World Class Pioneers

Medix Biochemica specializes in monoclonal antibodies and diagnostic tests for numerous medical conditions. Medix Biochemica has succeeded in combining the scientific community and high-tech diagnostics.

More than twenty years ago, we were one of the first companies in the world to produce monoclonal antibodies. We immediately understood their enormous potential in healthcare. Today Medix Biochemica is a dynamic high-tech corporation with a global customer base.

Reliable test results in minutes

As a token of our respected global reputation, more than 150 companies in over 30 countries use medixMab™ monoclonal antibodies and numerous laboratories and physicians rely on our actim™ diagnostic healthcare tests.

High quality has always been the cornerstone of all our operations. To ensure continuous high quality the entire company is certified as being in conformity with EN ISO-9001:2000 and ISO13485:1996. We also value research and development. Currently over 20% of our turnover is devoted to R&D.

Our expertise covers the whole production chain from raw materials (monoclonal antibodies) to finished healthcare products, such as the actim™ diagnostic tests.

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actim™

Medix Biochemica

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MA03E32702-01

For reliable screening of acute pancreatitis.

actim™ PANCREATITIS

Test kit

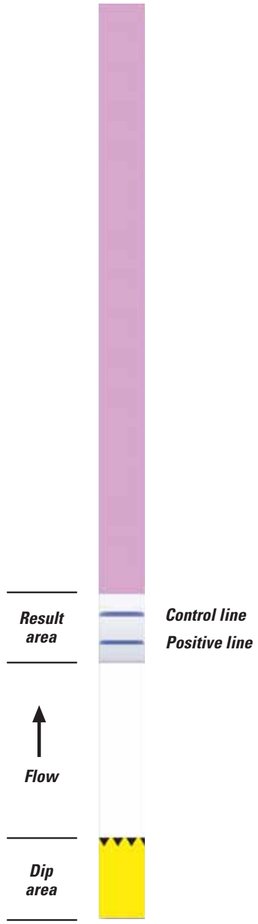
Medix Biochemica

actim™ PANCREATITIS

Test kit

Ruling out acute pancreatitis is as important as detecting it.

The acute inflammatory process of pancreas, acute pancreatitis, is typically caused by alcohol abuse and/or gallstones. Fortunately, it can be often treated successfully, if diagnosed early. Since 20 to 30 percent of cases may lead to serious complications like pancreatic necrosis and sepsis, early treatment is essential. In cases of severe acute pancreatitis the mortality rate can rise as high as 40%. What's more, it has been estimated that even 30-40 % of pancreatitis cases are actually only diagnosed in autopsy.



actim™

www.actim.info

Abdominal pains, however, can have numerous other causes, so in addition to diagnosing acute pancreatitis, you should also be able to rule it out to ensure proper and effective treatment. Immunological actim™ Pancreatitis urine dipstick test helps you accomplish just that, quickly and specifically.

Traditional methods neither specific nor sensitive enough

The traditional methods of detecting acute pancreatitis include measurement of amylase in urine or serum and measurement of lipase in serum. But both of these markers have serious drawbacks.

Amylase is found in many other organs than pancreas and its specificity and sensitivity is limited. In addition, amylase levels start to decline after just 1-3 days. Serum lipase has better specificity and is more sensitive than amylase, but is still far from satisfactory indication of acute pancreatitis.

Comparison of actim™ Pancreatitis test and amylase and lipase in detection of acute pancreatitis

	Sensitivity	*Specificity*
Actim™ Pancreatitis	94 %	95 %
S-Amylase 900 U/l	70 %	97 %
S-Amylase 300 U/l	85 %	91 %
From Kemppainen et al. NEJM 1997		
	Sensitivity	*Specificity*
Actim™ Pancreatitis	93 %	92 %
S-Lipase 600 U/l	55 %	99 %
S-Lipase 200 U/l	79 %	88 %
From Kylänpää-Bäck et al. Hepato-Gastroenterology 2002		

Actim™ Pancreatitis test detects acute pancreatitis with high specificity and sensitivity.

Patents:

US5976809, EP777680, EP677170, US5712170, US5965458

Levels of different analytes in healthy controls, acute abdominal pain controls, patients with mild AP and severe AP
Hedström et al. 1996

	Healthy controls	*Acute abdominal pain controls*	*Mild AP*	*Severe AP*
U-trypsinogen-2	1.0 (0.2-84)	2.9 (1.0-130)	890 (15-175000)	9000 (67-190000)
U-amylase		700 (120-13000)	8200 (130-120000)	3300 (170-120000)
S-amylase		200 (53-490)	990 (67-8000)	3300 (390-14000)

U-trypsinogen-2 is strongly elevated in the urine of acute pancreatitis patients.

Novel analyte for increased accuracy

Actim™ Pancreatitis uses a novel analyte, trypsinogen-2, for acute pancreatitis screening. It is the most accurate analyte for both detecting and ruling out acute pancreatitis. Trypsin is produced by the pancreatic acinar cells and is secreted into pancreatic juice as a proenzyme trypsinogen. The two major trypsinogen isoforms in pancreas are trypsinogen-1 (cationic) and trypsinogen-2 (anionic). The trypsinogens represent 19% of total protein in pancreatic juice.

Early detection for immediate treatment

Trypsinogen-2 levels in urine are strongly elevated already in early stages of acute pancreatitis and, most importantly, remain elevated for several days or even weeks. So even if the patient does not contact a physician quickly, actim™ Pancreatitis test can still be taken and the results will remain reliable.

Actim™ Pancreatitis as a screening test for acute pancreatitis

	Subjects	*AP*	*Sens.*	*Spec.*	*PPV*	*NPV*
Kemppainen et al 1997	500	53	94	95	68	99
Kylänpää-Bäck et al 2000	525	45	96	92	54	99.6
Delcenserie et al. 1999	250	26	89.7	92	51.1	99

In several studies done so far, it has been demonstrated that actim™ Pancreatitis rapid dipstick test can detect severe pancreatitis without exception.

Both specificity and sensitivity extremely high

Several studies have also demonstrated that actim™ Pancreatitis test is simultaneously highly specific and sensitive. In this respect, actim™ Pancreatitis clearly outclasses both amylase and lipase tests. The cut-off value of 50 µg/l enables you to detect even slight increases of the trypsinogen-2 levels.

The negative predictive value is therefore extremely high, 99%, so a negative test result from a urine sample is an exceptionally valid reason to rule out acute pancreatitis.

Compared to actim™ Pancreatitis, the amylase test has a much higher percentage of false positives. This can lead to a high number of unnecessary CT-scans. The better precision of actim™ Pancreatitis effectively limits the need for costly CT scans. In addition, the high negative predictive value (NPV) of actim™ Pancreatitis considerably diminishes the risk of sending patients, who actually have acute pancreatitis, back home.

References

Kylänpää-Bäck M-L, Kemppainen E, Puolakkainen P, Hedström J, Haapiainen R, Perhoniemi V, Kivilaakso E, Korvuo A, Stenman U-H. Reliable screening for acute pancreatitis with rapid urine trypsinogen-2 test strip. Br J Surg (2000), 87:49-52.

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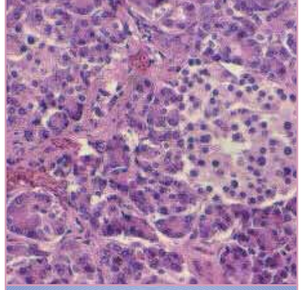
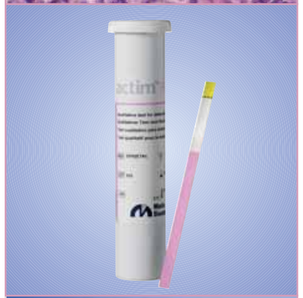


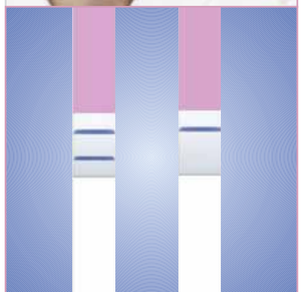
Actim™ Pancreatitis test does not need to be processed at a laboratory. A simple urine sample is all that is required.



Clear results are visible in just five minutes.

All you need to do is dip the actim™ Pancreatitis dipstick in urine until the liquid front rises to the result window.

Then remove the dipstick from the sample and place it in horizontal position. In just five minutes you can read the result.



Two lines in the result window indicate a positive result and one line a negative result. It's as simple as that.