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

Control Kit

B-KPELA-CONSET
Version A1

For *In Vitro* Diagnostic Use

Rx Only

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INTENDED USE

The BÜHLMANN fPELA® turbo Control Kit is intended for use with the BÜHLMANN fPELA® turbo Reagent Kit, for quality control, in the determination of fecal pancreatic elastase levels in extracted stool samples.

For laboratory use only.

CONTROL VALUE

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

REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
Controls Low / High Controls containing an assigned concentration of recombinant human pancreatic elastase	3 x 2 vials 1 mL/vial	B-KPELA-CONSET	Ready to use

Table 1

REAGENT STORAGE AND STABILITY

Unopened controls
Store at 2-8°C. Do not use kit past expiration date printed on the labels.
Opened controls
Store for up to 3 months at 2-8°C, capped.

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 Calibrator Kit Calibrators 1-6 for instrument calibration	1 x 6 vials 1 mL/ vial	B-KPELA-CASET

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 controls of different lots or switch caps between reagents.
- Avoid evaporation of the controls.

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.

QC controls

The BÜHLMANN fPELA® turbo Control Kit should be assayed each day before running patient fecal sample extracts. This is to validate the calibration curve established with the BÜHLMANN fPELA® turbo Calibrator Kit. The controls have assigned, lot-specific value ranges indicated on the QC-data sheet enclosed. The control measurements must be within the indicated value ranges to obtain valid results for patient fecal sample extracts.
If the control values are not valid, repeat measurement with fresh controls. If control values remain invalid, recalibrate the instrument. If valid control values cannot be reproduced, after performing the steps described above, contact BÜHLMANN support.