Leading Technology in Fluid-Stable Reagents from DiaSys

- More than 25 years experience in development and production of clinical chemistry tests
- Premium service in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

DiaSys offers reagent kits for manual and automated use plus appropriate calibrators and controls. Detailed information about α-amylase, pancreatic amylase and lipase test is available on our website **www.diasys-diagnostics.com/products/reagents** and in our product catalog.

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DiaSys
Diagnostic Systems

DiaSys
Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

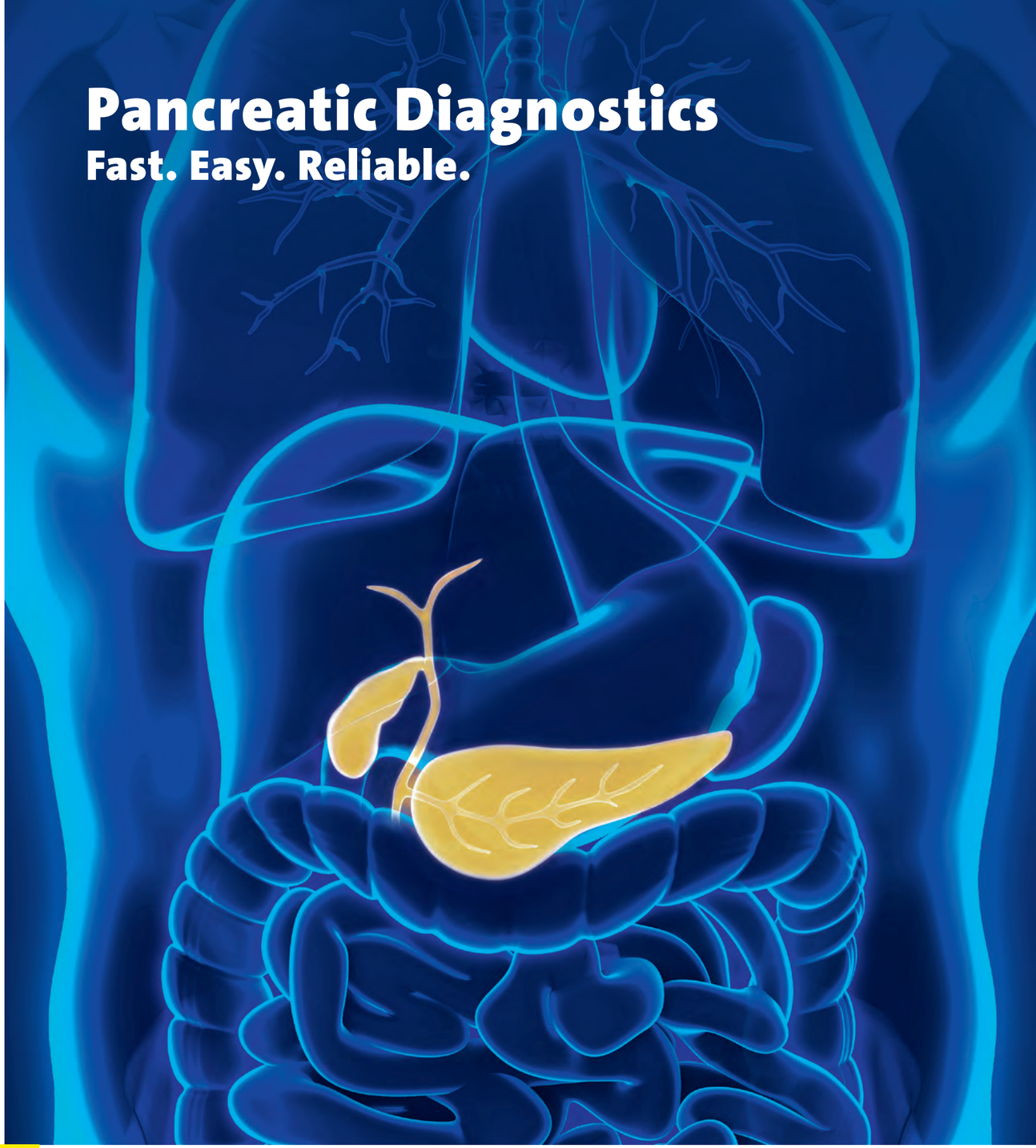
Phone: +49 6432 9146-0
Fax: +49 6432 9146-32
E-Mail: reagents@diasys.de
www.diasys-diagnostics.com

820020 I September 2019

CHOOSING QUALITY.

Pancreatic Diagnostics

Fast. Easy. Reliable.



- **Lipase**
- **α-Amylase**
- **Pancreatic Amylase**

DiaSys
Diagnostic Systems

CHOOSING QUALITY.

Clinical Use

Pancreatic disorders, both inflammatory and neoplastic, are increasingly occurring in industrialized countries. Clinical chemistry tests for α-amylase, pancreatic amylase and lipase are used in detection and follow-up of acute pancreatitis and diagnosis of abdominal disorders. Amylase in serum consists of two isoenzymes: Salivary amylase originating from the salivary glands and pancreatic amylase produced by the pancreas, of which only pancreatic amylase is specific for pancreatic disorders. Lipase represents a further specific parameter for pancreatic diseases. Due to its long half-life, lipase values are elevated longer after a pancreatitis than those of alpha and pancreatic amylase. The combination of both, lipase and pancreatic amylase, highly increases the sensitivity for the detection of pancreatitis.

Methods

Lipase DC FS: The DiaSys test is a state-of-the-art direct colorimetric assay. It uses a substrate in a microemulsion with colipase and bile acids, thus simulating physiological conditions and, therefore, avoiding non-specific enzyme reactions.
α-Amylase CC FS and Pancreatic amylase CC FS: Both tests have the same reaction principle. The DiaSys method uses an Ethylidene protected p-Nitrophenyl-α-D-maltoheptaoside (EPS-G7) as substrate and a bacterial α-glucosidase as recommended by the IFCC (International Federation of Clinical Chemistry). This combination leads to a very stable reagent with fast and complete color release. For the specific measurement of pancreatic amylase, two monoclonal antibodies are used to inhibit the salivary amylase.

DiaSys Reagents for Diagnostics of Pancreatic Diseases

- Liquid stable up to the expiry date, even after opening
- Ready to use – no reconstitution, directly available for stat analysis
- Adaptable to automated clinical chemistry analyzers, validated applications available

Lipase DC FS
- Direct colorimetric method: High signal, high measuring range
- Specific substrate in microemulsion with bile acids and colipase avoids unspecific reactions
- Use of serum and heparin plasma
- Linearity up to 300 U/L*
- Calibration/onboard stability 12 weeks (BioMajesty® JCA-BM6010/C)

α-Amylase CC FS
- IFCC recommended EPS-G7 method
- Linearity up to 2000 U/L*
- Good correlation to other methods (e. g. CNP-G3)
- Use of serum, plasma and urine
- Mixed reagent stability 6 months
- Calibration/onboard stability 6 weeks (BioMajesty® JCA-BM6010/C)

Pancreatic amylase CC FS
- EPS-G7 method, based on IFCC recommendation
- Immunoinhibition of salivary amylase: Specific for pancreatic diagnostics
- Use of serum, plasma and urine
- Linearity up to 2000 U/L*
- Calibration/onboard stability 6 weeks (BioMajesty® JCA-BM6010/C)

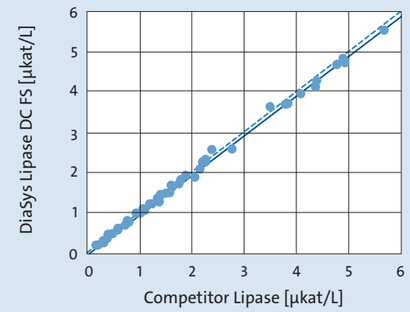
* May vary according to specific applications.

Lipase DC FS: Precision studies and method comparison to competitor Lipase (on BioMajesty® JCA-BM6010/C)

Precision

Intra-assay	Mean (U/L)	Mean (µkat/L)	CV (%)
Sample 1	30.9	0.52	1.26
Sample 2	60.9	1.02	0.611
Sample 3	286	4.78	0.263
Total	**Mean (U/L)**	**Mean (µkat/L)**	**CV (%)**
Sample 1	30.2	0.50	2.01
Sample 2	59.9	1.00	1.20
Sample 3	284	4.74	1.10

Method Comparison



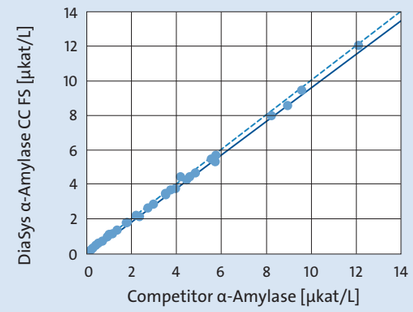
n = 107, Passing/Bablock: y = 0.982 x – 0.003 µkat /L, r = 0.999

α-Amylase CC FS: Precision studies and method comparison to competitor α-Amylase (on BioMajesty® JCA-BM6010/C)

Precision

Intra-assay	Mean (U/L)	Mean (µkat/L)	CV (%)
Sample 1	36.9	0.62	1.86
Sample 2	74.9	1.25	1.11
Sample 3	238	3.97	0.78
Inter-assay	**Mean (U/L)**	**Mean (µkat/L)**	**CV (%)**
Sample 1	37.3	0.62	1.83
Sample 2	119	1.98	1.59
Sample 3	242	4.04	1.90

Method Comparison



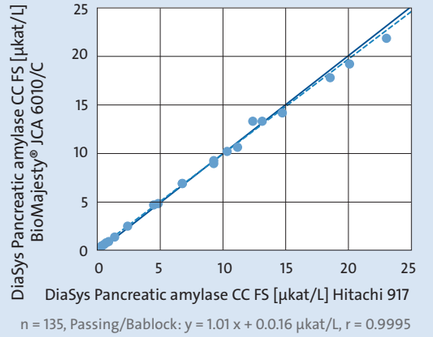
n = 100, Passing/Bablock: y = 0.973 x – 0.053 µkat/L, r = 0.999

Pancreatic amylase CC FS: Precision studies and instrument comparison of DiaSys Pancreatic amylase CC FS on Hitachi 917 vs. BioMajesty® JCA-BM6010/C

Precision

Intra-assay	Mean (U/L)	Mean (µkat/L)	CV (%)
Sample 1	26.3	0.44	0.90
Sample 2	115	1.91	0.64
Sample 3	252	4.20	0.61
Inter-assay	**Mean (U/L)**	**Mean (µkat/L)**	**CV (%)**
Sample 1	44.9	0.75	1.40
Sample 2	142	2.37	0.86
Sample 3	247	4.13	0.59

Instrument Comparison



n = 135, Passing/Bablock: y = 1.01 x + 0.0.16 µkat/L, r = 0.9995