First insights into the analytical performance and stability assessment of the Quantum Blue® fPELA assay

M. Ueberschlag, L. Anchling, J. Schneider, A. Voitl, C. Reinhard, J.Afonso, B. Ricken, T. Schuster, C.B. Gerhold

BÜHLMANN Laboratories AG, Schönenbuch, Switzerland

BACKGROUND AND AIMS

Fecal pancreatic elastase (fPELA) is an established biomarker for the assessment of pancreatic function in patients suffering from pancreatic exocrine insufficiency (PEI). Elastase is very stable during intestinal transit. The present work assesses the stability and evaluates the analytical performance of a new fPELA lateral flow assay (Quantum Blue® fPELA) to determine elastase levels in extracts of human stool samples.

METHODS

Potentially interfering substances such as oral pharmaceuticals, nutritional supplements as well as hemoglobin were assessed in the Quantum Blue® fPELA assay according to the CLSI EP07-Ed3 guideline. Extracts at two different concentration levels were spiked with the recommended test concentration of presumable interfering substances and compared to unspiked extracts. Bias in results exceeding 30% was considered interfering. Pancreatic enzyme replacement therapy interference was tested by comparison from patients under Creon® therapy (N=33) and a control group (N=15) measured with Quantum Blue® fPELA (QB fPELA) and the BÜHLMANN fPELA® turbo (comparative method with no Creon® interference up to 757.5 kU/day). The differences between bias in creon-negative samples and bias in creon-positive samples exceeding 10% was considered interfering. Test cassette stabilities, i.e., accelerated, transport and in-use stability were established according to the CLSI EP 25 2nd ed guideline with an allowable deviation from baseline of ±30%.

RESULTS

Interference

Interference study results confirmed that the substances tested up to the listed concentrations did not interfere with the detection of the analyte (Table 1).

In addition, human CELA 2A, trypsin (porcine), chymotrypsin (bovine) and elastase (porcine) did not show any antibody cross reactivity at a concentration of 1 µg/mL. No Creon® interference was detected (difference of mean bias = 1.2) in patients' samples under replacement therapy with daily doses ranging from 12 to 560 kU (Figure 1).

Interferent	Test Concentration	% Difference	
		Level 1	Level 2
Fluimucil®	120 µg/mL	4.7	0.8
Trikafta®	14 µg/mL Elexacaftor 7 µg/mL Tezacaftor 10.5 µg/mL Ivacaftor	0.7	-2.2
Metformin	120 µg/mL	4.0	1.7
Glimepiride	0.084 µg/mL	-6.5	6.7
Prednison	60 µg/mL	-3.9	-9.6
Prednisolon	60 µg/mL	-4.4	-10.2
Esomeprazol	2.2 µg/mL	2.2	-1.9
Pantoprazol	1.9 µg/mL	-0.8	1.3
Omeprazol	2.9 µg/mL	-2.8	2.3
Lansoprazol	4.6 µg/mL	6.3	6.8
Ciprofloxacin	19.5 µg/mL	-9.1	5.6
Multivitamin (Berocca®)	0.6 µg/mL	5.8	11.3
Ibuprofen	96 µg/mL	5.6	-4.4
Hemoglobin	10 µg/mL	-0.1	-6.9

Table 1 – Results of interference study with oral pharmaceuticals, nutritional supplement and endogenous substance.

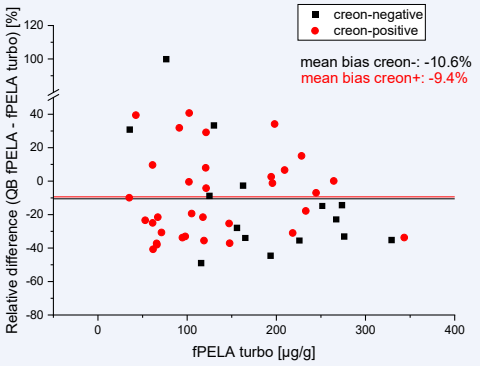
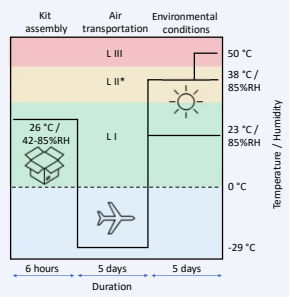


Figure 1 – Difference plots of creon-negative and creon-positive samples. Samples with elastase concentration ranging from 30-370 µg/g were plotted.

Transport stability

The test cassettes are stable under extreme transport condition of 5 days at -29°C, followed by 3 days at 38°C and 85% RH as well as 2 days at 50°C (Figure 2).



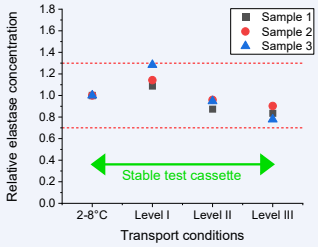


Figure 2 – Results of 3 samples measured on test cassettes stored at extreme transport conditions.

In-use stability

The in-use stability results show that opened test cassettes stored at room temperature can be used up to 4 hours (Figure 3).

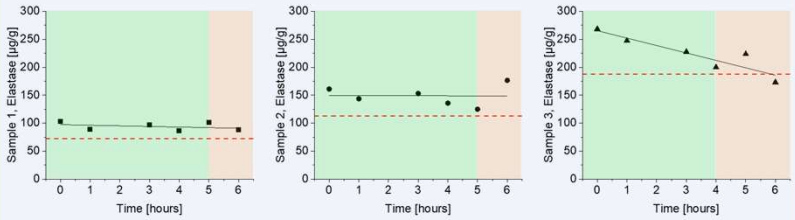


Figure 3 – Drift analysis of three samples measured on test cassettes stored opened at room temperature up to 6 hours. Red dotted line: allowable limit.

Accelerated stability of test cassettes

The study was conducted at three elevated temperatures (35, 40 and 45°C), with three samples. A preliminary initial shelf life of at least 12 months at 2-8°C was confirmed by Arrhenius analysis.

CONCLUSION

The Quantum Blue® fPELA showed no interferences for the substances of interest. The test cassettes are stable for at least 12 months at 2-8°C, they can endure extreme transport conditions (even 2 days at 50°C) and are stable after been opened for up to 4 hours at room temperature. Overall, the rapid test is an easy to use and robust solution to measure fecal pancreatic elastase in small laboratories without the need for expensive equipment.

Correspondence author: mu@buhlmannlabs.ch

All authors are employees of BÜHLMANN Laboratories AG.

BÜHLMANN