BÜHLMANN fPELA® turbo

Immuno turbidimetric fecal ELASTASE Assay

Unique in
Speed
Quality
Flexibility

Fecal Pancreatic Elastase results within 10 minutes

- Optimize your workflow with automation
- Integrate fecal samples into routine testing
- Measuring Range from 10 to 5000 µg/g

Simplify and improve fecal extraction with CALEX® Cap

- High quality for fast and efficient extraction
- Two fecal markers with one extraction
  Fecal calprotectin / pancreatic elastase

High correlation to manual reference method

- Continue with the established cut-off
- Specific to human enzymatic isoforms

BÜHLMANN fPELA® turbo is FDA Exempt.
For *in vitro* Diagnostic Use

BÜHLMANN

BÜHLMANN fPELA® turbo

Fecal pancreatic elastase result within 10 minutes

BÜHLMANN fPELA® turbo, the turbidimetric immunoassay, is a flexible solution to be applied on most clinical chemistry analyzers.

The technology is a milestone in automation of pancreatic elastase quantification. It allows very rapid and flexible random access use, as well as being the ideal solution for high throughput applications in the routine laboratory. The fPELA turbo assay reduces the hands-on time dramatically from existing methods- results in as little as 10 minutes.

Fecal pancreatic elastase in PEI

Pancreatic exocrine insufficiency (PEI), is a condition in which people are unable to adequately digest fats, carbohydrates and proteins due to a lack of digestive enzymes being produced from the pancreas. This results in nutrient malabsorption and malnutrition with severe consequences in the quality of life.

The determination of pancreatic Elastase levels is the most commonly employed indirect test for exocrine pancreatic function. The concentration of the enzyme in feces is five times higher than that in the pancreatic juice. It reflects the level of pancreatic output and correlates also with the output of other pancreatic enzymes such as lipase, amylase, and trypsin[1,2]).

[1]) Lévy, Gastroenterol Clin Biol. 2006;30(6-7)
[2]) Van de Vijver, J Pediatr Gastroenterol Nutr. 2011;53(1)

PRODUCT DESCRIPTION	
Method	Particle-enhanced turbidimetric immunoassay (PETIA)
Sample Type	Fecal extract
Kit Format	2 reagents (R1/ R2) Calibrators and controls provided separately Reagent set lasts for ≥100 tests
Sample Preparation	CALEX® Cap extracts ready to use without dilution
Reagent on board	Stable for 3 months
Calibration	Stable for 30 days
Calibration range	0-500 µg/g
Measuring range	10-5000 µg/g
Sample volume	~10 µL centrifuged fecal Extract (1:500)
Time to result	~10 min CALEX® Extraction ~20 min

Combination fecal calprotectin and pancreatic elastase

PEI is usually associated with other medical conditions, including cystic fibrosis, chronic pancreatitis, pancreatic cancer, diabetes, gastrointestinal surgery, coeliac disease, irritable bowel syndrome, or inflammatory bowel disease.

A significant amount of laboratory requests combines the quantification of fecal calprotectin and pancreatic elastase. The CALEX® Cap extraction device prefilled with a unique extraction buffer allows using the same fecal extract for quantification of both analytes, at the same time. This synergy allows an additional significant reduction and streamlining of work load for fecal testing in the modern automated laboratory.

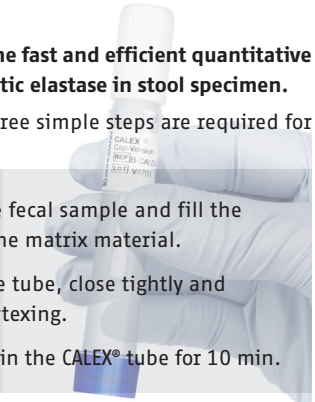
Application notes available			
cobas® c501 / c502	yes	Advia 1800 / 2400 / XPT	planned
cobas® c701 / c702	yes	Beckmann AU Series	yes
cobas® Pro (c503)	planned	BS-380 Mindray	yes*
Alinity	yes*	Optilite / Indiko	planned
Architect c	yes	BA200	yes*
Atellica	planned		

*under validation

Simplify and improve fecal extraction with CALEX® Cap

The CALEX® Cap is a unique device for the fast and efficient quantitative extraction of calprotectin and pancreatic elastase in stool specimen.

The prefilled tubes are ready to use. Three simple steps are required for extraction:



STEP 1: Dip the dosing tip into the fecal sample and fill the grooves completely with the matrix material.

STEP 2: Place the pin back into the tube, close tightly and extract by soaking and vortexing.

STEP 3: Centrifuge the extract within the CALEX® tube for 10 min.

The resulting extract (1:500) is ready to use in the turbidimetric assays. The CALEX® Cap extraction method correlates well with the manual weighting method.

Specificity and correlation to the manual reference method

The BÜHLMANN fPELA® turbo is based on polyclonal antibodies specific for the relevant human isoforms of the enzyme.

The assay is not affected by PERT (pancreatic enzyme replacement therapy).

Method comparison: A total of 130 stool samples from normal donors and PEI patients spanning the assay range were tested by the BÜHLMANN fPELA® turbo assay and a commercial Elastase-1 monoclonal antibody assay. Results are summarized in the table below. Applying a cut-off at 200 µg/g, an overall agreement of 93.1% was found.

BÜHLMANN fPELA® turbo	Elastase 1 ELISA			
	>200 µg/g	100-200 µg/g	<100 µg/g	Total
>200 µg/g	37	9	2	48
100-200 µg/g	5	22	9	36
<100 µg/g	1	8	37	46
Total	43	39	48	130

BÜHLMANN fCAL® turbo + CALEX® Cap (K191718): FDA 510(k) cleared. For in vitro Diagnostic Use.

BÜHLMANN Laboratories AG
Switzerland
info@buhlmannlabs.ch
Phone: +41 61 487 12 12

BUHLMANN Diagnostics Corp
USA/Canada
info@buhlmannlabs.com
Phone: 844-300-9799

BÜHLMANN fPELA® turbo Ordering Codes:

Kit	KK-PELA	
Reagent Kit (~100 tests)	B-KPELA-RSET	R1 27 ml, R2 5.1 ml
Calibrator Kit	B-KPELA-CASET	6 levels, 1 ml each; Ready to use
Control Kit	B-KPELA-CONSET	3x2 levels, 1 ml each; Ready to use

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