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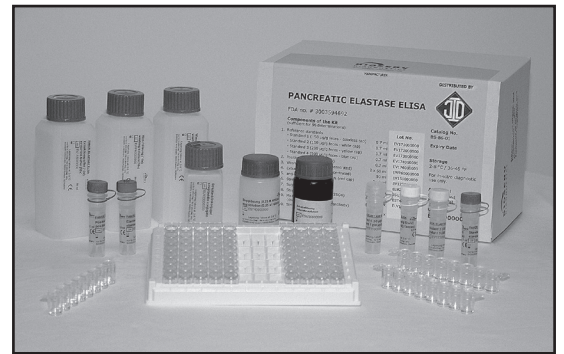
AN EXOCRINE PANCREATIC INSUFFICIENCY SCREEN

*A Fast, Non-Invasive, Affordable and
Accurate Way to Measure Pancreatic Elastase*

The first report of the enzyme elastase appeared in 1878, when Wälchli¹ found that ground-up ox pancreas digested elastin, a component of connective tissue. Physicians, who did most of the research in that era, were only scratching the surface of what is now known as protein chemistry, or as some might say now, enzymology. It took more than 100 years since Wälchli to arrive where we are today: to easily measure the level of excreted elastase and make an initial diagnosis of exocrine pancreatic insufficiency. Although today's diagnostic gold standard for this condition is the invasive pancreatic stimulation and endoscopy procedure, having the ability to screen patients with a fast, non-invasive and affordable ELISA test has been an enormous benefit to physicians around the world.

Pancreatic elastase is a relatively small protein (~30kDa) with a unique mission: the hydrolysis of elastin. Since proteases such as trypsin, chymotrypsin and pepsin don't hydrolyze elastin, an appropriate physiological level of elastase is important. Although the biochemistry is not yet well understood for each condition, an exocrine pancreatic insufficiency of elastase can raise a red flag for chronic pancreatitis, pancreatic cancer, diabetes mellitus, cystic fibrosis and other rare conditions such as Shwachmann syndrome and Zollinger–Ellison syndrome.

Prior to the availability of antibody-based diagnostics, physicians stimulated the pancreas by various means and invasively collected a specimen. Today, the initial screen is done with a non-invasive, affordable, antibody-based ELISA test. If the ELISA test confirms levels of less than 200 µg/g of stool it can indicate an exocrine insufficiency.



The Pancreatic Elastase ELISA kit from BIOSERV (exclusively distributed by JOLI Medical Products, Inc.) is easy to use, very affordable, and delivers quick results.

This is where the FDA and EU registered **Pancreatic Elastase ELISA kit** from BIOSERV² (exclusively distributed by **JOLI Medical Products, Inc., Williamsville, NY**) makes it easy for the physician and patient to arrive at a proper diagnosis. The test (Pancreatic Elastase ELISA, JOLI catalog #BS-86-01) is easy to use, very affordable and delivers quick results.

So how does it work? The physician collects a well-formed stool sample from the patient; a watery stool may give a false reading due to the dilution of pancreatic elastase. Although clinical tests have shown³ that assay results are not affected by patients taking supplemental enzymes, it is recommended that patients should reduce or eliminate supplementation before submitting a sample. Once the sample is placed in a container it is ready to be tested. If the sample can't be tested right away, you can store it frozen at -20°C or -70°C for future analysis.

The ELISA assay developed by BIOSERV uses the well documented polyclonal sandwich antibody technique. As this assay was being developed and optimized, clinical tests showed⁴

that polyclonal antibodies gave the best results. Not only does each antibody in the polyclonal antisera detect the correct isoform of elastase, but each has been raised against various peptide sequences common to the isoforms. Although other kits had good sensitivity and selectivity, the BIOSERV test showed better results in sensitivity and significantly higher selectivity⁵ than monoclonal antibody (MAB) tests.

Once your sample is ready to assay, the Pancreatic Elastase ELISA instructions are very straightforward. After weighing and extracting the stools, the test takes about three hours to run. Always remember when handling biological samples to handle the samples with utmost care as they may harbor infectious organisms. The materials you'll need to run this assay are fairly common biological assay tools. All you need is a microplate reader with standard optical filters at 450 nm (with a ≥ 550 nm reference filter), microliter pipettes with disposable tips, dilution tubes and distilled or deionized water. That's it. You're ready to go.

The idea behind the assay is to present to the polyclonal coated microplate an extracted buffer from your stool sample possibly containing your analyte (elastase) and then compare it to standards supplied with the kit. Once the samples, standards, blanks and all reagents are in the microplate the magic begins. Within each well, if any pancreatic elastase is present it will bind to the polyclonal antibody already coated in the well. After 60 minutes, the wells are washed with washing buffer and a second anti-human pancreatic elastase antibody

is added. This time, however, the second antibody is linked to a biotin molecule. At this point, if elastase is present in any of the wells, it has been 'sandwiched' between two polyclonal antibodies which is the basis of the assay. After another 30 minutes the wells are washed again and a reagent that binds with biotin is added, a streptavidin peroxidase conjugate. A short 30 minutes later a substrate is added and after 20 minutes the reaction is stopped and the microplate wells can be measured in the microplate reader. Since the reaction forms a color the microplate reader measures how much light reaches the detector after passing through the sample. The higher the concentration of elastase the deeper the color, so a linear correlation can be made when known amounts (the standards) are measured along with your samples.

When the results of the test are calculated (using software typically available with the microplate reader), the clinician has very useful, and timely information. The results are given in microgram of elastase per gram of stool with $<200 \mu\text{g/g}$ as the threshold for pancreatic insufficiency.

Although the BIOSERV test is easy to run, you may not have a lab in your facility. One option is to send it to JOLI Diagnostic, Inc.,⁶ who will run the test for you at a very reasonable cost.

Upon reviewing the results, if the test shows any pancreatic insufficiency, the physician may elect to stimulate the pancreas and collect the pancreatic juice via endoscope. These aspirated duodenal fluid samples can also be sent to JOLI Diagnostic, Inc. for analysis.

Conclusion

The BIOSERV Pancreatic Elastase ELISA test—exclusively distributed through JOLI Medical Products, Inc. for the determination of human pancreatic elastase—is a state-of-the-art clinical measurement that is indispensable for the gastroenterology community. Clinicians and patients will benefit from the assay's sensitivity, selectivity, and speed as the initial screen for this important pancreatic marker. ♦



To Learn More

For more information concerning **JOLI Medical Products, Inc.**, please call 1-716-639-0521, or email joli@jolimedicalproducts.com.

For more information concerning **JOLI Diagnostic, Inc.**, please call 1-716-639-0443; send email to joli@jolidiagnostic.com; or visit the Web site at www.jolidiagnostic.com.

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