

## Application Note

<b>Products</b>	BÜHLMANN fCAL® turbo: BÜHLMANN fCAL® turbo Reagent Kit (B-KCAL-RSET) BÜHLMANN fCAL® turbo Control Kit (B-KCAL-CONSET) BÜHLMANN fCAL® turbo Calibrator Kit (B-KCAL-CASET)	<b>CE</b>
<b>Analyzer</b>	Beckman Coulter AU480 / AU5800	
<b>Version</b>	20230420	

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. Equilibrate reagents at room temperature before loading. 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 AU480

Reagent ID: 256

Specific Test Parameters											
General		LIH	ISE	Range							
Test Name:		FCA1G ▾		< >		Type:	Other ▾		Operation:	Yes ▾	
Sample Volume	10		μL	Dilution	0		μL	OD Limit			
Pre-Dilution Rate	1			Min. OD	-2.000		Max. OD	3.000			
R1(R1-1)	130		μL	Dilution	0		μL	Reagent OD limit:			
	First Low	-2.000		High	3.000						
	Last Low	-2.000		High	3.000						
R2 (R2-1)	26		μL	Dilution	0		μL	Dynamic Range Low	30.0		
	High	2000.0									
Wavelength:	Pri.	540		nm	Sec.	None		nm	Correlation Factor A	1	
	B	0									
Method:	FIXED		▾								
Reaction slope:	+		▾								
Measuring Point 1:	First	11		Last	18		LIH Influence Check				No ▾
Measuring Point 2:	First			Last			Lipemia	+		▾	
Linearity:			%								
No Lag Time:	No		▾								
	Icterus	+		▾							
	Hemolysis	+		▾							
Onboard Stability	90		Day	0		Hour					

Specific Test Parameters																
General		LIH	ISE	Range												
Test Name:		fCAL ▾		< >		Type:	Other ▾									
Value/Flag:	#		▾		Level L:	#		Level H:	#							
Specific Ranges:																
	From	Year		Month	Year	Month	Low	High								
<input type="checkbox"/>	1.	Sex	#	#	#	#	#	#	#	#						
<input type="checkbox"/>	2.	#	#	#	#	#	#	#	#	#						
<input type="checkbox"/>	3.	#	#	#	#	#	#	#	#	#						
<input type="checkbox"/>	4.	#	#	#	#	#	#	#	#	#						
<input type="checkbox"/>	5.	#	#	#	#	#	#	#	#	#						
<input type="checkbox"/>	6.	#	#	#	#	#	#	#	#	#						
	7.	No demographics														
	8.	Not within expected values														
Unit	μg/g		Decimal Places		1											
<table border="1" style="margin-left: auto;"> <tr> <th colspan="2">Panic Value</th> </tr> <tr> <td>Low</td> <td>High</td> </tr> <tr> <td>#</td> <td>#</td> </tr> </table>											Panic Value		Low	High	#	#
Panic Value																
Low	High															
#	#															

<b>Product</b>	BÜHLMANN fCAL® turbo
<b>Analyzer</b>	Beckman Coulter AU480 / AU5800
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Calibration Specific	
General	ISE
Test Name:	FCA1G < > Type: Other < > <input type="checkbox"/> Use Serum Cal.
Calibration Type:	6AB Formula: SPLINE Counts: 2
<Calibrator Parameters>	
Calibrator	OD Conc Factor Range Low High Slope Check
Point 1:	# < > ** -9999999 9999999 None < >
Point 2:	# < > ** -9999999 9999999
Point 3:	# < > ** -9999999 9999999
Point 4:	# < > ** -9999999 9999999
Point 5:	# < > ** -9999999 9999999
Point 6:	# < > ** -9999999 9999999
Point 7:	< >
Point 8:	< >
Point 9:	< >
Point 10:	< >
<Point Cal. For Master Curve>	
Calibrator	No. of Correction Points OD Conc OD Range Low High
Point 1:	< > < > < > < > < > < >
Point 2:	< > < > < > < > < > < >
MB Type Factor:	< > 1-Point Calibration Point < > <input type="checkbox"/> With CONC-0

#User specific  
\*\*lot dependent

## AU5800

Reagent ID: 256

Parameters		Specific Test Parameters			
General	LIH	ISE	HbA1c	Calculated Test	Range
Test Name:	FCA1G < >	Type:	Other < >	Operation	Yes < >
Sample Volume	10 μL	Dilution	0 μL	OD Limit	
Pre-Dilution Rate	1 < >	Diluent Bottle	# < >	Min.OD	-2.0000 Max.OD 3.0000
Rgt. Volume	R1(R1-1) 130 μL	Dilution	0 μL	Reagent OD Limit	
	R1-2 < > μL	Dilution	< > μL	1st. Low	-2.0000 High 3.0000
	R2(R2-1) 26 μL	Dilution	0 μL	Last Low	-2.0000 High 3.0000
Common Rgt. Type	None	Name	None	Dynamic Range Low	30.0 High 2000.0
Wavelength	Pri 540 < > nm	Sec.	None < > nm	Correlation Factor A	1 B 0
Method	FIXED < >	Factor for Maker A	1	B	0
Reaction Slope	+ < >	Onboard Stability Period	90 Day	0 Hour	
Measuring Point1 1st	11	Last	18	LIH Influence Check	No < >
Measuring Point2 1st	< >	Last	< >	Lipemia	+ < >
Linearity Limit	< > %			Icterus	+ < >
Lag Time Check	No < >			Hemolysis	+ < >

Parameters		Specific Test Parameters			
General	LIH	ISE	HbA1c	Calculated Test	Range
Test Name:	FCA1G < >	Type:	Other < >		
Value/Flag:	# < >	Level	Low # High #		
Specific Ranges:	From	To	Low	High	
Sex	Year	Month	Year	Month	Low High
<input type="checkbox"/> 1.	# < >	# < >	# < >	# < >	# < > # < >
<input type="checkbox"/> 2.	# < >	# < >	# < >	# < >	# < > # < >
<input type="checkbox"/> 3.	# < >	# < >	# < >	# < >	# < > # < >
<input type="checkbox"/> 4.	# < >	# < >	# < >	# < >	# < > # < >
<input type="checkbox"/> 5.	# < >	# < >	# < >	# < >	# < > # < >
<input type="checkbox"/> 6.	# < >	# < >	# < >	# < >	# < > # < >
7.	Standard demographics				# < > # < >
8.	Not within expected values				# < > # < >
Panic Value	Low	#	High	#	Unit μg/g Decimal Places #

Beckman Coulter AU series application for BÜHLMANN fCAL® turbo  
AU480 and AU5800 are registered trademark of Beckman Coulter Inc, US

BÜHLMANN Laboratories AG, Baselstrasse 55, 4124 Schönenbuch, Switzerland. Tel: +41 61 487 1212, Fax +41 61 487 1234, www.buhlmannlabs.ch



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## Performance Data

Parameter	Acceptance Criteria	Performance
<b>Method comparison</b>	Slope: 0.8- 1.2 Mean Bias: ≤15% ±15 % bias at clinical decision points of 80 µg/g and 160 µg/g	Slope: 0.994 Mean bias: -2.99 % Bias at 80 and 160µg/g: -6.8% and -3.7% (see Table 1)
<b>Precision</b>	≤ 15 % for samples ≥ 50 µg/g	Total Precision: 1.3% to 8.8% (see Table 2)
<b>Analytical sensitivity</b>	LoB ≤ LoD LoD ≤ LoQ Limit of Quantification (LoQ): ≤ 30.0 µg/g	30.0 µg/g
<b>Analytical measuring interval (AMI)</b>		30 to 2000 µg/g
<b>Linearity</b>	R <sup>2</sup> ≥ 0.95 Allowable nonlinearity: samples < 75µg/g: 7.5 µg/g ; sample ≥75µg/g: 10%	19.0 to 11265.3 µg/g
<b>Extended measuring interval (EMI)</b>		30.0 to 11265.3 µg/g
<b>Sample carry-over</b>	Mean carry-over ≤ 0.32% Otherwise a technical precaution must be included in the instrument-specific application note	No significant sample carry-over
<b>Calibration curve stability</b>	Time interval for re-calibration should be at least 30 days depending on the clinical chemistry analyzer.	58 days
<b>On-board stability</b>	up to 30 days at 2-15°C	up to 90 days at 2-15°C

**Table 1 Detailed method comparison performance.**

N	Reference range	Passing-Bablok Regression Analysis					Bland-Altman Analysis		
		Slope	Intercept (µg/g)	Bias % at 80 µg/g	Bias % at 160 µg/g	r	Mean bias %	Lower LoA %	Upper LoA %
45	41.4 to 8555.5	0.994	-4.96	-6.8	3.7	1.000	-2.99	-15.79	9.81

**Table 2 Detailed precision performance**

ID	Mean µg/g	Within-run (repeatability)	Between-day	Between-run	Total Precision
P1	52.2	7.4	4.8	0.0	8.8
P2	77.2	5.9	8.1	0.0	10.1
P3	174.0	2.0	2.9	0.3	3.6
P4	684.0	0.9	2.4	1.7	3.1
P5	1635.5	0.8	3.9	1.8	4.3
P6	6383.3	1.0	4.8	0.9	5.0