BÜHLMANN fCAL® turbo Precision Profile (Mindray)

The BÜHLMANN fCAL® turbo shows a very high precision. The precision is analyzer dependent and might slightly differ from analyzer to analyzer. Precision profiles are given in the specific application notes.

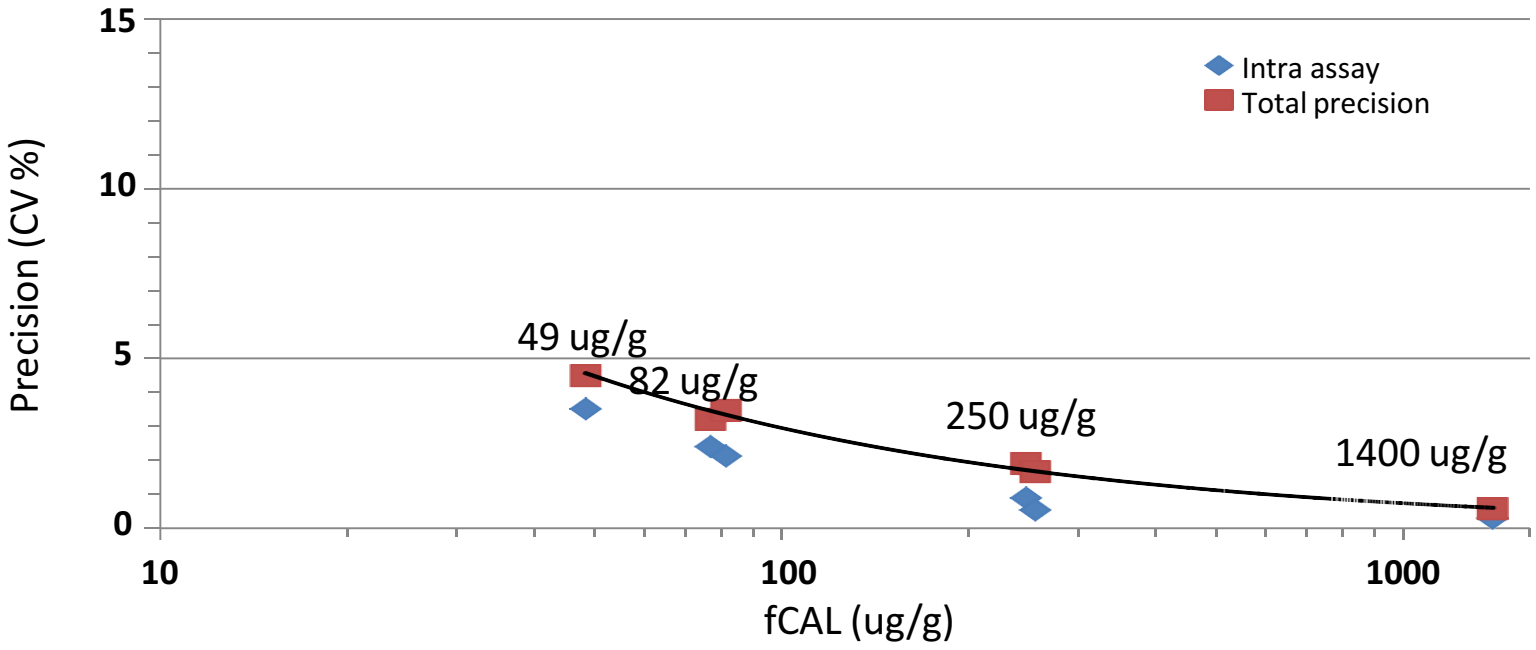


Fig. 3:
Precision profile intra und inter-assay (total) precision.

The precision profile above represents the validation data generated by the manufacturer and is part of the technical documentation.

BÜHLMANN fCAL® turbo Published Data –Nilsen et al, 2016

Precision data: 2 controls & 4 samples, measured during 20 days (BS-380) and 6 days (Cobas c501).

TABLE 4 Precision data for the F-calprotectin method on (a) Cobas c501 and (b) Mindray BS-380. The total coefficient of variation (CV) was calculated for four different sample concentrations and two control levels

	Sample 1	Sample 2	Sample 3	Sample 4	Control low	Control high
(a) Cobas c501						
n	24	24	24	24	24	24
Mean	37.8	90.5	380	919	76	256.2
CV	8.13	6.14	2.26	1.61	4.52	1.57
(b) Mindray BS-380						
n	80	80	80	80	80	80
Mean	49	82	248	1392	77	256
CV	4.5	3.5	1.9	0.6	3.2	1.7

Nilsen, T. et. al. A novel turbidimetric immunoassay for fecal calprotectin optimized for routine chemistry analyzers. J Clin Lab Anal. 2016 Sep 15. PMID: 27629827
The publication describes the technical performance of the BÜHLMANN's fCAL® turbo turbidimetric assay on the cobas c501 and the Mindray BS-380.

BÜHLMANN fCAL® turbo Published Data –Nilsen et al, 2016

Linearity data

TABLE 3: Linearity testing of the fecal calprotectin method on (a) Cobas c501 and (b) Mindray BS- 380. A high sample was diluted with a low sample to achieve different fecal calprotectin concentrations. The observed values were compared with the expected values and the recovery was calculated. The linearity is acceptable according to the preset criteria for the (a) Cobas c501 and (b) Mindray BS- 380 in the entire range tested.

Fraction of high (%)	Observed value (µg/g)	Expected value (µg/g)	Recovery (%)
(a) Cobas c501			
100	1966	1955	100.6
80	1565	1565	99.9
60	1194	1176	101.5
40	836	787	106.2
20	443	398	111.3
10	226	203	110.9
5	127	106	119.4
2.5	66	57	115.1
1.25	38	33	115.2
0.625	25	21	117.6
0	9	9	103.8

Fraction of high (%)	Observed value (µg/g)	Expected value (µg/g)	Recovery (%)
(b) Mindray BS-380			
100	2154	2146	100.3
80	1713	1719	99.7
60	1297	1291	100.4
40	873	864	101.1
20	437	436	100.1
10	229	222	103.1
5	124	116	107.1
2.5	66	62	105.9
1.25	36	35	100.3
0.625	24	22	109.0
0	9	9	103.8

Nilsen, T. et. al. A novel turbidimetric immunoassay for fecal calprotectin optimized for routine chemistry analyzers. J Clin Lab Anal. 2016 Sep 15. PMID: 27629827
The publication describes the technical performance of the BÜHLMANN's fCAL® turbo turbidimetric assay on the cobas c501 and the Mindray BS-380.

BÜHLMANN fCAL® turbo Published Data- Noebauer B. et al. 2017

Precision data: 2 controls & 4 Extracts, measured during 20 days in duplicates with 2 runs per day.

Table 1. Precision data analysis for the fully automated particle-enhanced turbidimetric immunoassay (PETIA) on VITROS® 5600

	Sample 1	Sample 2	Sample 3	Sample 4	Control low	Control high
Mean	50.6	82.6	277.5	1078.7	77.0	243.8
Within run CV (µg/g)	6.63	2.47	0.97	0.46	5.10	2.15
Between day CV (%)	< 0.01	4.72	2.81	2.82	1.35	0.90
Between run CV (%)	6.05	3.10	2.63	1.17	< 0.01	< 0.01
Total CV (%)	8.89	6.16	3.97	3.09	5.27	2.33

Four distinct sample concentrations and two controls were used for the assessment of different coefficients of variations (CVs).

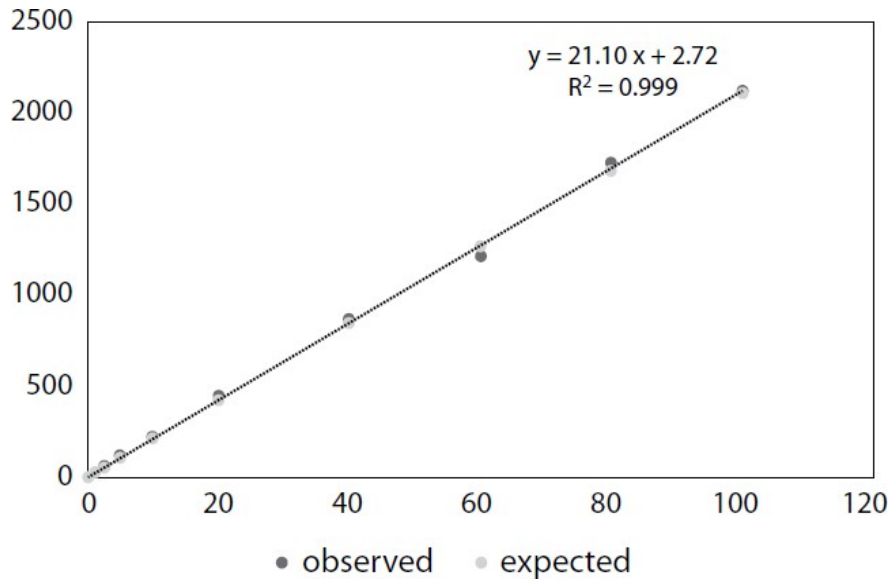
Noebauer, B., Ramic, L. et al. Analytical evaluation of a fully automated immunoassay for faecal calprotectin in a paediatric setting. Biochemia Medica, 2017;27(3):030710.
DOI: 10.11613/BM.2017.030710

BÜHLMANN fCAL® turbo Published Data- Noebauer B. et al. 2017

Linearity data

Figure 1: Linearity testing of the fully automated particle enhanced turbidimetric immunoassay (PETIA) on the VITROS® 5600. Linearity was tested and confirmed in the range from 20 to 2100 µg/g. ND – not detected.

Fraction of high calibrator (%)	Observed value (µg/g)	Expected value (µg/g)	Recovery (%)
100	2113	2105	100.4
80	1720	1684	102.1
60	1209	1263	95.7
40	867	842	103.0
20	446	421	106.0
10	218	210	103.4
5	115	105	109.2
2.5	57	53	107.6
1.25	23	26	87.0
0.625	3	13	19.0
0	0	0	ND



Noebauer, B., Ramic, L. et al. Analytical evaluation of a fully automated immunoassay for faecal calprotectin in a paediatric setting. Biochemia Medica, 2017;27(3):030710.
DOI: 10.11613/BM.2017.030710

BÜHLMANN fCAL® turbo Published Data- Havelka et al. 2017

Precision data: 2 controls & 4 samples, measured during 5 days on cobas® c111 and 10 days on BS-200E.

Table 3A. Precision data for the fecal calprotectin method on cobas® c111.

cobas® c501	Sample 1	Sample 2	Sample 3	Sample 4	Low control	High control
n	20	20	20	20	20	20
Mean (µg/g)	43.7	92.8	273.0	1382.6	71.4	252.4
Within run CV (%)	3.86	1.30	0.57	0.98	2.14	0.93
Between day CV (%)	5.27	6.25	1.67	2.26	1.07	0.70
Between run CV (%)	1.99	1.60	0.75	0.78	0.1	1.63
Total CV (%)	6.83	6.58	1.92	2.59	2.39	2.00

CV was calculated for four different sample concentrations and two control levels.

Table 3B. Precision data for the fecal calprotectin method on Mindray BS-200E.

Mindray BS-200E	Sample 1	Sample 2	Sample 3	Sample 4	Low control	High control
n	20	20	20	20	20	20
Mean (µg/g)	43.5	67.5	433	1271	75.0	267.7
Within run CV (%)	4.1	5.8	1.53	0.6	2.9	1.1
Between day CV (%)	1.8	2.0	1.42	3.0	6.3	0.8
Between run CV (%)	2.9	0.5	2.1	2.2	2.0	2.2
Total CV (%)	5.50	3.89	2.92	3.82	7.2	2.6

CV was calculated for four different sample concentrations and two control levels.

Mandic-Havelka, A. Nilsen, T. et. al. Turbidimetric Determination of Fecal Calprotectin Using Two Table Top Chemistry Analyzers: Mindray BS-200E and Cobas® c111. Clin Lab. 2017 May 1;63(5):907-913. doi: 10.7754/Clin.Lab.2016.161032. PMID: 28627817

BÜHLMANN fCAL® turbo Published Data- Havelka et al. 2017

Linearity data

Table 2A. Linearity study of fecal calprotectin method on cobas® c111.

Fraction of high - %	Observed value - µg/g	Expected value - µg/g	Recovery (%)
100	1964.75	1961	100.2
80	1737.95	1570	110.7
60	1177.00	1179	99.9
40	763.70	787	97.0
20	360.45	396	91.0
10	212.65	201	105.9
5	107.85	103	104.7
2.5	56.45	54	104.4
1.25	29.75	30	100.3
0.625	18.60	17	106.8
0	4.10	5	below LOQ

A high sample was diluted with a low sample to achieve different fecal calprotectin concentrations. The observed values were compared with the expected values, and the recovery was calculated. Acceptance criteria for deviation: < 10%. The linearity is acceptable according to the preset criteria for the cobas® c111 in the entire tested range. LOQ - limit of quantification.

Table 2B. Linearity testing of the fecal calprotectin method on Mindray BS-200E.

Fraction of high - %	Observed value - µg/g	Expected value - µg/g	Recovery (%)
100	1514	1514	100.0
80	1198	1211	98.9
60	864	908	95.1
40	586	606	96.8
20	298	303	98.5
10	153	151	101.1
5	78.5	76	103.3
2.5	40.0	38	105.7
1.25	24.5	19	below LOQ
0.625	19.5	9	below LOQ
0	0.5	0	below LOQ

A high sample was diluted with a low sample to achieve different fecal calprotectin concentrations. The observed values were compared with the expected values and the recovery was calculated. Acceptance criteria for deviation: < 10%. The linearity is acceptable according to the acceptance criteria for the Mindray BS-200E in the entire tested range. LOQ - limit of quantification.

Mandic-Havelka, A. Nilsen, T. et. al. Turbidimetric Determination of Fecal Calprotectin Using Two Table Top Chemistry Analyzers: Mindray BS-200E and Cobas® c111. Clin Lab. 2017 May 1;63(5):907-913. doi: 10.7754/Clin.Lab.2016.161032. PMID: 28627817

BÜHLMANN fCAL® turbo Published Data- Noebauer B. et al. 2017

Method Comparison of fCAL ELISA to fCAL Turbo on two analyzers:

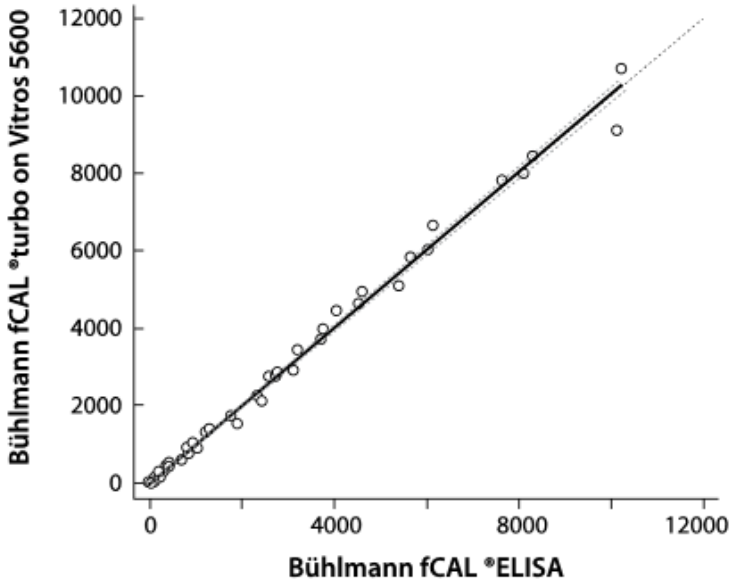


Figure 2. Passing-Bablok regression analysis of the fully automated particle-enhanced turbidimetric immunoassay (PETIA) performed on the VITROS® 5600 analyzer and an ELISA assay for faecal calprotectin. N = 95; concentration range: PETIA = 0 – 10,692 µg/g, ELISA = 0 – 10,237 µg/g; Pearson correlation coefficient R = 0.99; P < 0.001. Regression line equation with corresponding 95% CI for intercept and slope was y = 1.53 (- 0.69 to 3.14) + 1.01 (0.99 to 1.02) x. Cusum test for linearity indicates no significant deviation from linearity (P = 0.22).

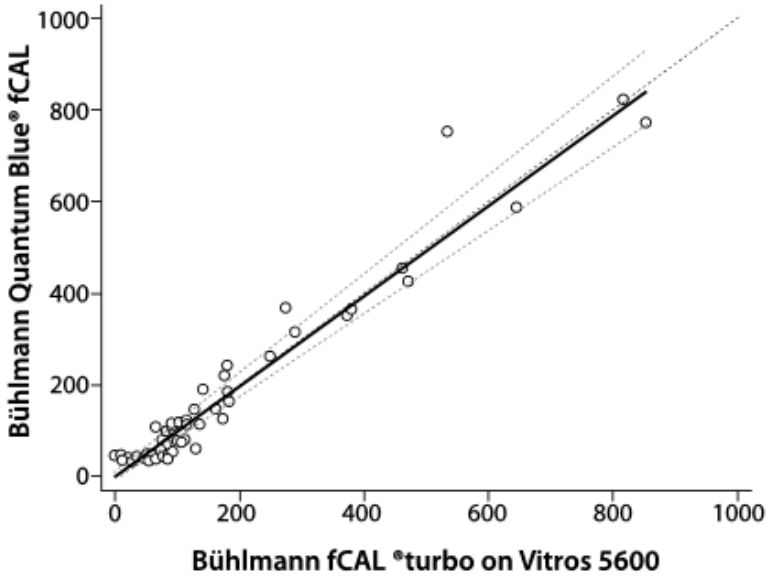


Figure 4. Method comparison of the automated particle-enhanced turbidimetric immunoassay (PETIA) performed on the VITROS® 5600 analyzer and a semi-quantitative lateral flow assay for faecal calprotectin. N = 53; concentration range: PETIA 0 – 852 µg/g, semi-quantitative lateral flow assay 31 – 820 µg/g. Pearson correlation coefficient R = 0.93, P < 0.001. Regression line equation with corresponding 95% CI for intercept and slope was y = 0.35 (- 10.03 to 7.38) + 0.99 (0.91 to 1.08) x. Cusum test for linearity indicates no significant deviation from linearity (P = 0.28).

Noebauer, B., Ramic, L. et al. Analytical evaluation of a fully automated immunoassay for faecal calprotectin in a paediatric setting. Biochemia Medica, 2017;27(3):030710.
DOI: 10.11613/BM.2017.030710