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Application Note

Products	BÜHLMANN fPELA® turbo: BÜHLMANN fPELA® turbo Reagent Kit (B-KPELA-RSET) BÜHLMANN fPELA® turbo Control Kit (B-KPELA-CONSET) BÜHLMANN fPELA® turbo Calibrator Kit (B-KPELA-CASET) CE
Analyzer	Beckman Coulter DxC 500 AU
Version	20231219

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

Name Fecal Pancreatic Elastase REF C69666 DxC 500 AU Settings Reagent ID 257
Name Fecal Pancreatic Elastase Calibrator REF C69668

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name: Test | Rev | Discipline: Chemistry
Test ID: fPELA | Calculated Result: ☐
LIS Code: fPELA | 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: fPELA | Reagent ID: 257 | ☐ FSE Test
ABB Name: FPE1G | Parameter Long Name: Fecal Pancreatic Elastase C69666 FPE1G Fecal
Region: ☒US ☒OUS ☒AP ☐JP ☒EU ☐Other

GENERAL PARAMETERS

SAMPLE VOLUME
Sample Volume 3.0 µL | Dilution 0 µL
Predilution Rate 1

REAGENT VOLUME
R1-1 160 µL | Dilution 0 µL
R2-1 30 µL | Dilution 0 µL

WAVELENGTH
Primary 540 nm | Secondary 800 nm

METHOD: END

REACTION SLOPE: +

MEASURING POINT
Point 1: First 11 | Last 18
Point 2: First | Last

Linearity Limit: 0 %

Lag Time Check: ☐ Perform Lag Time Check

REACTION OD LIMIT
Low -2.0000 | High 3.000

REACTION BLANK OD LIMIT
First: Low -2.0000 | High 3.000
Last: Low -2.0000 | High 3.000

ANALYTICAL MEASURING RANGE
Low 12.9 | High 500.0

MANUFACTURER FACTOR
A 1 | B 0

REAGENT ONBOARD STABILITY
91 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
Add: fPELA
Positive Cutoff:
☐ SLOPE CHECK
Number of Levels: 6
Slope Check: None

STABILITY AND INTERVAL

Reagent Blank Stability	41	Days	0	Hours	Interval: Lot
Calibration Stability	41	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	fPELA-1		-2.0000	3.0000
Point 2	fPELA-2		-2.0000	3.0000
Point 3	fPELA-3		-2.0000	3.0000
Point 4	fPELA-4		-2.0000	3.0000
Point 5	fPELA-5		-2.0000	3.0000
Point 6	fPELA-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		Decision Values	
Point 1	0	Value 1	0
Point 2	0	Value 2	0
Point 3	0	Value 3	0

Limit Points: Limit 1: 0; Limit 2: 27

Check Pattern: Pattern: Pattern 1

☐ Logic Check 2

Check Points		Decision Values	
Point 1	0	Value 1	0
Interval	1	Value 2	0

Limit Points: Limit 1: 0; Limit 2: 27

☐ Logic Check 3

Check Points		Decision Values	
Point 1	0	Value 1	0
Interval	1	Value 2	0

Limit Points: Limit 1: 0; Limit 2: 27

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Performance Data

Parameter	Acceptance Criteria	Performance
Method comparison	Slope: 0.8- 1.2 Mean Bias: ≤20% Bias at cutoff: ± 15%	Slope: 1.001 Mean bias: 4.7% Bias at 200 µg/g: 4.0 (see Table 1)
Precision	≤ 10 % for samples ≥ 25 µg/g and ≤ 20 % for samples < 25 µg/g	Total Precision: 1.0% to 4.2% (see Table 2)
Analytical sensitivity	Limit of Quantification (LoQ): ≤ 20 µg/g	12.9 µg/g
Analytical measuring interval (AMI)		12.9 to 500 µg/g
Extended measuring interval (EMI)		12.9 to 2792.7 µg/g
Linearity	R2 ≥ 0.95 deviation from linearity of less than 10 µg/g / 10%	19.3 to 2792.7 µg/g
Sample carry-over	Mean carry-over ≤ 0.75% Otherwise a technical precaution must be included in the instrument-specific application note.	No significant sample carry-over
High Dose Hook Effect	A sample with concentration of 2500 µg/g must return a measured value > 500 µg/g in the first measurement.	No HDHE up to 7756 µg/g
Calibration curve stability	Time interval for re-calibration should be at least 14 days depending on the clinical chemistry analyzer.	41 days
Onboard stability		up to 91 days at 2-15˚C

Table 1 Detailed method comparison performance.

N	Reference range	Passing-Bablok Regression Analysis				Bland-Altman Analysis		
		Slope	Intercept	% Bias at 200 µg/g	r	Mean bias %	Lower LoA	Upper LoA
48	7.0 to 2865.4	1.001	7.8	4.0	0.997	4.7	-14.0	23.5

Table 2 Detailed precision performance

ID	Mean µg/g	Within-run (repeatability)	Between- day	Between- run	Total Precision
		CV%			
Low	84.6	3.3	0.0	2.6	4.2
Medium Low	223.4	0.8	0.0	0.6	1.0
Medium High	303.4	1.1	0.3	0.6	1.3
High	481.5	0.5	0.6	0.6	1.0
High3	1630.9	0.9	0.7	0.5	1.2