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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 AU480 / AU680 / AU5800 / DxC 700 AU
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: 257

Specific Test Parameters

General | LIH | ISE | Range

Test Name: FPE1G ▽ < > Type: Other-1 ▽ Operation: Yes ▽

Sample Volume		3 µL	Dilution	0 µL	OD Limit			
Pre-Dilution Rate		1			Min. OD	-2.000	Max. OD	3.000
	R1(R1-1)	160 µL	Dilution	0 µL	Reagent OD limit:			
					First Low	-2.000	High	3.000
					Last Low	-2.000	High	3.000
	R2 (R2-1)	30 µL	Dilution	0 µL				
					Dynamic Range Low	9.8	High	500.0
					Correlation Factor A	1	B	0
Wavelength:	Pri.	540 nm	Sec.	None nm	Factor for Maker A	1	B	0
Method:		END ▽						
Reaction slope:		+ ▽			Onboard Stability	91 Day	0	Hour
Measuring Point 1:	First	11	Last	16	LIH Influence Check	No ▽		
Measuring Point 2:	First		Last		Lipemia	+ ▽		
Linearity:		%			Icterus	+ ▽		
No Lag Time:		No ▽			Hemolysis	+ ▽		

Specific Test Parameters

General | | ISE | Range

Test Name: FPE1G ▽ < > Type: Other-1 ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

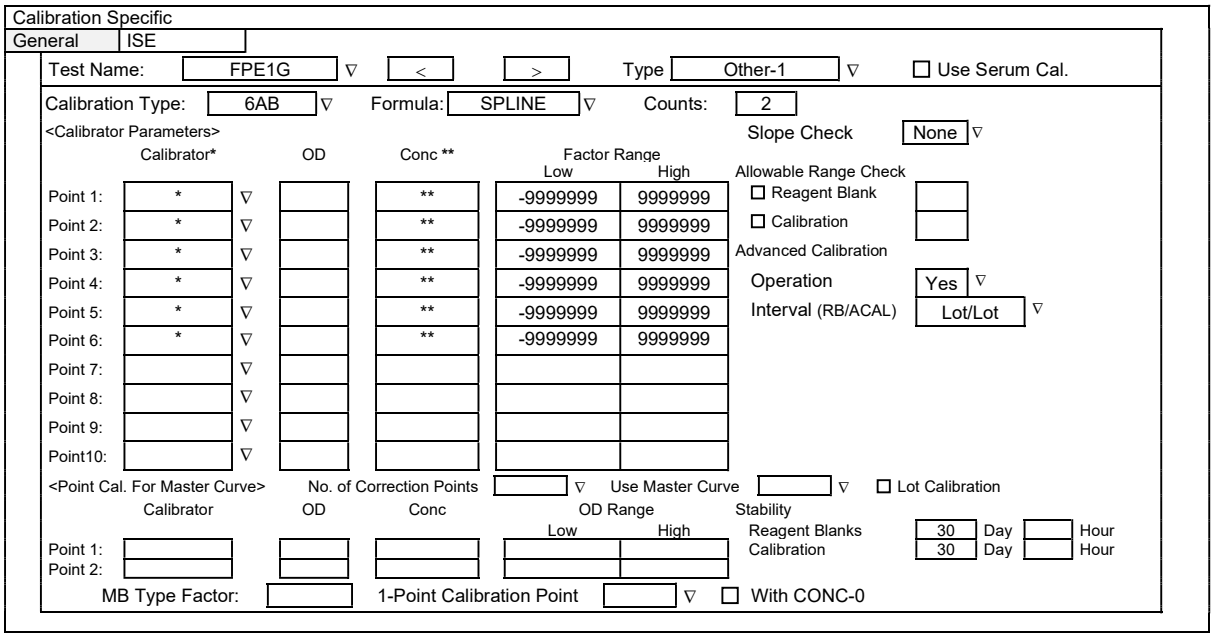
	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit µg/g Decimal Places 1

Product	BÜHLMANN fPELA® turbo
Analyzer	Beckman Coulter AU480 / AU680 / AU5800 / DxC 700 AU
Version	20230420



*user defined **lot specific

Product	BÜHLMANN fPELA® turbo
Analyzer	Beckman Coulter AU480 / AU680 / AU5800 / DxC 700 AU
Version	20230420

AU680

Reagent ID: 257

Specific Test Parameters

General | LIH | ISE | Range

Test Name: FPE1G ▽ < > Type: Other-1 ▽ Operation: Yes ▽

Sample Volume	3 µL	Dilution	0 µL	OD Limit			
Pre-Dilution Rate	1				Min. OD	-2.000	Max. OD 3.000
Reagents Volume: R1(R1-1)	160 µL	Dilution	0 µL	Reagent OD limit:			
					First Low	-2.000	High 3.000
					Last Low	-2.000	High 3.000
R2 Volume	30 µL	Dilution	0 µL				
					Dynamic Range Low	9.8	High 500.0
Common Reagent Type	None	Name			Correlation Factor A	1	B 0
Wavelength: Pri.	540 nm	Sec.	None nm		Factor for Maker A	1	B 0
Method:	END ▽						
Reaction slope:	+ ▽				Onboard Stability	91 Days	0 Hour
Measuring Point 1: First	11	Last	16		LIH Influence Check	No ▽	
Measuring Point 2: First		Last			Lipemia	+ ▽	
Linearity:	%				Icterus	+ ▽	
No Lag Time:	No ▽				Hemolysis	+ ▽	

Specific Test Parameters

General | | ISE | Range

Test Name: FPE1G ▽ < > Type: Other-1 ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value: Low # High #

Unit µg/g Decimal Places 1

Calibration Specific

General | ISE

Test Name: FPE1G ▽ < > Type Other-1 ▽ ☐ Use Serum Cal.

Calibration Type: 6 AB ▽ Formula: SPLINE ▽ Counts: 2

<Calibrator Parameters> Slope Check None ▽

	Calibrator*	OD	Conc **	Factor Range Low	Factor Range 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:	▽				
Point10:	▽				

Allowable Range Check: ☐ Reagent Blank ☐ Calibration

Advanced Calibration: Operation Yes ▽ Interval (RB/ACAL) Lot / Lot ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High	Stability
Point 1:						Reagent Blanks 30 Day 0 Hour
Point 2:						Calibration 30 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ▽ ☐ With CONC-0

*user defined **lot specific

Product	BÜHLMANN fPELA® turbo
Analyzer	Beckman Coulter AU480 / AU680 / AU5800 / DxC 700 AU
Version	20230420

AU5800

Reagent ID: 257

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: FPE1G ▽ < > Type: Other-1 ▽ Operation Yes ▽

Sample Volume		3 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate		1 ▽	Diluent Bottle	# ▽		Min.OD	-2.000	Max.OD	3.000
Rgt. Volume	R1(R1-1)	160 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µL	Dilution	µL	1st.	Low	-2.000	High	3.000
					Last	Low	-2.000	High	3.000
	R2(R2-1)	30 µL	Dilution	0 µL					
					Dynamic Range	Low	9.8	High	500.0
Common Rgt. Type		None	Name	None	Correlation Factor	A	1	B	0
Wavelength	Pri	540 ▽nm	Sec.	None ▽nm	Factor for Maker	A	1	B	0
Method		END ▽							
Reaction Slope		+ ▽			Onboard Stability Period		91 Day	0 Hour	
Measuring Point1 1st		11	Last	16	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: FPE1G ▽ < > Type: Other-1 ▽

Value/Flag: # ▽

Level Low # High #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. Standard demographics						#	#
8. Not within expected values						#	#

Panic Value Low # High # Unit µg/g Decimal Places 1

Parameters | Calibration Parameters

Calibrators | Calibration Specific

General | ISE

Test Name: FPE1G ▽ < > Type Other-1 ▽ Cuvette . ▽

☐ Use Serum Cal.

Calibration Type: 6 AB ▽ Formula: SPLINE ▽ Counts: 2 ▽

<Calibrator Parameters>

	Calibrator*	OD	Conc**	Range Low	Range 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:	▽				

Slope Check ▽

Allowance Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration Operation Yes ▽

Interval (RB/ACAL) Lot/Lot ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	▽				
Point-2	▽				

Stability: Reagent Blank 30 Day Hour; Calibration 30 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ▽ ☐ with Conc-0

*user defined **lot specific

Product	BÜHLMANN fPELA® turbo
Analyzer	Beckman Coulter AU480 / AU680 / AU5800 / DxC 700 AU
Version	20230420

DxC 700 AU

Reagent ID: 257

General | LIH | ISE | Calculated Test | Range

Test Name: FPE1G ▼ Test No **Type:** Other-1 ▼ Operation Yes ▼

Sample Volume		3 µL	Dilution	0 ▼ µL	OD Limit					
Pre-Dilution Rate		1 ▼					Min. OD	-2.0000	Max OD	3.0000
Reagent Volume	R1 (R1-1)	160 µL	Dilution	90 µL	Reagent OD Limit 1st		Low	-2.0000	High	3.0000
	R1-2	µL	Dilution	µL		Last	Low	-2.0000	High	3.0000
	R2 (R2-1)	30 µL	Dilution	15 µL	Analytical Measuring Range		Low	9.8	High	500
Common Reagent	Type	None	Name	None	Correlation Factor		A	1	B	0
Wavelength	Pri	540 ▼ nm	Sec	none ▼ nm	Manufacturer Factor		A	1	B	0
Method		END ▼								
Reaction Slope		+ ▼			Onboard Stability Period		91 Day		0	Hour
Measuring Point-1	1st	11	Last	16	LIH Influence Check		No ▼			
Measuring Point-2	1st		Last		Lipemia		+ ▼			
Linearity Limit		%			Icterus		+ ▼			
Lag Time Check		▼			Hemolysis		+ ▼			

General | LIH | ISE | Calculated Test | Range

Test Name: FPE1G ▼ Test No **Type:** Other-1 ▼

Value/Flag # Level Low # High #

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits Low # High # Unit µg/g Select Decimal Places 1

Calibrators | General | ISE

Test Name: FPE1G ▼ **Type:** Other-1 ▼

☐ Use Serum Cal.

Calibration Type: 6AB ▼ Formula: Spline ▼ Counts: 2

<Calibrator Parameters>

Slope Check none ▼

	Calibrator*	OD	Conc**	Range Low	Range 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	▼				

☐ Reagent Blank ☐ Calibration

Advanced Calibration Operation Yes ▼

Interval (RB) Lot ▼

Interval (ACAL) Lot ▼

MB Type Factor 1-Point Calibration Point ▼ ☐ with Conc-0

Stability
Reagent Blank 30 Day 0 Hour
Calibration 30 Day 0 Hour

*User Defined **Lot dependent

Product	BÜHLMANN fPELA® turbo
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Performance Data

Parameter	Acceptance Criteria	Performance
Method comparison	Linear regression fit with slope 0.8-1.2 Bland-Altman: Bias ± 20% Bias at cutoff: Passing-Bablok: ± 15%	Slope: 0.995 Mean bias: 2.3% Cutoff bias: 3.1% (see Table 1)
Precision	≤ 10 % CV for samples ≥ 25 µg/g and ≤ 20 % CV for samples < 25 µg/g	Total Precision: 1.1% to 3.8% (see Table 2)
Analytical sensitivity	Goal Limit of Quantification (LoQ) ≤ 20 µg/g	9.8 µg/g
Analytical measuring interval (AMI)		9.8 to 500 µg/g
Linearity	≤10 µg/g or 10% for fPELA or recovery between 80 and 120% no CV criterion for samples < LoQ	13.9 to 2391.6 µg/g
Extended measuring interval (EMI)		9.8 to 2391.6 µg/g
High dose hook effect	A sample with concentration of at least 2500 µg/g measures a value > 500 µg/g in the first run.	No HDHE up to 19031 µg/g
Sample carry-over	Mean carry-over < 0.75%	No significant sample carry-over
Calibration curve stability	Minimum stability of 14 days	30 days
On-board stability	Minimum stability of 30 days	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 %
63	15.6 to 3852.0	0.995	7.1	3.1	0.998	2.3	-17.0	21.5

Table 2 Detailed precision performance

ID	Mean µg/g	Within-run (repeatability)	Between-day	Between-run	Total Precision
		CV%			
Low1	81.5	3.2	1.5	1.1	3.8
Mid Low	142.1	2.3	0.6	0.0	2.3
Mid High	266.0	1.1	0.3	0.4	1.2
High1	427.7	0.8	0.7	0.3	1.1
High3	2010.1	3.4	1.7	0.0	3.8

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