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.

SYMBOLS

BÜHLMANN use symbols and signs listed and described in ISO 15223-1. In addition the following symbols and signs are used:

EN: electronic instruction for use available in different languages at:/ **BG**: електронни инструкции за употреба на различни езици на адрес:/ **CS**: elektronický návod k použití dostupný v různých jazycích na adrese:/ **DA**: elektronisk brugsanvisning på forskellige sprog på:/ **DE**: elektronische Gebrauchsanweisung in verschiedenen Sprachen verfügbar unter:/ **EL**: ηλεκτρονικές οδηγίες χρήσης διαθέσιμες σε διάφορες γλώσσες στη διεύθυνση:/ **ES**: instrucciones de uso electrónicas disponibles en diferentes idiomas en:/ **ET**: elektrooniline kasutusjuhend, mis on saadaval erinevates keeltes aadressil:/ **FR**: un mode d'emploi électronique disponible en différentes langues à l'adresse:/ **HU**: különböző nyelveken elérhető elektronikus használati utasítás a következő címen:/ **IT**: istruzioni elettroniche per l'uso disponibili in diverse lingue su:/ **LT**: elektroninės naudojimo instrukcijos įvairiomis kalbomis:/ **LV**: dažādās valodās pieejama elektroniska lietošanas instrukcija:/ **NO**: elektronisk instruksjon for bruk tilgjengelig på forskjellige språk på:/ **PL**: elektroniczna instrukcja obsługi dostępna w różnych językach na stronie:/ **PT**: instrução electrónica para utilização disponível em diferentes línguas em:/ **RO**: instrucțiuni electronice de utilizare disponibile în diferite limbi la adresa:/ **SK**: elektronický návod na použitie dostupný v rôznych jazykoch na:/ **SL**: elektronska navodila za uporabo so na voljo v različnih jezikih na:/ **SR**: elektronsko uputstvo za upotrebu dostupno na različitim jezicima na:/ **SV**: elektronisk bruksanvisning på olika språk på följande adress:

www.buhlmannlabs.ch/support/downloads/

CE 0123

BÜHLMANN

BÜHLMANN fPELA® turbo

Pancreatic elastase turbidimetric assay
for professional use

Calibrator Kit

B-KPELA-CASET
Version A2

For *In Vitro* Diagnostic Use

Rx Only

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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.
- This kit contains components classified in accordance with the Regulation (EC) No. 1272/2008: 2-methyl-4-isothiazolin-3-one hydrochloride (conc. ≥ 0.0015%), thus the reagents may cause allergic skin reactions (H317).
- 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, each day before running patient fecal sample extracts. Refer to the instruction for use for BÜHLMANN fPELA® turbo Control Kit for further information.

CHANGELOG

Date/Version	Change
2022-07-20/ A2	Update to chapter “warnings and precautions”, revision of chapter “symbols”, inclusion of notified body number to CE-mark – conformity assessment procedure according to IVDR 2017/746