**Manual**

# *IDK*® TurbiPEL®

***For the quantitative in vitro determination of human pancreatic elastase 1 in stool***

Valid from 2021-07-28

REF **TU1011.1**
**TU1011.2**
**TU1011.8**

Σ 100/200/800

+8 °C
+2 °C

IVD

CE

**Immundiagnostik AG**, Stubenwald-Allee 8a, 64625 Bensheim, Germany
Tel.: +49 6251 70190-0 Fax: + 49 6251 70190-363
e.mail: info@immundiagnostik.com www.immundiagnostik.com

# Table of Contents

**1. INTENDED USE** 2

**2. INTRODUCTION** 2

**3. MATERIAL SUPPLIED** 3

**4. MATERIAL REQUIRED BUT NOT SUPPLIED** 3

**5. STORAGE AND PREPARATION OF REAGENTS** 3

**6. STORAGE AND PREPARATION OF SAMPLES** 3

*Sample storage and stability* 3
*Extraction of the stool samples* 4

**7. ASSAY PROCEDURE** 5

*Principle of the test* 5
*Test Procedure* 5

**8. QUALITY CONTROL** 6

*Reference Range* 7

**9. PERFORMANCE CHARACTERISTICS** 7

*Analytical sensitivity* 7
*Prozone* 7
*Clinical sensitivity and specificity* 7
*Interferences* 8
*Cross reactivity* 8

**10. LIMITATIONS** 8

**11. PRECAUTIONS** 8

**12. DISPOSAL** 9

**13. GENERAL NOTES ON THE TEST AND TEST PROCEDURE** 9

**14. REFERENCES** 10

**15. ANNEX - COMPATIBLE TURBIDIMETRIC ANALYSERS** 10

## 1. INTENDED USE

***IDK*® TurbiPEL®** assay is a latex turbidimetric assay for the quantitative detection of human pancreatic elastase 1 (E1) in stool samples. Test results should be exclusively used to evaluate exocrine pancreatic function in stool samples.

This assay has a simple performance and multiple applications. This product is optimised for several automated analysers. For professional *in vitro* diagnostic use only.

## 2. INTRODUCTION

The enzyme pancreatic elastase plays an important role in the digestion of food by breaking down ingested protein. It is exclusively produced in the exocrine tissue of the pancreas and is afterwards secreted into the duodenum. As pancreatic elastase itself remains undigested during the intestinal transit, it is a good non-invasive biomarker to determine the secretory function of the exocrine pancreas tissue.

An exocrine pancreas insufficiency (EPI) is marked by the malabsorption of nutrients due to insufficient production, release, and/or decreased activation of enzymes from pancreatic acinar cells (e.g. amylases, lipases, and proteases). Patients suffering from EPI are unable to digest their food properly. This causes malabsorption of nutrients and eventually leads to deficiencies of fat-soluble vitamins (A, E, D, and K) and iron. Thus, it is essential to diagnose affected patients early in order to avoid secondary disorders.

The most common causes of EPI are chronic pancreatitis in adults and cystic fibrosis in children. In addition, patients suffering from diabetes type 1 and type 2 are also at an increased risk. Typical clinical symptoms of EPI are steatorrhea, weight loss, abdominal pain and bloating. However, clinical symptoms only become evident when the exocrine function of the pancreas falls below 10 %. Therefore, it is important to regularly monitor the secretory function of the pancreas in patients at risk.

***IDK*® TurbiPEL®** is a non-invasive *in vitro* diagnostic method, based on monoclonal antibodies and used to monitor exocrine pancreatic function of humans.

## 3. MATERIAL SUPPLIED

| Label | Kit components | Quantity for cat. no. | | |
|---|---|---|---|---|
| | | TU1011.1 | TU1011.2 | TU1011.8 |
| Reagent 1 | Reagent 1, ready-to-use | 1 x 24 ml | 2 x 24 ml | 8 x 24 ml |
| Reagent 2 | Reagent 2, ready-to-use | 1 x 4 ml | 1 x 6 ml | 4 x 6 ml |
| CAL 0–5 | Calibrators 0–5, ready-to-use | 6 x 1 ml | 6 x 1 ml | 6 x 1 ml |
| CTRL 1 | Control 1, ready-to-use | 2 x 1 ml | 2 x 1 ml | 2 x 1 ml |
| CTRL 2 | Control 2, ready-to-use | 2 x 1 ml | 2 x 1 ml | 2 x 1 ml |

The supplied reagents are in neutral tubes that are not compatible with the used analyzer. Therefore, it is necessary to fill the corresponding reagents into compatible reagent vessels.

## 4. MATERIAL REQUIRED BUT NOT SUPPLIED

- Sample collection container
- Centrifuge, 3 000 *g*
- Vortex
- Calibrated precision pipets (adjustable volume) and 10–1 000 µl single-use tips
- Disposable gloves and laboratory equipment
- Automated analyser (list of compatible analysers see annex information)
- Reagent vessels that are approved for the used analyser
- ***IDK*® TurbiTUBE®** for sample collection (cat. no.: TU0091.A)

## 5. STORAGE AND PREPARATION OF REAGENTS

- All test reagents are ready-to-use. Test reagents are stable until the expiry date (see label) when stored at 2–8 °C. Do not freeze any component of the kit. Keep away from direct sunlight.
- Always consider that the reagent containers must be properly closed to avoid any contamination.

# 6. STORAGE AND PREPARATION OF SAMPLES

## *Sample storage and stability*

- Collect a sufficient amount of human stool in a clean and dry container (no preservatives or transport media is necessary).
- According to literature, the stability of pancreatic elastase 1 in raw stool is 3 days at room temperature and 7 days at 2–8 °C. If not immediately tested, stool samples can be frozen and stored at -20 °C for a maximum of 6 months. In this case, the sample must be totally thawed, and brought to room temperature (15–30 °C) before testing.
- Stool samples must be homogenised as thoroughly as possible prior to preparation.
- Stool extract is stable at 2–8 °C for 7 days.

## *Extraction of the stool samples*

Stool Sample Application System (***IDK*® TurbiTUBE®**) (cat. no.: TU0091.A)

***Stool sample tube – Instructions for use***

Please note that the dilution factor of the final stool suspension depends on the amount of stool sample used and the volume of the buffer.

***IDK*® TurbiPEL® *with 1.5 ml sample extraction buffer:***

| | |
|---|---|
| Applied amount of stool: | 15 mg |
| Buffer Volume: | 1.5 ml |
| Dilution Factor: | 1:100 |

Please follow the instructions for the preparation of stool samples using the ***IDK*® TurbiTUBE®** as follows:

a) The raw stool sample has to be thawed and brought to room temperature (15–30 °C). For particularly heterogeneous samples we recommend a mechanical homogenisation using an applicator, inoculation loop or similar device.

b) Unscrew the tube (yellow part of cap) to open. Insert the yellow dipstick into the sample. The lower part of the dipstick has notches which need to be covered completely with stool after inserting it into the sample. Place dipstick back into the tube. When putting the stick back into the tube, excess

material will be stripped off, leaving 15 mg of sample to be diluted. Screw tightly to close the tube.

**Hint:** In case of liquid stool samples we recommend to pipette 15 µl of liquid sample into the tube.

Vortex the tube well until no stool sample remains in the notches. **Important:** Please make sure that you have a maximally homogenous suspension after shaking. Especially with more solid samples, soaking the sample in the tube with sample extraction buffer for ~ 10 minutes improves the result.

c) Samples should be centrifuged for ~ 10 minutes at 3 000 *g* to obtain a sediment-free sample. Floating material such as grain shells can be neglected.

d) Carefully unscrew the complete cap of the tube including the blue ring plus the dipstick. Discard cap and dipstick. Make sure that the sediment will not be dispersed again.

## 7. ASSAY PROCEDURE

### *Principle of the test*

***IDK*® TurbiPEL®** is a latex turbidimetric assay for the quantitative detection of pancreatic elastase 1 in human stool samples. It is exclusively intended to be used to evaluate pancreatic elastase 1 levels in stool samples associated with pancreatic insufficiency.

***IDK*® TurbiPEL®** assay is based on agglutination reactions. These involve *in vitro* aggregation of microscopic latex particles. This aggregation consists in the specific reaction between antigen and monoclonal antibodies. Antigens contained in the sample bind with the antibodies' anti-antigen coated on polystyrene latex particles. The sample is mixed with a suspension containing antibodies against the antigen bound to latex particles. If antigen is present in the sample, it will react with the antibodies and form an aggregate. If no antigen is present in the sample, the mixture will maintain its clear appearance.

### *Test Procedure*

**Preparation of the calibration curve**

For calibration use only ***IDK*® TurbiPEL®** calibrator vials. They are ready-to-use liquid calibrators containing recombinant pancreatic elastase 1 at different concentrations. The exact concentrations are indicated on the label of each vial.

Calibration of the system at least once a month is highly recommended. The system must be recalibrated when the reagent lot is changed or when the controls are out of the assigned range (see the quality control protocol provided with the kit).

**Calibration and control vials**

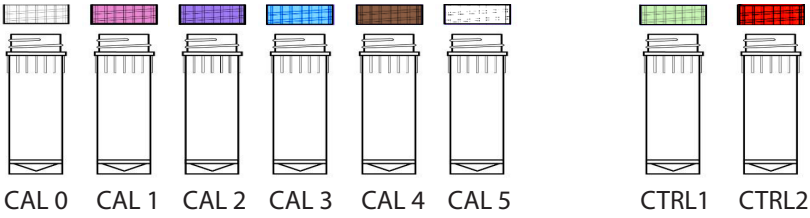


Fig 1: Prepared calibrators (5 points and blank) and controls for performing the calibration curve.

| Label | Concentration | Lid Colour |
|---|---|---|
| CAL 0 | 0 µg/g | transparent |
| CAL 1 | 25 µg/g | pink |
| CAL 2 | 50 µg/g | purple |
| CAL 3 | 100 µg/g | blue |
| CAL 4 | 200 µg/g | brown |
| CAL 5 | 400 µg/g | white |
| CTRL 1 | Control 1* | green |
| CTRL 2 | Control 2* | red |

* The batch-dependent concentration is given by the quality control protocol.

## 8. QUALITY CONTROL

For quality control use only *IDK*® **TurbiPEL**® Control 1 (CTRL 1) and *IDK*® **TurbiPEL**® Control 2 (CTRL 2). These are two ready-to-use liquid controls containing different concentrations of recombinant pancreatic elastase 1. The respective concentration for each vial is given by the quality control protocol.

The use of control materials at two different concentrations is recommended in order to verify test precision. Controls should be assayed every day before running extracted patient samples to validate the calibration curve. If the obtained results are out of the tolerance range, the equipment, the reagents and the technique must be reviewed.

Since the sample dilution is already considered in the calibration curve, the dilution factor is 1.

In case **another dilution factor** has been used, multiply the obtained result by the dilution factor used.

### *Reference Range*

We recommend each laboratory to establish its own reference concentration range.

**Reference range in stool samples**[5]

1 g stool is equivalent to 1 ml.

| | |
|---|---|
| > 200 µg/g | normal value |
| 100–200 µg/g | slight to moderate exocrine pancreatic insufficiency |
| < 100 µg/g | exocrine pancreatic insufficiency |

## 9. PERFORMANCE CHARACTERISTICS

### *Analytical sensitivity*

Limit of Detection (LoD): **See application note.**

### *Prozone*

Studies have been made up to a concentration of 1 250 µg of pancreatic elastase E1/g of stool and no false negative results have been observed. Studies using higher concentrations have not been carried out.

***Data obtained by the analyser Biolis 24i (Tokyo Boeki)***

### *Clinical sensitivity and specificity*

An evaluation was performed comparing a turbidimetric assay (***IDK*® TurbiPEL®**) and another commercial immunoassay (Pancreatic elastase 1™, Schebo®). The results were as follows:

| | Sensitivity | Specificity |
|---|---|---|
| ***IDK*® TurbiPEL®**<br>vs<br>Pancreatic elastase 1™ Schebo® | **100 %** | **93 %** |

The results showed a high sensitivity and specificity to detect human pancreatic elastase 1 (E1) using ***IDK*® TurbiPEL®**.

### *Interferences*

An evaluation was performed to determine the interferences of ***IDK*® TurbiPEL®** with other substances. No interferences were found against tested substances: BSA, Hemin, Ascorbic acid.

### *Cross reactivity*

An evaluation was performed to determine the cross reactivity against porcine pancreatic elastase; no cross reactivity was found.

## 10. LIMITATIONS

***IDK*® TurbiPEL®** should only be used in human stool samples. ***IDK*® TurbiPEL®** must be used with properly extracted faecal samples.

Values in the range of 100–200 µg/g should be consider as mild to moderate pancreatic insufficiency, and they should be reviewed by the specialist.

## 11. PRECAUTIONS

- All reagents in the kit package are for *in vitro* diagnostic use only.
- A trained person in the turbidimetric technique and the use of the autoanalyser is required. Manual application of the test kit is not possible.
- The analyser should be ready before performing any assay.
- Read and follow the instructions for use provided with the kit.
- If the result exceeds the measurement range, use the sample diluent to dilute the sample and repeat the assay again.
- Reagents should not be used beyond the expiration date stated on the kit label.
- Reagents should not be used if the primary packaging is damaged or opened.
- Do not interchange different lot numbers of any kit component within the same assay.
- Only **new** empty reagent vessels are strictly recommended, because washed or recycled/reused reagent vessels may influence the test result.

## 12. DISPOSAL

- Liquid test components, pipets tips, tubes etc. are to be treated as ordinary laboratory waste, unless otherwise stated. The solutions should be discarded in a proper container after testing following local regulations.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. Other potentially infectious materials (e.g. sample collection container) must be disposed in accordance with official regulations.

## 13. GENERAL NOTES ON THE TEST AND TEST PROCEDURE

- This assay was produced and distributed according to the IVD guidelines of 98/79/EC.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, eye protection and mask. Do not eat, drink or smoke in the working area.
- In the event of warranty claims, notifications of defects or serious incidents, notify Immundiagnostik AG immediately, but at the latest within 14 days after the problem occurring. Please send the product together with a written complaint (including e-mail, address and telephone number) to Immundiagnostik AG.
- If stored properly (2–8 °C), Immundiagnostik AG guarantees, after the first opening, no loss of activity of the kit components for the following three months and at least 20 opening-closing cycles.
- Any variation of the test procedure, which is not coordinated with the producer, may influence the results of the test. Immundiagnostik AG can therefore not be held responsible for any damage resulting from incorrect use.
- *IDK*® **TurbiPEL**® is a trademark of Immundiagnostik AG.

## 14. REFERENCES

1. Andriulli, A. et al. Exocrine pancreatic insufficiency, as assessed by fecal elastase-1 levels in diabetic patients: an estimate of prevalence in prospective studies. J Diabetes Metab 2014, 5:6.
2. Borowitz, D. et al. Use of fecal elastase-1 to classify pancreatic status in patients with cystic fibrosis. J Pediatr 145 : 322–326. 2004.
3. Cade, A. et al. Evaluation of fecal pancreatic elastase as a measure of pancreatic exocrine function in children with cystic fibrosis. Pedr Pulmonol 29 (3): 172–176. 2000.
4. Dominguez-Muñoz, J.E. et al. Potential for screening for pancreatic exocrine insufficiency using the fecal elastase-1 test. Dig Dis Sci. 62 (5) : 1119–1130.
5. Löser, C., Möllgaard, A. & Fölsch, U.R., 1996. Faecal elastase 1: a novel, highly sensitive, and specific tubeless pancreatic function test. Gut, 39(4), pp.580–6.

## 15. ANNEX - COMPATIBLE TURBIDIMETRIC ANALYSERS

| | |
|---|---|
| **Abbott:** | Alinity C-Serie, Architect C-Serie |
| **Awareness:** | Chemwell-T |
| **Binding Site** | Optilite |
| **Biobase:** | BK-Mini |
| **Mindray:** | BS-200 |
| **Siemens:** | Atellica |
| **Tokyo Boeki:** | Biolis 24i/30i/50i |

Applications notes for the use of our turbidimetric products on various instruments can be obtained on request from our technical support.

***Used symbols:***

| | | | |
|---|---|---|---|
|  | Temperature limitation |  | Catalogue number |
|  | In Vitro Diagnostic Medical Device |  | To be used with |
|  | Manufacturer |  | Contains sufficient for <n> tests |
|  | Lot number |  | Use by |
|  | Attention |  | Consult instructions for use |
|  | Consult specification data sheet | | |

**Immundiagnostik AG**

Stubenwald-Allee 8a
64625 Bensheim, Germany

Tel.: +49 6251 70190-0
Fax: +49 6251 70190-363

info@immundiagnostik.com
www.immundiagnostik.com