

Application Note

Products	BÜHLMANN fCAL® turbo:	CE0123 IVD US only: Rx Only
	BÜHLMANN fCAL® turbo Reagent Kit (B-KCAL-RSET)	
	BÜHLMANN fCAL® turbo Control Kit (B-KCAL-CONSET)	
	BÜHLMANN fCAL® turbo Calibrator Kit (B-KCAL-CASET)	
Analyzer	QuidelOrtho Vitros® 5600 / XT 7600 / 4600	
Version	20250526	

Before installation, please read the appropriate assay instructions for use. Additionally, refer to the analyzer manual for additional instructions.

The reagents supplied are ready to use. Mix gently before loading onto the instrument. Load according to the instrument manual. Use the designated bottles provided by the instrument manufacturer. Avoid bubble formation.

Instrument Settings

OPTIONS & CONFIGURATION – User Defined Assays

Full Assay name	fCAL turbo*
Short Assay Name	fCAL*
Fluid Type	Urine
Assay Model Type	End Point
Template	EPT1 R1-R2-S

Cal Model Type		Cubic Spline	
Calibrator Bottles	6	Replicates Per Cal	2

Edit Dilution Parameters

Diluent	Water	Standard Dilution Factor	1.0
REFLEX DILUTION			
Reflex Dilution	☒ On	☐ Off	
Dilution Factor	10.0		
Reduction Factor	1.0		

OPTIONS & CONFIGURATION – Edit Result Parameters

Reporting Type ☒ Quantitative ☐ Qualitative

RESULT PARAMETERS

Significant Digits	6	Precision Digits	2
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USER ADJUSTED PARAMETERS

Slope	1.00	Intercept	0.00
Cuve Tip Expiration time	35		
Temperature Sensitive	no		

RANGES

Reference	0.00	50.00
Supplementary	0.00	90000000
Measuring (reportable)	30.00	2000.00

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Edit End Point Additional Parameters

Initial Absorbance Limits	
-0.200	2.700
Blank Absorbance Limits	
-0.200	2.700

OPTIONS & CONFIGURATION – Edit Protocol Parameters

1.	Reagent	Volume (µL)	130.0	Pack/Bottle (UD01)	A
2.	Incubation	Seconds	14.25		
3.	Reagent	Volume (µL)	26.0	Pack/Bottle (UD01)	B
4.	Incubation	Seconds	114.00		
5.	Read	Wavelength	575 nm		
6.	Sample	Volume (µL)	10.0		
7.	Incubation	Seconds	175.75		
8.	Read	Wavelength	575 nm		

OPTIONS & CONFIGURATION – Enter/Edit Calibration Parameters

			Lot	4101**
Bottle Number	Dilution Factor	Calibrator Replicate Response Range	Calibrator Value**	
1	1.0	0.20000	0.00	
2	1.0	0.20000	51.50	
3	1.0	0.20000	206.00	
4	1.0	0.20000	515.00	
5	1.0	0.20000	1030.00	
6	1.0	0.20000	2061.00	
			Expiration Date	09/30/16**

Edit Cubic Spline Additional Parameters

Monotonicity	☒ Increase	☐ Decrease		
Max. Response High	3.000		Min Response High	3.000
Max Response Low	-3.000		Min Response Low	-3.000
			Calibration Interval	56 days

Edit Triple Read Parameters

	Measuring (Reportable) Concentration	Triple Read Limit
Measuring (Reportable) Min	30.00	16.00
Critical Concentration	1110.00	12.0 %
Measuring (Reportable) Max	2000.00	18.0 %

*user defined

**lot specific

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Performance Data

Parameter	Acceptance Criteria	Performance
Method comparison	±15 % bias at clinical decision points of 80 µg/g and 160 µg/g	80 µg/g: 11.9% 160 µg/g: 9.1% (see Table 1)
Precision	≤ 15% CV for samples ≥ 50 µg/g	Total Precision: 5.7% to 9.8% (see Table 2)
Analytical sensitivity	LoB ≤ LoD LoD ≤ LoQ LoQ ≤ 30 µg/g	LoB: 16.47 µg/g LoD: 22.82 µg/g LoQ: 30.0 µg/g
Analytical measuring interval (AMI)		30 to 2000 µg/g
Extended measuring interval (EMI)		30 to 11878 µg/g
Linearity	R ² ≥ 0.95 deviation from linearity of less than 7.5 µg/g / 10%	R ² =1.000 30.7 to 11878 µg/g
Sample carry-over	Mean carry-over ≤ 0.32% Otherwise a technical precaution must be included in the instrument-specific application note.	No significant sample carry-over
Calibration curve stability	Drift analysis with deviation limit from baseline of ± 20%	56 days
On-board stability	up to 30 days at 2-15°C	90 days

Table 1 Detailed method comparison performance.

N	Reference range	Passing-Bablok Regression Analysis					Bland-Altman Analysis		
		Slope	Intercept	Bias % at 80 µg/g	Bias % at 160 µg/g	r	Mean bias %	Lower LoA %	Upper LoA %
45	41.5 to 8555.5	1.062	4.557	11.9	9.1	0.999	8.72	-12.34	29.78

Table 2 Detailed precision performance

ID	Mean [µg/mL]	Within-run (repeatability)	Between- day	Between- run	Total Precision
		CV[%]			
P1	56.2	4.7	4.0	2.0	6.3
P2	93.3	2.2	9.5	0.7	9.8
P3	178.1	2.1	5.1	1.6	5.7
P4	656.9	3.6	5.6	4.7	7.4
P5	1542.1	1.3	8.1	3.9	9.1
P6	6537.1	1.6	8.4	1.9	8.7