ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	IT	**Pancreatic Elastase**	Instructions For Use	CE
		REF R3330000099	**100 Test**	**IVD**
		R1 1x 18.3mL	**R2** 1x 2.5mL	IFU-90059-00-C

Intended Use

Pancreatic Elastase a latex turbidimetric assay for the quantitative detection of Pancreatic Elastase in human solid stool samples and is intended for use on the IVD analyser.

For professional in vitro diagnostic use only.

Diagnostics Application

Exocrine pancreatic insufficiency (IPE) is one of the main complications in pancreas illness. It is due to the inability of the pancreas to synthesize this enzyme in the required amount. Pancreatic elastase E1 is produced in the acinar cells of the pancreas. This enzyme is involved in food digestion, and its value is clinically relevant. Human pancreatic elastase 1 (E1) remains undegraded during intestinal tract, becoming in the perfect marker to determine IPE in stool samples

Method

Pancreatic Pancreatic Elastase latex turbidimetric 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, antigen contained in the sample and 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 keep its appearance as a smooth suspension. Such turbidity is measured as an increase in absorbance at the determinate wave and is proportional to the quantity of antigen contained in the sample.

Reagents Provided

R1	**Reagent 1**:	1 Vials x 15.8 mL	Ready to Use
R2	**Reagent 2**:	1 vials x 15.8 mL	Ready to Use

Stability and Storage

The reagents are stable until expiry date on the label when stored at 2-8°C. DO NOT FREEZE
After opening the reagents are stable for 1 month at 2-8°C.

Reagents required but not supplied.

The following materials are required to run test samples and must be ordered separately from your local authorized ISE S.r.l representative.

Reference   Description
- R3330000101 Standard Set Pancreatic elastase
- R3330000100 Control Set Pancreatic Elastase

Sample collection and preparation

Samples should be collected utilising the Universal Stool collection Tubes. Homogenize stool samples as thoroughly as possible prior to preparation.

- R33300000061   Universal Stool collection Tubes.

ℹ️ Consult the Universal Stool collection Tubes instructions for use for correct stool sample extraction.

The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing.

ASSAY PROCEDURE

Application parameters

The Application parameters are included in the autoanalyser software. In the event of a missing the Pancreatic Elastase protocol please contact your authorised ISE representative.

Any application not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance.

IVD Autoanalyser Use

ℹ️ Consult the instrument user manual for instructions on the proper use of the analyser.

Material Preparation

- Ensure samples are collected correctly in accordance with the sample preparation procedure.
- Allow reagents and stool samples to reach room temperature (15-30°C) prior to testing.
- Allow any calibrator or control material to reach room temperature (15-30°C) prior to testing.

Calibration curve establishment

A calibration curve must be performed prior to running samples. The curve must be validated with controls.

Calibration Stability

The calibration is recommended to be run every 7 days on the IVD analyser.

Quality control

For quality control purposes only use the following materials:

- R3330000100   Control Set Pancreatic Elastase

Concentration is indicated on the label of the vial. The use of control materials at two different concentrations is recommended in order to verify test precision across the measuring range. Control frequency should be run in accordance with the laboratory's quality management system.

If the obtained results are out of the tolerance range;
- Ensure all materials are not expired
- Ensure all materials have been stored and prepared correctly
- Perform a calibration

In the event of controls results not meeting the defined tolerances please contact you local ISE authorised representative for support.

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ANALYTICAL CHARACTERISTICS / PERFORMANCE

NORMAL VALUES

Pancreatic Elastase cut-off value:

Pancreatic Elastase E1 values equal or higher than 200 µg of Pancreatic elastase E1/g of stool are indicative of a normal pancreatic exocrine functioning.

Pancreatic Elastase E1 values between 100 and 200 µg of Pancreatic elastase E1/g of stool are indicative of mild to moderate pancreatic exocrine insufficiency.

Pancreatic Elastase E1 values lower than 100 µg of Pancreatic elastase E1/g of stool are indicative of a severe pancreatic exocrine insufficiency.

< 100 E1/g	a severe pancreatic exocrine insufficiency.
100 - 200 E1/g	mild to moderate pancreatic exocrine insufficiency
> 200 E1/g	normal pancreatic exocrine functioning.

Method Comparison

An evaluation was performed comparing the ISE S.r.l Pancreatic Elastase to a commercial immunoassay (Pancreatic Elastase 1 Quick®, Schebo). The results were as follows:

	Sensitivity	Specificity
Pancreatic Elastase vs Pancreatic Elastase 1 Quick®	**95%**	**> 99%**

Linearity

Pancreatic Elastase kit using calibrator kit is linear in the calibration range of 0-400 µg hEL/g of stool.

Limit of detection (LOD):

Limit of detection (LOD): **1.07 µg hEL/g of stool.**
The lower limit of detection of Pancreatic Elastase was determined on 20 samples and 2 sample replicates as the mean value+2·SD.

Limit of quantification (LOQ):

Limit of quantification (LOQ): **5.3 µg hEL/g of stool.**
The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected when imprecision is < 20% as CV%

Precision

Precision was assessed with 3 different controls

Precision	Low	Medium	High
Number	20	20	20
Mean (ug/mL)	25.0	101.9	390.6
SD	0.8	1.7	9.4
CV (%)	3	2	2

Prozone effect

No hook effect was observed up to 10000 µg hEL/g of stool. Samples with Pancreatic Elastase concentration of 10000 µg hEL/g of stool give a typical positive result >400 µg hEL/mL.

Disposal of reagent

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot or batch number
▲	Manufacturer
⧗	Expiry date
⌀	Temperature limitation
🛈	Consult Instructions for use