

## 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.

For definition of symbols see the symbol glossary at:

[www.buhmannlabs.ch/support/downloads/](http://www.buhmannlabs.ch/support/downloads/)

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:** külföldön is használható 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.buhmannlabs.ch/support/downloads/](http://www.buhmannlabs.ch/support/downloads/)

### US Distribution

**BÜHLMANN Diagnostics Corp**

Amherst, NH 03031, USA

Tel: (844)300-979

[info@buhmannlabs.com](mailto:info@buhmannlabs.com)

Release date: 2024-07-17



page 4

BÜHLMANN fPELA® turbo



## BÜHLMANN fPELA® turbo

Pancreatic elastase turbidimetric assay  
for professional use

## Calibrator Kit

B-KPELA-CASET

Version A3

For *In Vitro* Diagnostic Use

CLIA Complexity: High

Rx Only



Manufacturer

**BÜHLMANN Laboratories AG**

Baselstrasse 55

4124 Schönenbuch

Switzerland

Tel.: +41 61 487 12 12

Fax: +41 61 487 12 34

[info@buhmannlabs.ch](mailto:info@buhmannlabs.ch)



[www.buhmannlabs.ch/support/downloads/](http://www.buhmannlabs.ch/support/downloads/)

## 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 using a clinical chemistry analyzer. 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.

Release date: 2024-07-17

page 1

BÜHLMANN fPELA® turbo

## REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
<b>Calibrators</b> 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

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

Table 2

## MATERIALS REQUIRED BUT NOT PROVIDED

- The reagents described below are not delivered with the kit and must be ordered separately:

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

Table 3

- General laboratory equipment
- Clinical chemistry analyzer

## 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.  $\geq 0.0015\%$ ), 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
2024-07-17 / A3	Addition of Clinical Laboratory Improvement Amendments (CLIA) complexity (only for US customers) on front page Precising the <i>Intended Use</i> by adding the test platform Revision of chapter <i>Materials required but not provided</i>

## REFERENCES

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