## 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

# Control Kit

B-KPELA-CONSET
Version A2

For *In Vitro* Diagnostic Use

**Rx Only**


**Manufacturer**

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



**www.buhlmannlabs.ch/support/downloads/**

## 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**<br>Controls containing an assigned concentration of recombinant human pancreatic elastase | 3 x 2 vials<br>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**<br>Reaction Buffer (R1)<br>Immunoparticles (R2) | 1 vial/ 27.0 mL<br>1 vial/ 5.1 mL | B-KPELA-RSET |
| **BÜHLMANN fPELA® turbo Calibrator Kit**<br>Calibrators 1-6 for establishment of six-point calibration curve | 1 x 6 vials<br>1 mL/ vial | B-KPELA-CASET |

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 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.

## 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 |