REFERENCES

1. Blirup-Jensen et al.: Clin Chem Lab Med 2001; 39, 1110 – 22.
2. Blirup-Jensen et al.: Clin Chem Lab Med 2008; 46, 1470 – 9.

INCIDENT REPORTING IN EU MEMBER STATES

If any serious incident in relation to this device has occurred, please report without delay to the manufacturer and competent authority of your Member State.

SHIPPING DAMAGE

Please notify your distributor, if this product was received damaged.

REACH

None of the materials and reagents in the kit require a Material Safety Data Sheet (MSDS) according to CLP-Regulation (EC) No 1272/2008 and directive EC 1907/2006 (REACH).

SYMBOLS KEY

	Expiration date
	Consult Instructions for Use
	Manufacturer
REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot number
	Temperature limitations

Manufacturer
BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch, Switzerland

CE

BÜHLMANN

BÜHLMANN fPELA® turbo

Pancreatic elastase turbidimetric assay
for professional use

Calibrator Kit

B-KPELA-CASET
Version A1

For *In Vitro* Diagnostic Use

Rx Only

BÜHLMANN Laboratories AG
Baselstrasse 55
4124 Schönenbuch
Switzerland
Tel.: +41 61 487 12 12
Fax: +41 61 487 12 34
info@buhlmannlabs.ch

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INTENDED USE

The BÜHLMANN fPELA® turbo Calibrator Kit is intended for use with the BÜHLMANN fPELA® turbo Reagent Kit for the determination of fecal pancreatic elastase levels in extracted stool samples. Each calibrator establishes a point of reference for the calibration curve that is used to calculate test results from patient samples.

For laboratory use only.

CALIBRATOR VALUE

Calibrator values are assigned according to a value transfer protocol (Ref. 1-2) and are indicated in the enclosed QC-data sheet. The calibrator material comprises recombinant human pancreatic elastase and is standardized against an internal reference material.

REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
Calibrators Calibrators 1-6 containing an assigned concentration of recombinant human pancreatic elastase	1 x 6 vials 1 mL/ vial	B-KPELA-CASET	Ready to use

Table 1

REAGENT STORAGE AND STABILITY

Unopened calibrators
Store at 2-8 °C. Do not use kit past expiration date printed on the labels.
Opened calibrators
Store for up to 3 months at 2-8 °C, capped.
Calibration curve stability
Refer to the instrument specific application note.

Table 2

MATERIALS REQUIRED BUT NOT PROVIDED

Reagents	Quantity	Code
BÜHLMANN fPELA® turbo Reagent Kit Reaction Buffer (R1) Immunoparticles (R2)	 1 vial/ 27.0 mL 1 vial/ 5.1 mL	B-KPELA-RSET
BÜHLMANN fPELA® turbo Control Kit Controls low and high	3 x 2 vials 1 mL/ vial	B-KPELA-CONSET

Table 3

WARNINGS AND PRECAUTIONS

- This test is for *in vitro* diagnostic use only.
- It is recommended that the test be handled by qualified personnel, in accordance with Good Laboratory Practice (GLP).
- Before measuring please equilibrate reagents, controls, calibrators and samples as described in the application note.
- Do not mix calibrators of different lots or switch caps between reagents.
- Avoid evaporation of the calibrator.

ASSAY PROCEDURE

Application notes / assay installation

The assay procedure for the BÜHLMANN fPELA® turbo has been established on several clinical chemistry analyzers. Validated application notes describing installation and analysis on specific instruments are available from BÜHLMANN upon request.

Establishment of the calibration curve

The BÜHLMANN fPELA® turbo Calibrator Kit is used to establish a six point calibration curve according to the instrument manual. Calibrator values are lot-specific. A new calibration must be performed for each new calibrator and reagent lot. Otherwise, calibration should be performed every one to two months according to the instrument specific application notes. Refer to the enclosed QC-data sheet for assigned calibrator values. Contact BÜHLMANN support if calibration cannot be performed without error.

QC controls

The calibration curve must be validated with controls, low and high, (Code: B-KPELA-CONSET), each day before running patient fecal sample extracts. Refer to the instruction for use for BÜHLMANN fPELA® turbo Control Kit for further information.