



Application Note

Products	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)	  US only: Rx Only
Analyzer	Beckman Coulter AU480 / AU5800	
Version	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	
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	
						Correlation Factor A		1		B 0	
Wavelength:		Pri. 540		nm		Sec. None		nm		Factor for Maker A 1 B 0	
Method:		FIXED								Onboard Stability 90 Day 0 Hour	
Reaction slope:		+								LIH Influence Check No	
Measuring Point 1:		First 11				Last 18				Lipemia +	
Measuring Point 2:		First				Last				Icterus +	
Linearity:										Hemolysis +	
No Lag Time:		No									

Specific Test Parameters											
General		LIH		ISE		Range					
Test Name:		fCAL		< >		Type:		Other			
Value/Flag:		#				Level L: #		Level H: #			
Specific Ranges:										Panic Value	
		From		To						Low High	
		Sex Year Month		Year Month		Low		High		# #	
1.		# # #		# #		# #		# #			
2.		# # #		# #		# #		# #			
3.		# # #		# #		# #		# #			
4.		# # #		# #		# #		# #			
5.		# # #		# #		# #		# #			
6.		# # #		# #		# #		# #			
7.		No demographics				# #		# #			
8.		Not within expected values				# #		# #			
Unit		µg/g				Decimal Places		1			

Beckman Coulter AU480 / AU5800 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

Product	BÜHLMANN fCAL® turbo
Analyzer	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 Use Master Curve < > <input type="checkbox"/> Lot Calibration
Point 1:	< > < > < > < > < > < > < > < > Stability
Point 2:	< > < > < > < > < > < > < > < > Reagent Blanks Calibration
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	1 st 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 1 st	11	Last	18	LIH Influence Check	No < >
Measuring Point2 1 st	< >	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:	# < >				
Specific Ranges:	From	Level 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 #

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Parameters		Calibration Parameters	
Calibrators	Calibration Specific		
General	ISE		
Test Name:	FCA1G ▾	< >	Type: Other ▾
		<input type="checkbox"/> Use Serum Cal.	
Calibration Type:	6 AB ▾	Formula:	SPLINE ▾
		Counts:	2 ▾
<Calibrator Parameters>		Range	
Calibrator	OD	Conc	Low High
Point 1:	# ▾	**	-9999999 9999999
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		No. of Correction Points	<input type="checkbox"/> ▾ Use Master Curve
Master Curve>			<input type="checkbox"/> ▾ <input type="checkbox"/> Lot Calibration
Calibrator	OD	Conc	Low High
Point-1	# ▾		
Point-2	# ▾		
MB Type Factor:	<input type="checkbox"/> 1-Point Calibration Point	<input type="checkbox"/> ▾	<input type="checkbox"/> with Conc-0
Slope Check		<input type="checkbox"/> ▾	
Allowance Range Check		<input type="checkbox"/>	
<input type="checkbox"/> Reagent Blank		<input type="checkbox"/>	
<input type="checkbox"/> Calibration		<input type="checkbox"/>	
Advanced Calibration Operation		Yes ▾	
Interval (RB/ACAL)		Lot/Lot ▾	
Stability		Reagent Blank	58 Day 0 Hour
		Calibration	58 Day 0 Hour

#User specific

**lot dependent

For all instruments:

Calibration Specific		Repeat Parameters	
Repeat Common	Repeat Specific		
Test Name:	FCA1G ▾	< >	Type: Other ▾
Normal Repeat			
Sample Volume	10	Repeat Decision Range	Low -99999.99
Dilution	0		High 99999.99
Pre-Dilution	1	Reflex Range	Low -99999.99
			High 99999.99
Repeat with diluent			
		<input checked="" type="checkbox"/> Dynamic Range Check	
Sample Volume	10		
Dilution	0		
Pre-Dilution Rate	10		
Repeat with condense			
Sample Volume	1.0		
Dilution	0		
Pre-Dilution Rate	1		

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Performance Data

Parameter	Acceptance Criteria	Performance
Method comparison	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)
Precision	≤ 15 % for samples ≥ 50 µg/g	Total Precision: 3.1% to 10.1% (see Table 2)
Analytical sensitivity	LoB ≤ LoD LoD ≤ LoQ Limit of Quantification (LoQ): ≤ 30.0 µg/g	30.0 µg/g
Analytical measuring interval (AMI)		30 to 2000 µg/g
Linearity	R ² ≥ 0.95 Allowable nonlinearity: samples < 75µg/g: 7.5 µg/g ; sample ≥75µg/g: 10%	19.0 to 11265.3 µg/g
Extended measuring interval (EMI)		30.0 to 11265.3 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	Time interval for re-calibration should be at least 30 days depending on the clinical chemistry analyzer.	58 days
On-board stability	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