

## 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 DxC 700 AU / AU680	
<b>Version</b>	20230430	

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

### DxC 700 AU

Reagent ID: 256

General	LIH	ISE	Calculated Test	Range
<b>Test Name:</b> FCA1G <input type="button" value="Test No"/> <b>Type:</b> Other-1 <input type="button" value="Operation"/> Yes <input type="button" value="▼"/>				
Sample Volume	<input type="text" value="7.7"/> µL	Dilution	<input type="text" value="0"/> µL	OD Limit
Pre-Dilution Rate	<input type="text" value="1"/> ▼			Min. OD <input type="text" value="-2.000"/> Max OD <input type="text" value="3.000"/>
Reagent Volume	R1 (R1-1) <input type="text" value="100"/> µL	Dilution	<input type="text" value="0"/> µL	Reagent OD Limit 1 <sup>st</sup> Low <input type="text" value="-2.000"/> High <input type="text" value="3.000"/>
	R1-2 <input type="text" value=""/> µL	Dilution	<input type="text" value=""/> µL	Last Low <input type="text" value="-2.000"/> High <input type="text" value="3.000"/>
	R2 (R2-1) <input type="text" value="20"/> µL	Dilution	<input type="text" value="0"/> µL	Analytical Measuring Range Low <input type="text" value="30.0"/> High <input type="text" value="2000.0"/>
Common Reagent	Type <input type="text" value="None"/>	Name	<input type="text" value="None"/>	Correlation Factor A <input type="text" value="1"/> B <input type="text" value="0"/>
Wavelength	Pri <input type="text" value="540"/> nm	Sec	<input type="text" value="none"/> nm	Manufacturer Factor A <input type="text" value="1"/> B <input type="text" value="0"/>
Method	<input type="text" value="FIXED"/> ▼			
Reaction Slope	<input type="text" value="+"/> ▼			Onboard Stability Period <input type="text" value="90"/> Day <input type="text" value="0"/> Hour
Measuring Point-1	1st <input type="text" value="11"/>	Last	<input type="text" value="18"/>	LIH Influence Check <input type="text" value="No"/> ▼
Measuring Point-2	1st <input type="text" value=""/>	Last	<input type="text" value=""/>	Lipemia <input type="text" value="+"/> ▼
Linearity Limit	<input type="text" value=""/> %			Icterus <input type="text" value="+"/> ▼
Lag Time Check	<input type="text" value="No"/> ▼			Hemolysis <input type="text" value="+"/> ▼

General	LIH	ISE	Calculated Test	Range
<b>Test Name:</b> FCA1G <input type="button" value="Test No"/> <b>Type:</b> Other-1 <input type="button" value="▼"/>				
Value/Flag	<input type="text" value="#"/>	Level	Low <input type="text" value="#"/> High <input type="text" value="#"/>	
<b>Specific Ranges</b>				
	Sex	Year	From Month	To Year Month
<input type="checkbox"/> 1:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 2:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 3:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 4:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 5:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 6:	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
7:	Standard demographics			<input type="text" value="#"/>
8:	Not within expected values			<input type="text" value="#"/>
Critical Limits	Low <input type="text" value="#"/>	High <input type="text" value="#"/>	Unit <input type="text" value="µg/g"/>	Select <input type="button" value="Select"/> Decimal Places <input type="text" value="1"/>

Beckman Coulter DxC 700 AU and AU680 application for BÜHLMANN fCAL® turbo

DxC 700 AU / AU680 is a registered trademark of Beckman Coulter, US

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

<b>Product</b>	BÜHLMANN fCAL® turbo
<b>Analyzer</b>	Beckman Coulter DxC 700 AU / AU680
<b>Version</b>	20230430



Calibrators	General	ISE																																																		
<b>Test Name:</b> <input type="text" value="FCA1G"/> <b>Type:</b> <input type="text" value="Other-1"/>																																																				
<input type="checkbox"/> Use Serum Cal.																																																				
Calibration Type: <input type="text" value="6AB"/>	Formula: <input type="text" value="Spline"/>	Counts: <input type="text" value="2"/>																																																		
<b>&lt;Calibrator Parameters&gt;</b>		Slope Check <input type="text" value="none"/>																																																		
<table border="1"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Calibrator</th> <th rowspan="2">OD</th> <th rowspan="2">Conc</th> <th colspan="2">Range</th> </tr> <tr> <th>Low</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>Point-1</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> <tr> <td>Point-2</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> <tr> <td>Point-3</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> <tr> <td>Point-4</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> <tr> <td>Point-5</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> <tr> <td>Point-6</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> <tr> <td>Point-7</td> <td>#</td> <td></td> <td>**</td> <td>-2.000</td> <td>3.000</td> </tr> </tbody> </table>			Calibrator	OD	Conc	Range		Low	High	Point-1	#		**	-2.000	3.000	Point-2	#		**	-2.000	3.000	Point-3	#		**	-2.000	3.000	Point-4	#		**	-2.000	3.000	Point-5	#		**	-2.000	3.000	Point-6	#		**	-2.000	3.000	Point-7	#		**	-2.000	3.000	<input type="checkbox"/> Reagent Blank <input type="checkbox"/> Calibration Advanced Calibration Operation <input type="text" value="Yes"/>
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		Low	High																																																	
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Point-6	#		**	-2.000	3.000																																															
Point-7	#		**	-2.000	3.000																																															
MB Type Factor <input type="text"/>	1-Point Calibration Point <input type="text"/>	<input type="checkbox"/> with Conc-0 Interval (RB) <input type="text" value="Lot"/> Interval (ACAL) <input type="text" value="Lot"/>																																																		
Stability Reagent Blank <input type="text" value="58"/> Day <input type="text" value="0"/> Hour Calibration <input type="text" value="58"/> Day <input type="text" value="0"/> Hour																																																				

#User specific \*\*Lot specific

## AU680

Reagent ID: 256

Specific Test Parameters			
General	LIH	ISE	Range
<b>Test Name:</b> <input type="text" value="FCA1G"/> <b>Type:</b> <input type="text" value="Other"/> <b>Operation:</b> <input type="text" value="Yes"/>			
Sample Volume <input type="text" value="7.7"/> $\mu$ L	Dilution <input type="text" value="0"/> $\mu$ L	OD Limit	
Pre-Dilution Rate <input type="text" value="1"/>		Min. OD <input type="text" value="-2.000"/>	Max. OD <input type="text" value="3.000"/>
Reagents Volume: R1(R1-1) <input type="text" value="100"/> $\mu$ L	Dilution <input type="text" value="0"/> $\mu$ L	Reagent OD limit:	
		First Low <input type="text" value="-2.000"/>	High <input type="text" value="3.000"/>
		Last Low <input type="text" value="-2.000"/>	High <input type="text" value="3.000"/>
R2 Volume <input type="text" value="20"/> $\mu$ L	Dilution <input type="text" value="0"/> $\mu$ L	Dynamic Range Low <input type="text" value="30.0"/>	High <input type="text" value="2000.0"/>
Common Reagent Type <input type="text" value="None"/> Name <input type="text"/>		Correlation Factor A <input type="text" value="1"/>	B <input type="text" value="0"/>
Wavelength: Pri. <input type="text" value="540"/> nm	Sec. <input type="text" value="None"/> nm	Factor for Maker A <input type="text" value="1"/>	B <input type="text" value="0"/>
Method: <input type="text" value="FIXED"/>			
Reaction slope: <input type="text" value="+"/>		Onboard Stability <input type="text" value="90"/> Days	<input type="text" value="0"/> Hour
Measuring Point 1: First <input type="text" value="11"/> Last <input type="text" value="18"/>		LIH Influence Check <input type="text" value="No"/>	
Measuring Point 2: First <input type="text"/> Last <input type="text"/>		Lipemia <input type="text" value="+"/>	<input type="text"/>
Linearity: <input type="text"/> %		Icterus <input type="text" value="+"/>	<input type="text"/>
No Lag Time: <input type="text" value="No"/>		Hemolysis <input type="text" value="+"/>	<input type="text"/>

Specific Test Parameters			
General	ISE	Range	
<b>Test Name:</b> <input type="text" value="FCA1G"/> <b>Type:</b> <input type="text" value="Other"/>			
Value/Flag: <input type="text" value="#"/>	Level L: <input type="text" value="#"/>	Level H: <input type="text" value="#"/>	
<b>Specific Ranges:</b>			
	From	To	
<input type="checkbox"/> 1.	Sex <input type="text" value="#"/>	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>
<input type="checkbox"/> 2.	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	Low <input type="text" value="#"/>
<input type="checkbox"/> 3.	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	High <input type="text" value="#"/>
<input type="checkbox"/> 4.	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	Low <input type="text" value="#"/>
<input type="checkbox"/> 5.	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	High <input type="text" value="#"/>
<input type="checkbox"/> 6.	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	Low <input type="text" value="#"/>
<input type="checkbox"/> 7. No demographics			High <input type="text" value="#"/>
<input type="checkbox"/> 8. Not within expected values			High <input type="text" value="#"/>
Unit <input type="text" value="ug/g"/>	Decimal Places <input type="text" value="1"/>	<b>Panic Value</b> Low <input type="text" value="#"/> High <input type="text" value="#"/>	

Beckman Coulter DxC 700 AU and AU680 application for BÜHLMANN fCAL® turbo

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Confidential - Company Proprietary

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Calibration Type: <input type="text" value="6 AB"/> ▾	Formula: <input type="text" value="SPLINE"/> ▾																																																																				
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#User defined      \*\*Lot dependent

**For all instruments:**

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

<b>Product</b>	BÜHLMANN fCAL® turbo
<b>Analyzer</b>	Beckman Coulter DxC 700 AU / AU680
<b>Version</b>	20230430



## 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: 1.04 Mean bias: 7.0 % Bias at 80 and 160µg/g: 9.6% and 6.6% (see Table 1)
<b>Precision</b>	≤ 15 % for samples ≥ 50 µg/g	Total Precision: 4.0% to 9.9% (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>		30.0 to 2000.0 µg/g
<b>Linearity</b>	R2 ≥ 0.95 Allowable nonlinearity: samples < 75µg/g: 7.5 µg/g ; sample ≥75µg/g: 10%	25.2 to 13273.1 µg/g
<b>Extended measuring interval (EMI)</b>		30.0 to 13273.1 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	39.1 to 9075.4	1.04	4.84	9.6	6.6	0.999	7.0	-6.1	20.1

**Table 2 Detailed precision performance**

ID	Mean µg/g	Within-run (repeatability)	Between-day	Between-run	Total Precision
		CV%			
P1	60.5	8.4	0.0	5.3	9.9
P2	82.2	6.0	3.5	5.7	8.9
P3	180.9	2.7	2.1	3.1	4.6
P4	728.0	1.1	2.8	2.6	4.0
P5	1681.6	0.9	2.3	4.1	4.8
P6	6541.0	0.9	1.6	7.6	7.9