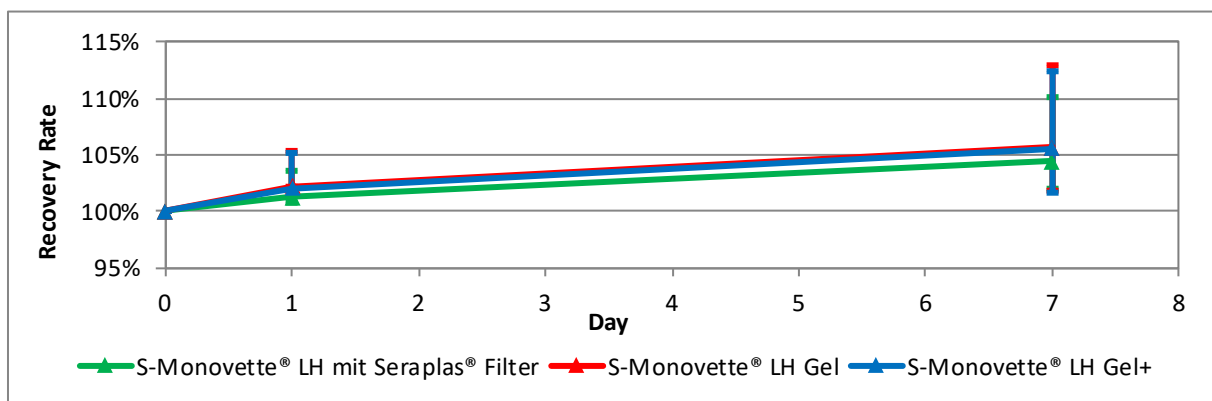
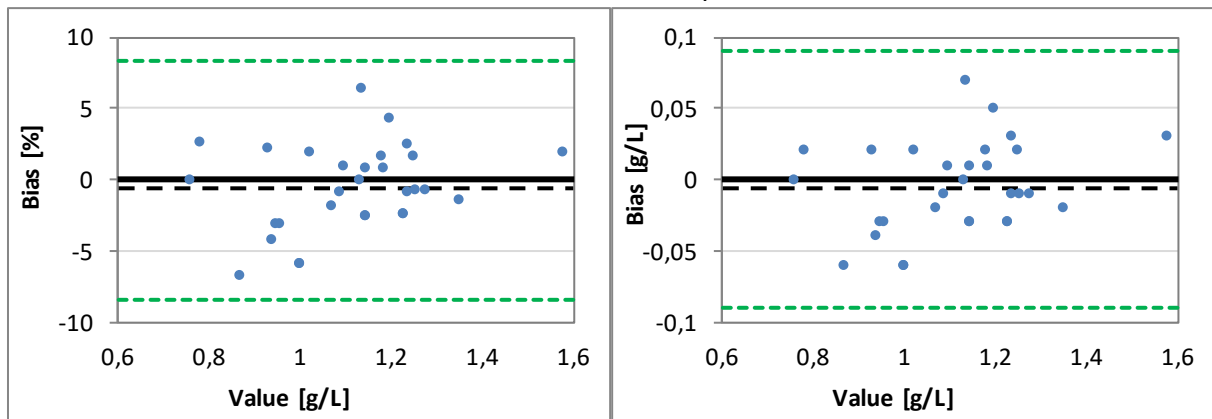


Complement C3

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

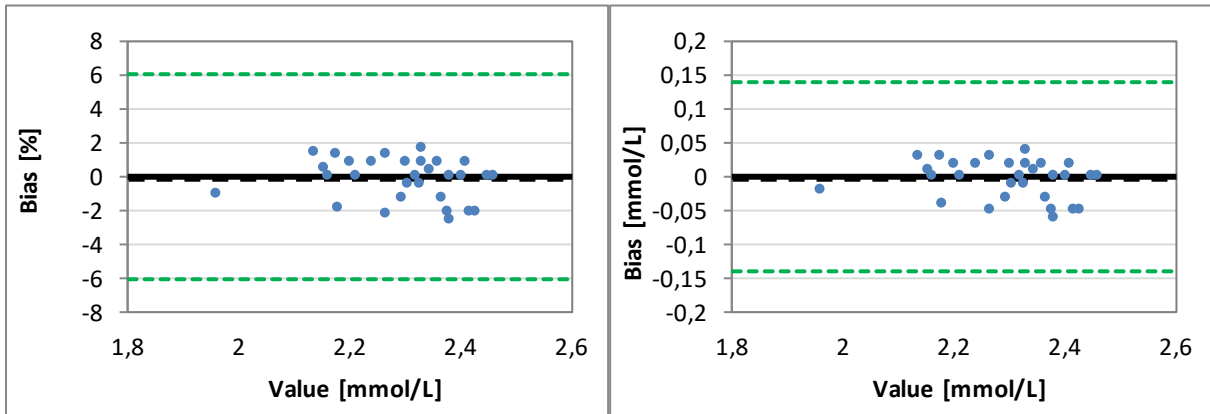


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

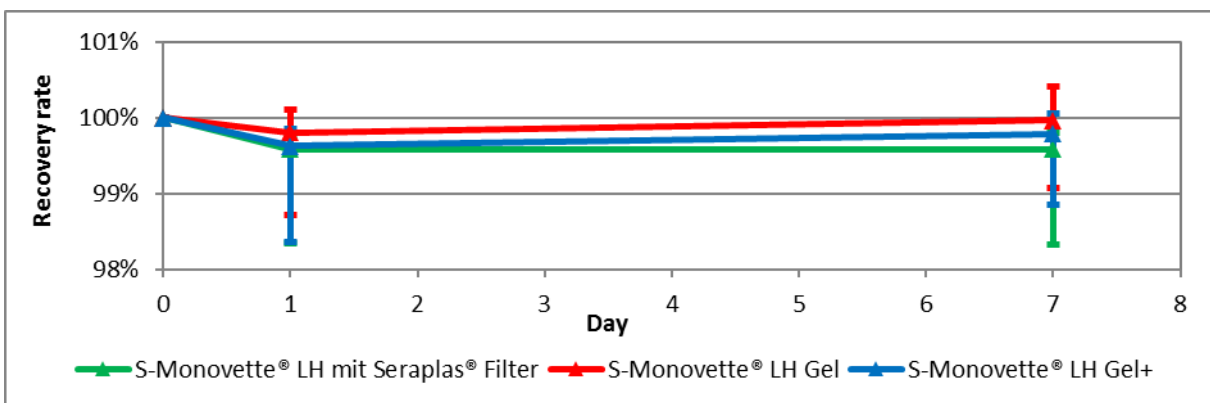
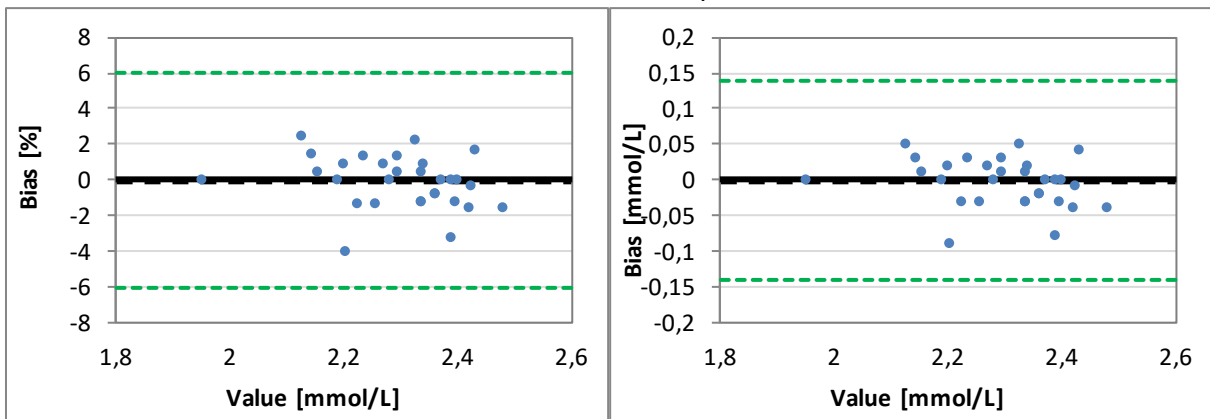


Calcium

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



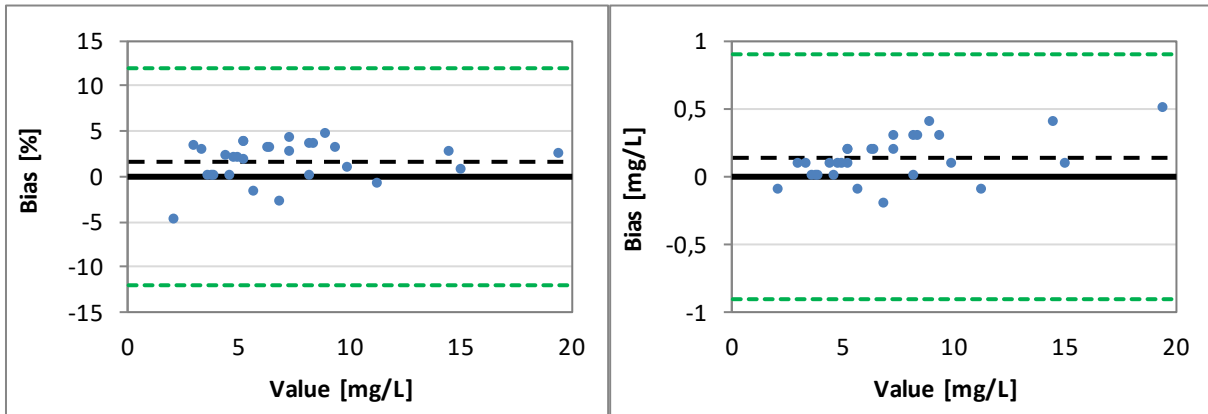
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



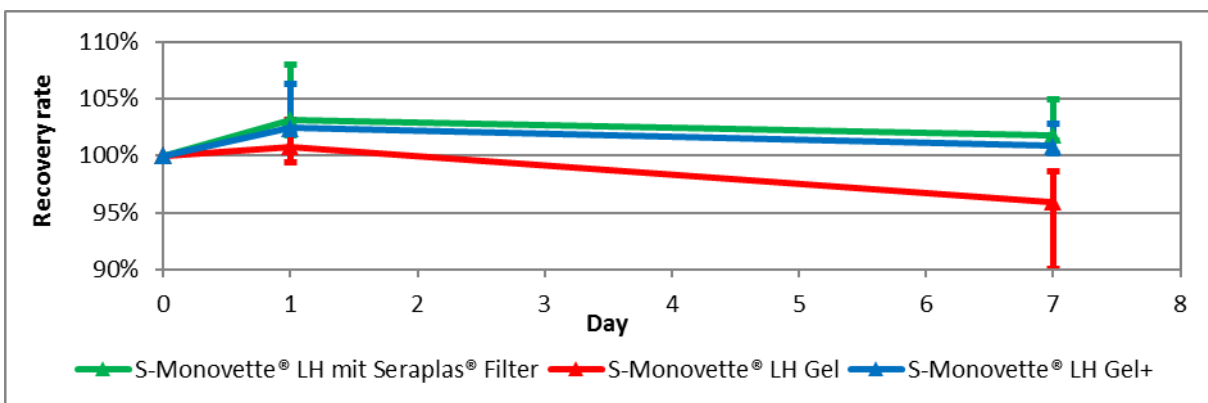
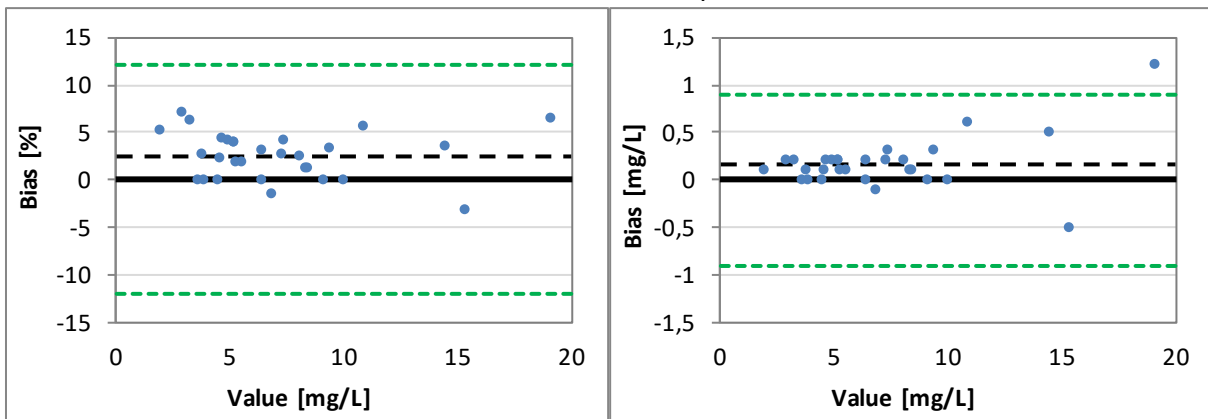


Carbamazepine

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



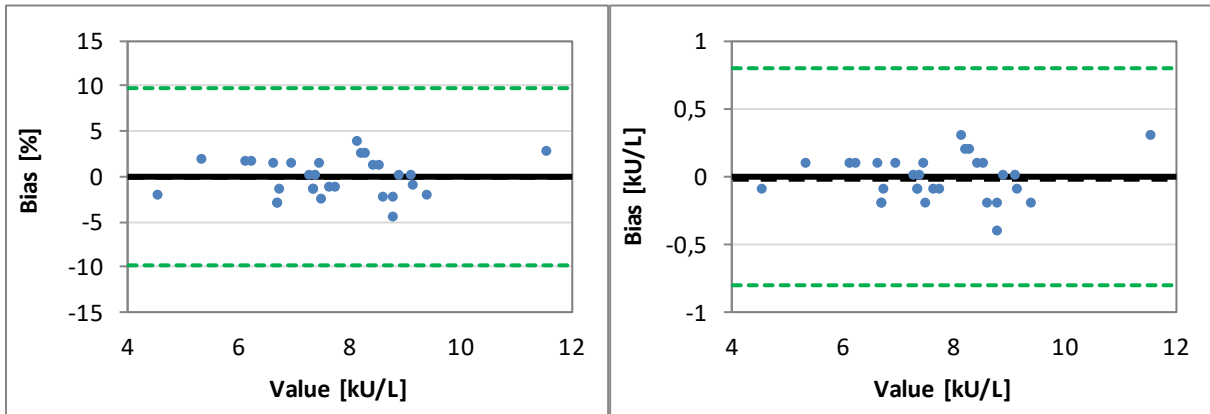
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



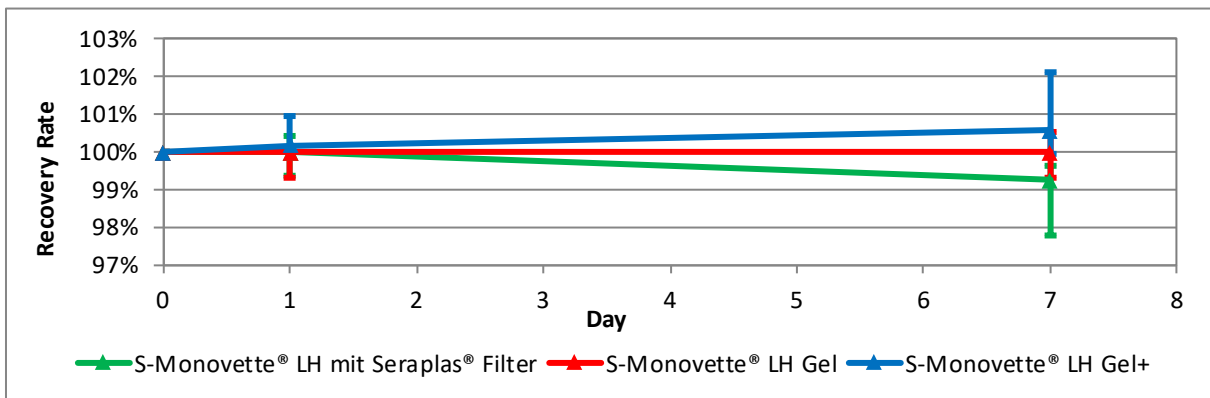
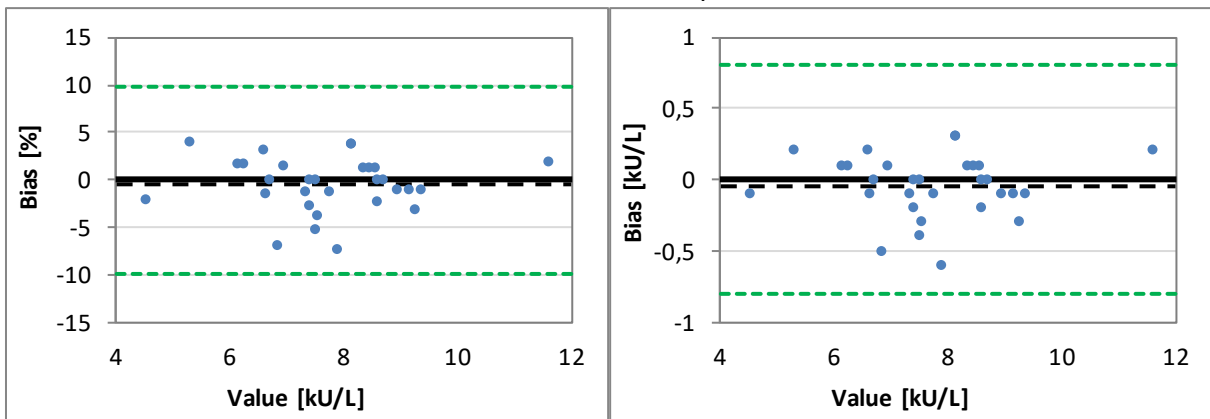


CHE

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



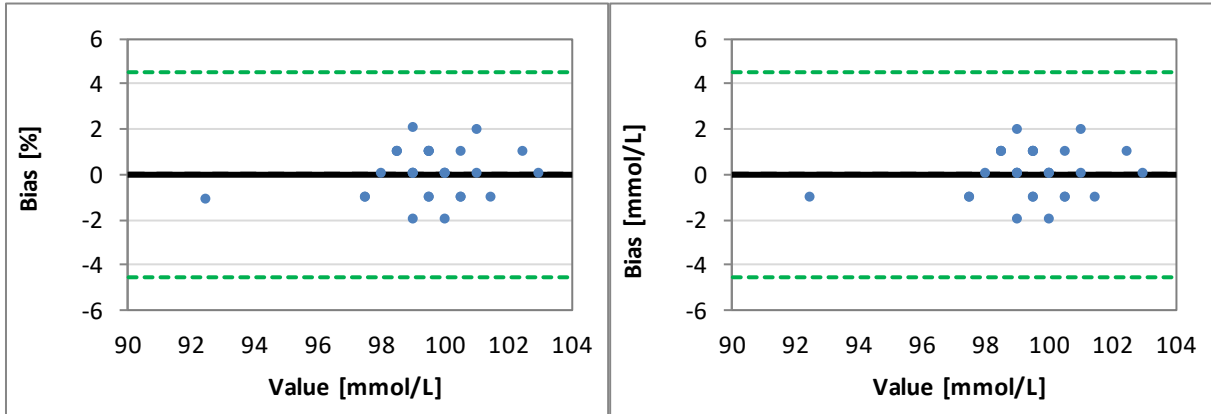
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



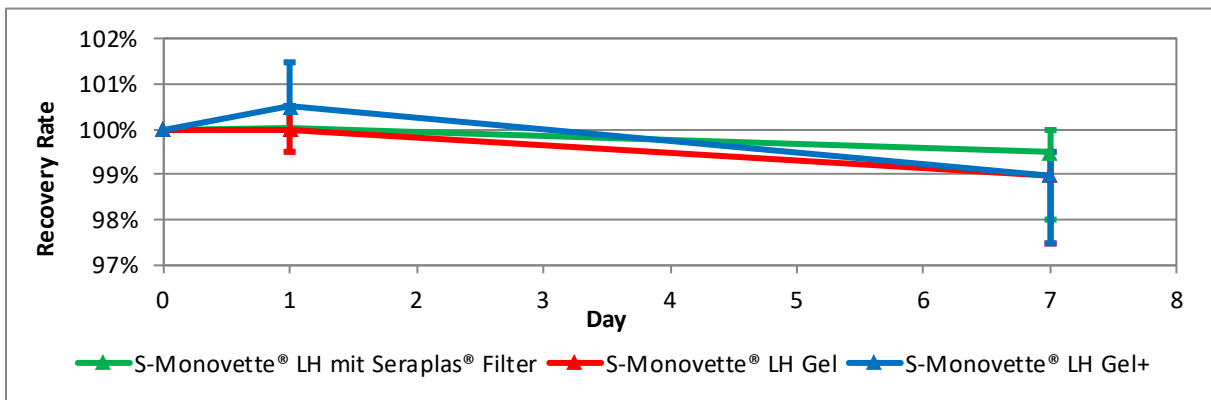
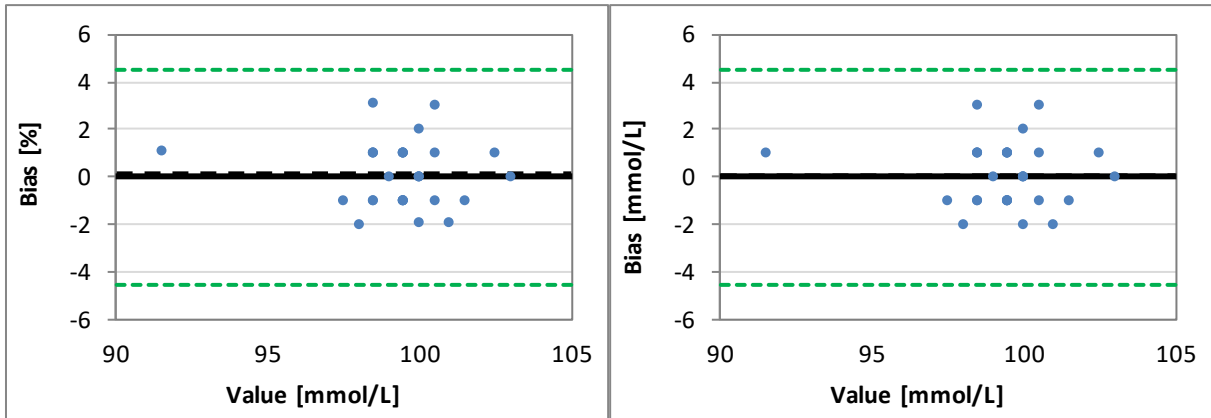


Chloride

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



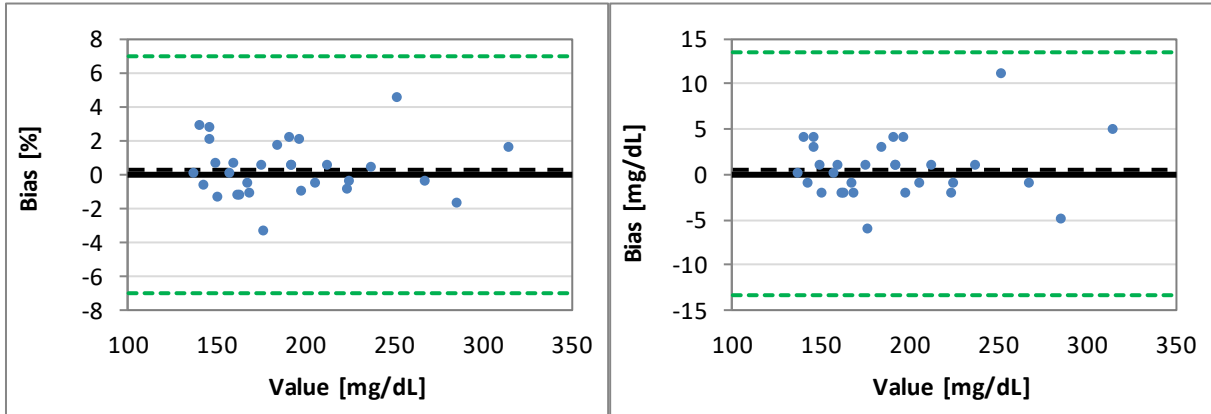
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



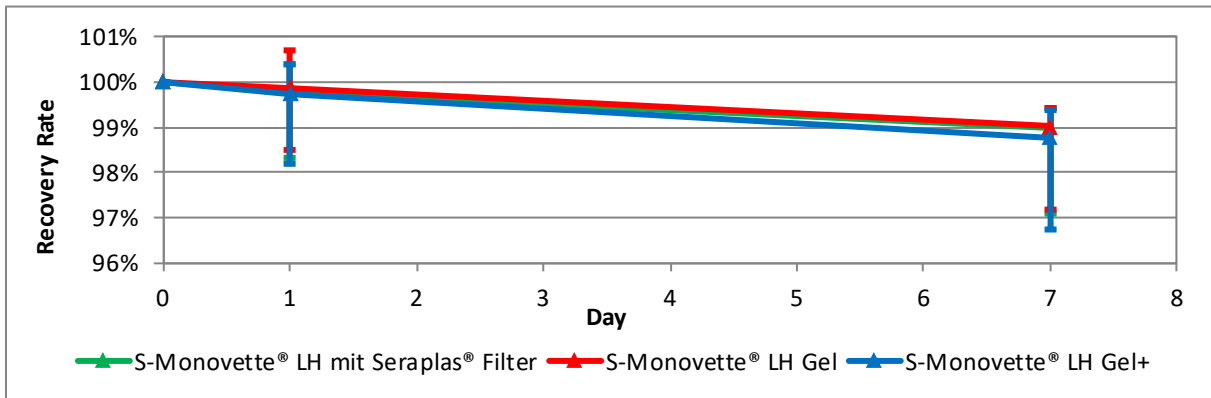
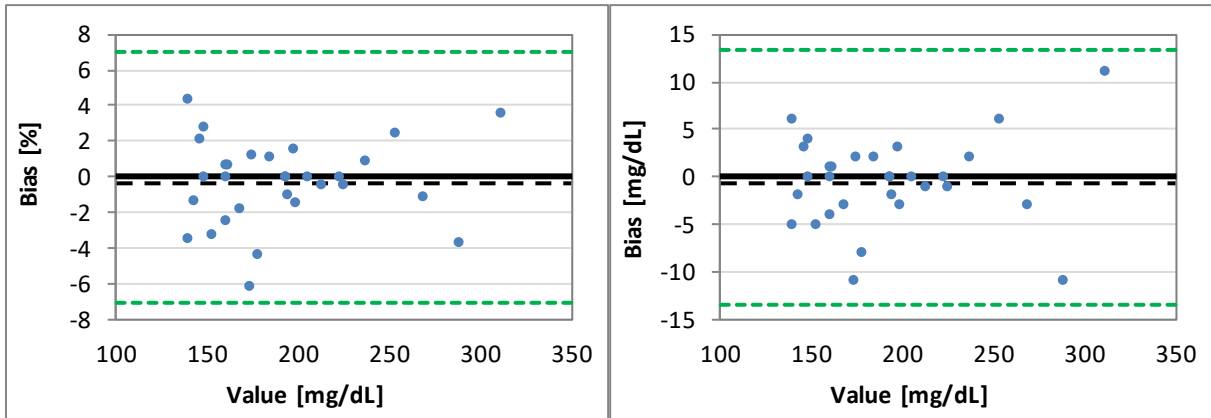


Cholesterol

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



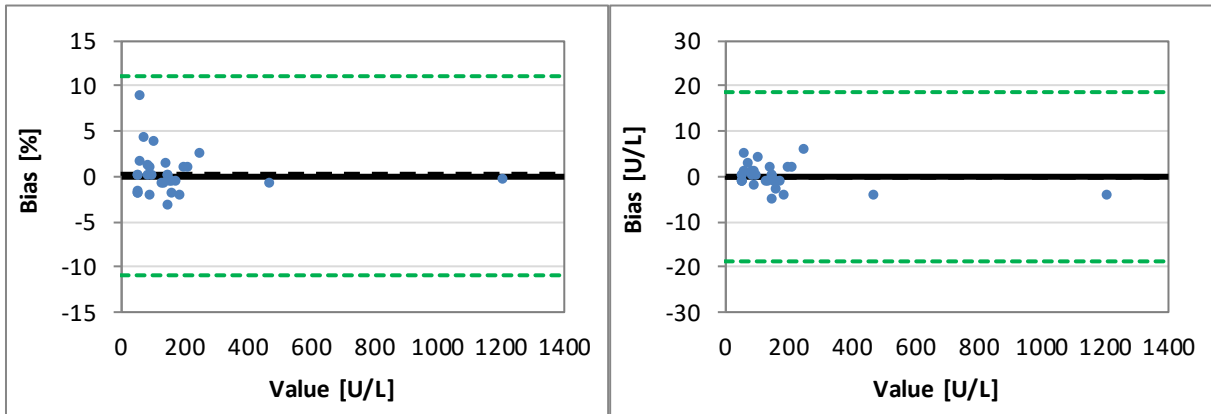
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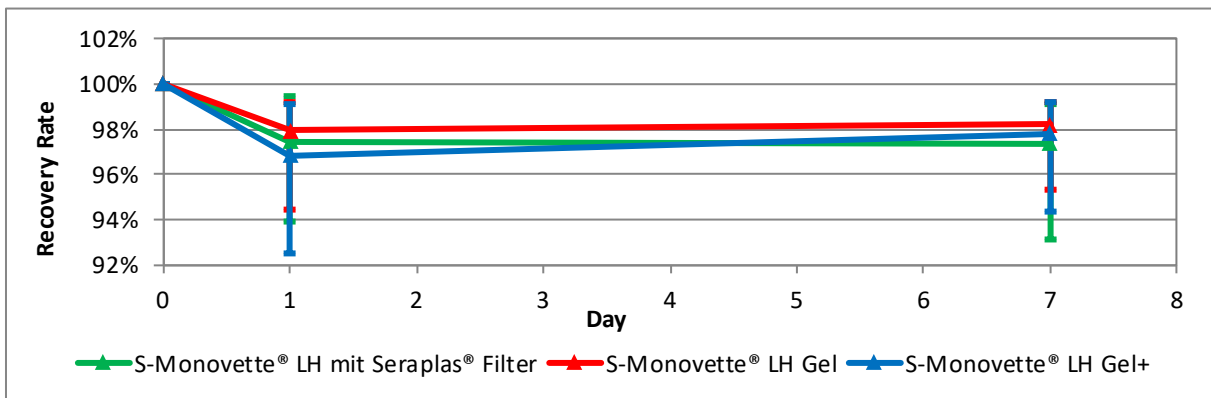
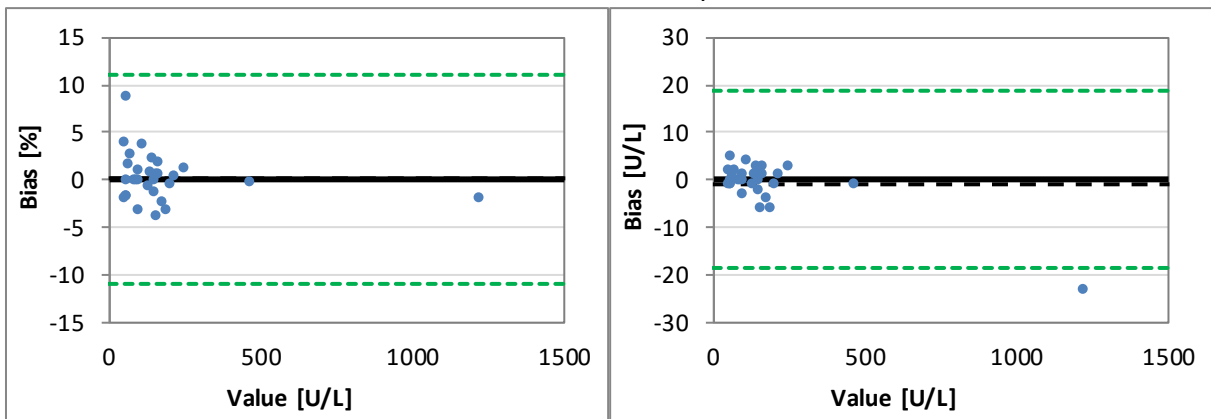


CK

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

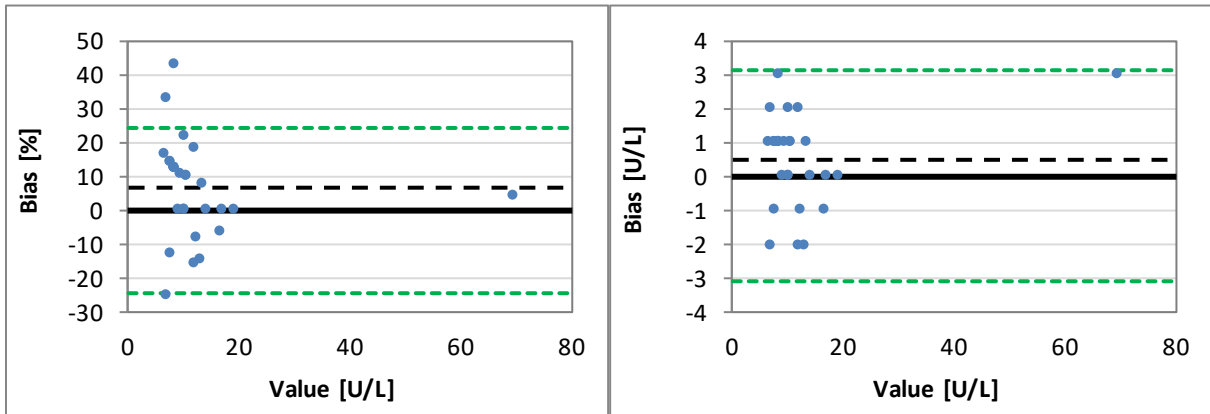


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

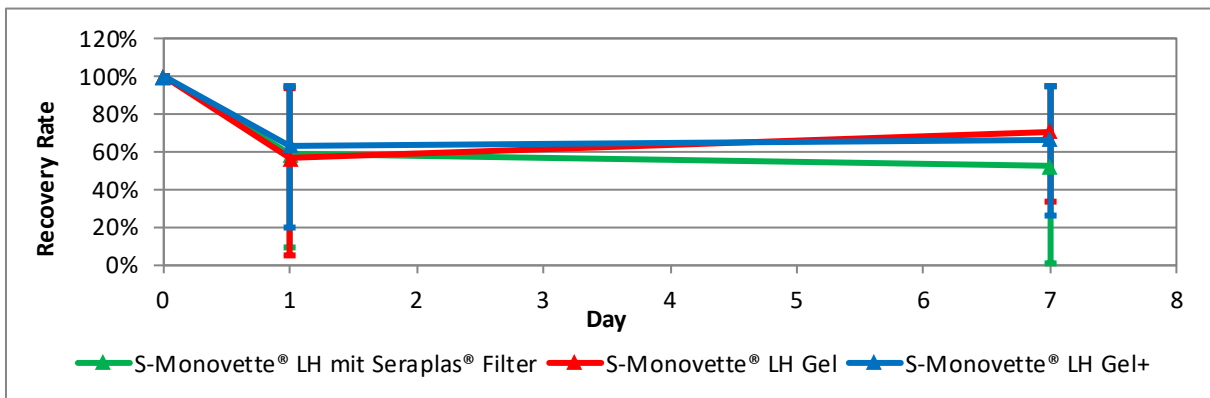
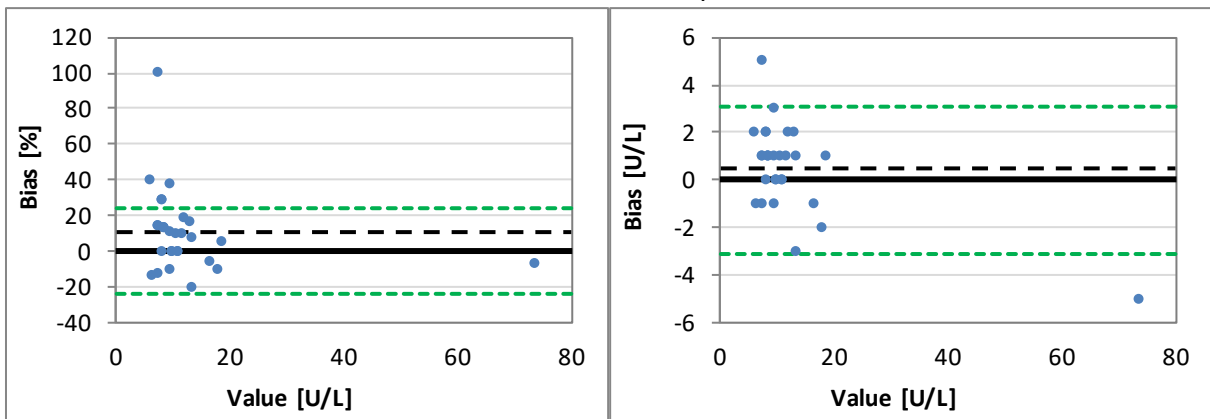


CK-MB

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



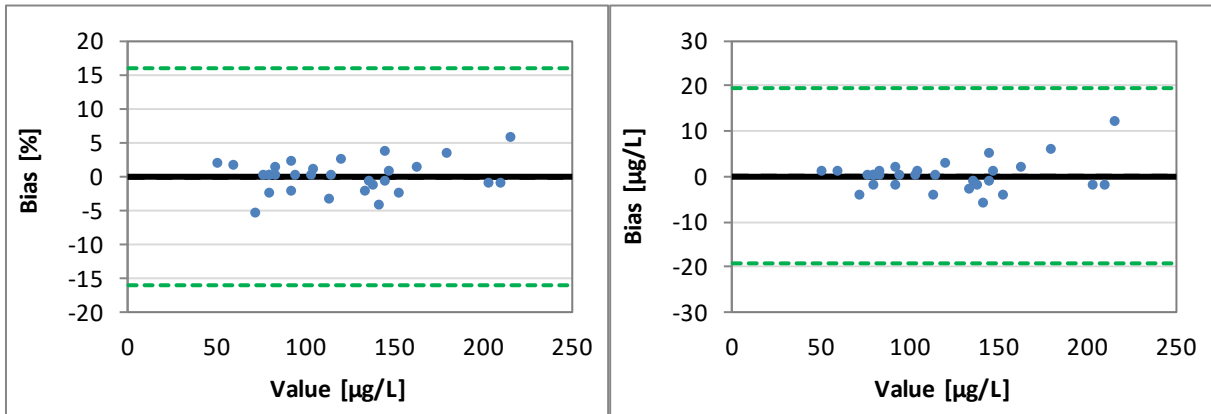
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



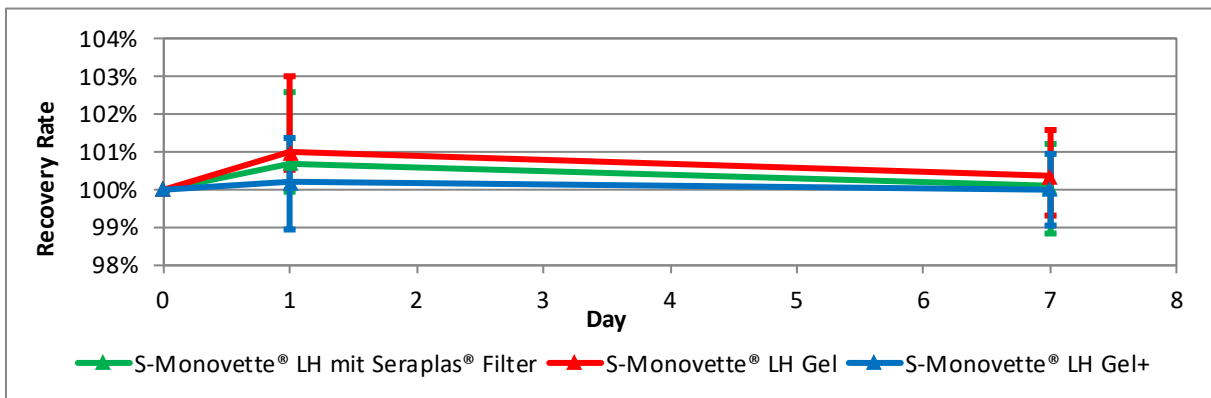
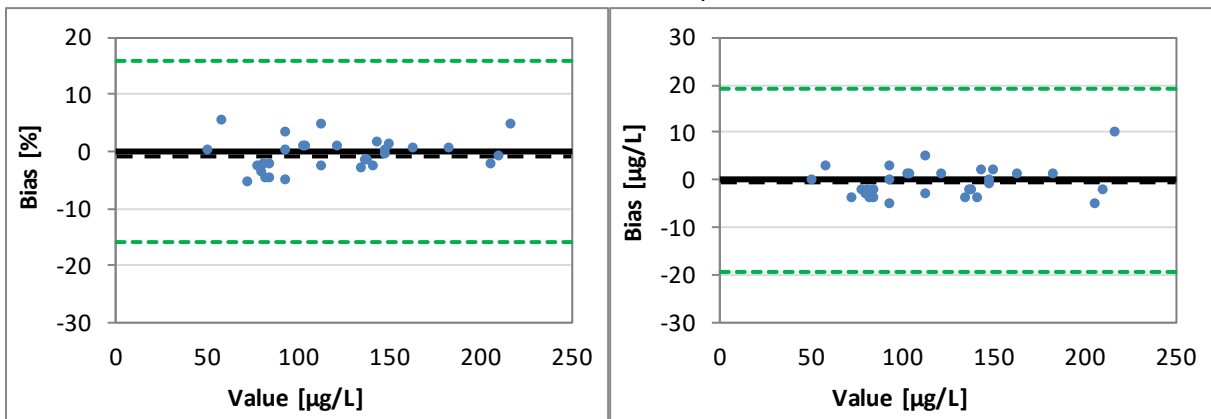


Cortisol

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



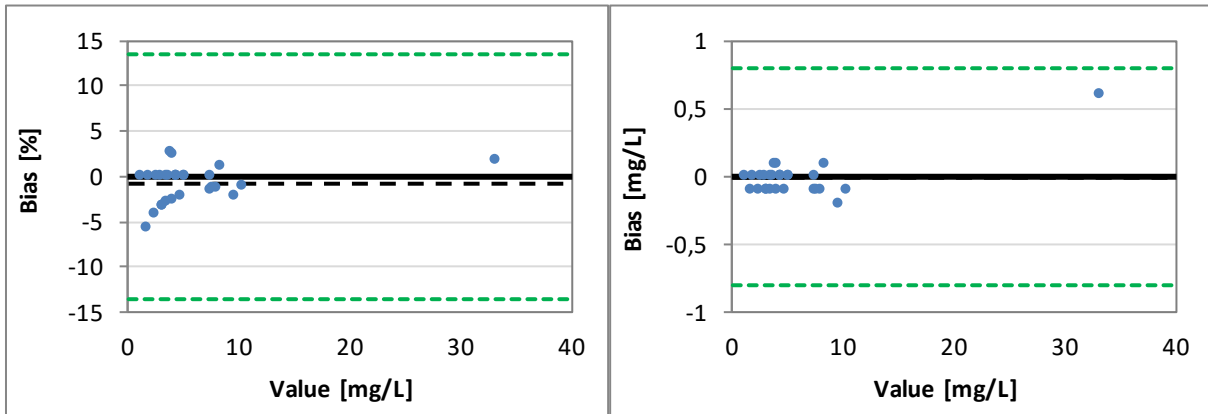
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



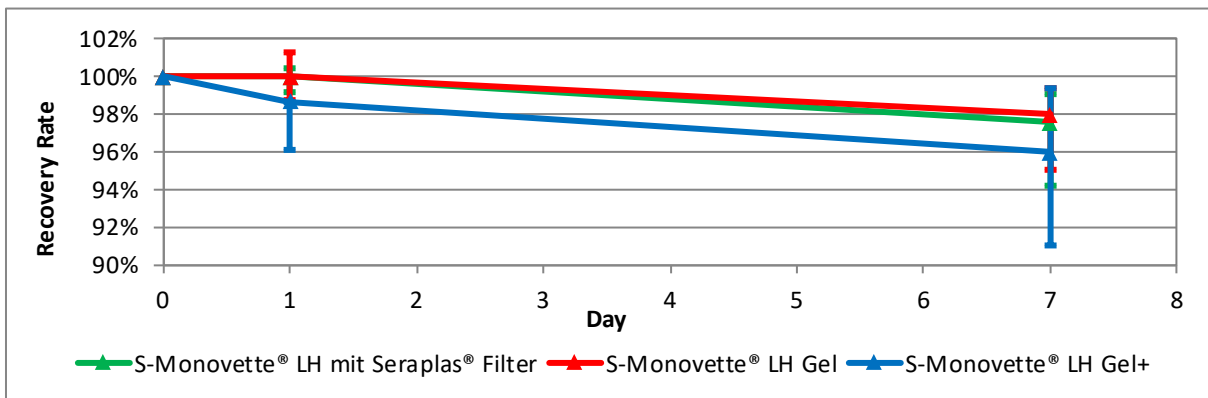
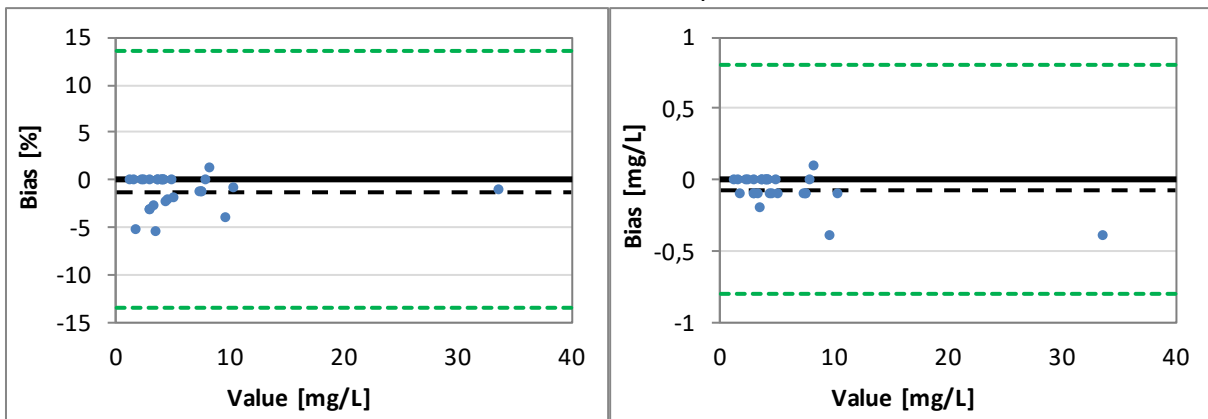


CRP

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

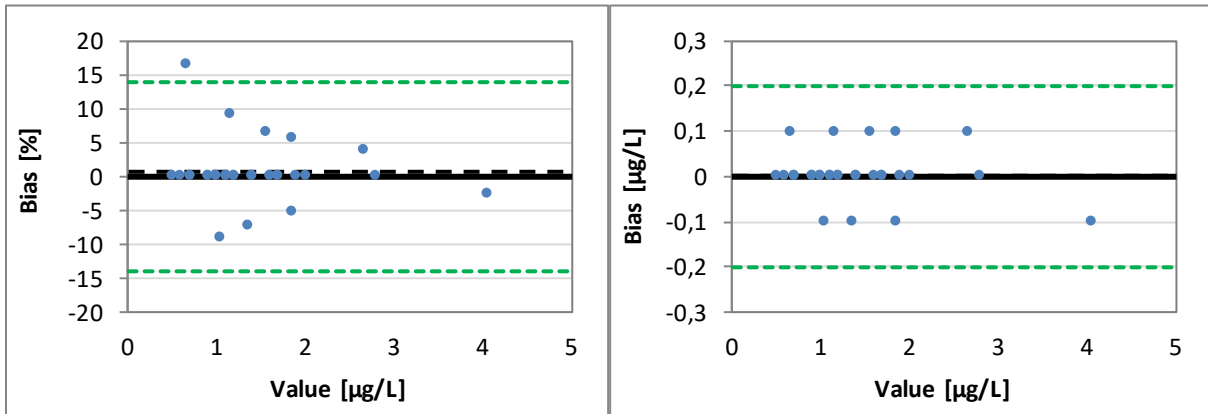


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

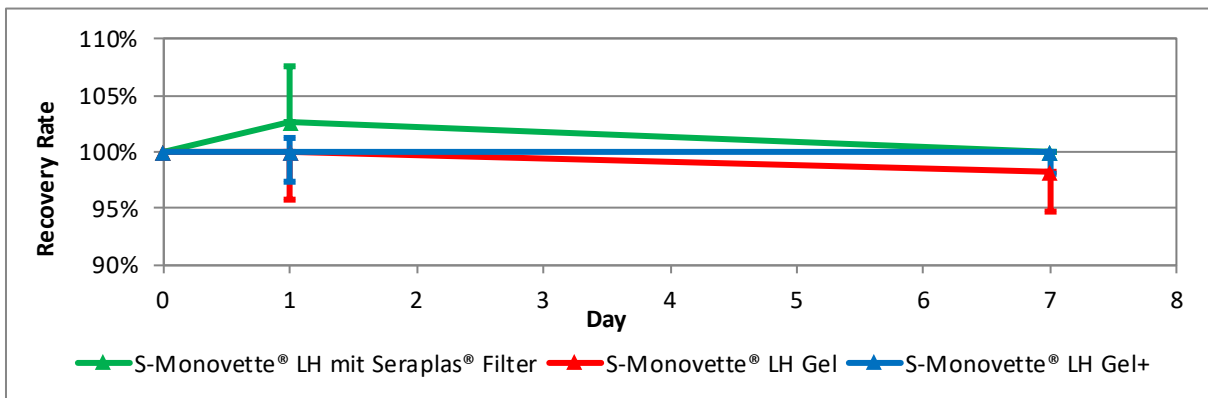
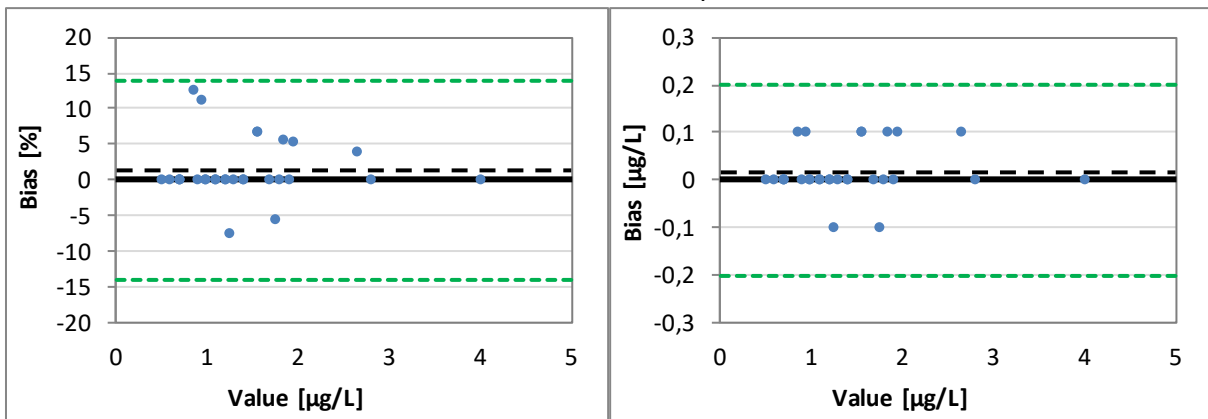


Digoxin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

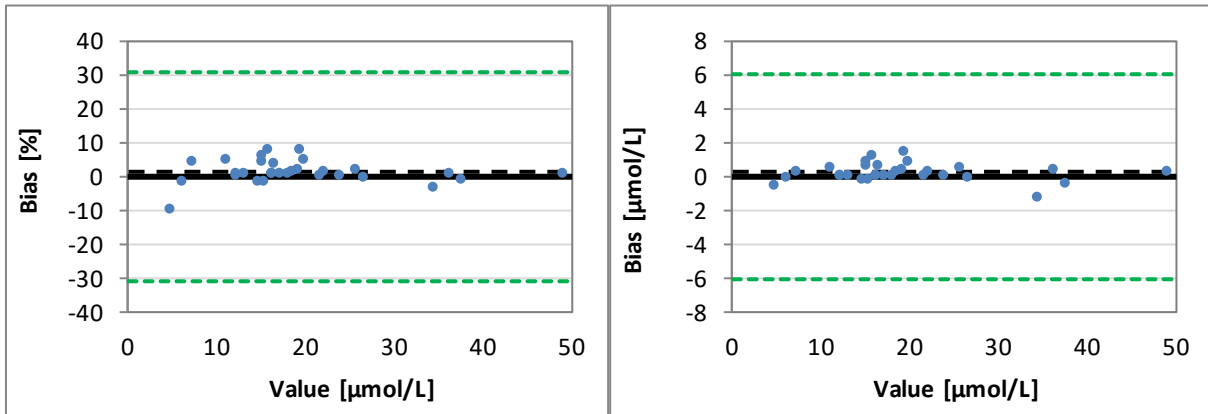


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

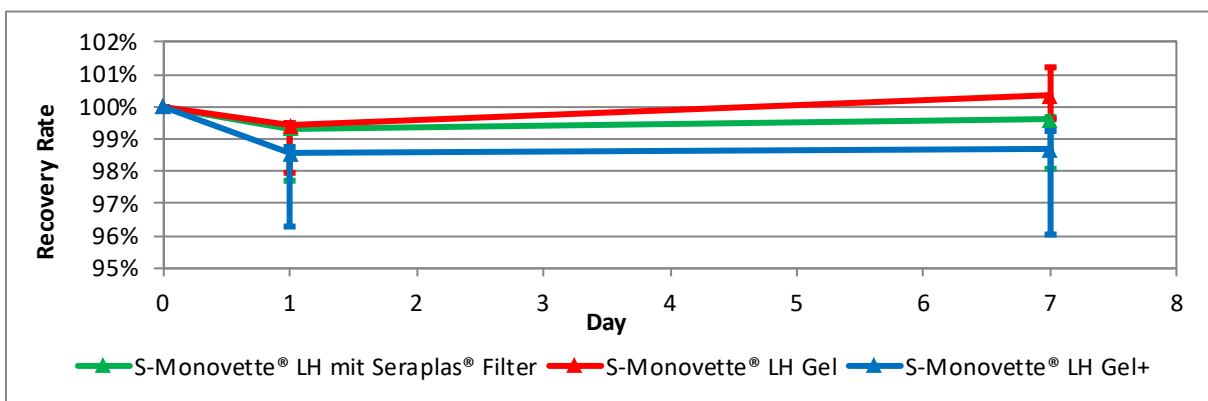
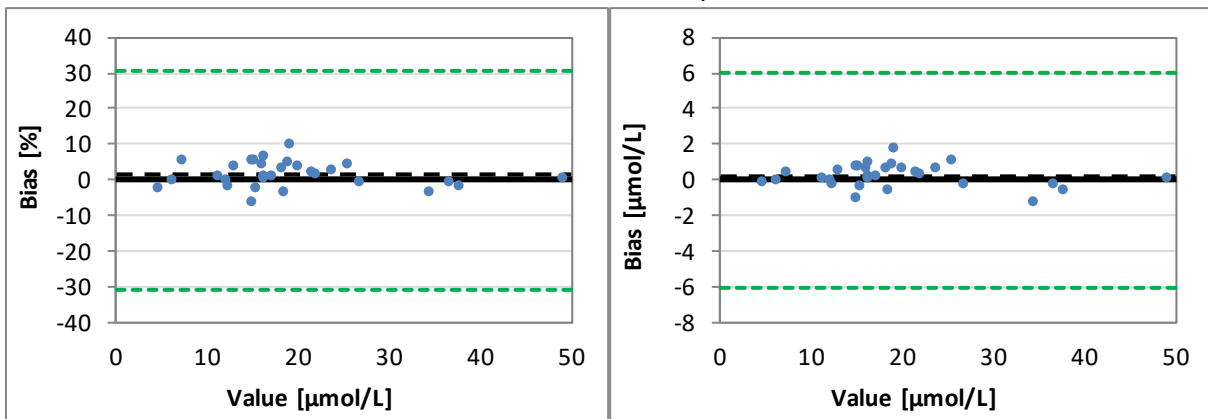


Iron

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



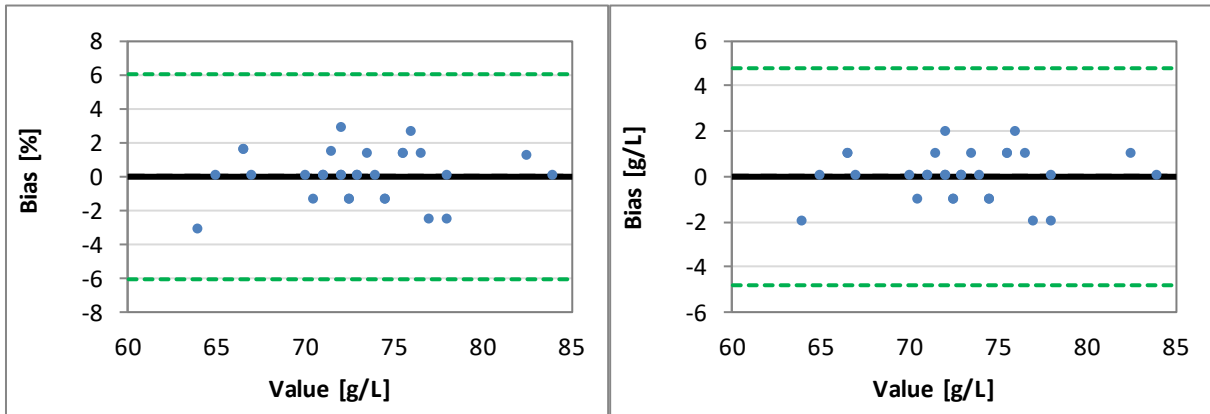
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



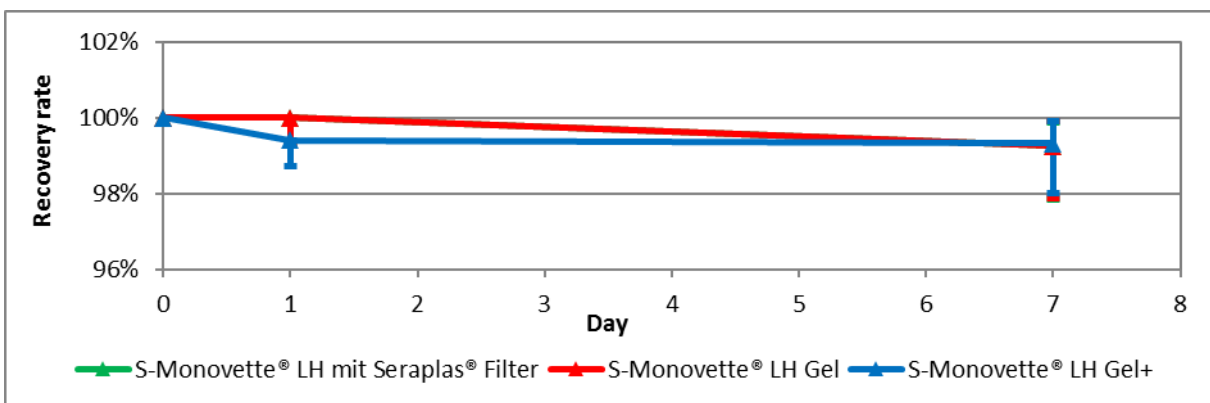
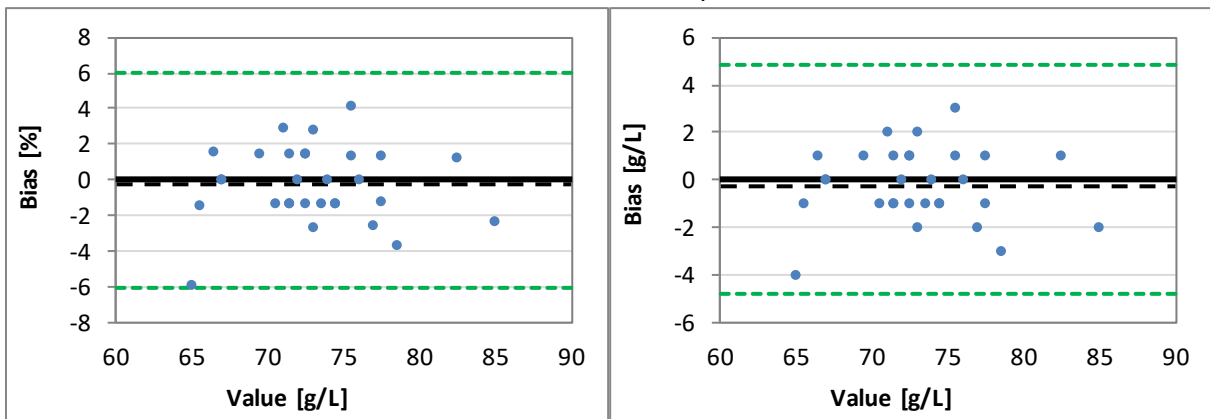


Total Protein

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

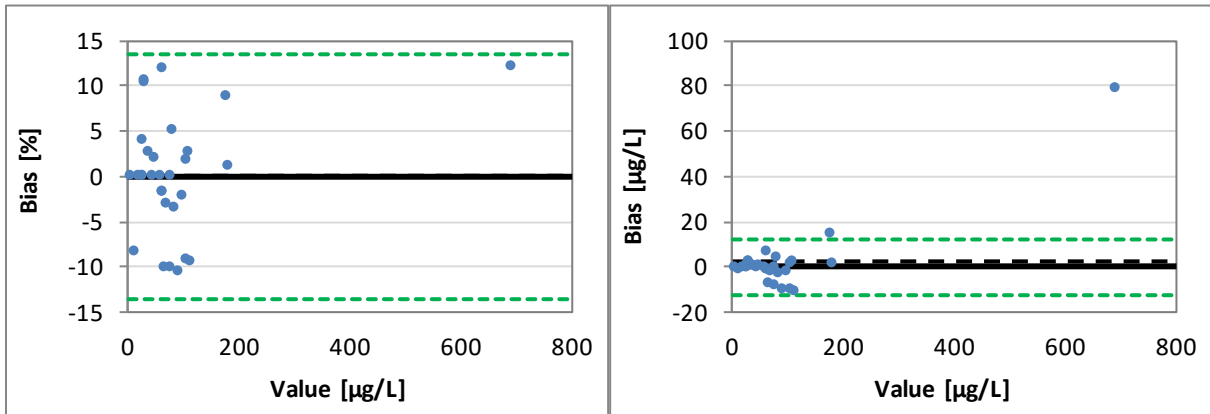


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

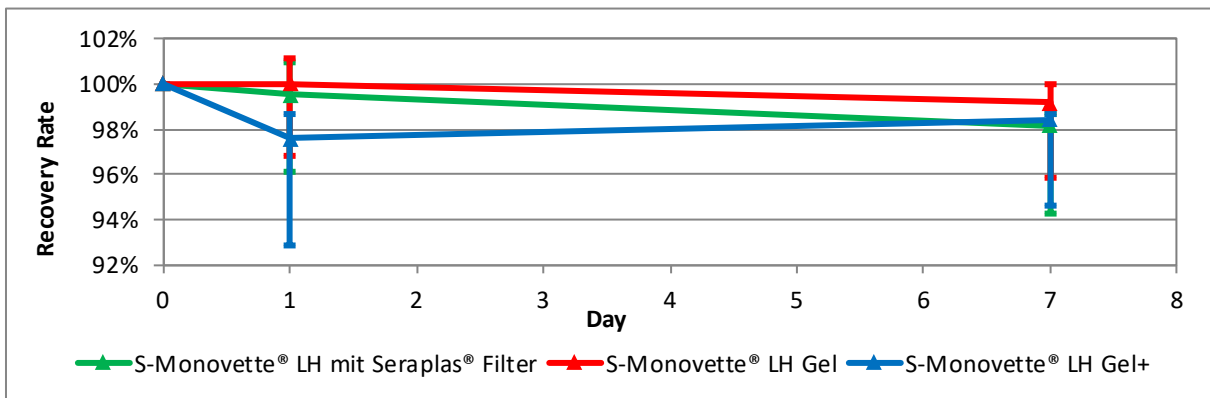
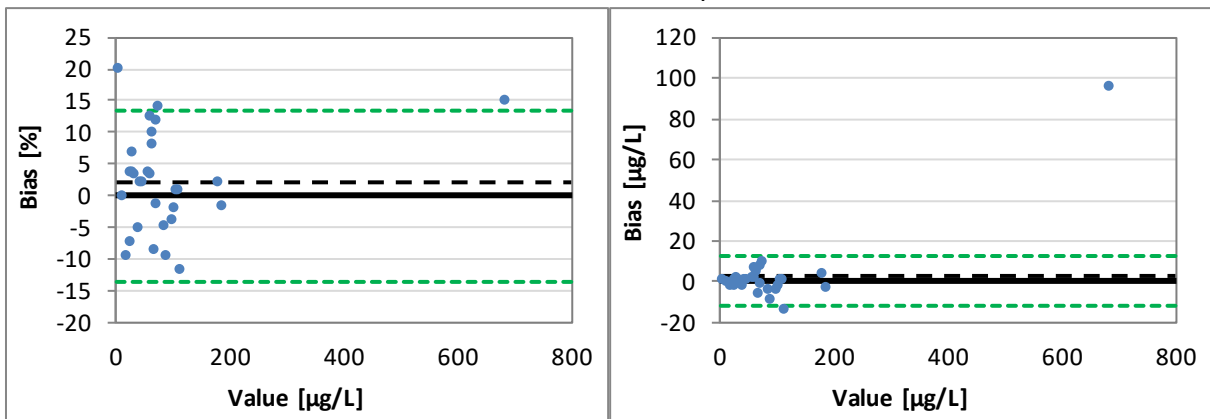


Ferritin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



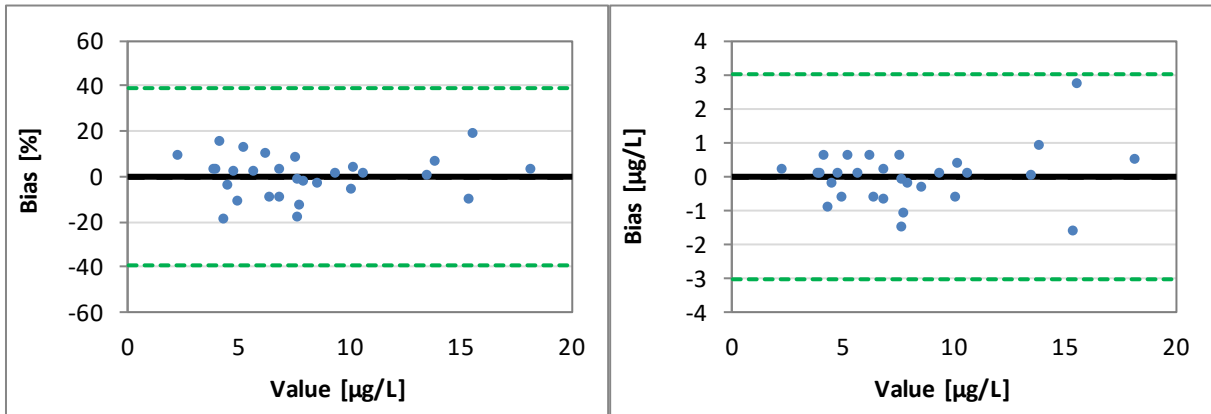
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



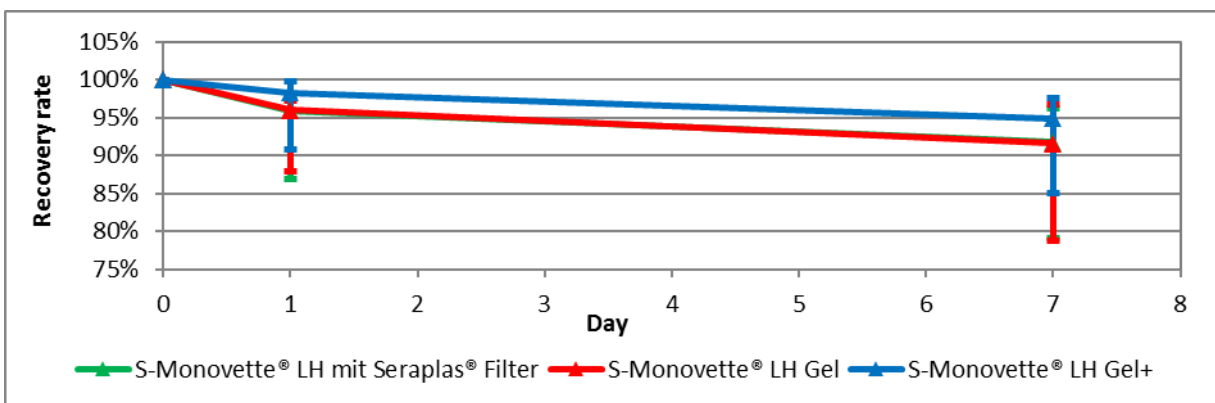
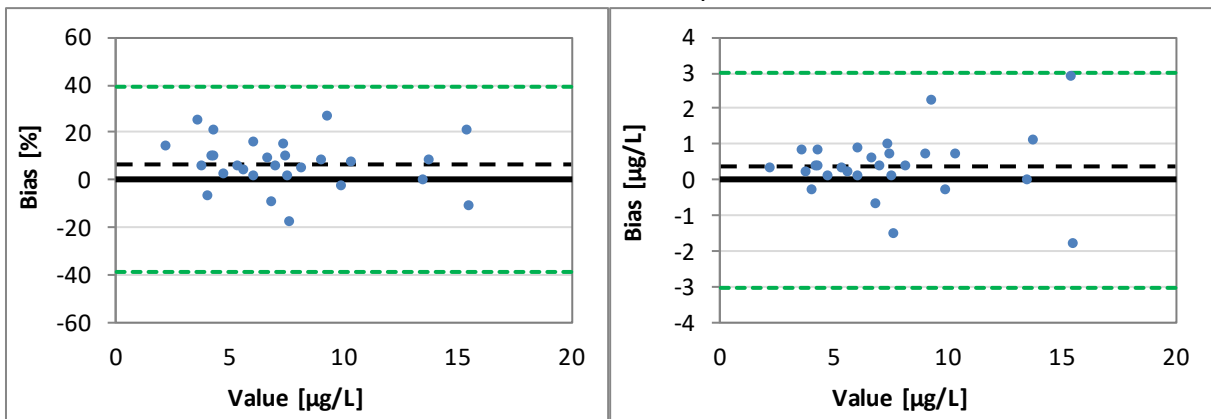


Folate

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

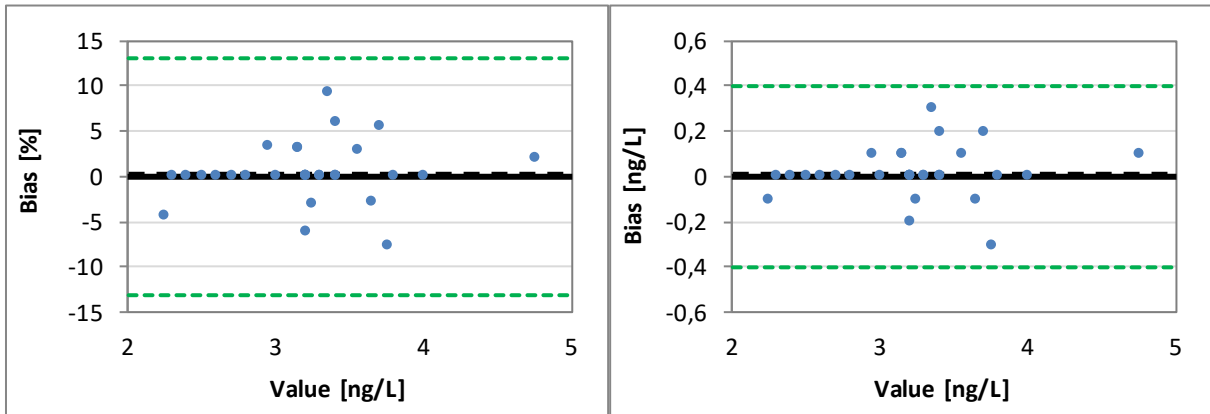


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

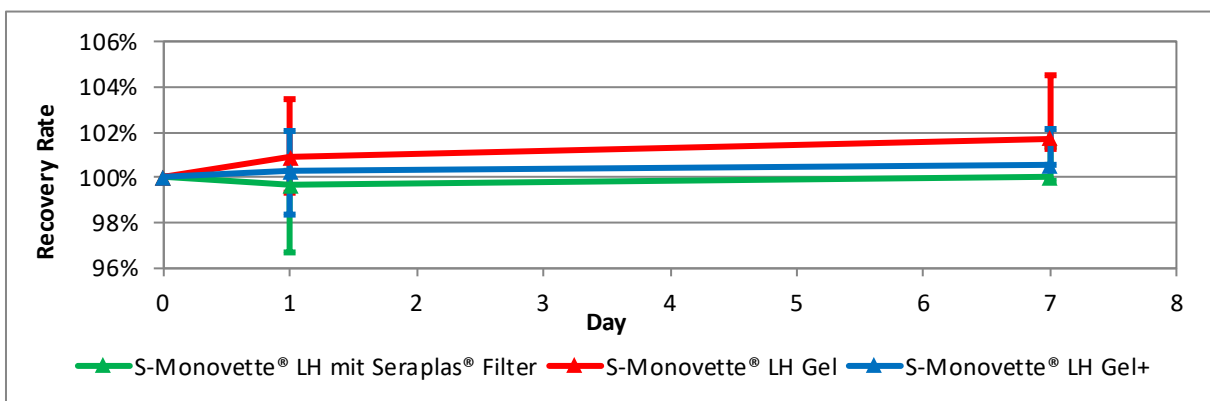
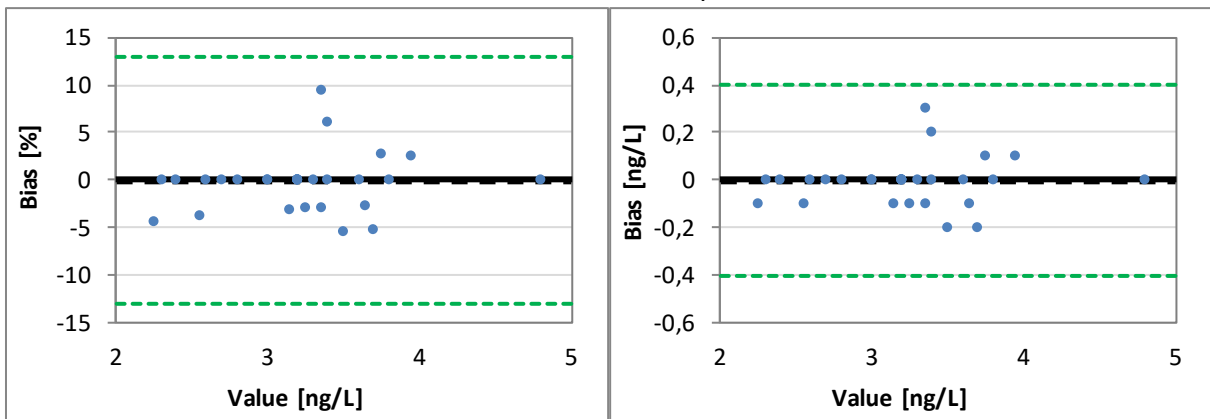


ft3

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

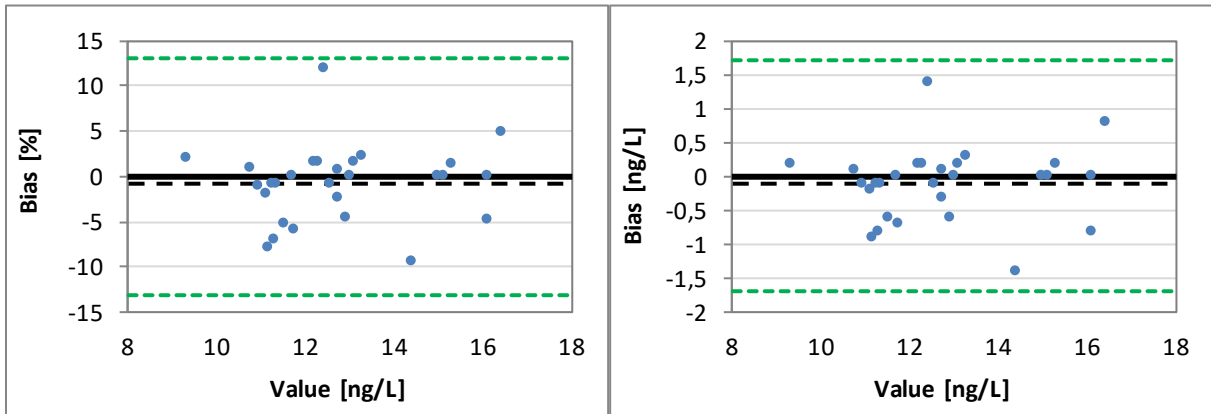


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

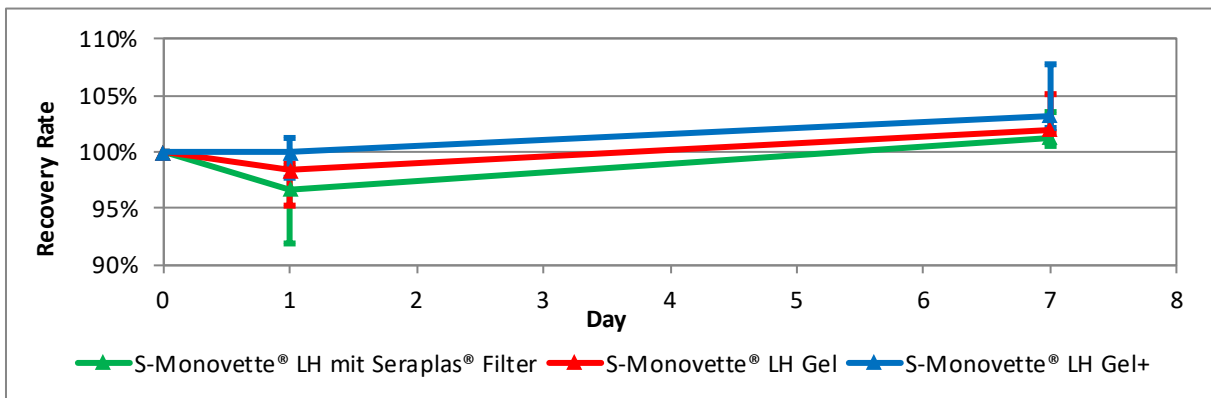
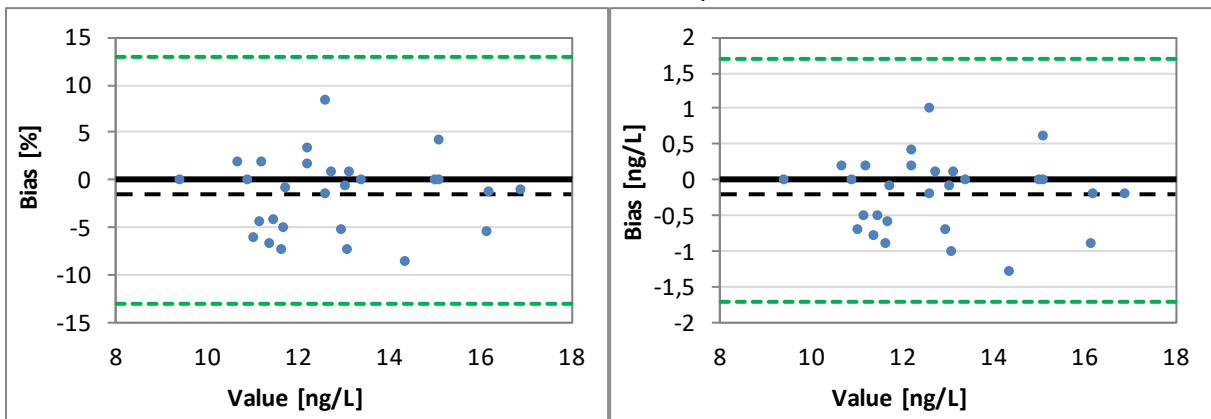


ft4

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



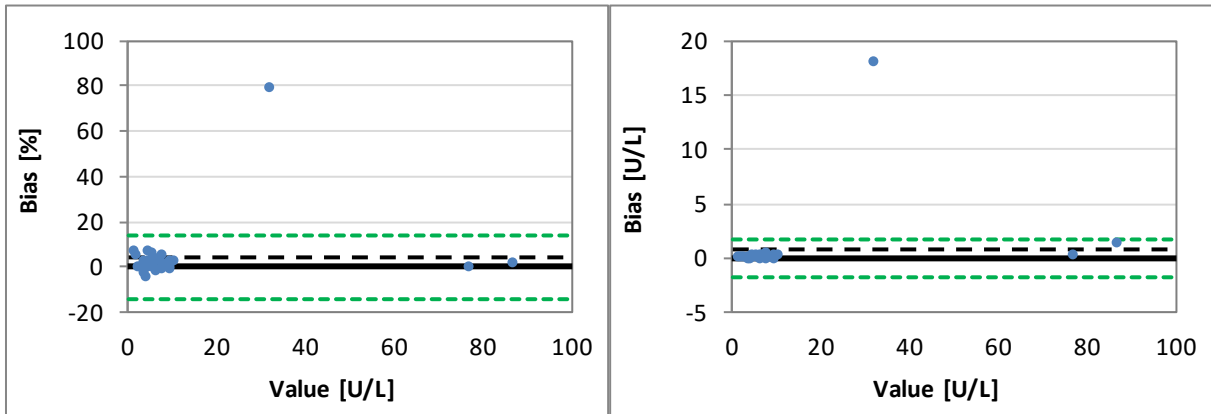
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



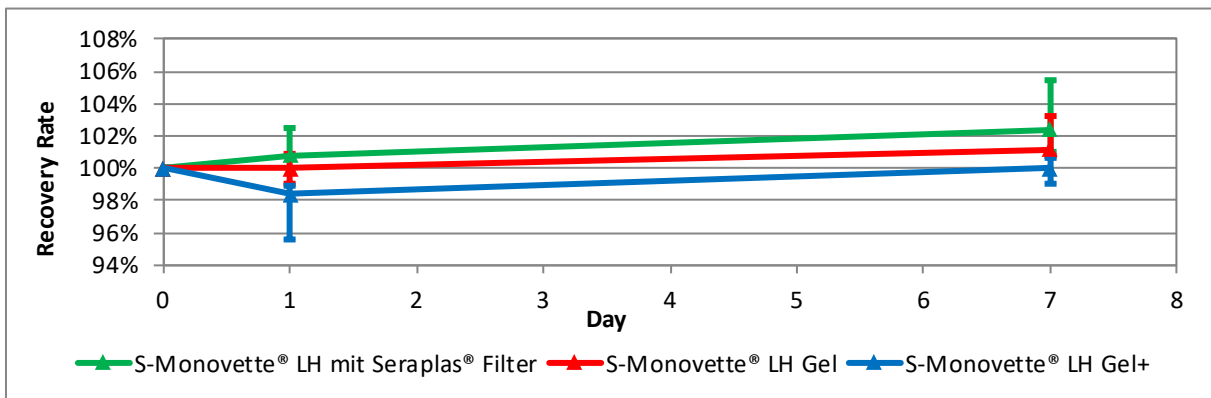
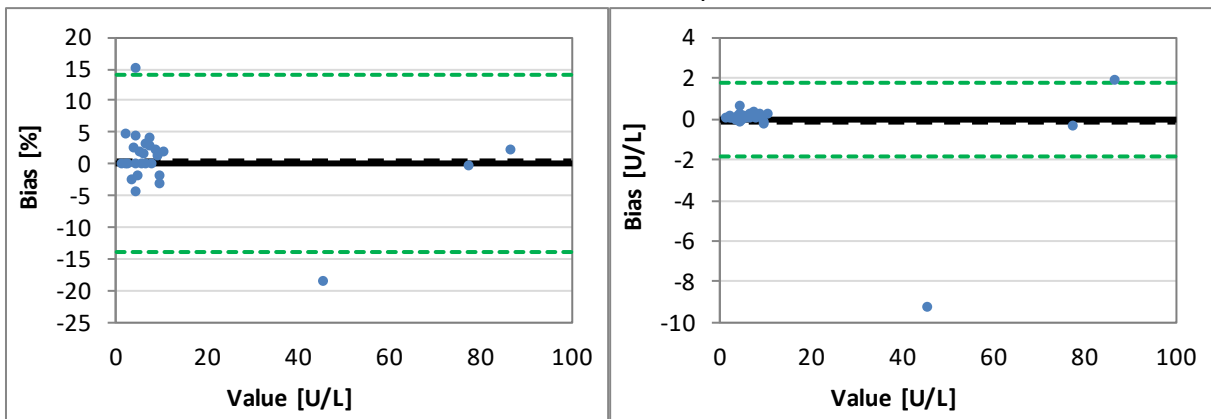


FSH

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

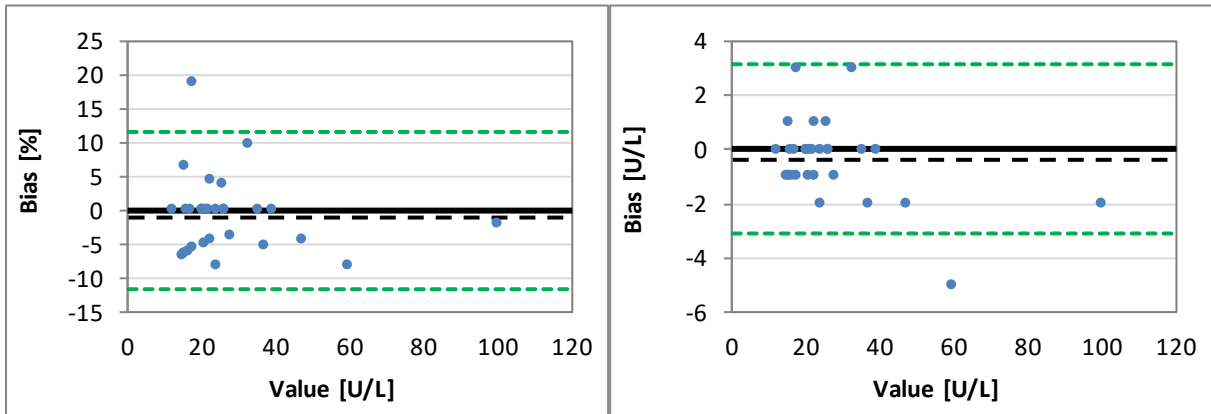


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

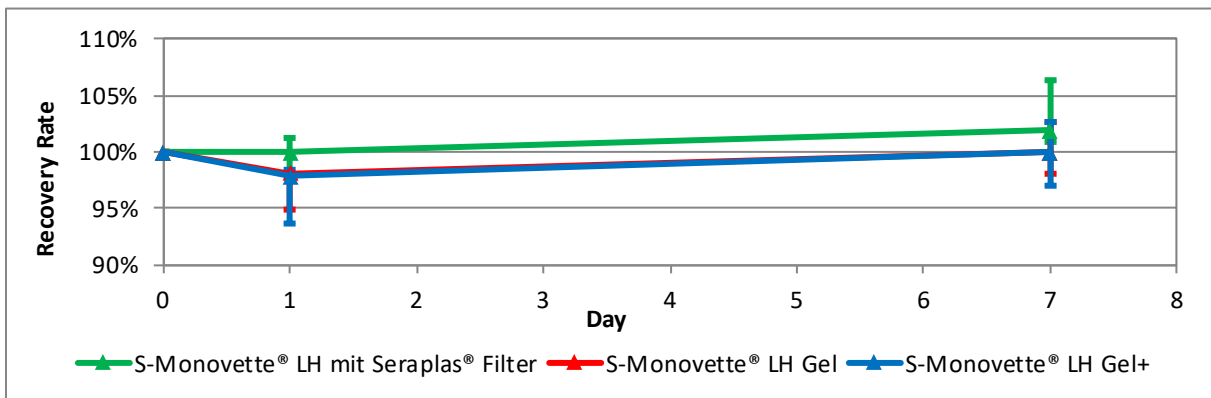
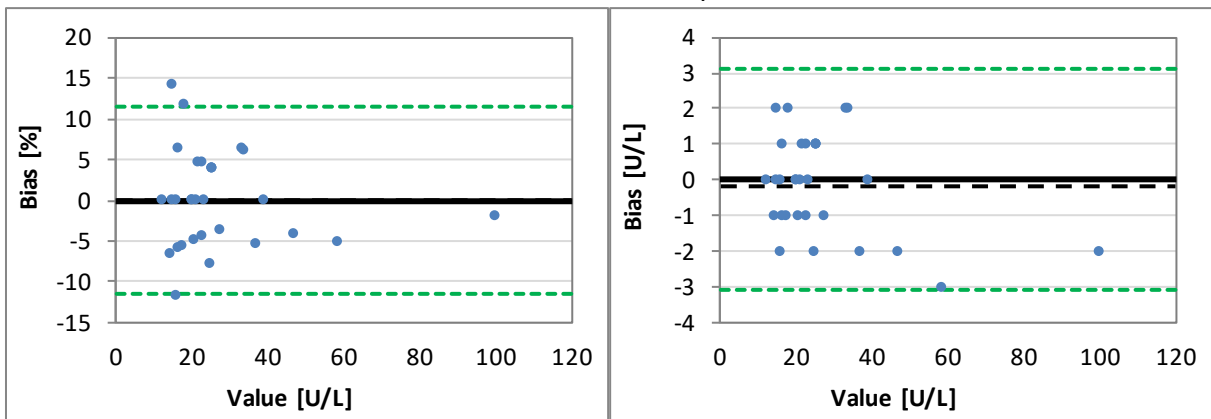


GGT

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



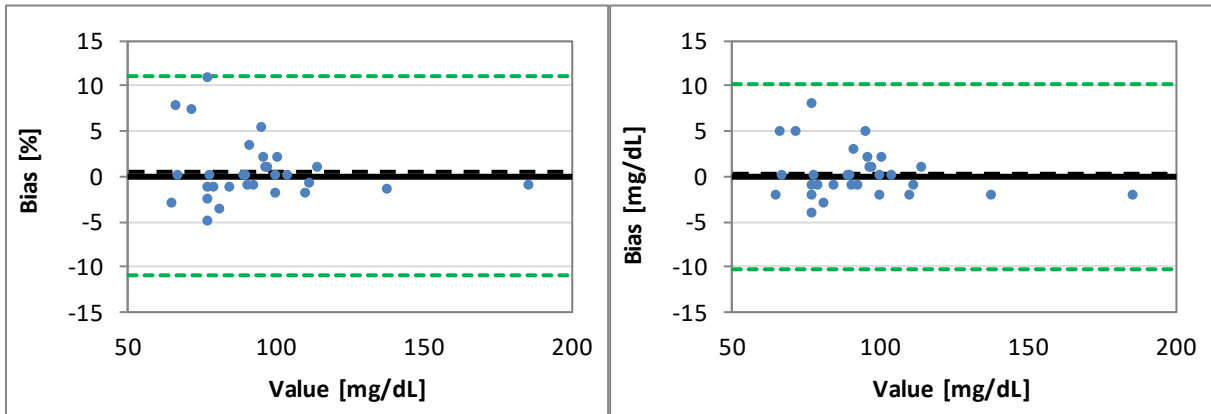
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



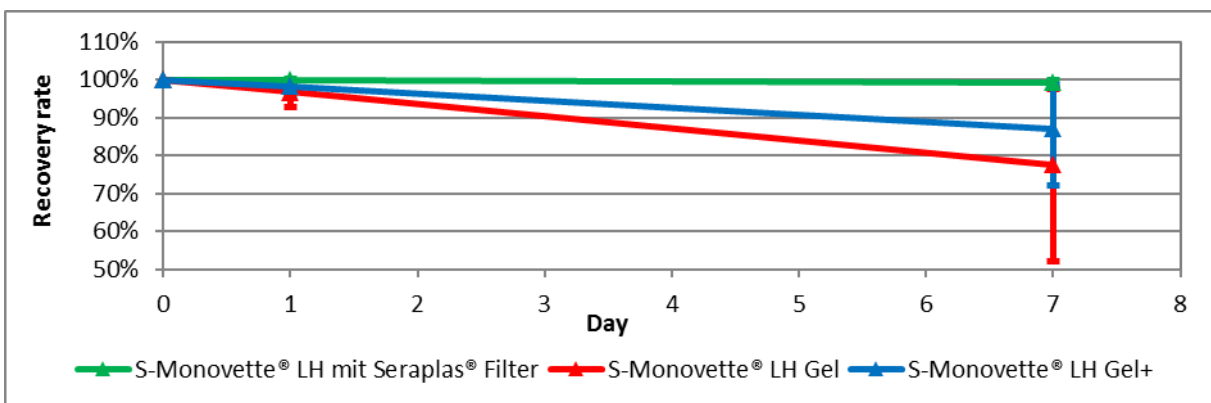
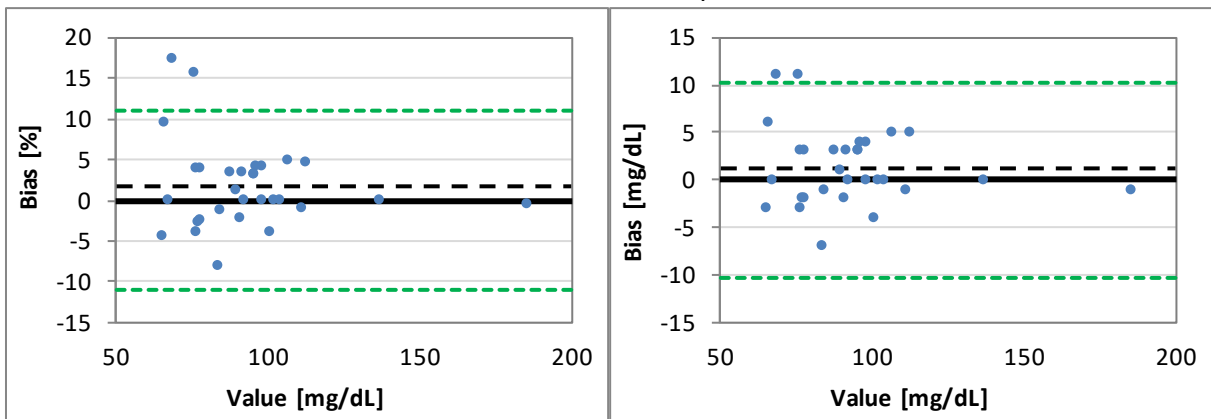


Glucose

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



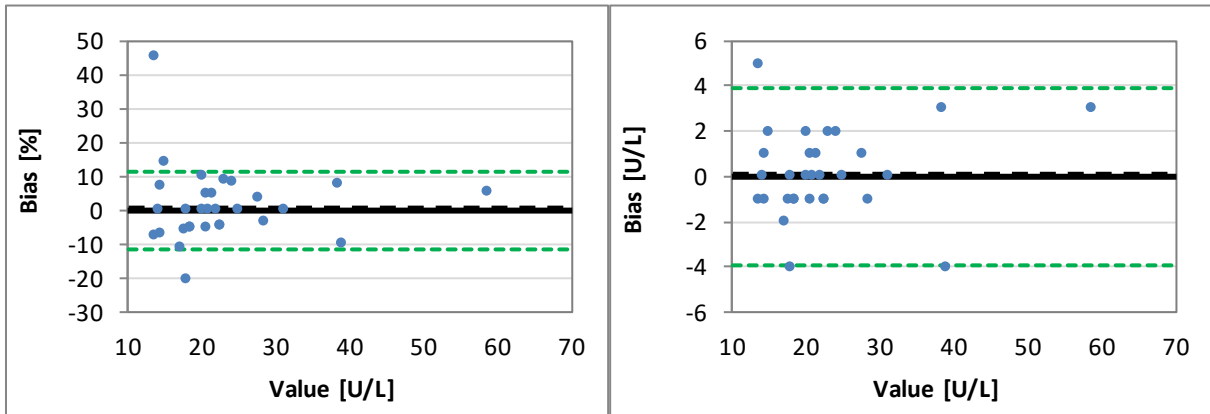
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



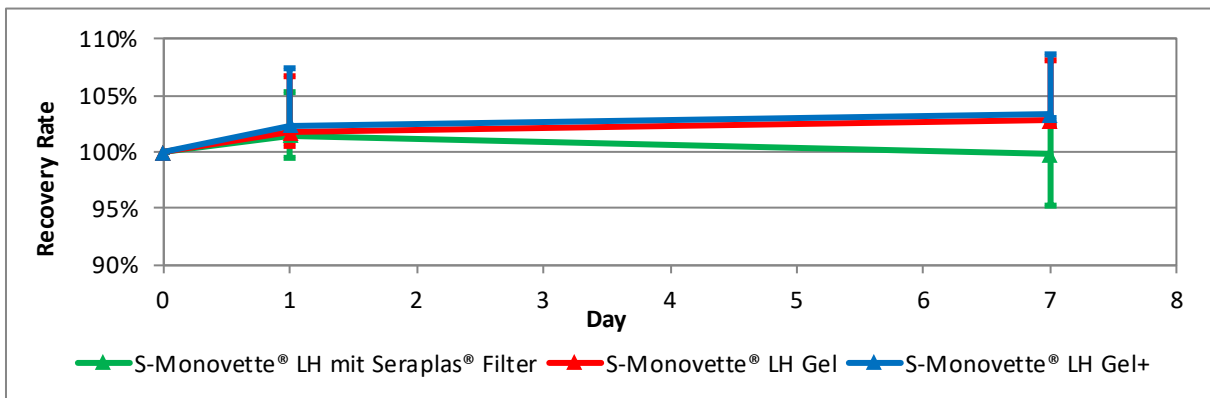
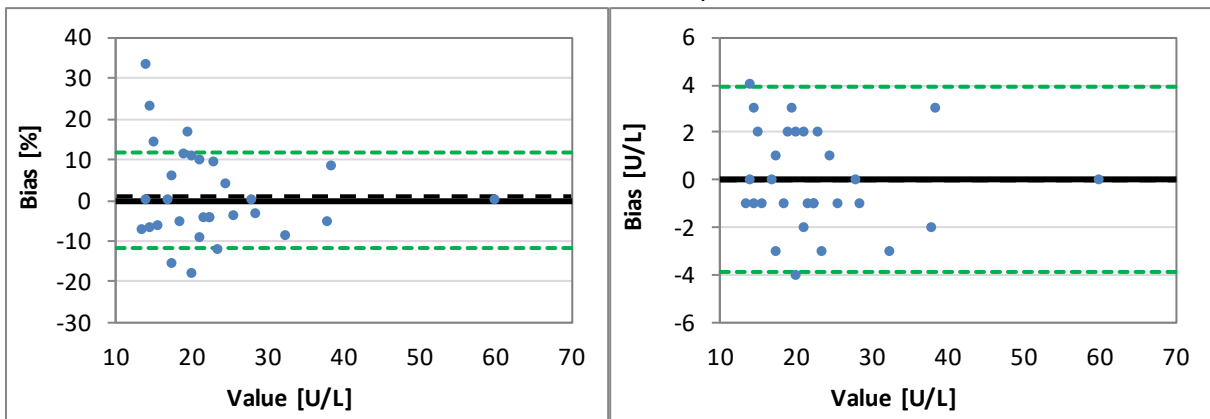


GOT (AST)

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



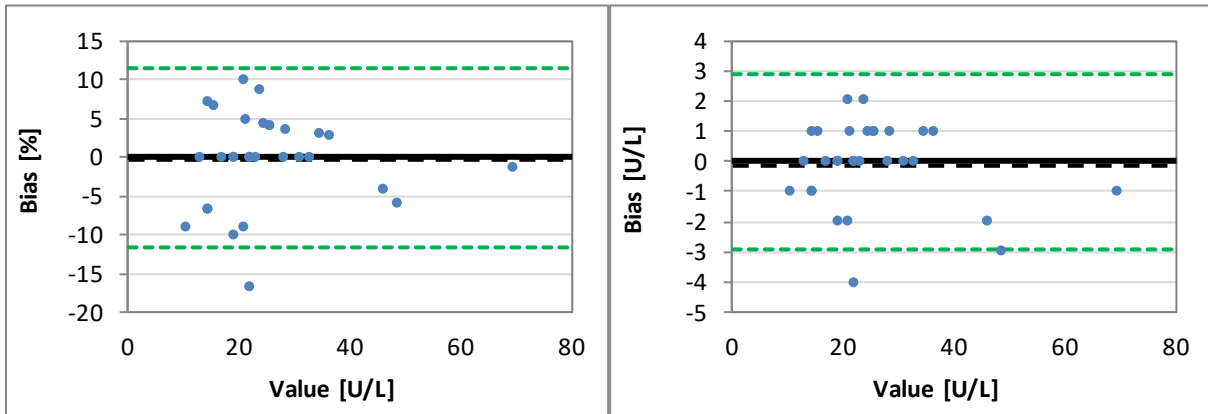
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



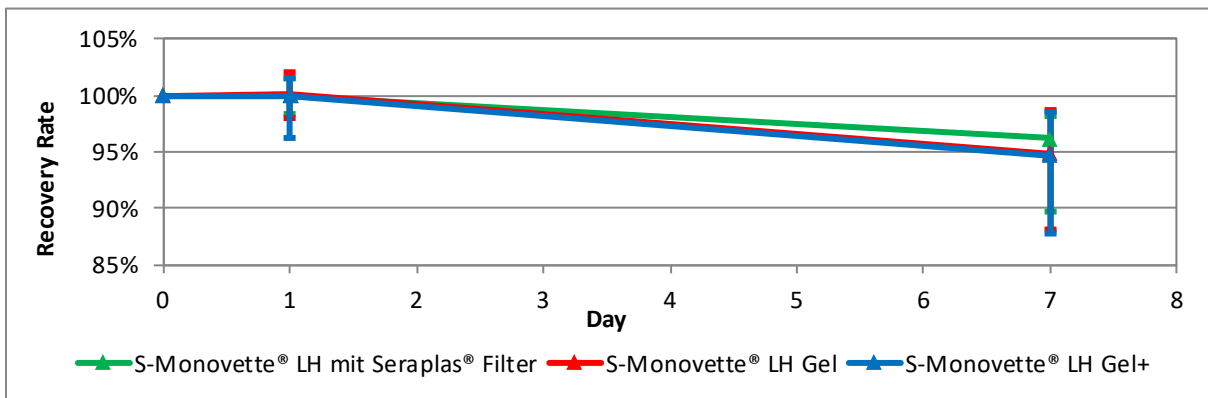
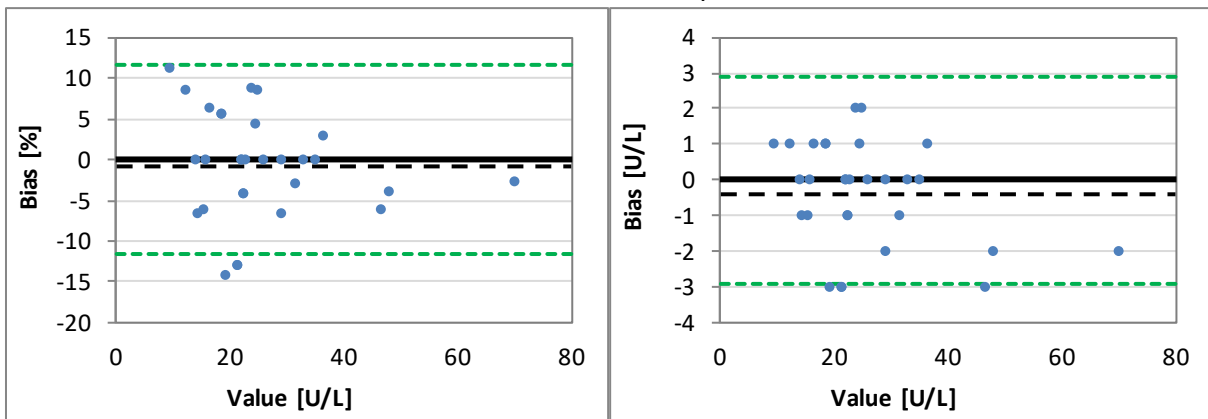


GPT (ALT)

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

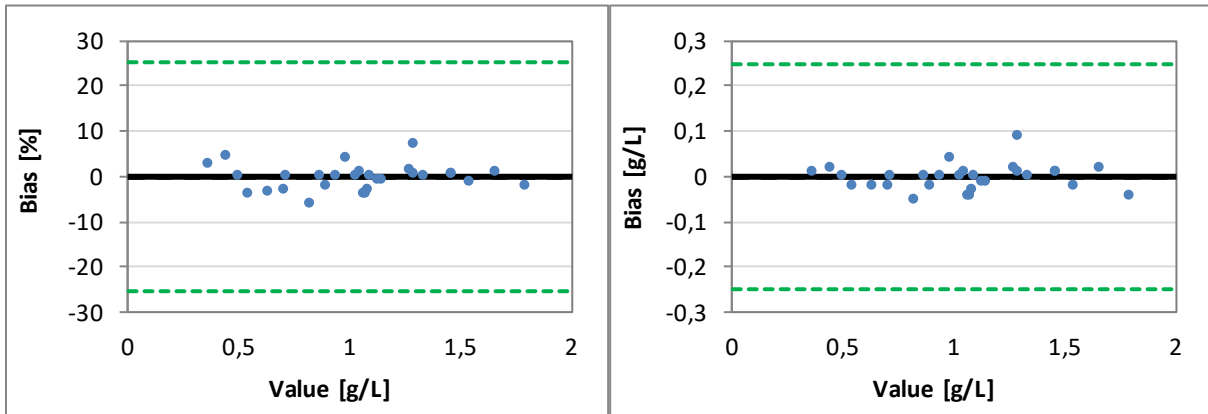


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

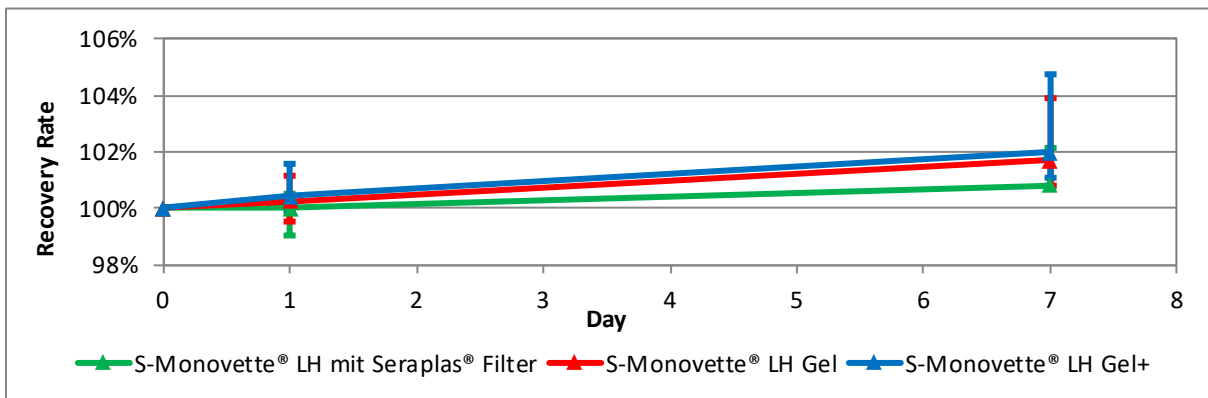
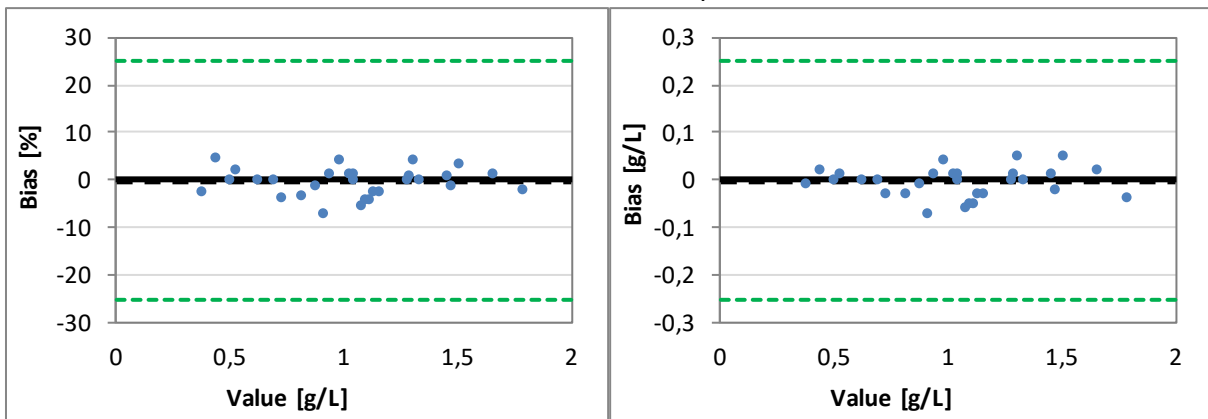


Haptoglobin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

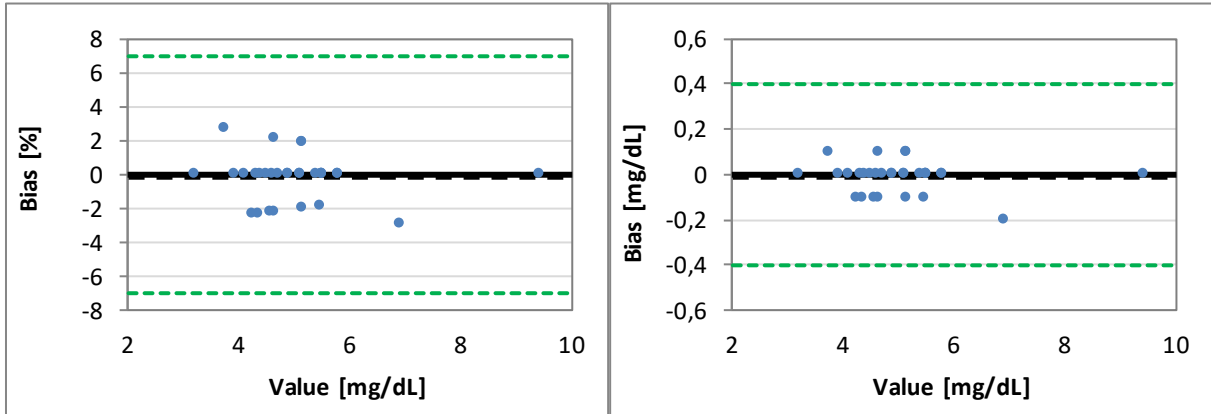


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

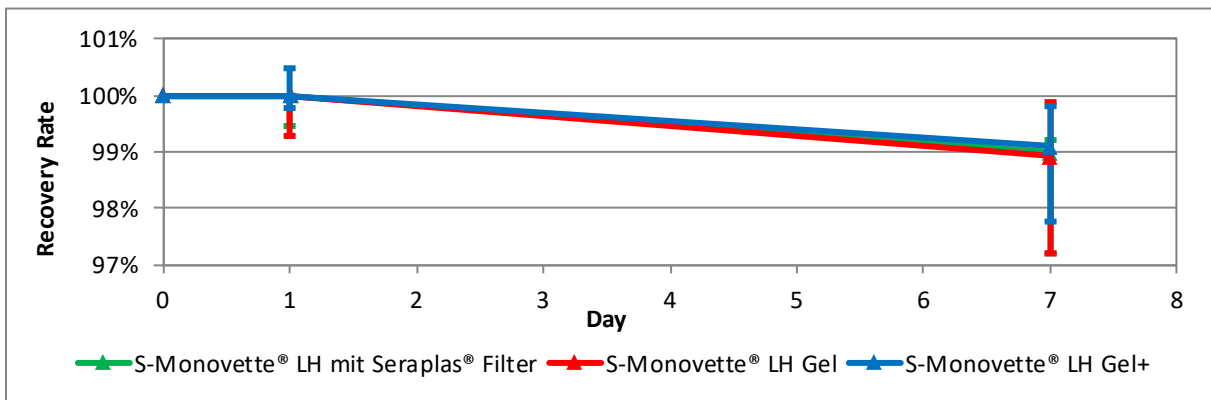
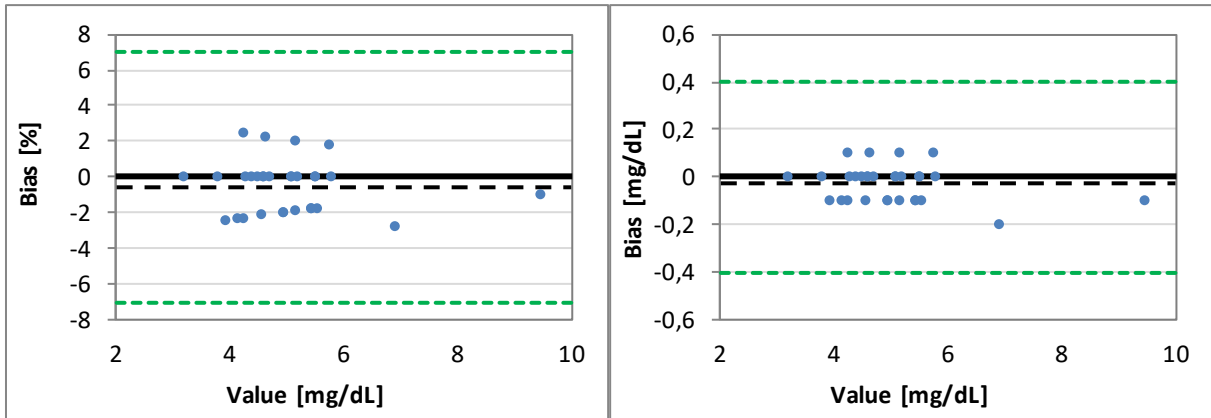


Uric Acid

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



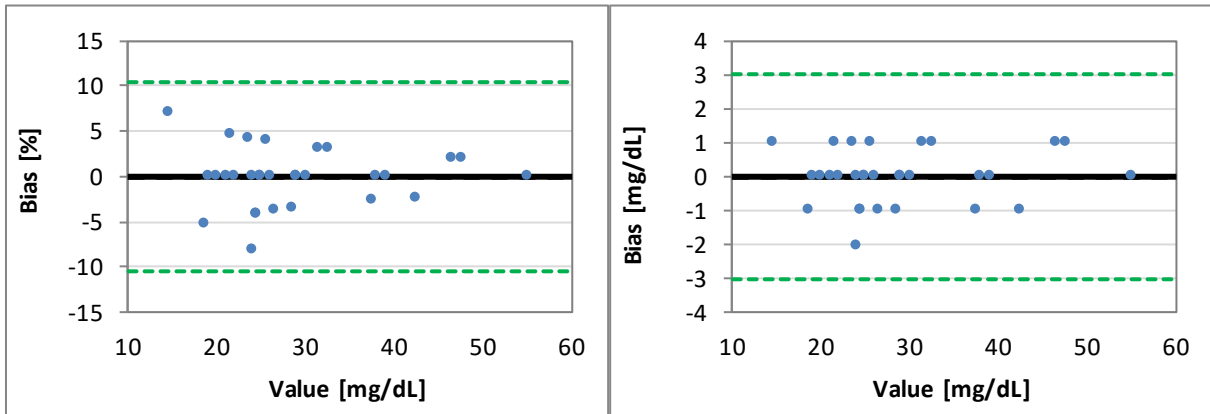
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



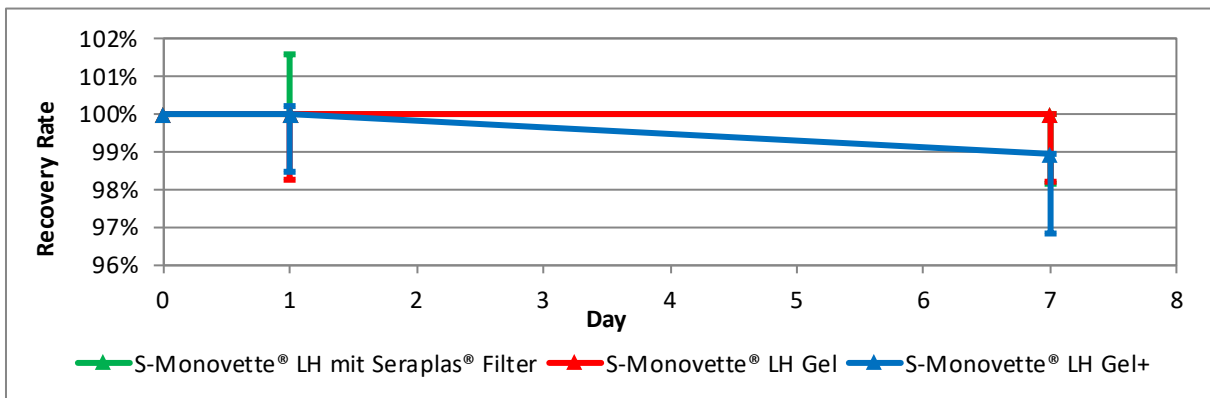
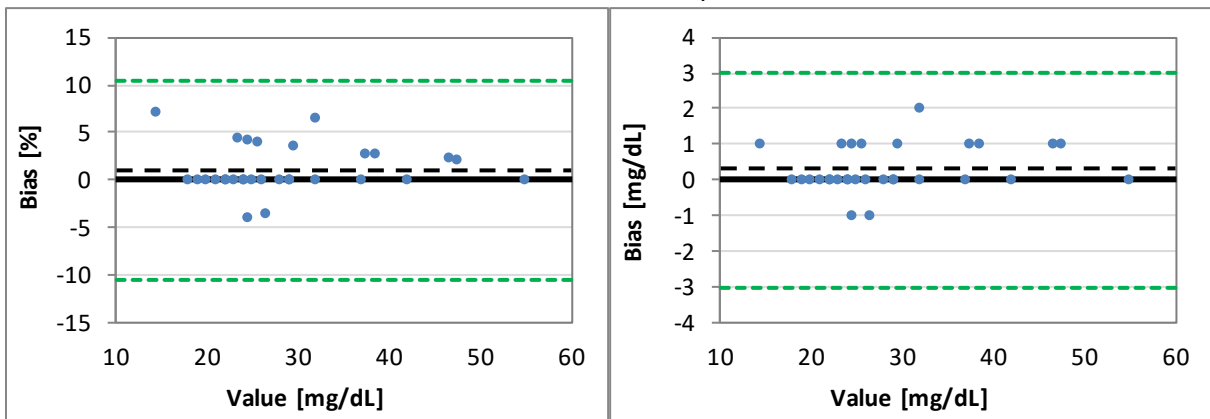


Urea

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



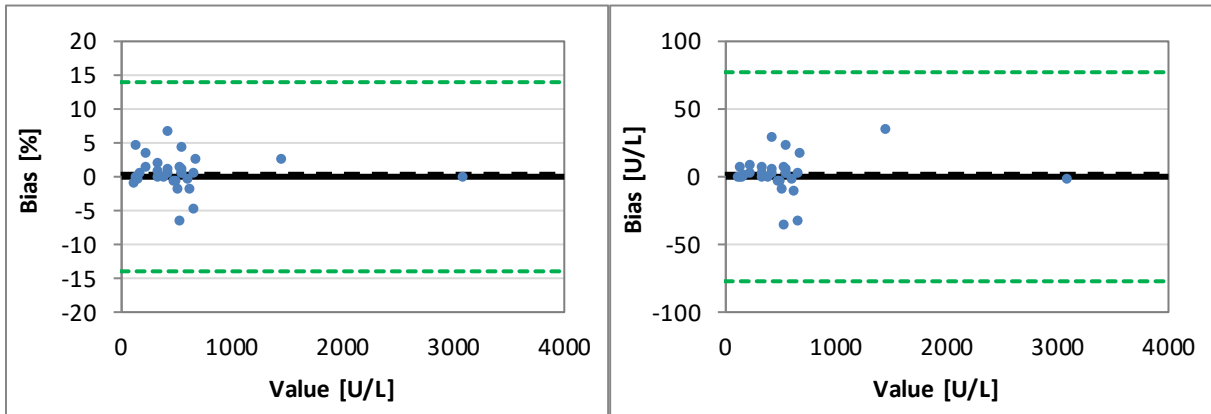
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



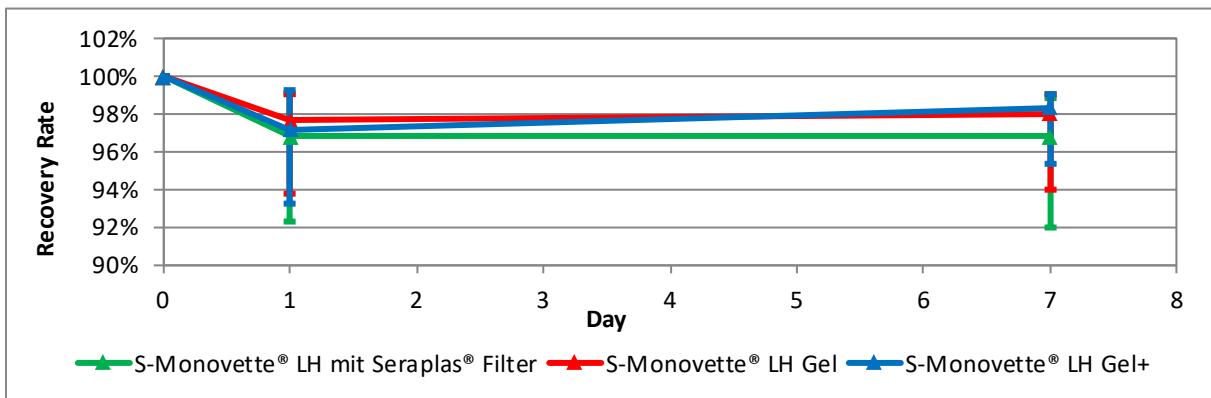
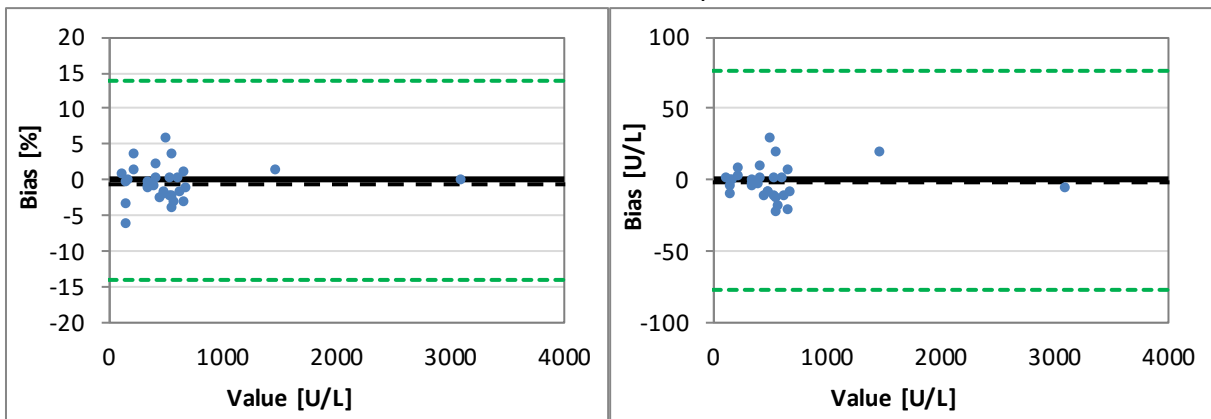


HCG

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



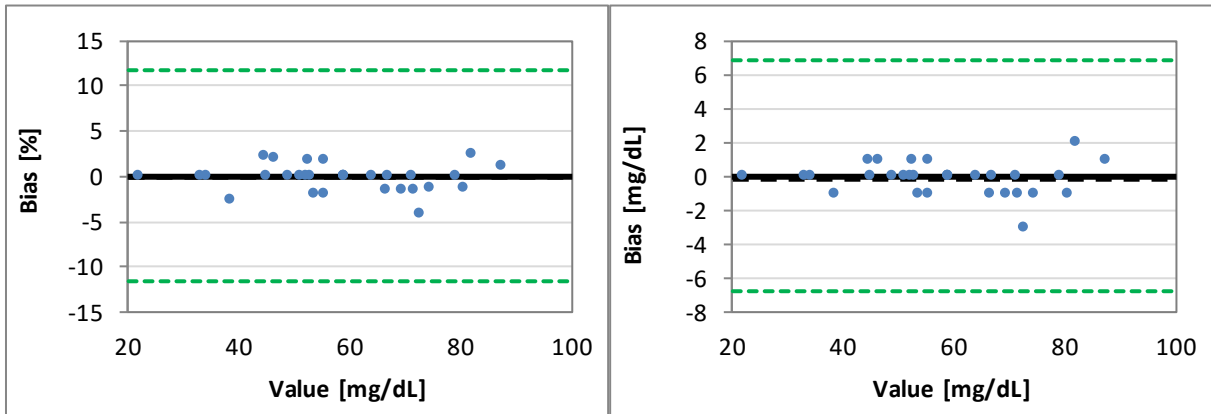
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



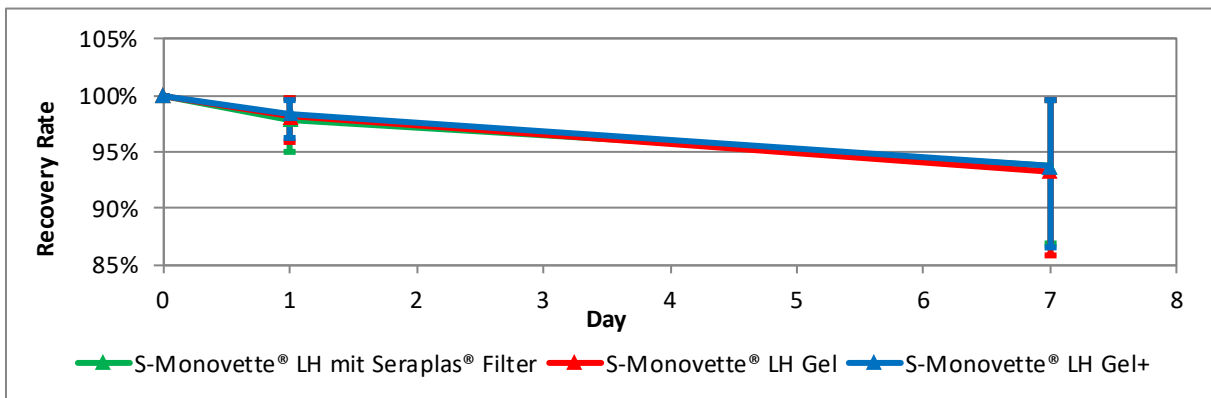
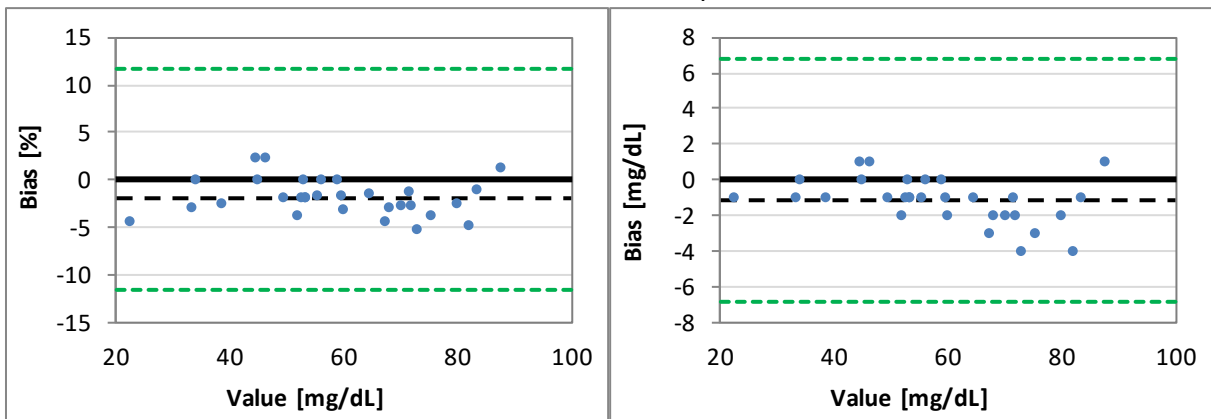


HDL

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

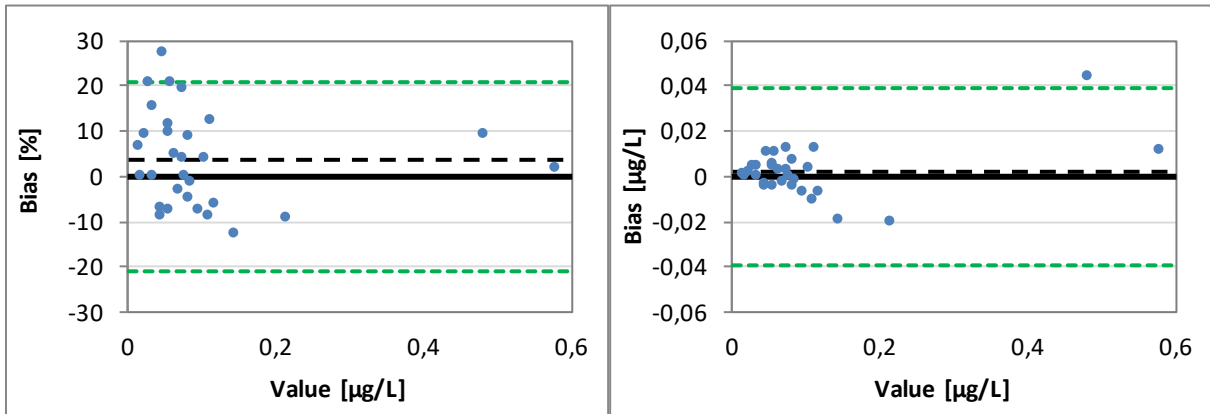


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

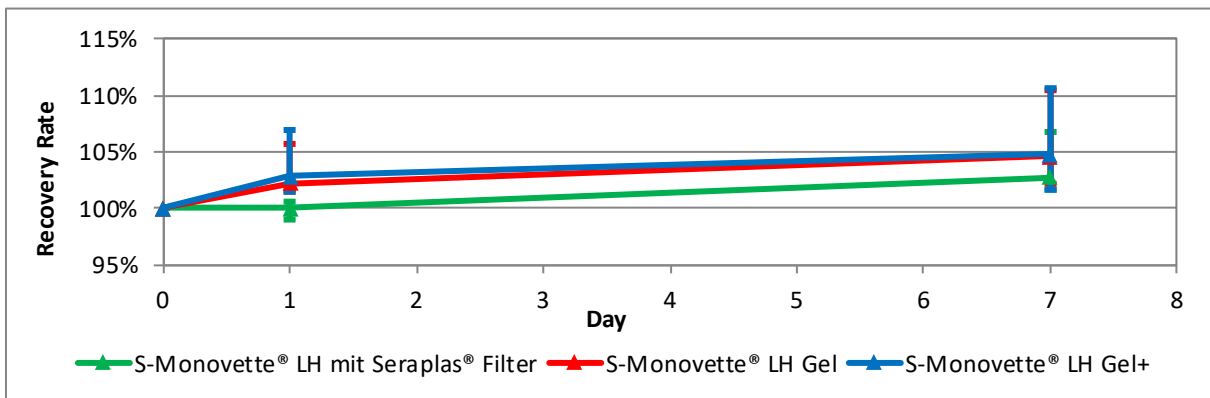
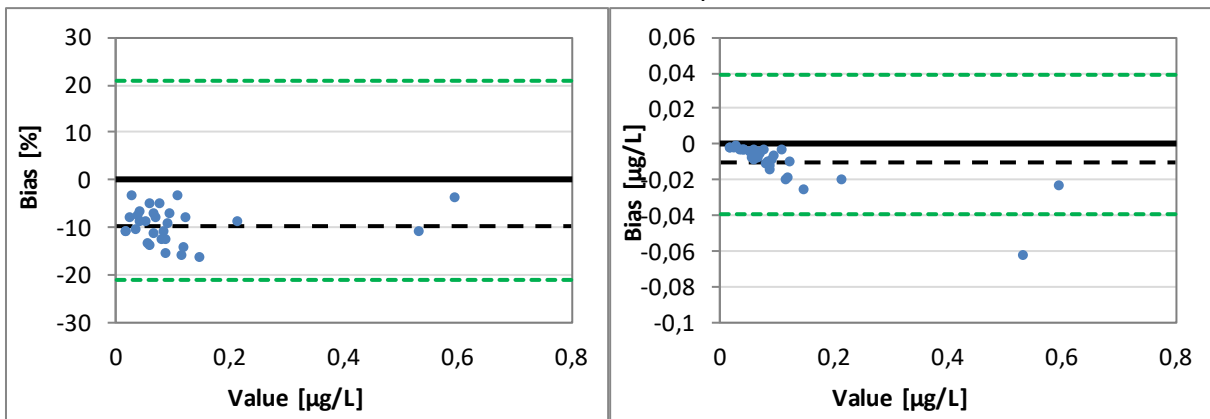


HS Troponin T

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



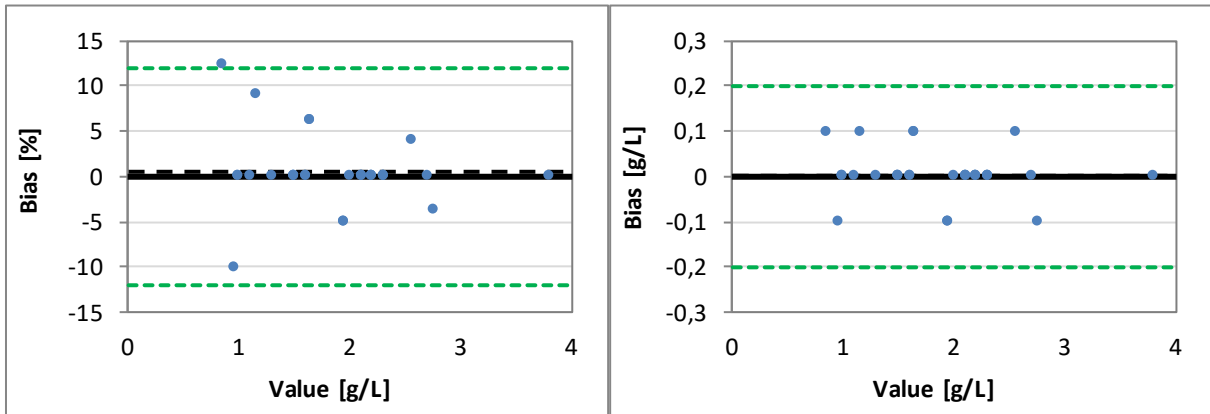
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



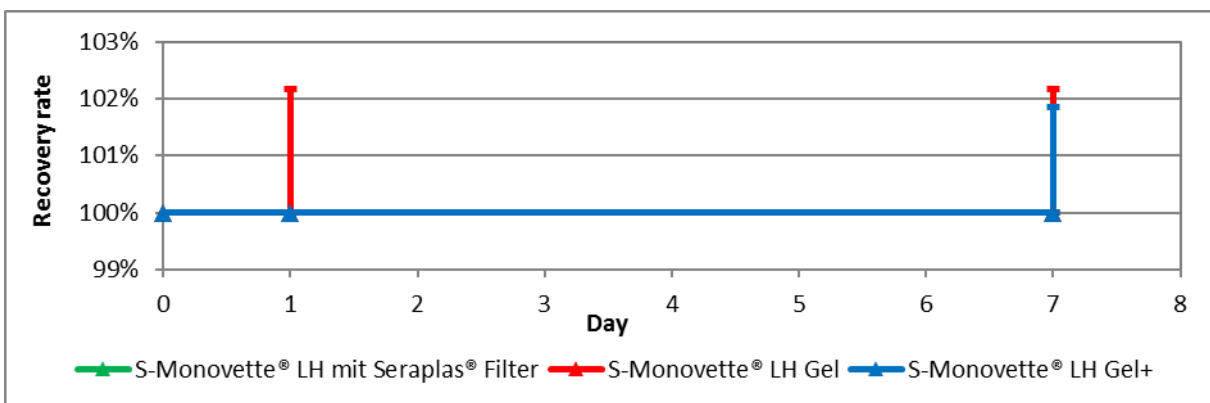
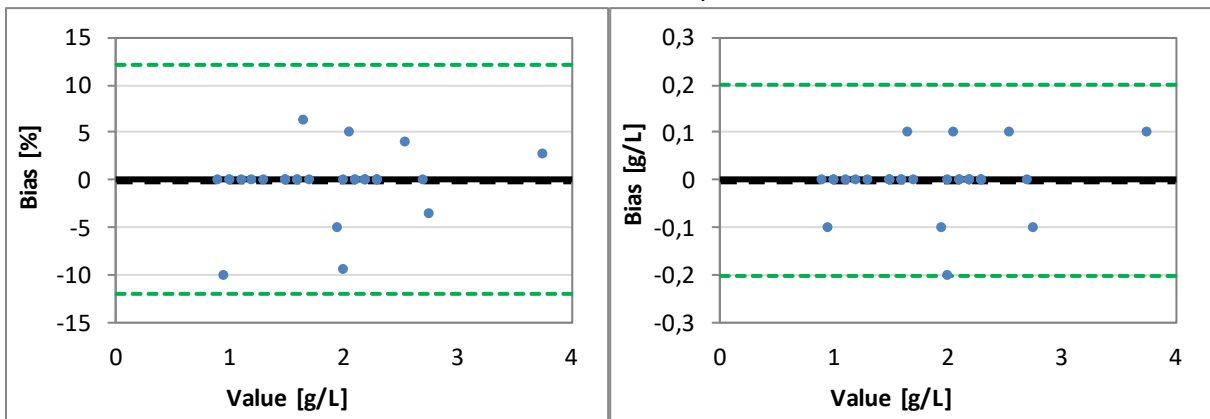


IgA

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

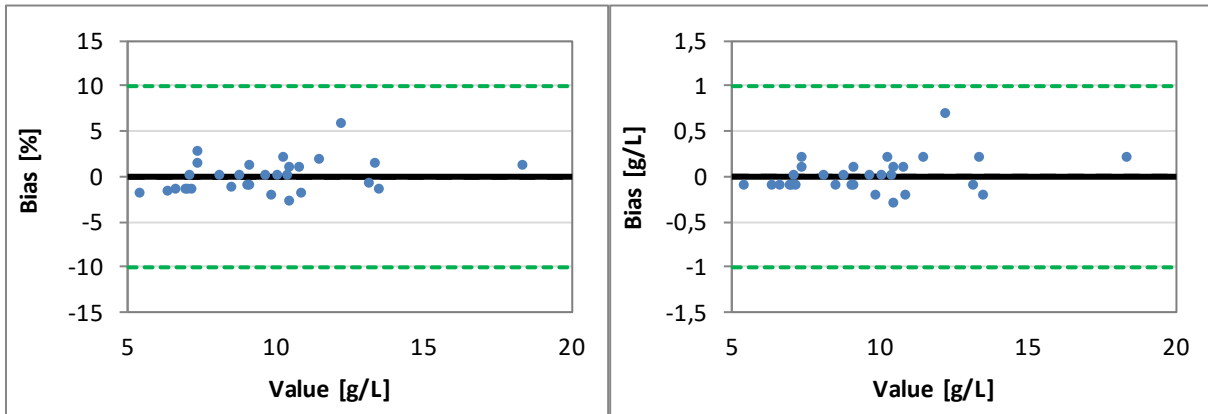


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

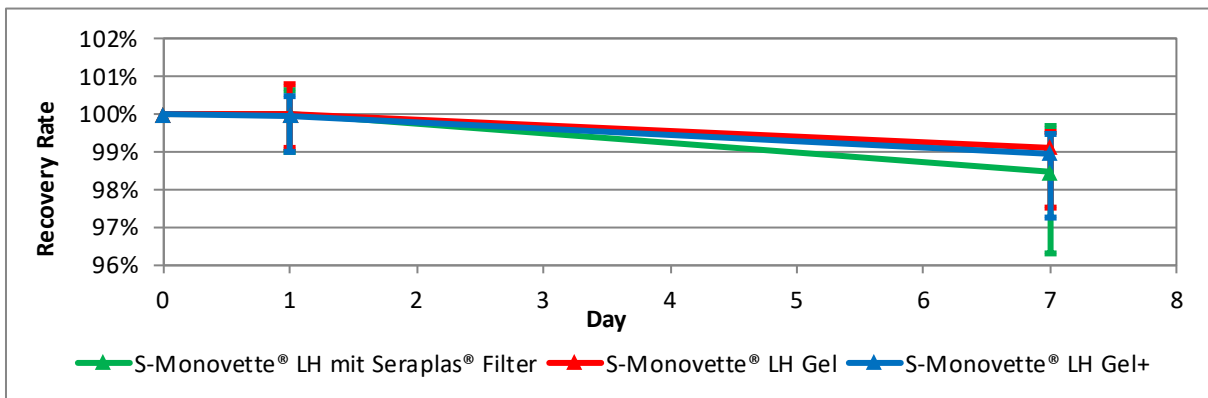
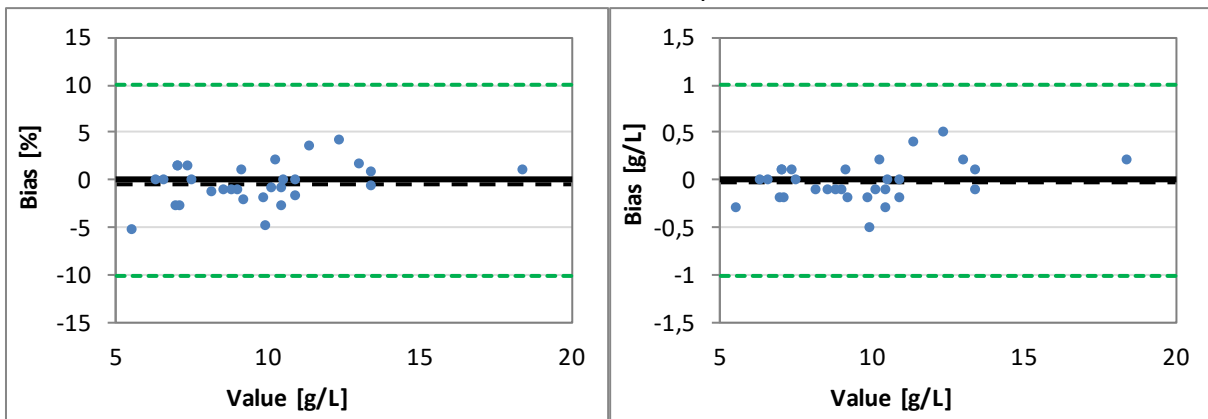


IgG

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

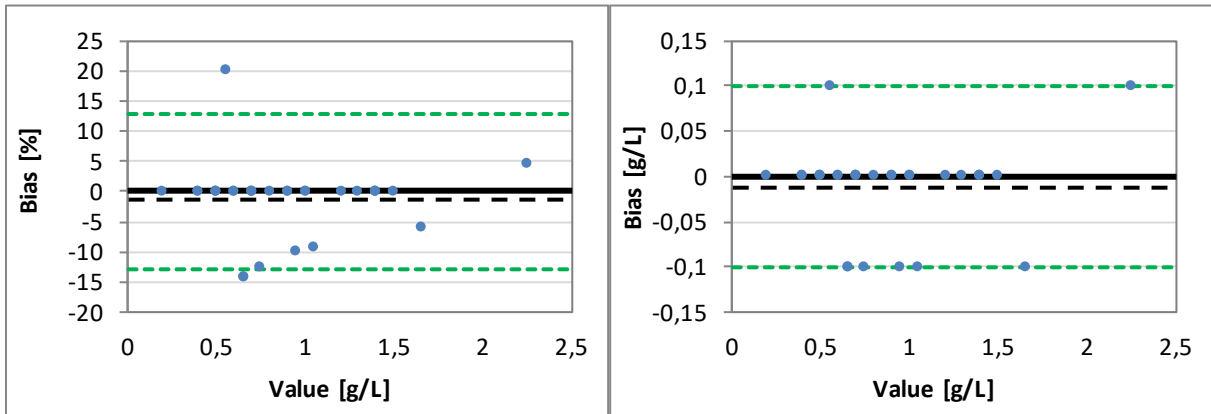


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

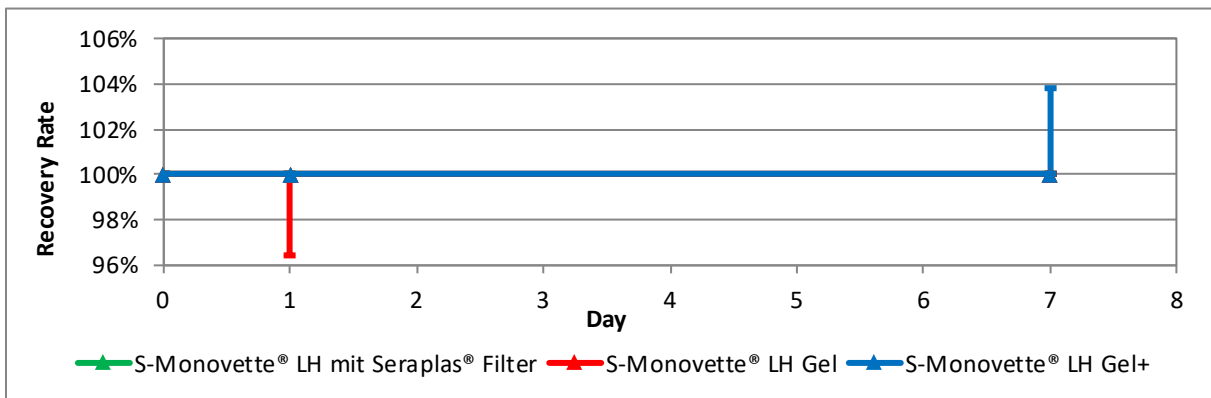
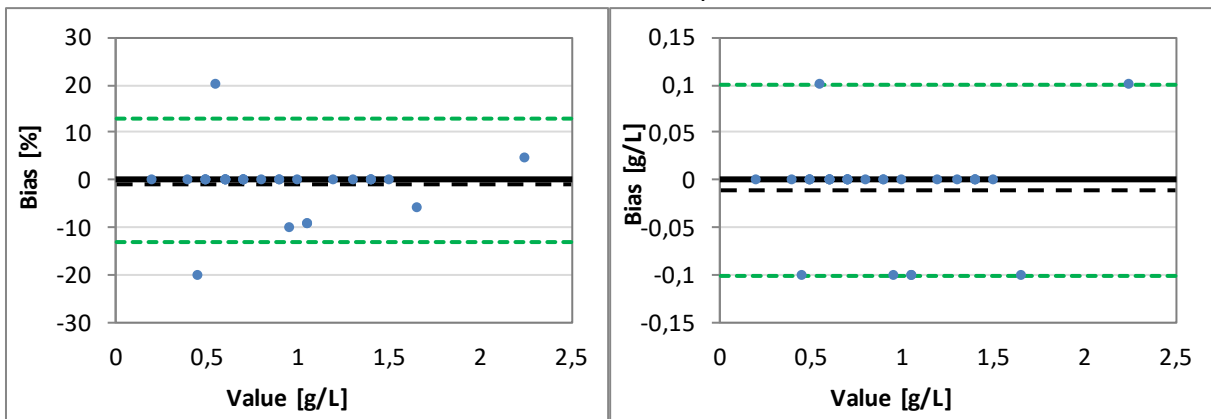


IgM

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

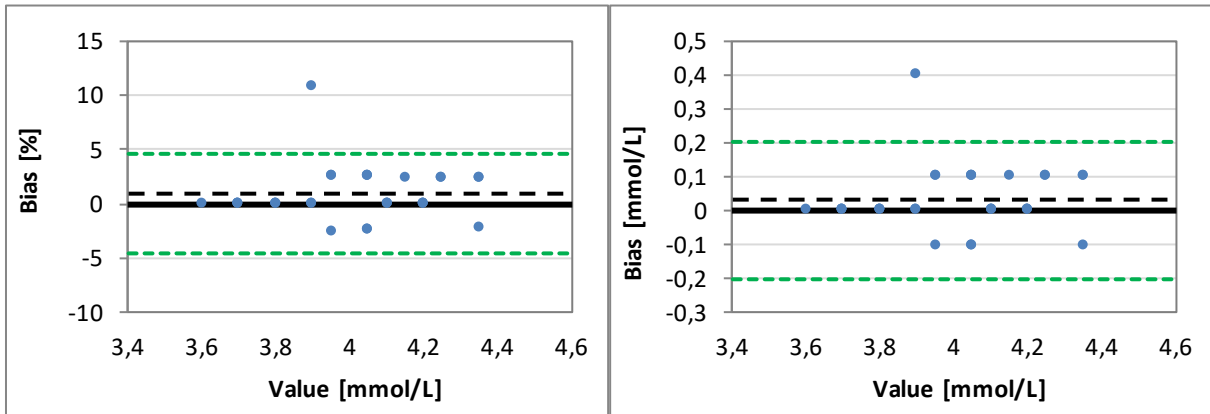


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

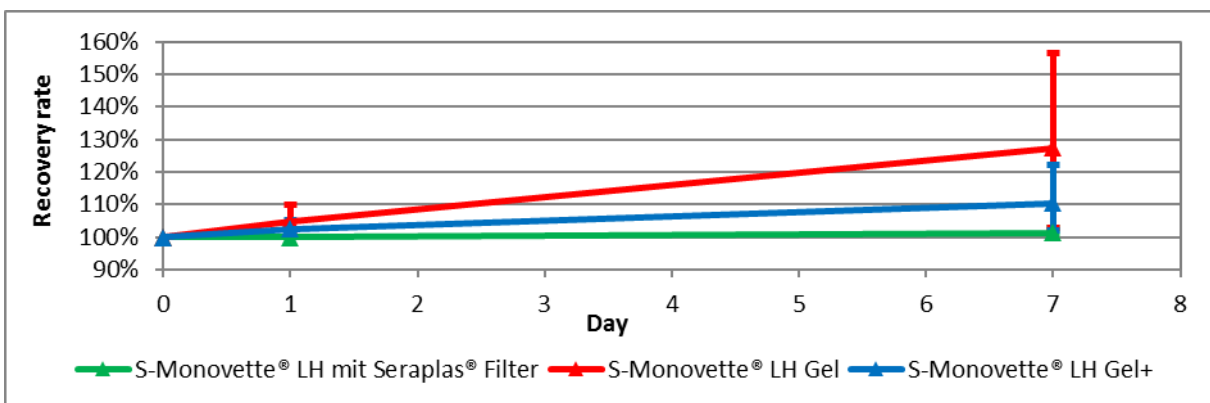
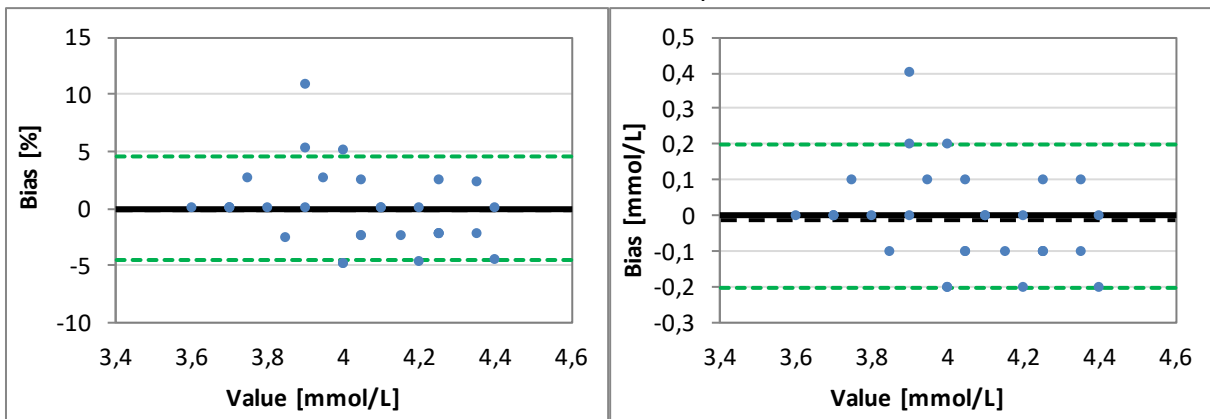


Potassium

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

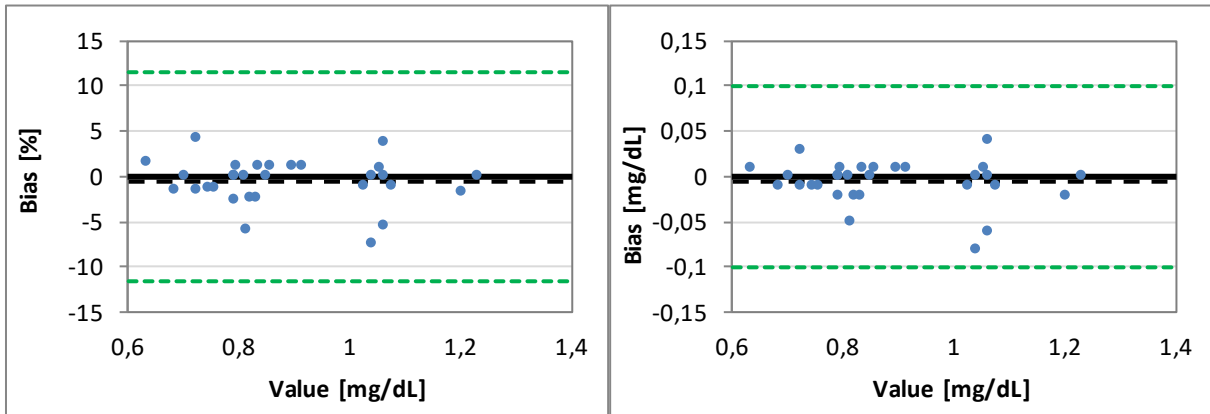


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

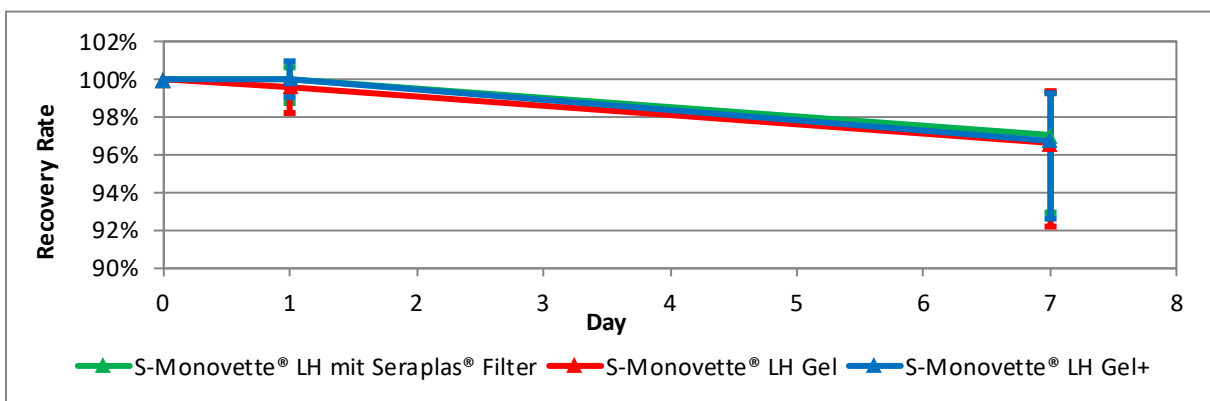
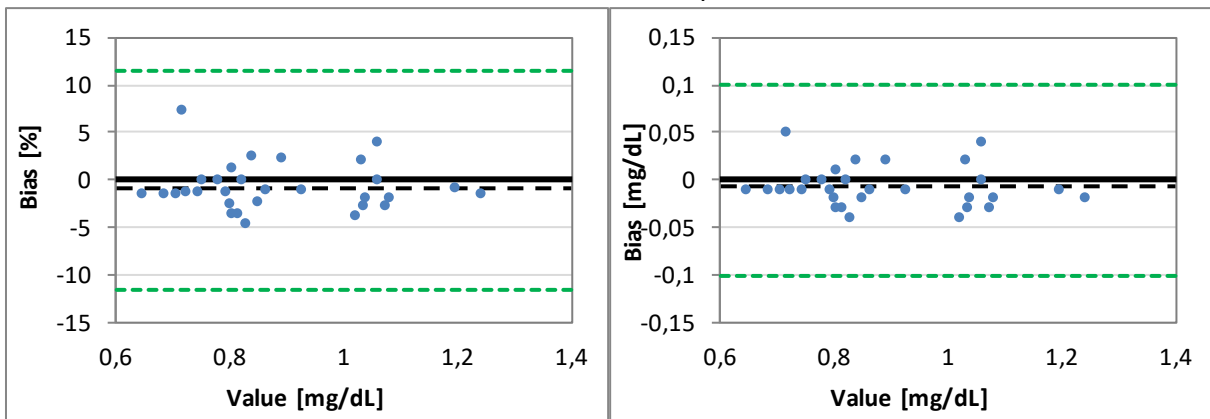


Creatinin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



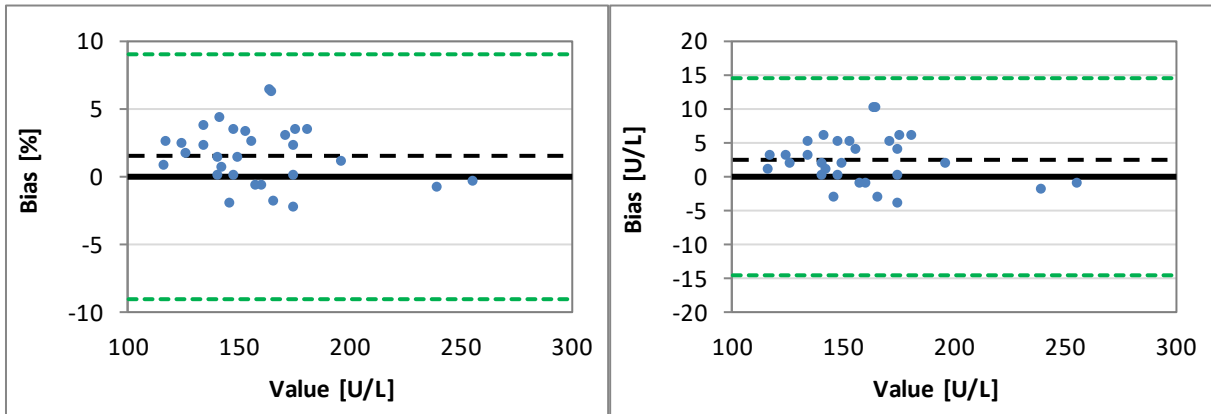
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



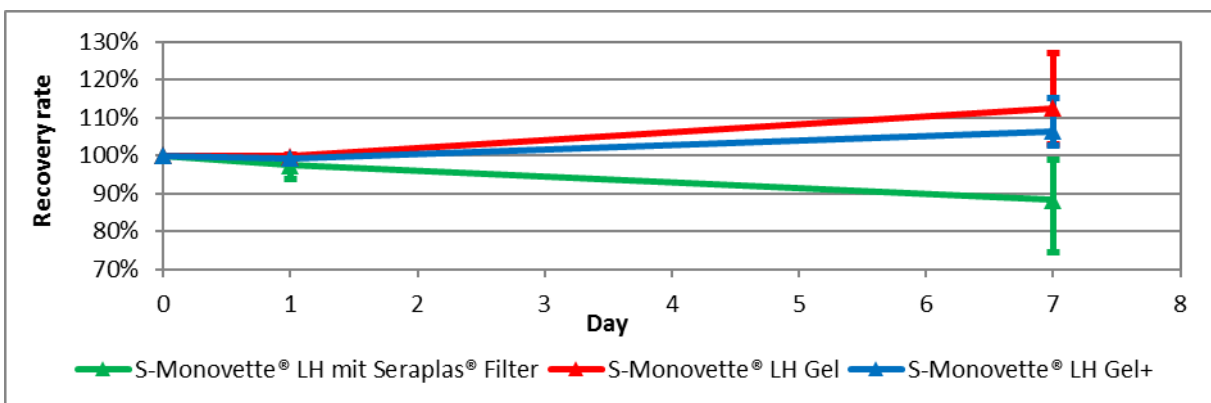
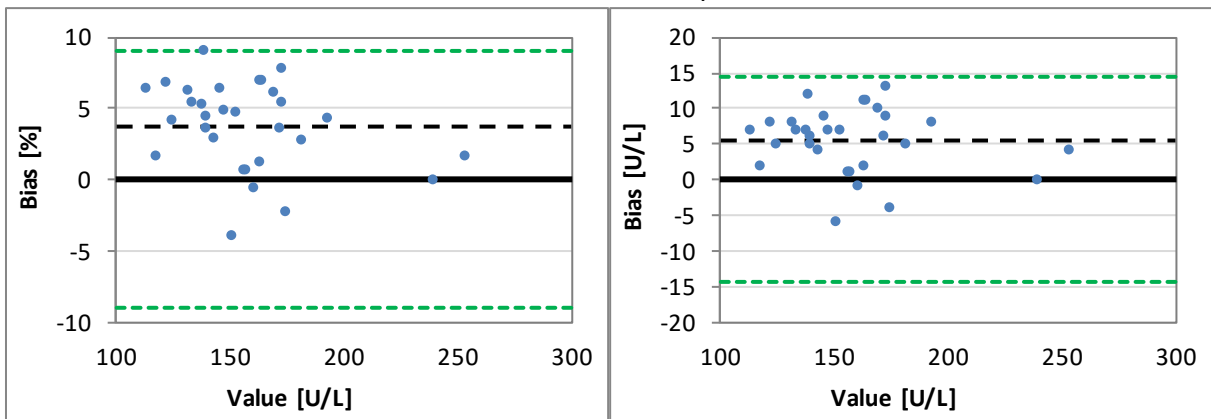


LDH

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



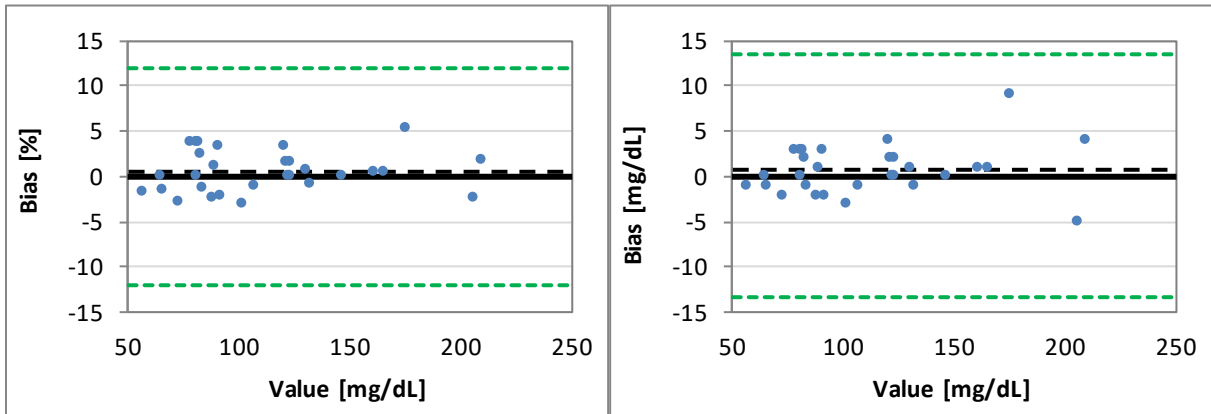
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



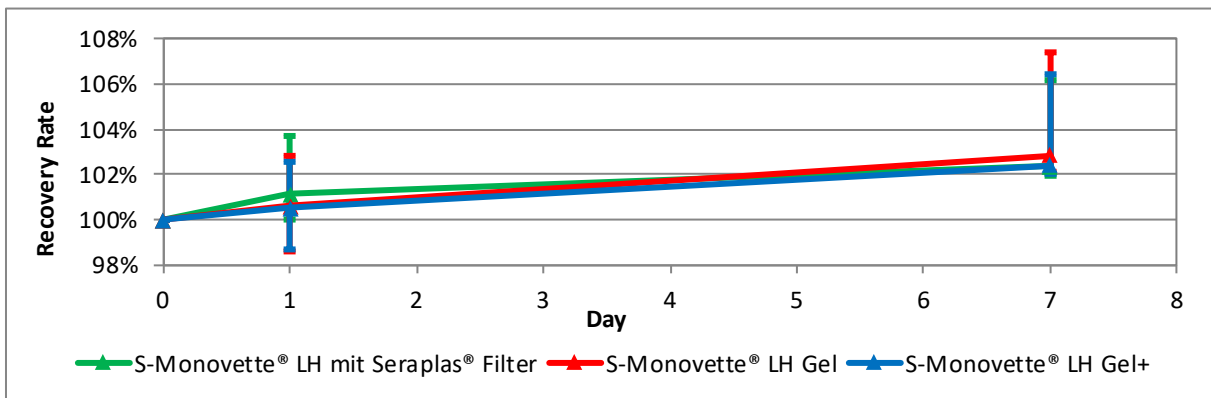
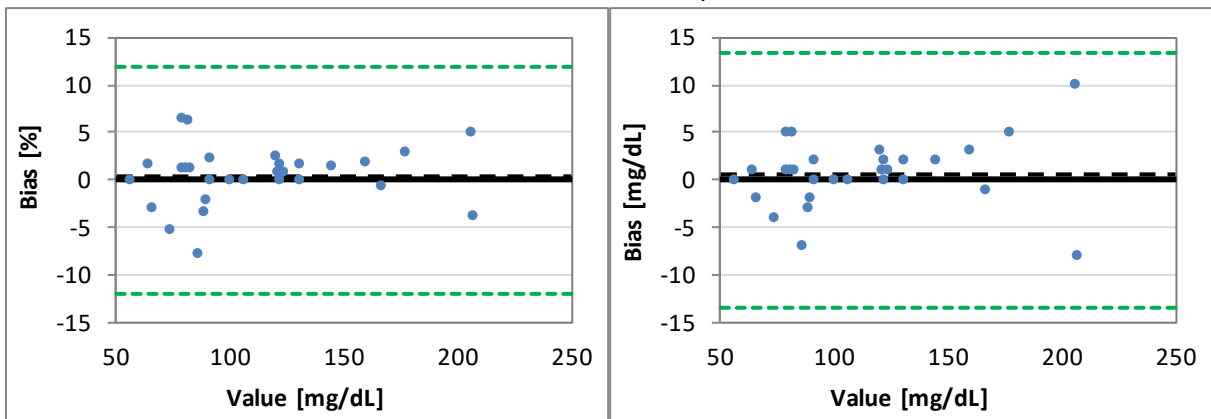


LDL

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

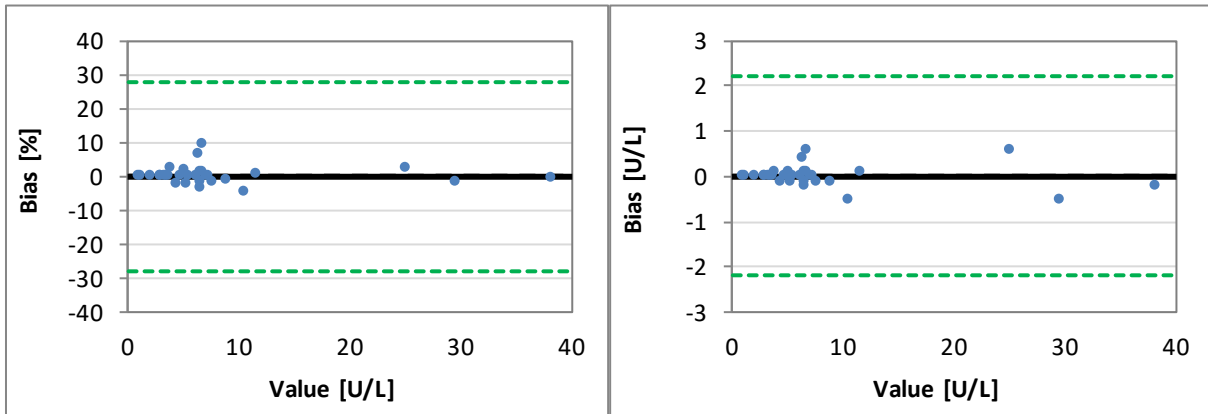


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

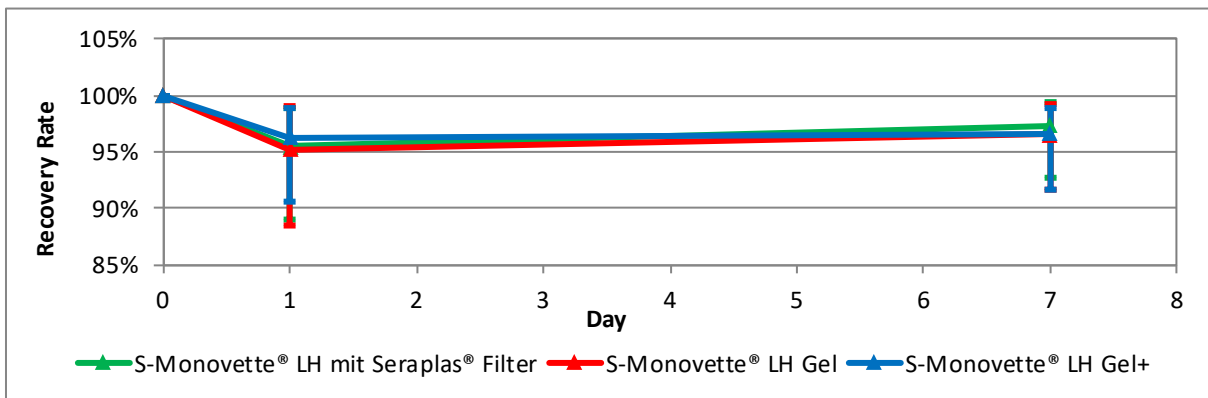
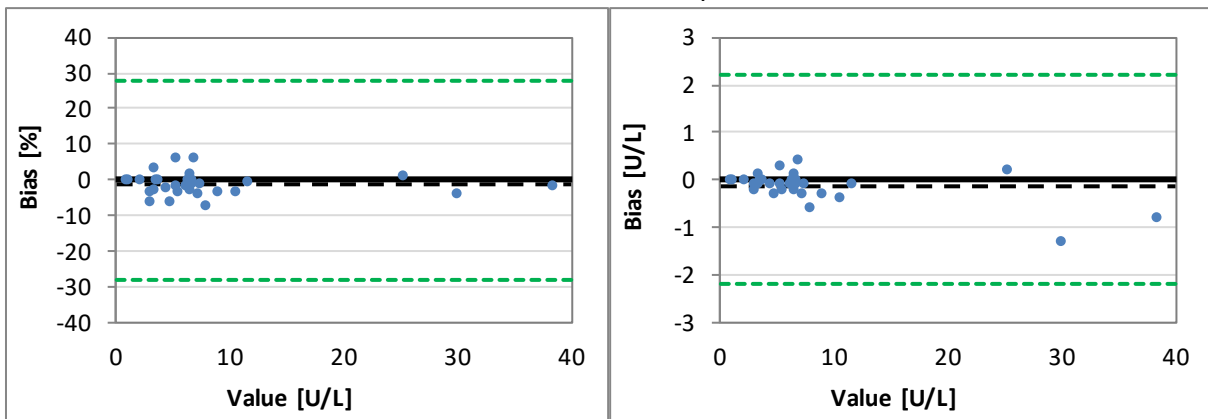


LH

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



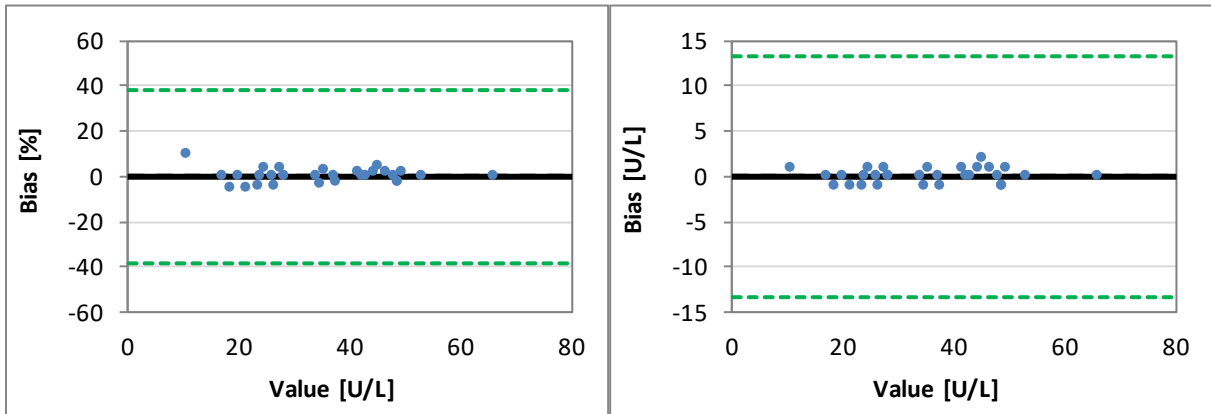
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



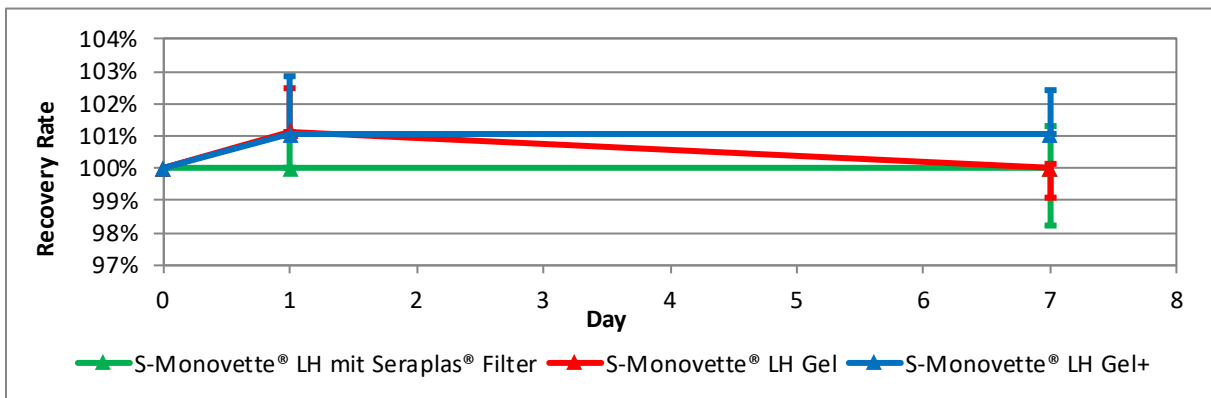
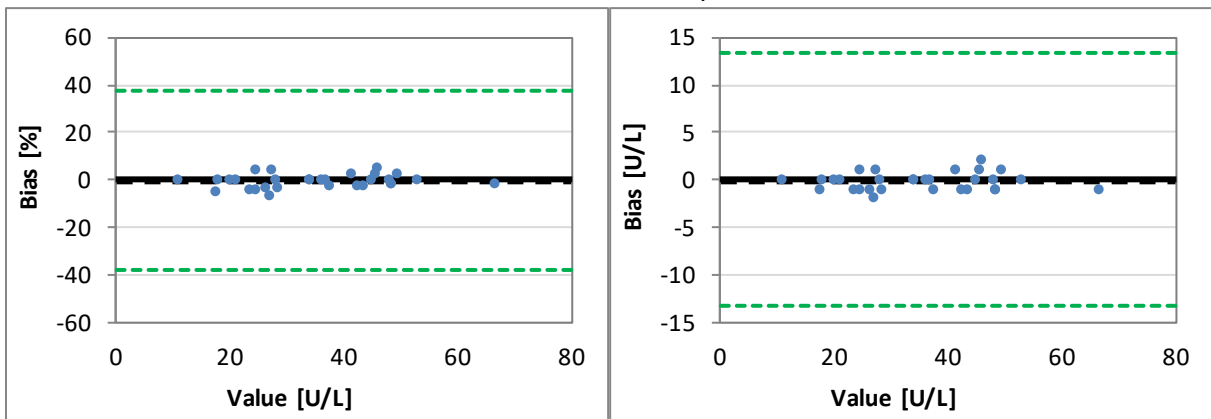


Lipase

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

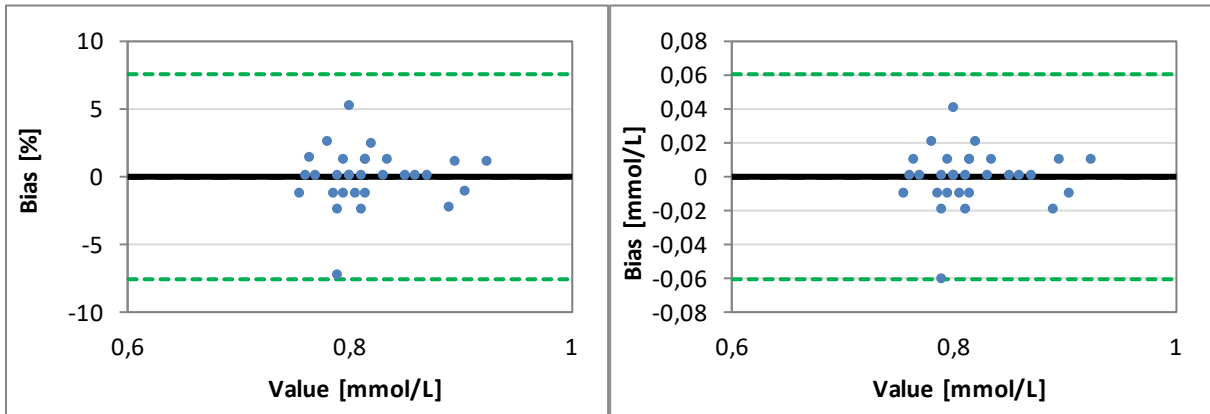


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

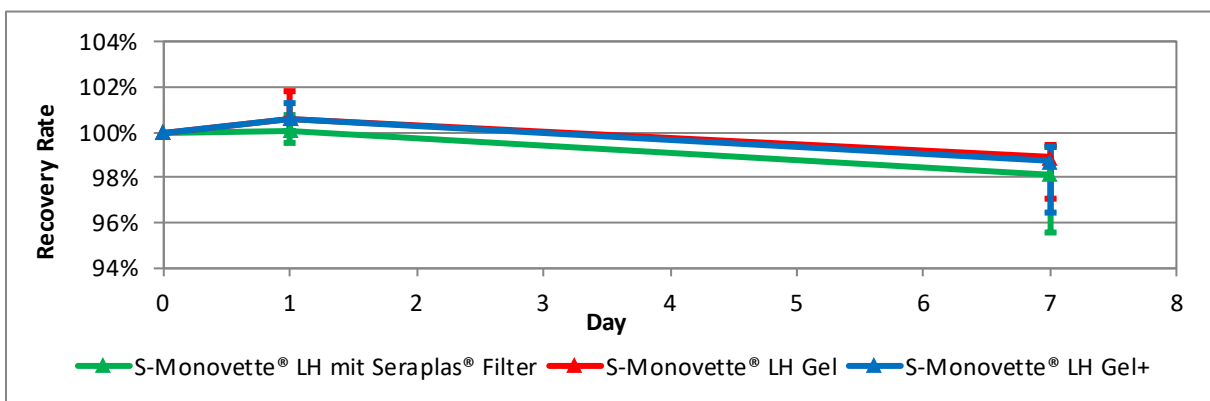
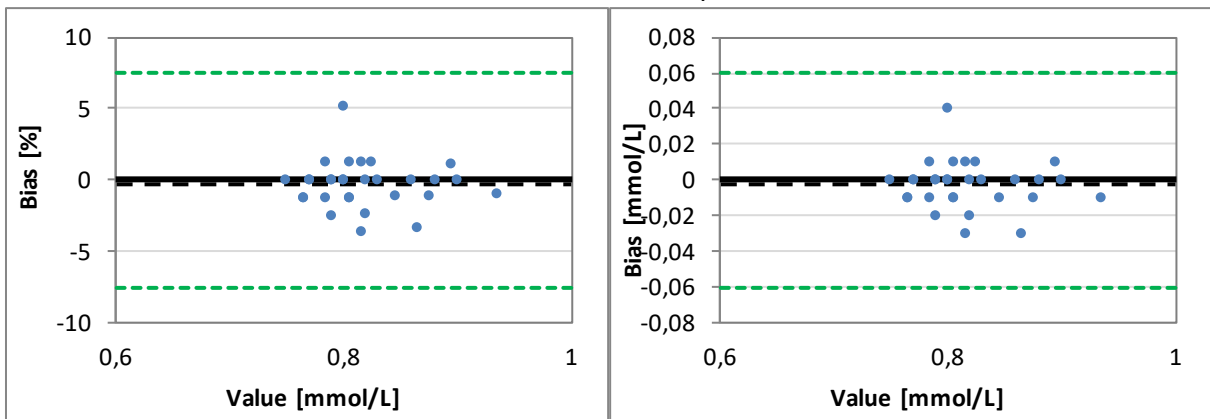


Magnesium

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



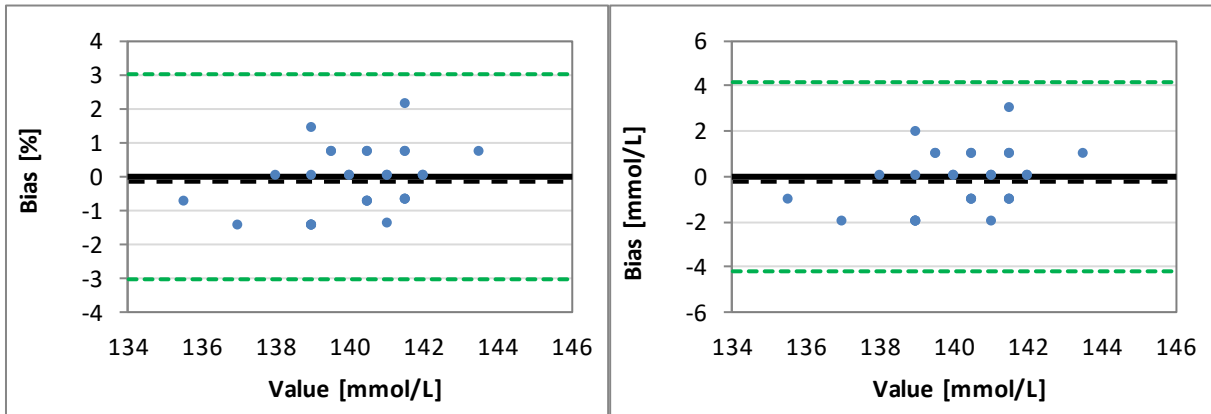
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



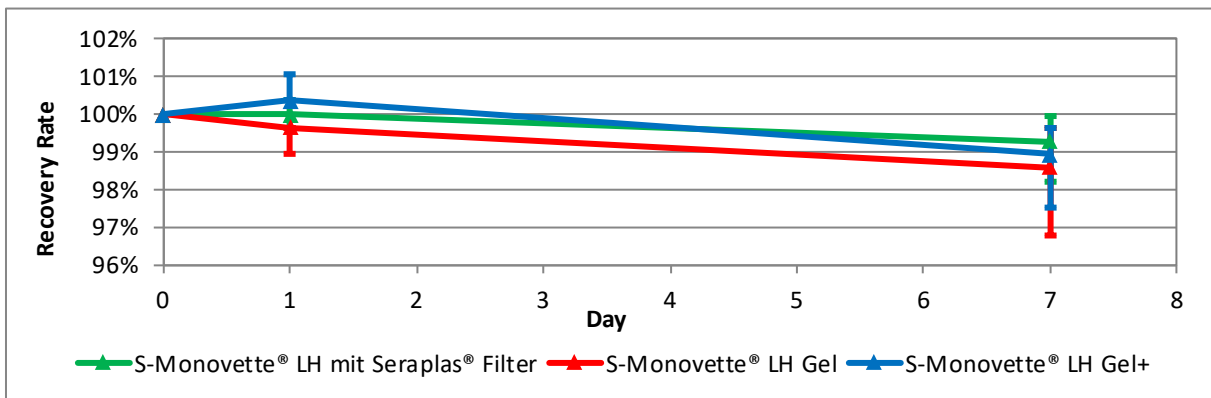
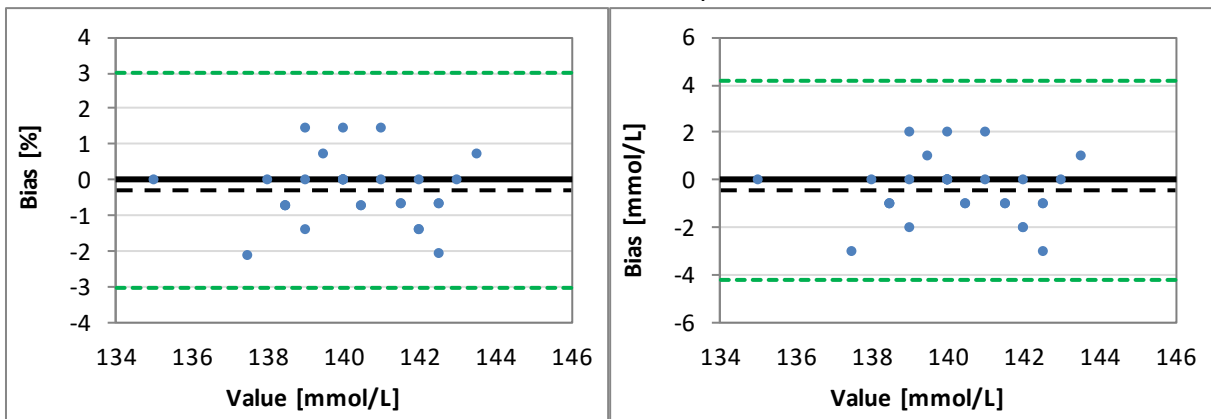


Sodium

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



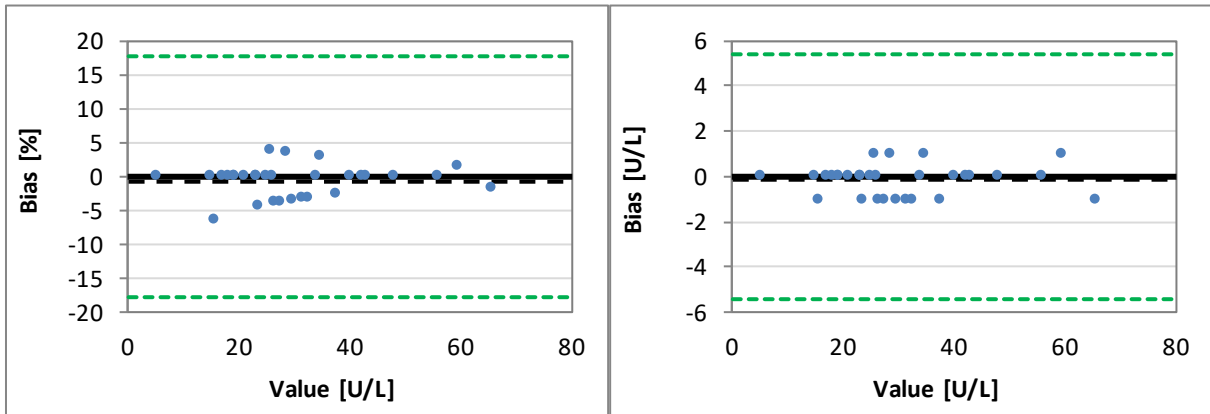
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



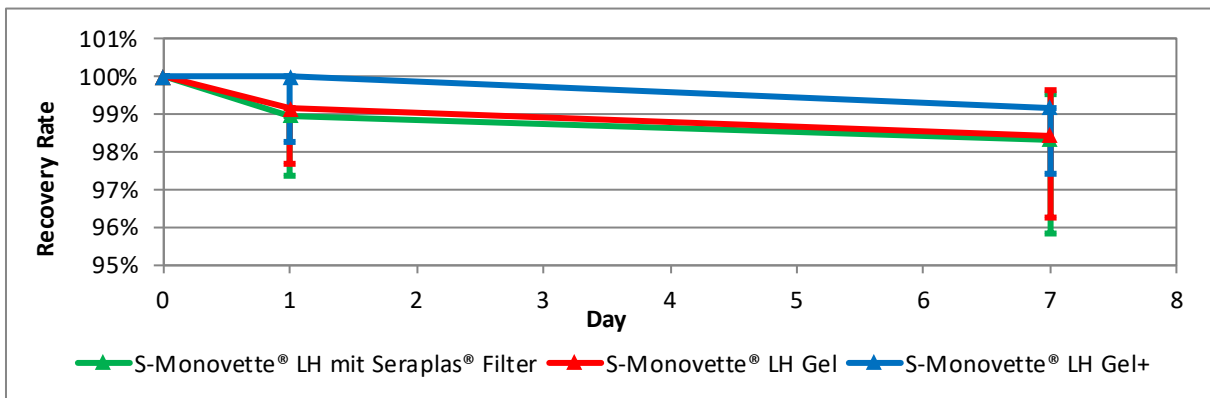
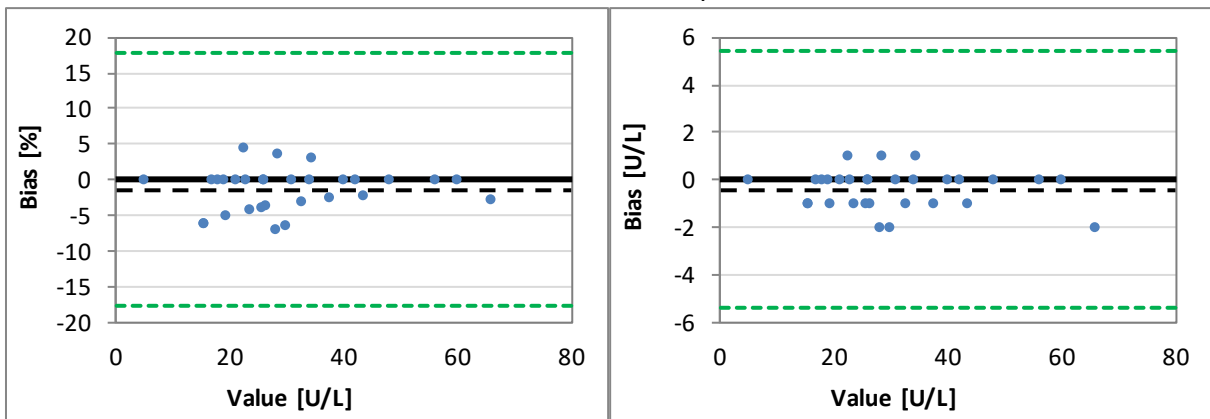


p-Amylase

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

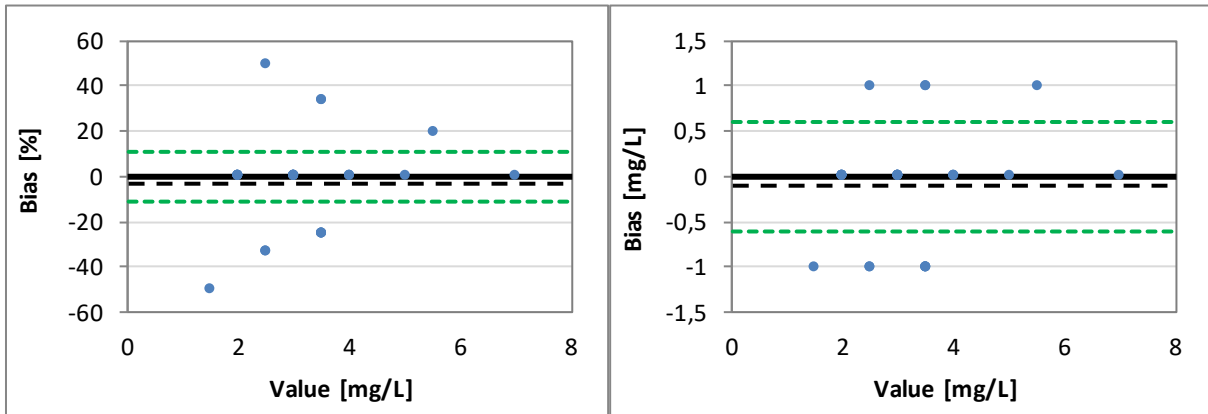


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

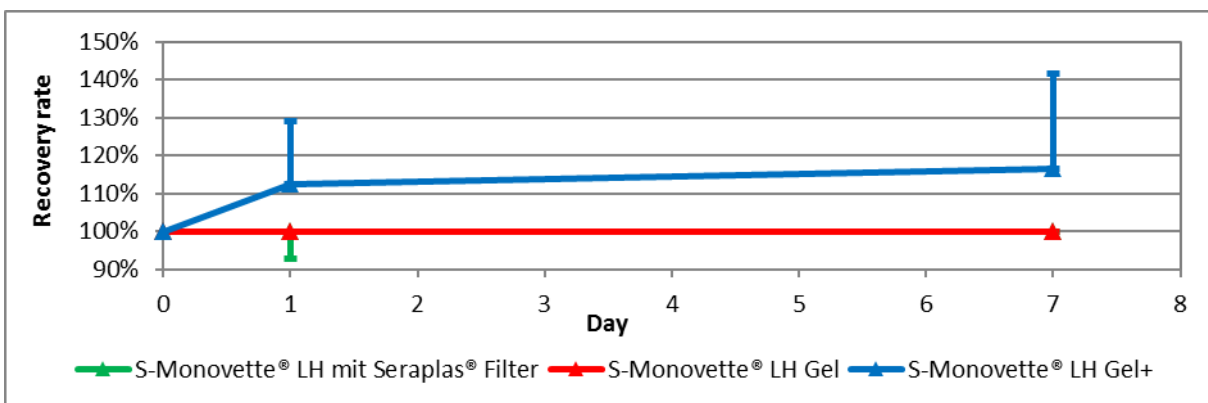
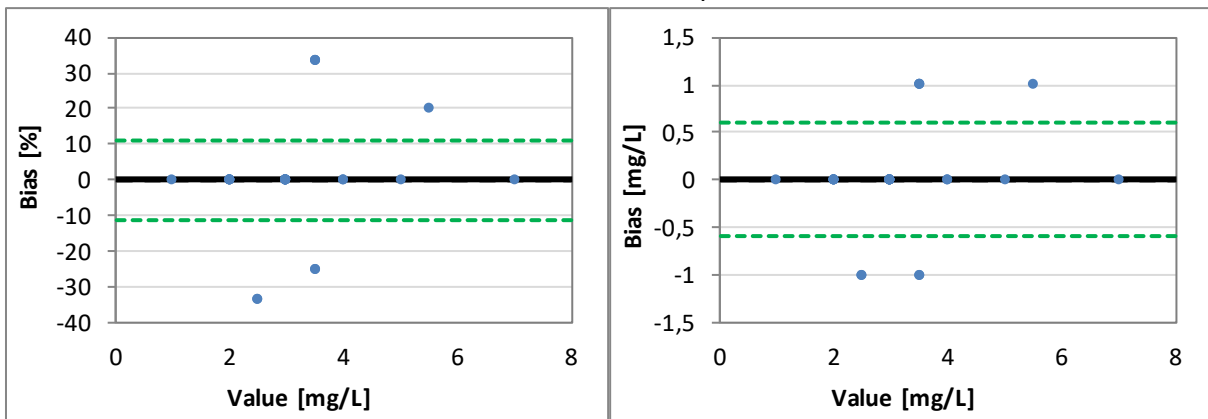


Phenytoin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



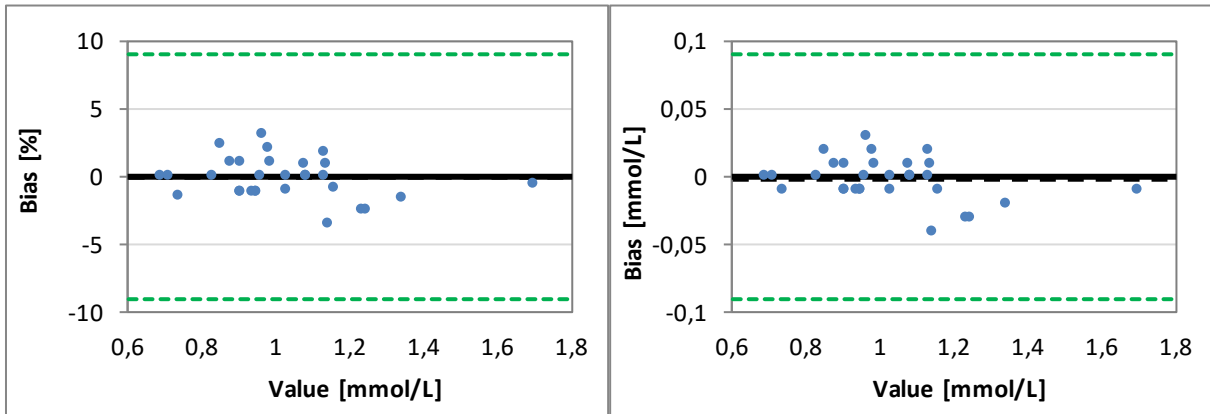
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



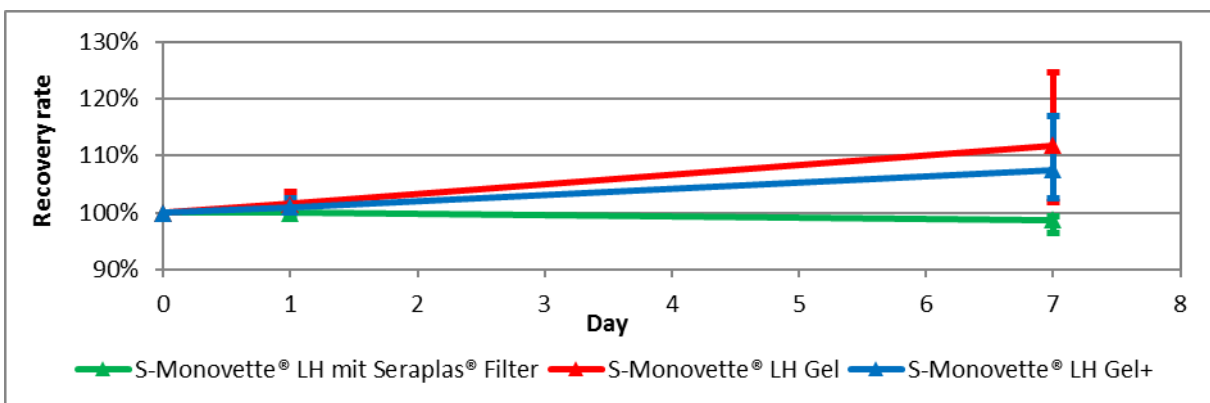
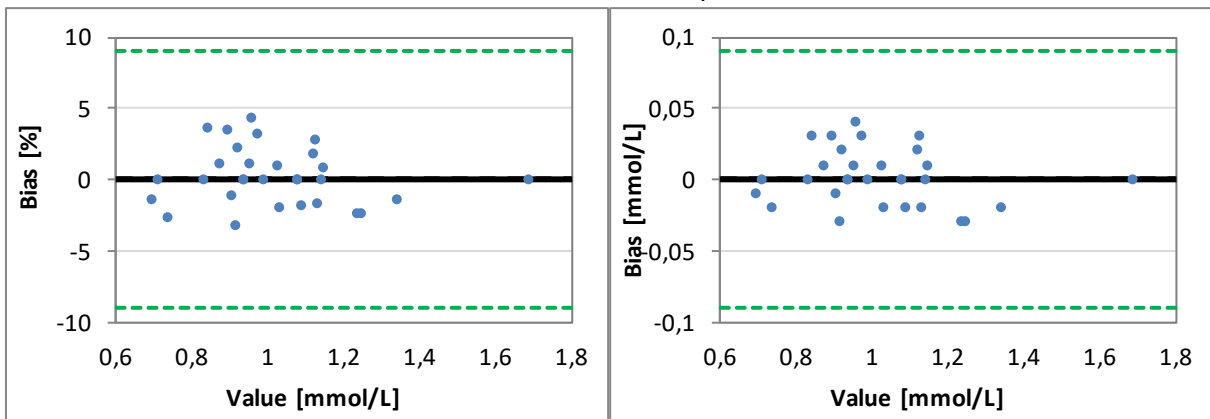


Phosphorous

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

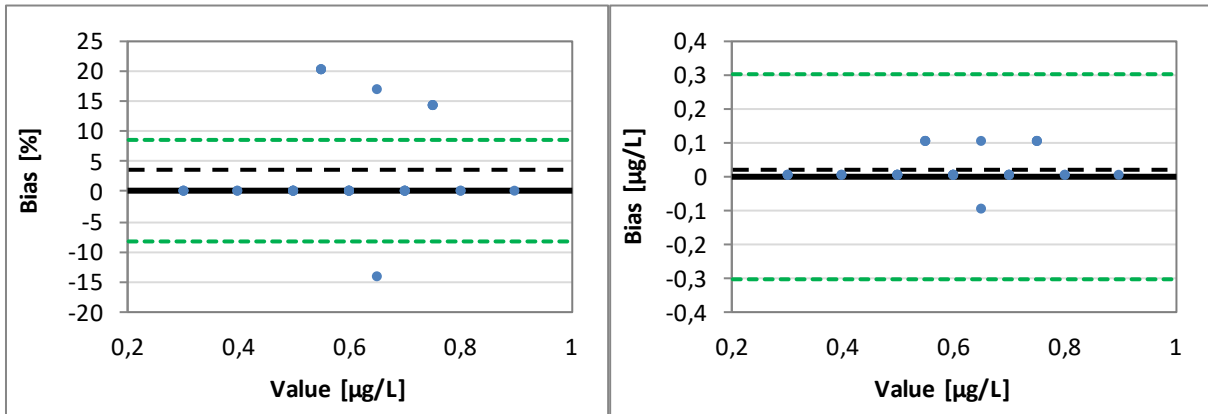


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

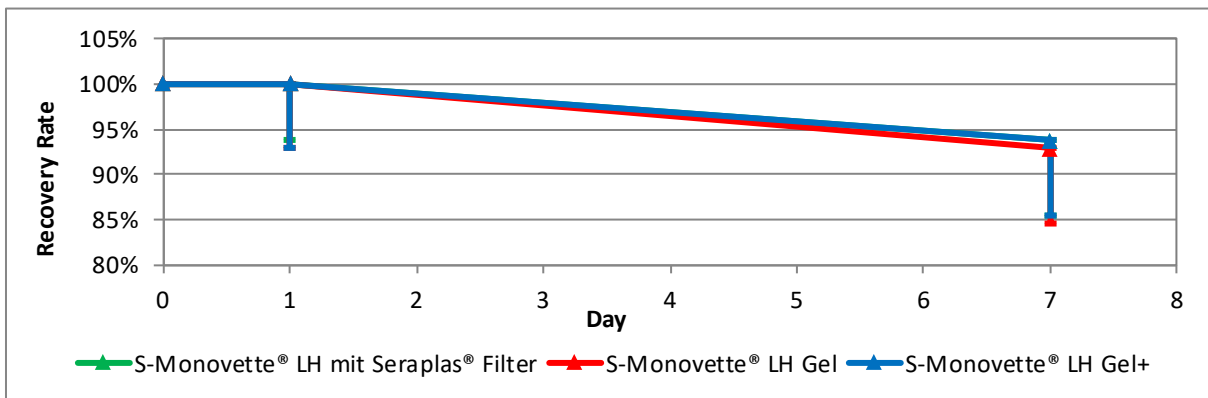
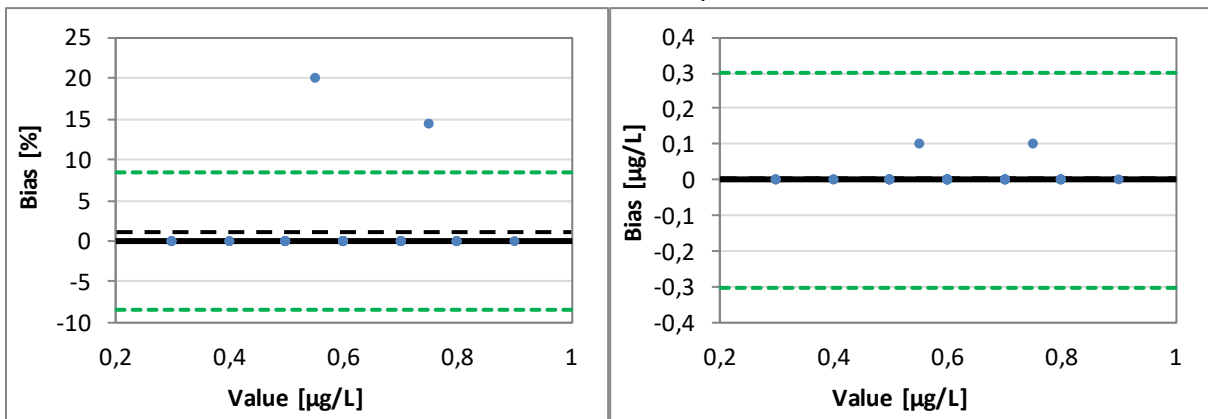


Procalcitonin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



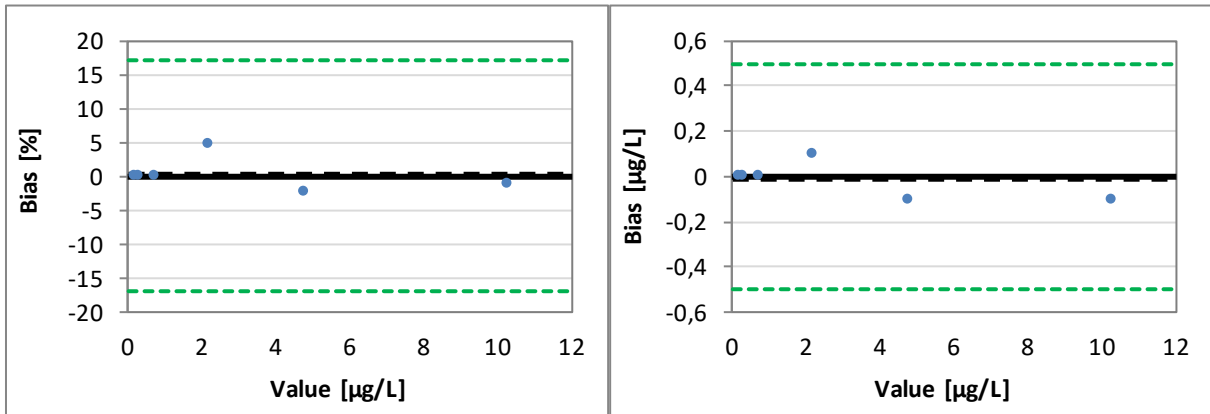
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



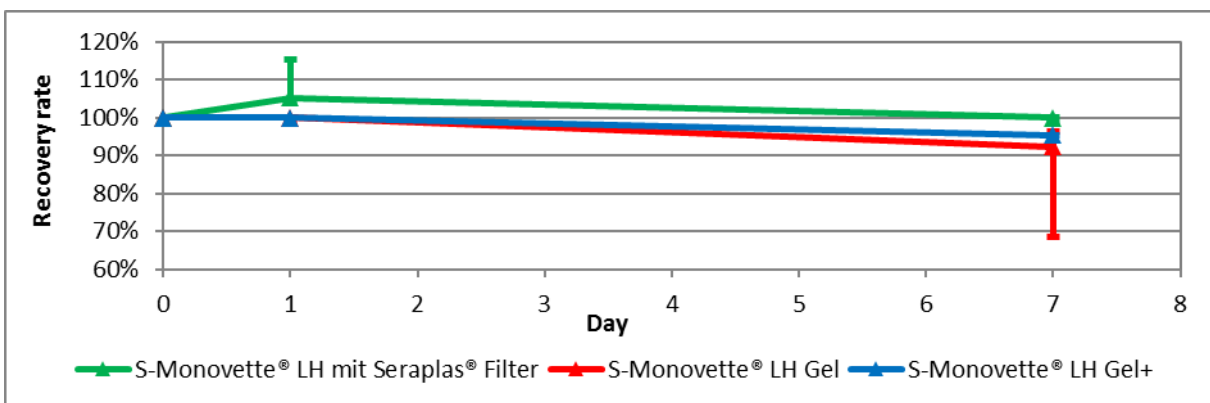
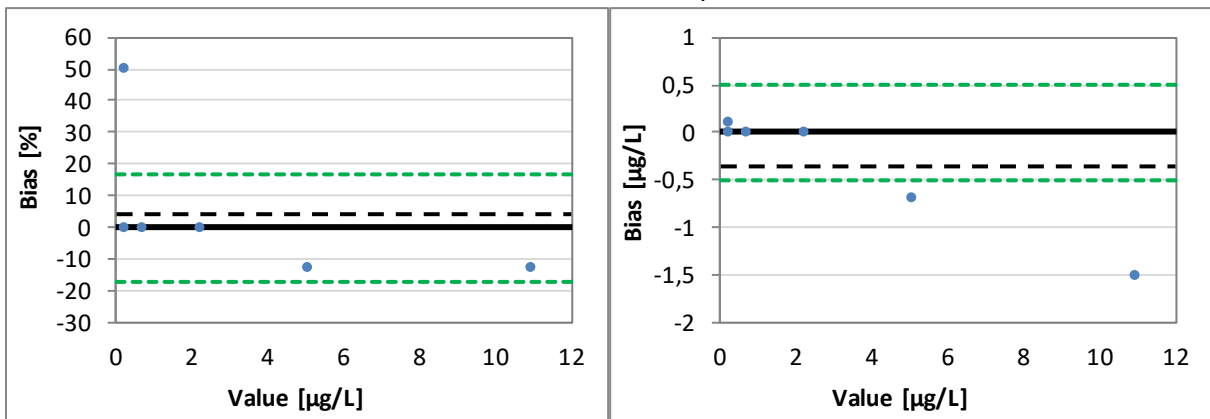


Progesterone

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

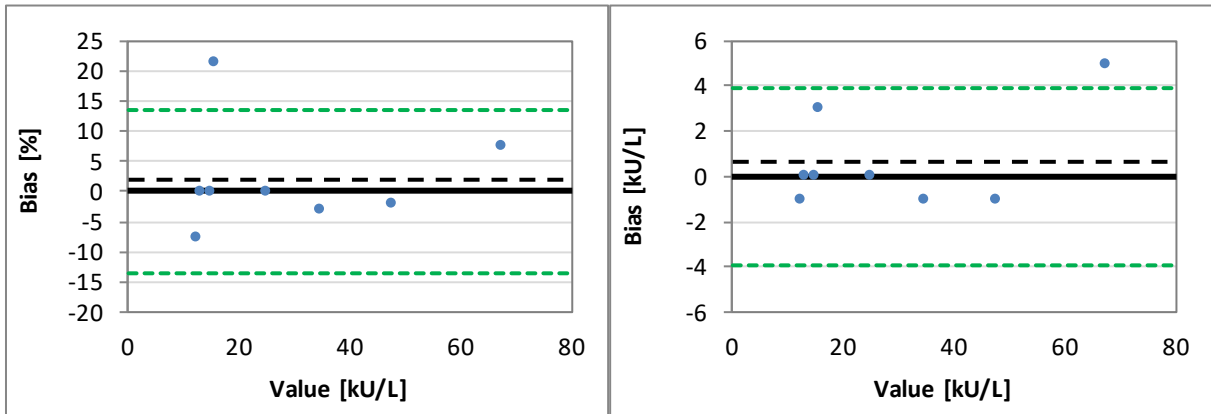


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

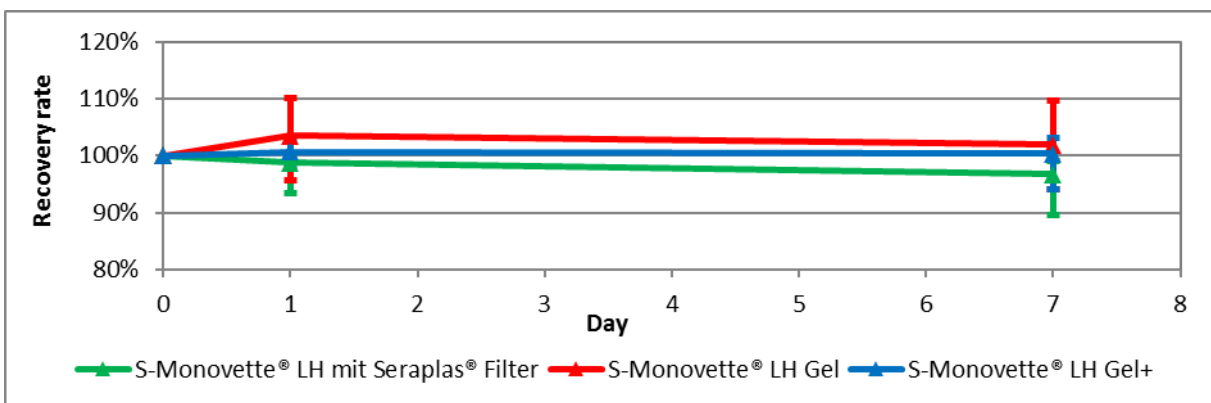
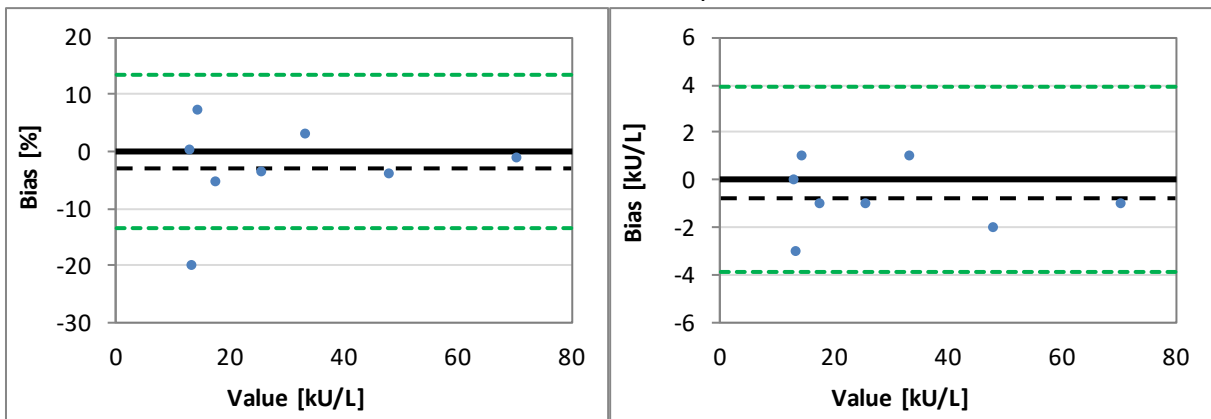


RF

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



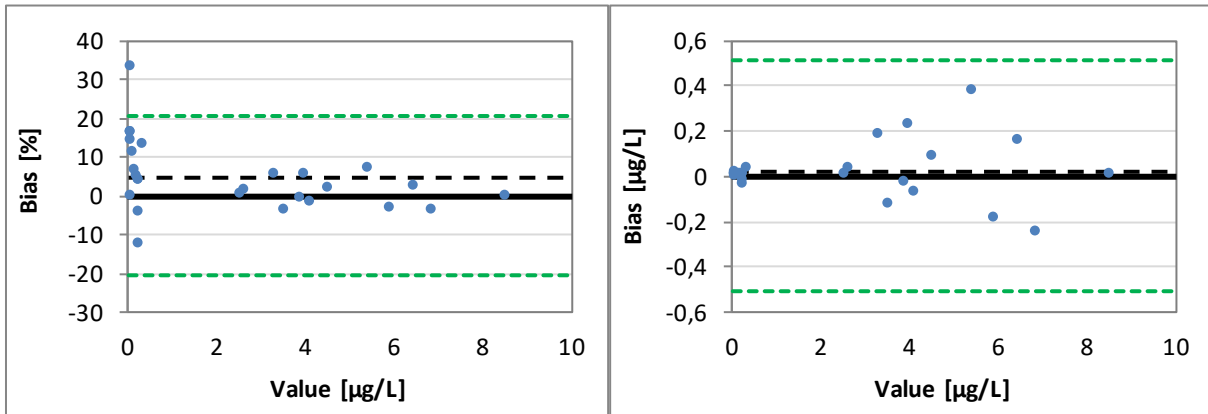
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



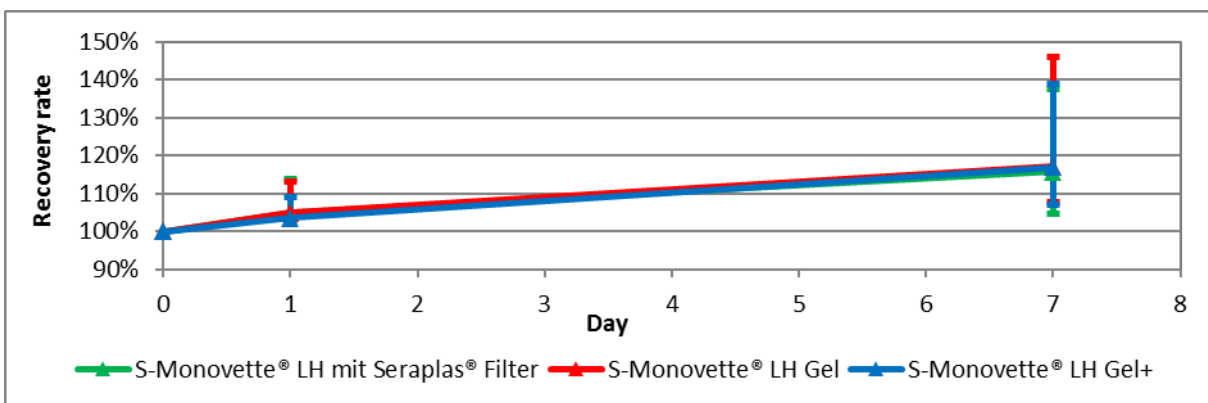
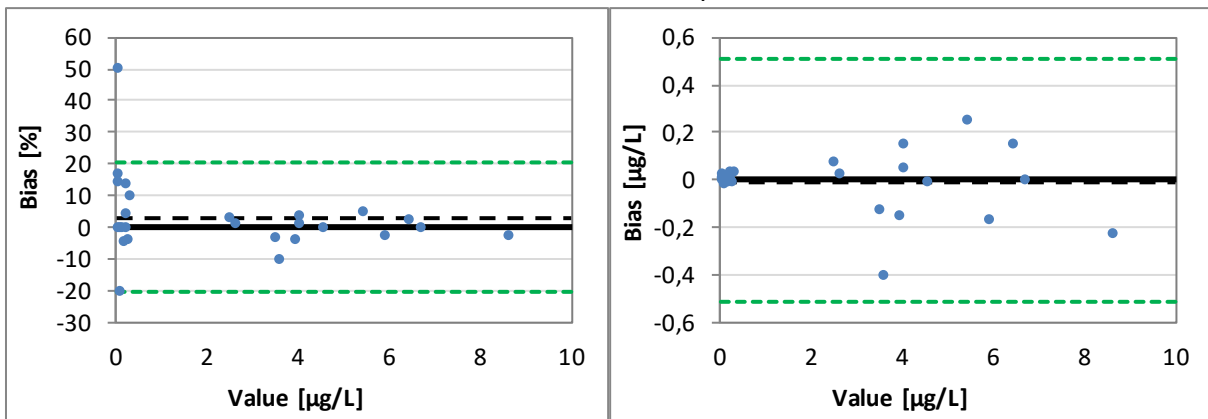


Testosterone

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

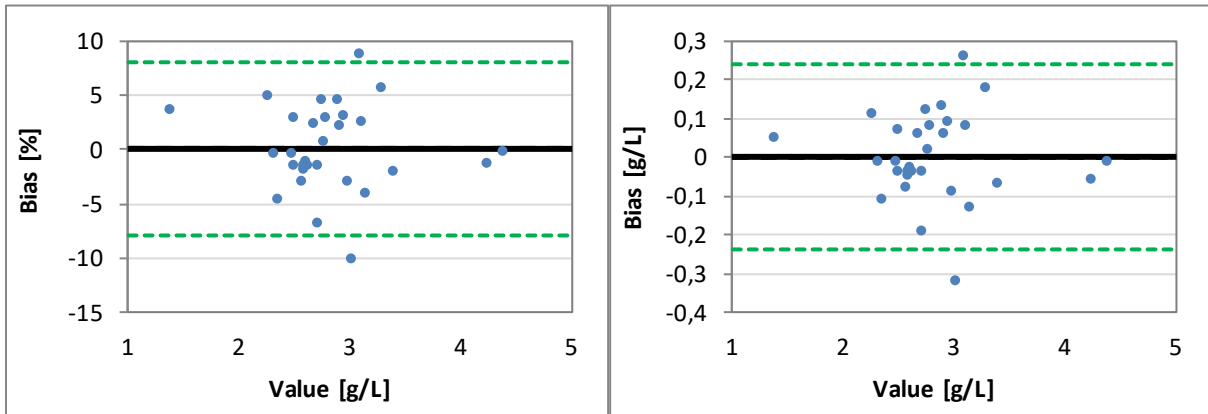


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

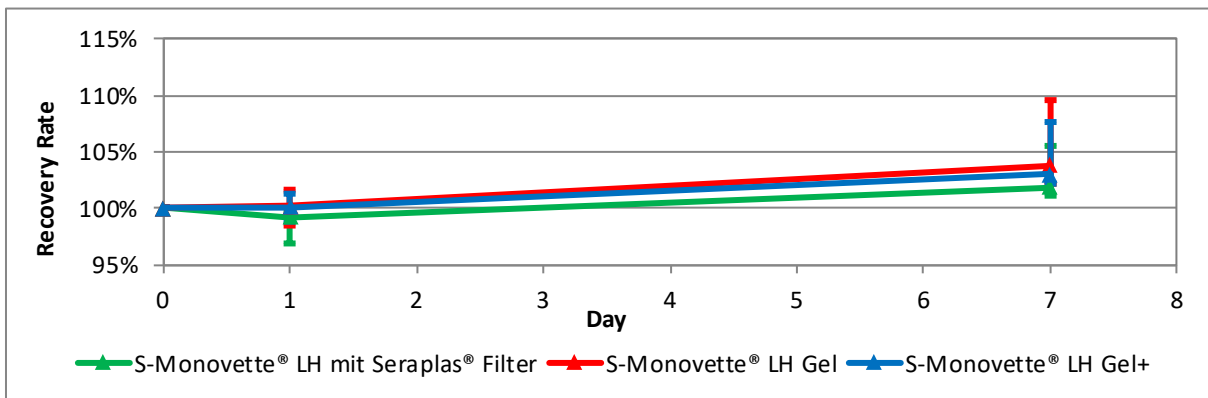
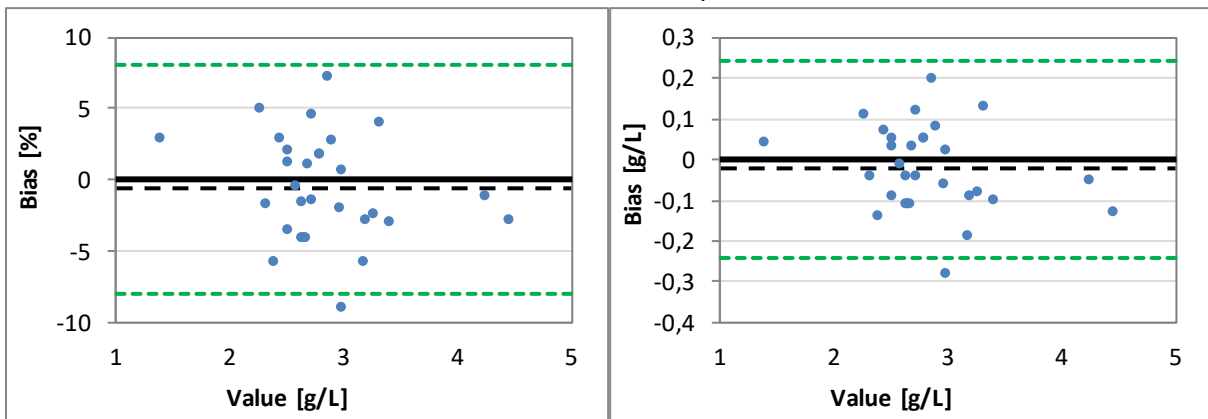


Transferrin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



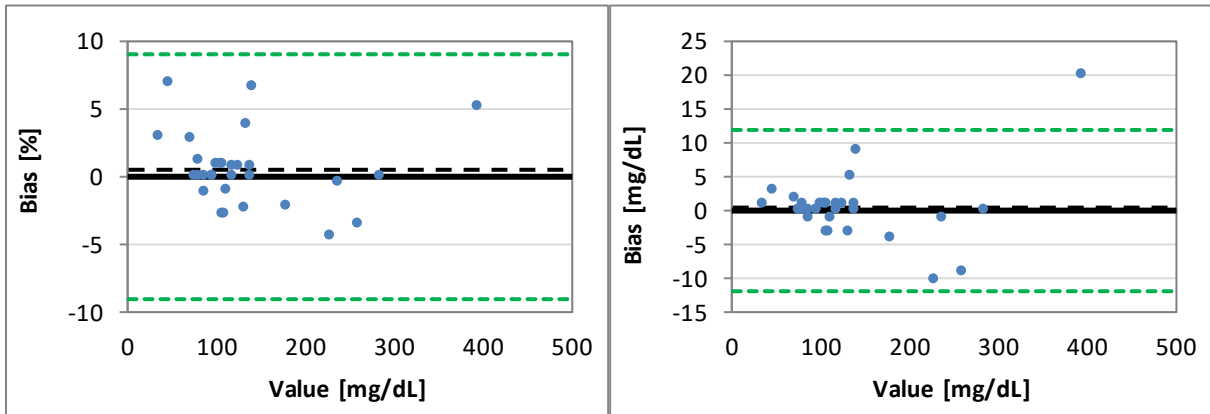
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



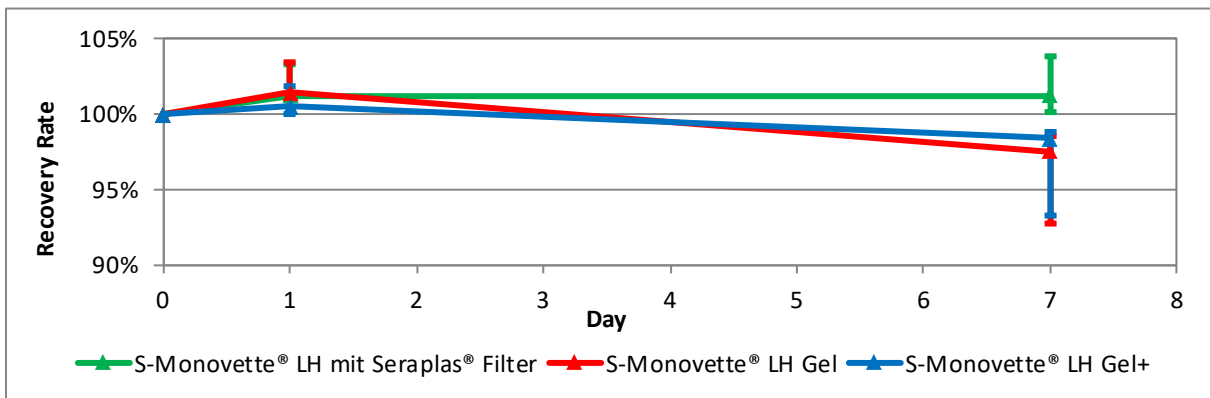
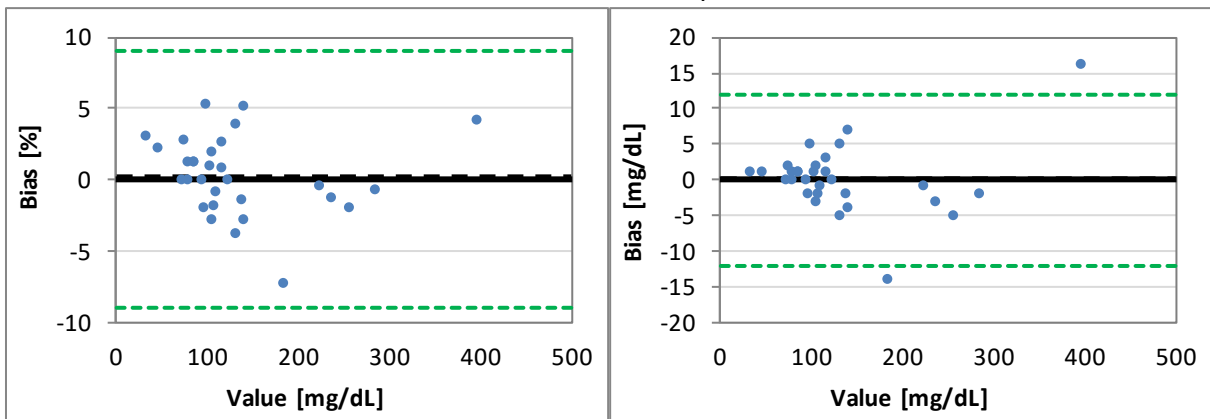


Triglyceride

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel

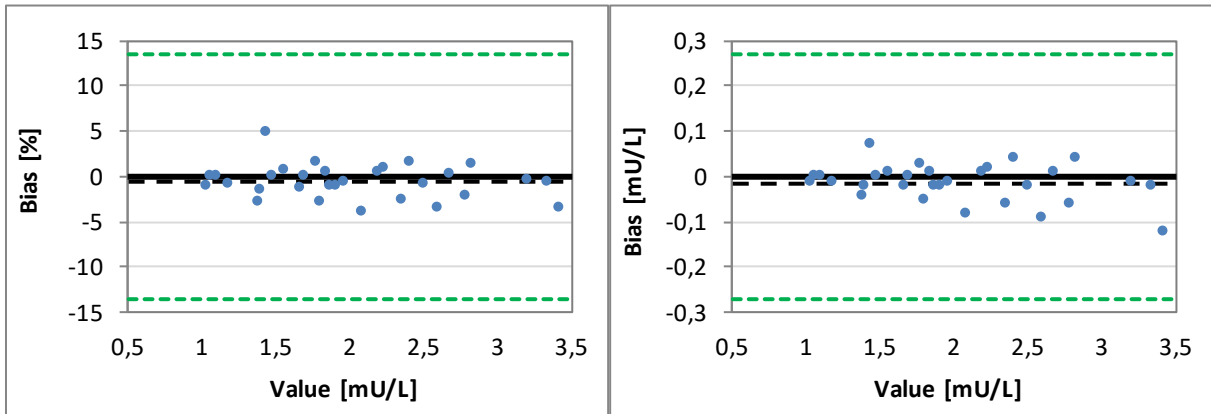


S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter

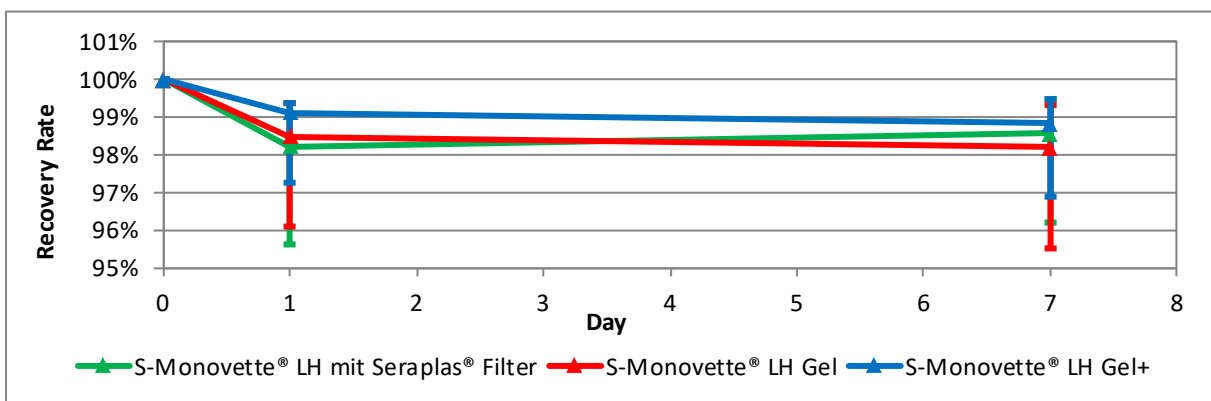
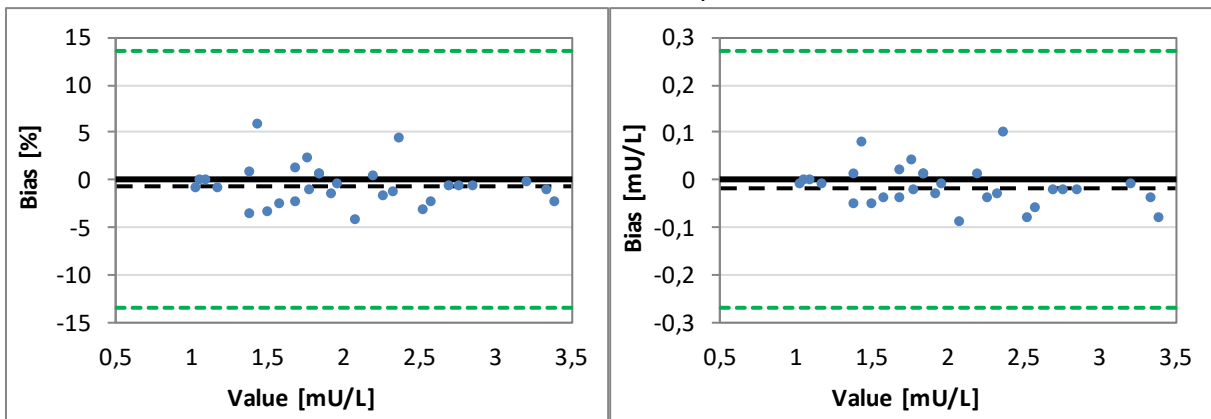


TSH

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



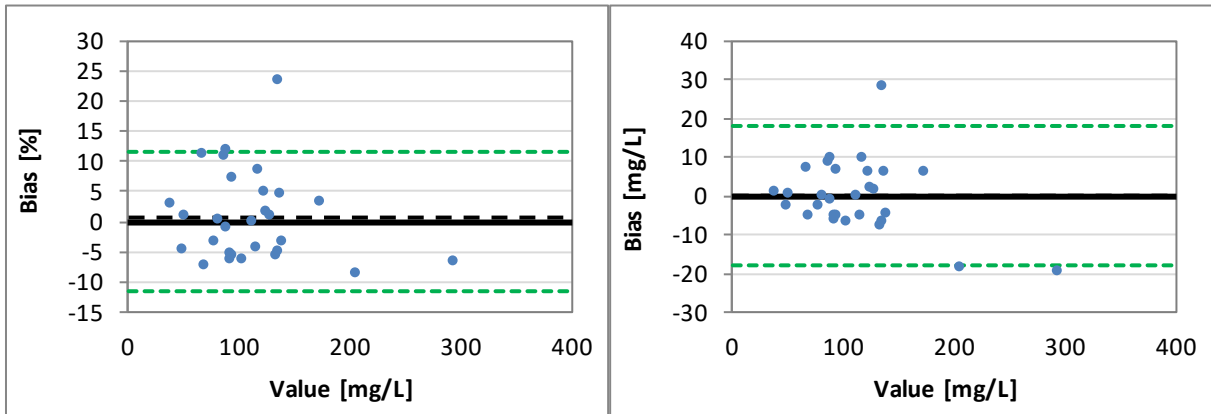
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



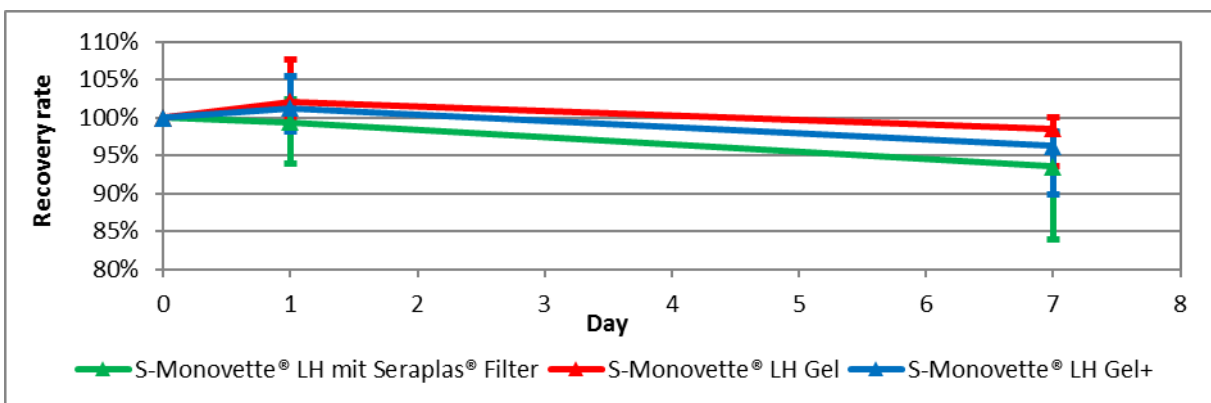
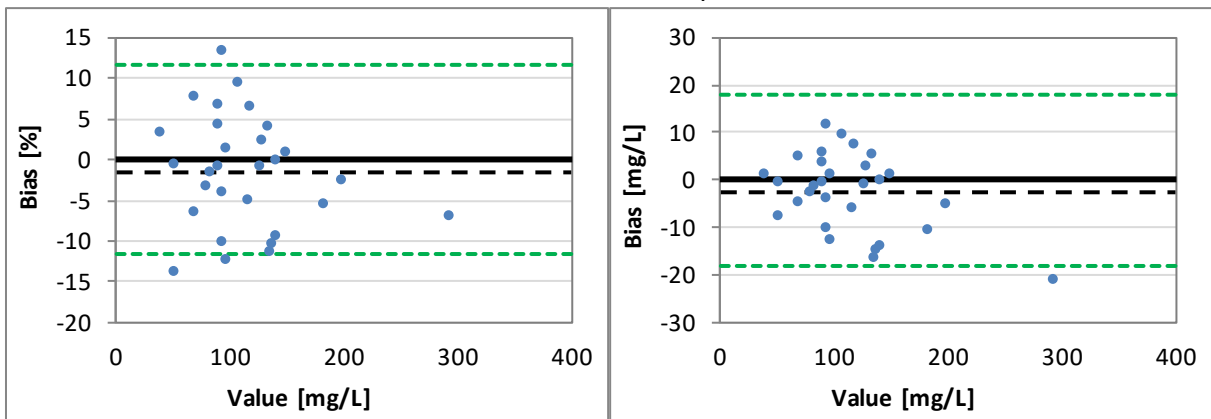


Valproic Acid

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



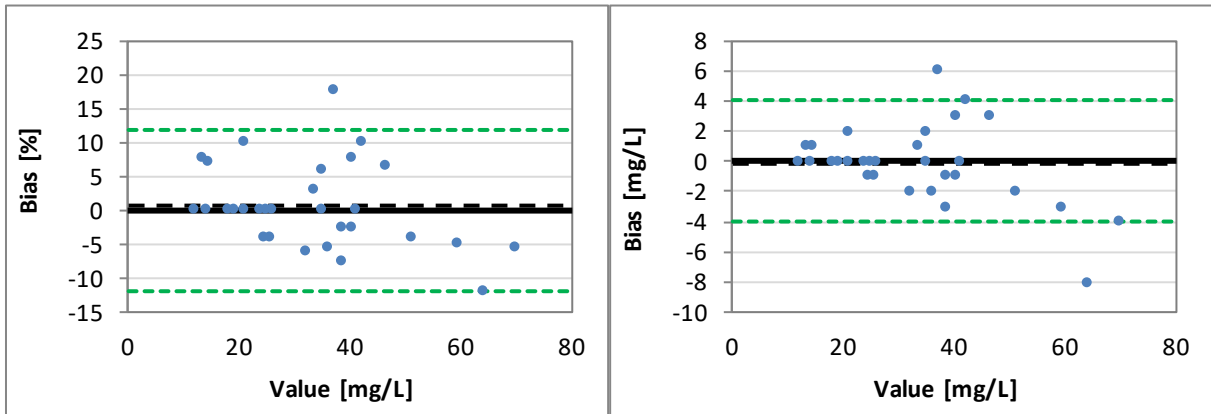
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



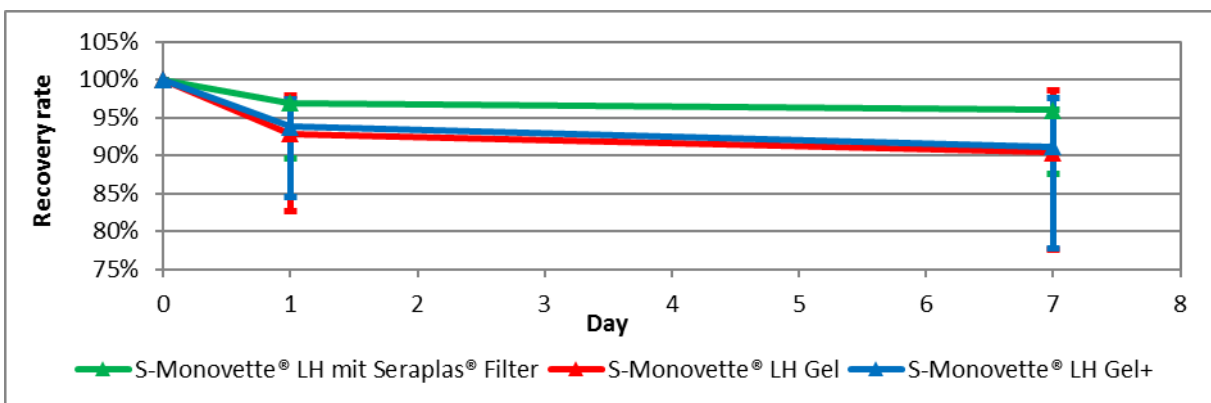
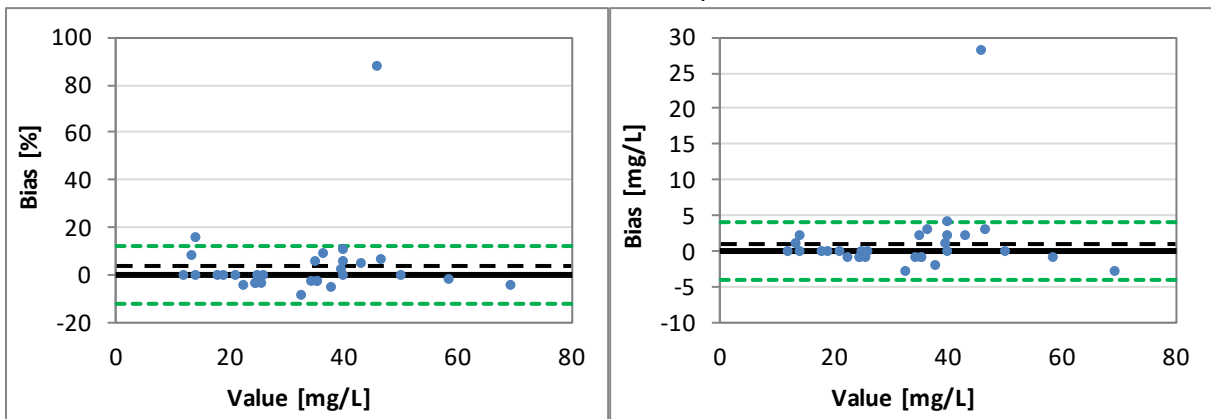


Vancomycin

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



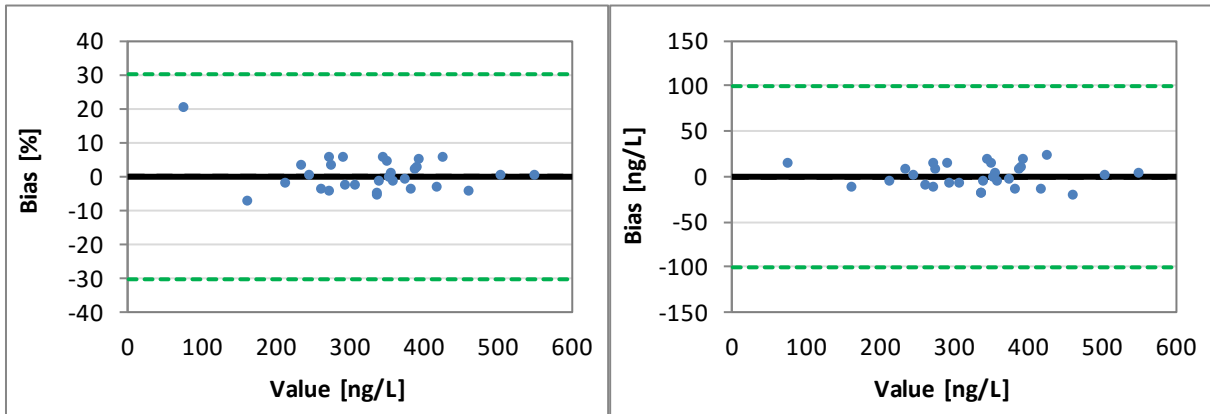
S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter



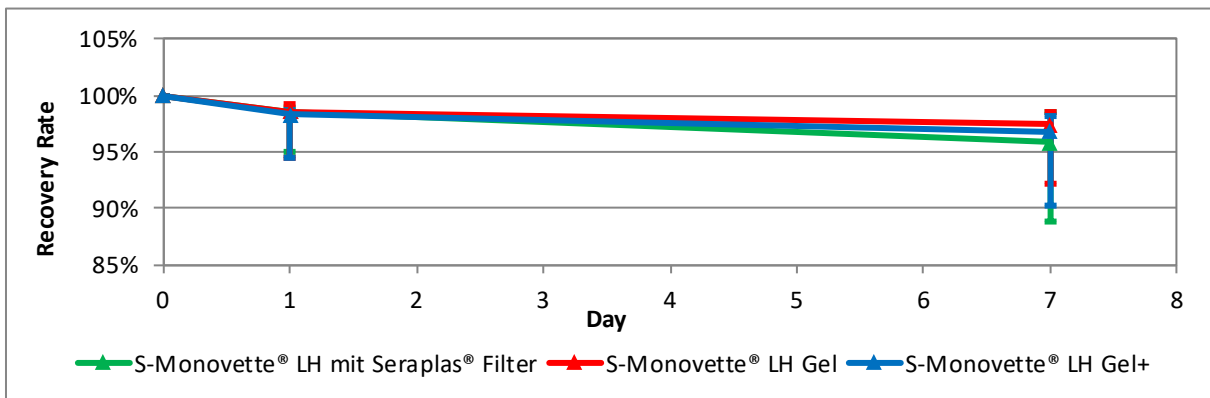
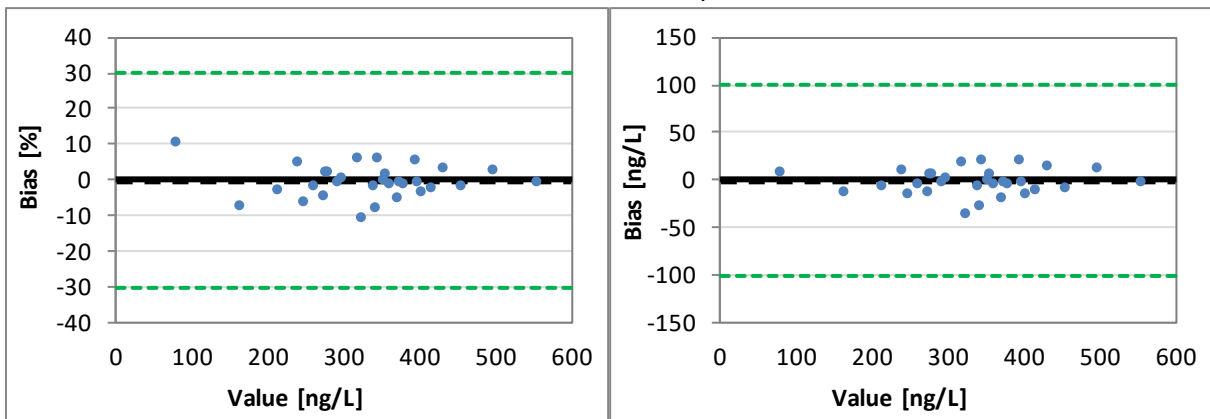


Vitamin B12

S-Monovette® LH Gel+ vs. S-Monovette® LH Gel



S-Monovette® LH Gel+ vs. S-Monovette® LH with Seraplas® Filter





II. Methods used

Parameter	Method*	Parameter	Method*
Albumin	ALB2	Urea	UREAL
AP	ALP2	HCG	HCG+β
Estradiol	Elecsys Estradiol III	HDL	HDLC3
Bilirubin (direct)	BILD2	HS Troponin T	Troponin T hs STAT
Bilirubin (total)	BILT3	IgA	IGA-2
Complement C3	Siemens N Antisera to Human Complement Factors	IgG	IGG-2
Calcium	CA2	IgM	IGM-2
Carbamazepine	CARB4	Potassium	ISE
CHE	CHE2	Creatinin	CREP2
Chloride	ISE	LDH	LDHI2
Cholesterol	CHOL2	LDL	LDL_C
CK	CK	LH	LH
CK-MB	CKMB	Lipase	LIPC
Cortisol	Elecsys Cortisol II	Magnesium	MG2
CRP	CRPL3	Sodium	ISE
Digoxin	DIG	p-Amylase	AMY-P
Iron	IRON2	Phenytoin	PHNY2
Total Protein	TP2	Phosphorous	PHOS2
Ferritin	Ferritin	Procalcitonin	Elecsys Prolactin II
Folate	Folate III	Progesterone	Progesterone III
ft3	FT3 III	RF	Siemens N Latex RF Kit
ft4	FT4 II	Testosterone	Testosterone II
FSH	FSH	Transferrin	TRSF2
GGT	GGT-2	Triglyceride	TRIGL
Glucose	GLUC3	TSH	TSH
GOT (AST)	ASTPM	Valproic Acid	VALP2
GPT (ALT)	ALTPM	Vancomycin	VANC2
Haptoglobin	HAPT2	Vitamin B12	Vitamin B12 II
Uric Acid	UA2		

*Roche unless otherwise stated