BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland

Phone +41 61 487 12 12
Fax +41 61 487 12 34
info@buhlmannlabs.ch
www.buhlmannlabs.ch

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) CE
Analyzer	Beckman Coulter DxC 500 AU
Version	20240119

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 500 AU

Reagent Name Fecal Calprotectin REF C34811 (OUS) D02562 (US) DxC 500 AU Settings Reagent ID 256
Calibrator Name Fecal Calprotectin Calibrator REF C34810

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name: Test: fCAL | Rev | Discipline | Chemistry

Test ID: fCAL — Calculated Result: ☐
LIS Code: fCAL — Result Type: Quantitative

UNITS AND RANGE SETTINGS

Other

Use Settings from: None — Units: µg/g — Decimal Places: x.x
Test Kind: General — Revision: 01 — ☒ Multi Reagent Switch
Reagent Name: fCAL — Reagent ID: 256 — ☐ FSE Test

ABB Name: FCA1G — Parameter Long Name: Fecal Calprotectin FCA1G Fecal

Region: ☒US ☒OUS ☒AP ☐JP ☒EU ☐Other

GENERAL PARAMETERS

SAMPLE VOLUME
Sample Volume: 8.0 µL — Dilution: 0 µL
Predilution Rate: 1

REAGENT VOLUME
R1-1: 100 µL — Dilution: 0 µL
R2-1: 20 µL — Dilution: 0 µL

WAVELENGTH
Primary: 540 nm — Secondary: None nm

METHOD: Fixed 1

REACTION SLOPE: +

MEASURING POINT
Point 1: First: 12 — Last: 16
Point 2: First: — Last:

Linearity Limit: 0 %

Lag Time Check: ☐ Perform Lag Time Check

REACTION OD LIMIT
Low: -2.0000 — High: 3.0000

REACTION BLANK OD LIMIT
First: Low: -2.0000 — High: 3.0000
Last: Low: -2.0000 — High: 3.0000

ANALYTICAL MEASURING RANGE
Low: 30.0 — High: 2000.0

MANUFACTURER FACTOR
A: 1 — B: 0

REAGENT ONBOARD STABILITY
90 Days — 0 Hours

LIH INFLUENCE CHECK
☐ Perform LIH check
Lipemia: +
Icterus: +
Hemolysis: +

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CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
µg/g	1	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type: 6 AB
Counts: 2
Formula: Spline
MB Factor:
Calibrator Name
Positive Cutoff:
Add: fCAL
☐ SLOPE CHECK
Number of Levels: 6
Slope Check: None

STABILITY AND INTERVAL

Reagent Blank Stability	32	Days	0	Hours	Interval: Lot
Calibration Stability	32	Days	0	Hours	Interval: Lot

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc*	Factor/OD Range Low	Factor/OD Range High
Point 1	fCAL-1		-2.0000	3.0000
Point 2	fCAL-2		-2.0000	3.0000
Point 3	fCAL-3		-2.0000	3.0000
Point 4	fCAL-4		-2.0000	3.0000
Point 5	fCAL-5		-2.0000	3.0000
Point 6	fCAL-6		-2.0000	3.0000
Point 7				

**Lot Dependent*

OD DELTA CHECK

☐ Reagent Blank	0.0000
☐ Calibration	0.0000

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points: Point 1: 0; Point 2: 0; Point 3: 0
Decision Values: Value 1: 0; Value 2: 0; Value 3: 0
Limit Points: Limit 1: 0; Limit 2: 27
Check Pattern: Pattern: Pattern 1

☐ Logic Check 2

Check Points: Point 1: 0; Interval: 1
Decision Values: Value 1: 0; Value 2: 0
Limit Points: Limit 1: 0; Limit 2: 27

☐ Logic Check 3

Check Points: Point 1: 0; Interval: 1
Decision Values: Value 1: 0; Value 2: 0
Limit Points: Limit 1: 0; Limit 2: 27

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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: -3.3% 160 µg/g: 3.5% (see Table 1)
Precision	≤ 15% CV for samples ≥ 50 µg/g	Total Precision: 4.4 to 10.2% (see Table 2)
Analytical sensitivity	LoB ≤ LoD LoD ≤ LoQ LoQ ≤ 30 µg/g	LoB: 10.5 µg/g LoD: 18.1 µg/g LoQ: 30.0 µg/g
Analytical measuring interval (AMI)		30 to 2000 µg/g
Extended measuring interval (EMI)		30 to 14160.7 µg/g
Linearity	$R^2 \geq 0.95$ Allowable nonlinearity: samples < 75µg/g: 7.5 µg/g ; sample ≥75µg/g: 10%	$R^2 = 0.999$ 29.5 to 14160.7 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%	32 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	39.1 to 9075.4	1.103	-10.9	-3.3	3.5	0.998	6.3	-22.6	35.1

Table 2 Detailed precision performance

ID	Mean µg/g	Within-run (repeatability)	Between-day	Between-run	Total Precision
		CV%			
P1	53.0	6.6	6.7	3.9	10.2
P2	81.6	5.7	3.3	3.3	7.4
P3	196.6	1.9	8.0	2.5	8.6
P4	800.6	0.9	7.5	2.5	7.9
P5	1786.5	0.8	3.5	2.4	4.4
P6	6840.4	1.2	6.5	3.0	7.3