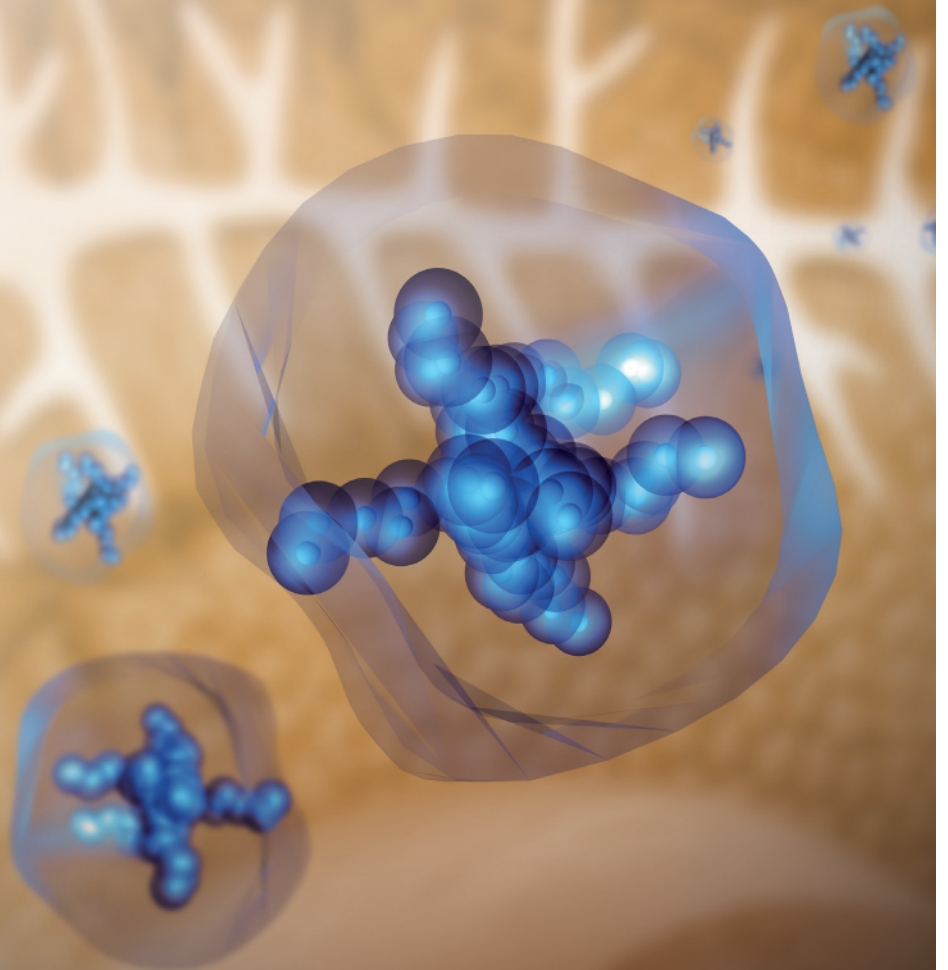


# Pancreatic elastase ELISA

## Marker for exocrine activity of the pancreas

- Quantitative determination of human pancreatic elastase in feces
- Easy and non-invasive diagnosis of pancreatic insufficiency
- Validated also for use on automatic 4-plate ELISA systems (e.g. DSX®)
- Accessories: Stool collection tubes for rapid, easy and clean sample collection



## Information of pancreatic elastase

Pancreatic elastase is an enzyme which is specific to the pancreas and stays active while passing through the gut. Stool takes up pancreatic elastase which has been excreted by the pancreas for digesting food. The amount of pancreatic elastase in stool is an indicator for the exocrine function of the pancreas.<sup>[1]</sup>

### Diabetes mellitus

It has been shown in several publications that about 50 % of type 1 diabetics and about 33 %

#### Main reasons for an impaired exocrine function of the pancreas are:

- Diabetes mellitus
- Mucoviscidosis (Cystic fibrosis)
- Chronic pancreatitis
- Gall stones (Cholelithiasis)
- Hereditary pancreatitis
- Pancreas carcinoma

of type 2 diabetics have a decrease of excreted pancreatic elastase.<sup>[2]</sup>

### Mucoviscidosis/Cystic fibrosis

About 75 - 80 % of mucoviscidosis patients show a decrease of pancreas excretion. For the physician who takes care of patients with cystic fibrosis, it is important to be able even to diagnose a very

low function of the exocrine pancreas for finding selective measures of therapy. With the additional standard the calculation of elastase concentrations below 50 µg/g will become even more precise.<sup>[3, 4]</sup>

## Pancreatic elastase ELISA

- Quantitative determination of human pancreatic elastase in feces
- Non-invasive gold standard for determining pancreatic function
- Results correlate with the invasive gold standard secretin-pancreozymin test
- More sensitive than pancreolauryl test and chymotrypsin tests <sup>[5, 6]</sup>
- Validated also for use on automatic 4-plate ELISA systems (e.g. DSX™)
- Available as 4 (G09038) or 5 standard version (G09040). Both G09038 and G09040 have standards at 50, 100, 200, 500 µg/g. The G09040 has one additional standard at 15 µg/g (SK15).
- Easy, fast and clean sample collection with prefilled Stool Preparation Set (GZ3008)

### References:

[1] Stein J, Jung M, Bieniek U, Scheefers H, Lembcke B, Caspary WF. Fäkale Pankreas-Elastase 1 (EI). Ein neuer zuverlässiger Parameter zur Diagnose der exokrinen Pankreasinsuffizienz. Tagung D. G. Verd. und Stoffw. 1993.

[2] Hahn JU, Wadowska K, Heinke P, Peters H, Rjasanowski I, Kerner W. The Frequency

of exocrine pancreatic insufficiency in Diabetes mellitus type 1 – also a methodical problem? Diabetes und Stoffwechsel 2001;10(1).

[3] Miendje Y, Maisin D, Sipewa MJ, Deprez P, Buts JP, De Nayer P, Philippe M. Polyclonal versus Monoclonal ELISA for the Determination of Faecal Elastase 1:

Diagnostic Value in Cystic Fibrosis and Chronic Pancreatic Insufficiency. Clinical Laboratory 2004;50(7+8):419 – 424.

[4] Rahman HA, Wahab AA, Abdel Rahman MO & Mostafa OAR. Faecal elastase-1 concentration in cystic fibrosis patients with CFTR I1234V mutation. Acta Paediatrica 2006; 95: 1066-1069.

[5] Keim V, Teich N, Moessner J. Clinical Value of a New Faecal Elastase Test for Detection of Chronic Pancreatitis. Clinical Laboratory 2003; 49(5+6):209 – 215.

[6] Keim V, Teich N, Moessner J. Value of polyclonal Elastase ELISA for diagnosis of chronic pancreatitis. Pancreas 2000; 21( 4):453.

## Performance data

### Reference value

Normal exocrine pancreatic function	>200 µg/g
Moderate exocrine pancreatic insufficiency	100 - 200 µg/g
Severe exocrine pancreatic insufficiency	<100 µg/g

### Diagnostic sensitivity

Severe chronic pancreatitis (below 100 µg/g)	94 %
Medium to light chronic pancreatitis (100 - 200 µg/g)	63 %
Pancreas carcinoma	61 %
Mucoviscidosis (Cystic fibrosis)	100 %

### Diagnostic specificity

Diagnostic specificity	95 %
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### Linearity

Linearity	up to 500 µg/g
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### Intra-assay variation coefficient

For the decision limit 100 µg/g	5.2 % (4.1 - 6.9 %)
For the decision limit 200 µg/g	4.3 % (2.8 - 6.8 %)

Two clinically significant levels near medical decision limits, i. e. 100 µg/g and 200 µg/g were tested three times in the same run and in 2

different runs each day for 20 days. Therefore 6 kits from 6 different batches (produced on different days) were used.

### Inter-assay variation coefficient

For the decision limit 100 µg/g	7.7 % (6.5 - 9.1 %)
For the decision limit 200 µg/g	7.9 % (7.1 - 8.9 %)

Two clinically significant levels near medical decision limits, i.e. 100 µg/g and 200 µg/g were tested three times in the same run and in 2 different runs each day for 20 days.

In order to determine the coefficient of interassay variation one strip each (8 wells) of 12 kits of 6 different batches (produced on different days) were used.

## R-Biopharm Gastroenterology – diagnostics at a glance

Product	Description	Tests	Matrix	Art. No.
<b>Enzyme immunoassays</b>				
RIDASCREEN® Haemoglobin	Enzyme immunoassay for the detection of haemoglobin	96	Stool	G09030
RIDASCREEN® Haemo-/Haptoglobin Complex	Enzyme immunoassay for the detection of haemoglobin/haptoglobin complex	96	Stool	G09031
RIDASCREEN® $\alpha_1$ -Antitrypsin	Enzyme immunoassay for the detection of $\alpha_1$ -Antitrypsin	96	Stool	G09034
RIDASCREEN® sIgA	Enzyme immunoassay for the detection of secretoric IgA	96	Stool	G09035
RIDASCREEN® Calprotectin	Enzyme immunoassay for the detection of calprotectin	96	Stool	G09036
Pancreatic Elastase ELISA	Enzyme immunoassay for the detection of pancreatic elastase	96	Stool	G09038
Pancreatic Elastase ELISA (SK15)	Enzyme immunoassay for the detection of pancreatic elastase; additional standard (SK15)	96	Stool	G09040
Pankrin® ELISA	Enzyme immunoassay for the detection of pancreatic elastase and other pancreatic enzymes	96	Serum	G09039
<b>Accessories for RIDASCREEN®</b>				
RIDA®TUBE Haemoglobin	For collection and preparation of stool samples • only use with RIDASCREEN® Haemoglobin G09030 and RIDASCREEN® Haemo-/Haptoglobin Complex G09031	50		GZ3012
RIDA®TUBE	For collection and preparation of stool samples • unfilled; to use after internal validation	50		GZ3013
RIDA®TUBE Calprotectin	For collection and preparation of stool samples • only use with RIDASCREEN® Calprotectin G09036	50		GZ3016
Stool Preparation Set	For collection and preparation of stool samples • only use with Pancreatic Elastase ELISA G09038 and G09040	45		GZ3008

For further details and information visit our website [www.r-biopharm.com](http://www.r-biopharm.com), contact your local distributor or Clinical Sales International.

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