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Application Note

Products	BÜHLMANN fPELA® turbo (KK-PELA) 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 0123 IVD US only: **Rx Only**
Analyzer	QuidelOrtho Vitros® XT 7600 / 4600 / 5600
Version	20250404

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

OPTIONS & CONFIGURATION - Review/Edit Assay

Full assay Name:	FPELA TURBO
Short Assay Name:	FPELA
Fluid Type:	Urine
Assay Model Type:	End Point
Template:	EPT1 R1-R2-S
Calibration Model Type:	Cubic Spine
Calibrator Bottles:	6
Replicates Per Cal:	2

Standard Dilution Factor:	1.0
Diluent	Water

REFLEX DILUTION

Reflex Dilution:	on
Dilution Factor:	10.0
Reduction Factor:	1.0

Reporting Type:	Quantitative
Units:	ug/mL
Significant Digists:	6
Precision Digits:	1
Slope:	1.00
Intercept:	0.00
CuveTip Expiration Time:	35 minutes
Temperature Sensitive:	No

RANGES

Reference:	0.0-200.0
Supplememtary:	0.0-900000000
Measuring (Reportable):	8.8-500.0

Sample Indices Check :	Disable

THRESHOLD LIMITS

Hemolysis:	1000
Icterus:	25
Turbidity:	800

	Measuring Conc.	Triple Read Limit
Measuring Min:	0.0	10.0
Critical Conc.:	200.0	10.0
Measuring Max:	500.0	10.0

Select a button to perform the corresponding function:

Reagent Lot | Dilution Parms | Result Parms | Protocol Parms | Calibration Parms | Triple Read Parms

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Edit Diluton Parameters

Edit Dilution Parameters.

Diluent **Water** Standard Dilution Factor: **1.0**

REFLEX DILUTION

Reflex Dilution: **On** Off

Dilution Factor: **10.0**

Reduction Faction: **1.0**

OPTIONS & CONFIGURATION - Edit Result Parameters

FPELA - Urine

Reporting Type: **Quantitative** Qualitative

RESULT PARAMETERS

Units ug/mL

Significant digits: 6 Precision Digits : 1

RANGES

Reference:	8.8	200.0
Supplementary:	0.0	9000000000
Measuring (Reportable):	8.8	500.0

USER ADJUSTED PARAMETERS

Slope: 1.00 Intercept: 0.00

CuveTip Aspiration Time: 35

Temperature Sensitive

OPTIONS & CONFIGURATION - Edit Protocol Parameters

FPELA - Urine

Protocol Steps

1. Reagent
2. Incubation
3. Reagent
4. Incubation
5. Read
6. Sample
7. Incubation
8. Read

View Protocol

1. Reagent:
   Volume (uL) = 180.0, Pack/Bottle=UDxx* / A
2. Incubation:
   Seconds=14.25
3. Reagent:
   Volume (uL) = 30.0, Pack/Bottle=UDxx* / B
4. Incubation:
   Seconds=152.00
5. Read:
   Wavelength:575 nm
6. Sample:
   Volume (uL) = 3.3
7. Incubation:
   Seconds=175.75
8. Read:
   Wavelength:575 nm

*User defined

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OPTIONS & CONFIGURATION - Enter/Edit Calibration Parameters

FPELA - Urine (ug/mL)

Kit: 75 Lot: 99*

Bottel Number	Dilution Factor	Calibrator Replicate Response Range	Calibrator Value**
1	1.0	0.20000	0.0
2	1.0	0.20000	25.0
3	1.0	0.20000	75.0
4	1.0	0.20000	125.0
5	1.0	0.20000	250.0
6	1.0	0.20000	550.0

Expiration Date**
MM/DD/YYYY

**Lot specific

Edit Cubic Spline Additional Parameters

Edit the Addittional Cal Parameters.

Monotonicity: **Increase** | Decrease

Max Response High: 3.000 Min Response High: 3.000

Max Response Low: -3.000 Min Response Low: -3.000

Calibration Interval: 35 Days

OPTIONS & CONFIGURATION - Review/Edit Assay

Inicial Absorbance Limits: -0.200 - 2.700

Blank Absorbance Limits: -0.200 - 2.700

Monotonicity:	Increase
Max Response High:	3.000
Max Response Low:	-3.000
Min Response High:	3.000
Min Response Low:	-3.000
Calibration Interval:	35 days

Bottel Number	Dilution Factor	Calibrator Value**	Calibrator Replicate Response Range
1	1.0	0.0	0.2000
2	1.0	25.0	0.2000
3	1.0	75.0	0.2000
4	1.0	125.0	0.2000
5	1.0	250.0	0.2000
6	1.0	550.0	0.2000

**Lot specific

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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: 1.026 Mean bias: 1.4% Bias at 200 µg/g: 3.8% (see Table 1)
Precision	≤ 10 % for samples ≥ 25 µg/g and ≤ 20 % for samples < 25 µg/g	1.4 to 2.2% (see Table 2)
Analytical sensitivity	Goal Limit of Quantification (LoQ) ≤ 20 µg/g	8.8 µg/g
Analytical measuring interval (AMI)		8.8 to 500 µg/g
Extended measuring interval (EMI)		8.8 to 2441.9 µg/g
Linearity	≤10 µg/g or 10% for fPELA or recovery between 80 and 120% no CV criterion for samples < LoQ	18.1 to 2441.9 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 3486 µg/g
Calibration curve stability	Time interval for re-calibration should be at least 14 days depending on the clinical chemistry analyzer	35 days
On-board stability	Up to 30 days at 2-15°C	91 days

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	6.2 to 3685.6	1.026	2.3	3.8	0.991	1.4	-44.0	46.7

Table 2 Detailed precision performance

ID	Mean [µg/mL]	Within-run (repeatability)	Between-run	Between-day	Total Precision
		CV[%]			
Low1	77.6	0.6	1.2	0.0	1.4
MidLow	131.6	0.6	1.7	0.0	1.8
MidHigh	242.7	0.6	1.9	0.0	2.0
High1	384.7	0.6	1.9	0.0	2.0
High3	2019.5	0.5	1.4	1.6	2.2

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