VITASSAY

Pancreatic Elastase -Turbidimetric Assay-

Rapid test for the quantitative detection of human Pancreatic elastase E1 in human stool samples.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only. Professional trained in turbidimetric techniques.

INTENDED USE

Vitassay Pancreatic Elastase–Turbidimetric Assay- is a rapid Turbidimetric assay for the quantitative detection of Pancreatic Elastase E1 in human stool samples.

Simple, non-invasive, and highly sensitivity assay for the presumptive diagnosis of Pancreatic Elastase E1 in stool samples. This product is optimized for several automated analyzer. Test results should be **exclusively be used to evaluate exocrine pancreatic function in stool samples.**

INTRODUCTION

Exocrine pancreatic insufficiency (EPI) is defined by a deficiency of exocrine pancreatic enzymes resulting in an inability to maintain normal digestion.

EPI is one of the major complications of chronic pancreatitis that has alcohol as the main etiological cause.

Human Elastase is synthetized by the acinar cells of the pancreas along with the other proteolytic enzymes, and under normal conditions. An advantage of fecal elastase 1 as a diagnostic marker is its low variability within an individual from day to day, indicating that its measurement in fecal samples is valid diagnostically.

PRINCIPLE

Vitassay Pancreatic Elastase–Turbidimetric Assay- is a quantitative turbidimetric assay for the detection of human Pancreatic Elastase E1 in human solid stool samples.

Vitassay Pancreatic Elastase Turbidimetric Assay is based on antigen-antibody agglutination reactions between the antigen contained in the sample and the antibodies anti-antigen coated on polystyrene latex particles.

Such agglutination is measured as an increase in absorbance proportional to the quantity of antigen contained in the sample.

The use of two external controls, Control 1 and Control 2, is used to verify that the test is working properly.

PRECAUTIONS

- For professional *in vitro* use only.
- A trained person in Turbidimetric technique and autoanalyzer use is required.
- Do not use after expiration date.
- Do not use the test if its primary containers are damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. Avoid contamination errors, follow proper work procedure.
- The reagents after use should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Pancreatic Elastase-Turbidimetric Assay-**. Do not use any other commercial component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles, and mask. Do not use any other commercial kit component.
- If measure range is exceeding, use the sample diluent to dilute the sample and repeat the assay again.
- Read and follow up the instructions for use provided in the kit.
- Prepare and adjust the analyzer before starting measurements.

STORAGE AND STABILITY

Store as packaged in the original primary container, the reagents should be preserved at refrigerated temperature (2-8ºC/35.6-46.4ºF), the sample diluent could be preserved refrigerated or at room temperature (2-30ºC/35.6-86ºF).

The product is stable until the expiration date printed on the label, if they have been preserved under the recommended conditions.

Do not freeze and keep away from the sunlight.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ Reagent R1 (Enhancer buffer) ▪ Reagent R2 (Latex particles) ▪ Calibrator 0 ▪ Calibrator 1 ▪ Calibrator 2 ▪ Calibrator 3 ▪ Calibrator 4 ▪ Calibrator 5 ▪ Control 1 ▪ Control 2 ▪ Universal vials with diluent for the sample dilution. ▪ Instruction for use. ▪ Additional screw cap	▪ Specimen collection container. ▪ Disposable gloves and laboratory equipment. ▪ Vortex. ▪ Automatic analyzer. ▪ Microcentrifugue (10000g).

SPECIMEN COLLECTION

Collect sufficient quantity of feces: 1-2 g or mL for liquid samples. Stool should be collected in clean and dry containers.

Samples can be stored in the refrigerator (2-8ºC/35.6-46.4ºF) for 7 days prior to testing. For longer storage, maximum 6 months, the

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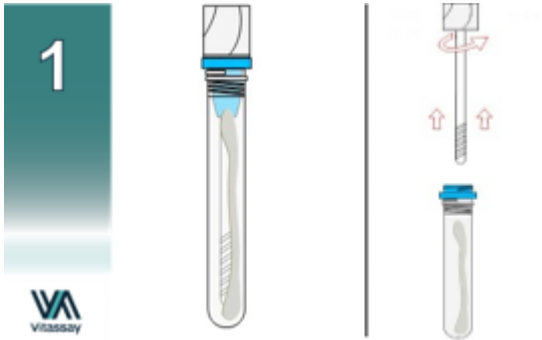
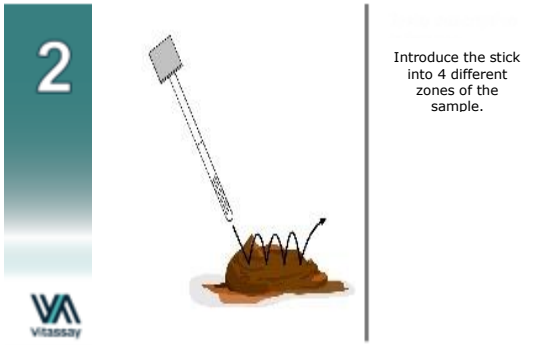
specimen must be kept frozen at -20ºC (-4ºF). Samples must be brought to room temperature (15-30ºC/59-86ºF) before testing. Homogenize stool samples as thoroughly as possible prior to preparation.

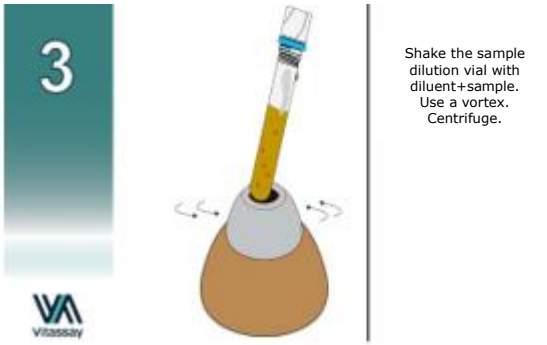
SPECIMEN PREPARATION

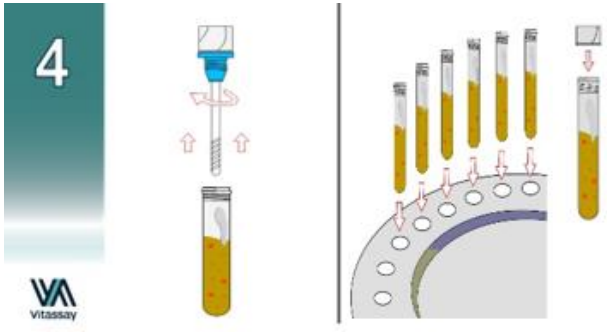
1. Label the vial with the patients´s identification.
2. Open the cap of the vial (anticlockwise) without removing the blue separator and use the stick to pick up sufficient quantity of sample (figure 1).
3. Use the stick to collect sufficient sample quantity. Introduce the stick into 4 different zones and rotate the stick in order to make the samples as homogenous as possible and make sure all grooves are filled with faecal material (figure 2).
4. Remove the stool excess by rotating the stick on the internal wall of the sterile container.
5. Insert the stick with the sample into the vial through the blue separator. Close the white cap by holding the blue separator to prevent it from opening.
6. Shake each vial (30-60 seconds) by Vortex in order to assure good sample dispersion (figure 3). Proceed to step 7 if the grooves are visually empty of any stool material, otherwise repeat the shaking up to 120 seconds and proceed to step 7 regardless some residual stool sample in the grooves. The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8ºC) prior to testing and bring the samples to room temperature.
7. Centrifuge the vial for 10 minutes at 1000-3000 x g in order to remove the possible residuals of faecal material. Alternatively, let the vial sit upright for a minimum of 15 minutes.
8. Remove the white screw cap and the blue separator from vials by rotating the separator (clockwise). The faecal extract is now ready to be tested. Insert the opened device directly into the clinical chemistry analyser or transfer the supernatant to an adaptor cup (not provided) (figure 4).
9. Close the collection vial by the provided additional screw cap (figure 4).

Note: Do not use the sample vials directly in the analyzer.









PROCEDURE

Reagent R1 y Reagent R2 are ready to use.

Calibration curve

For calibration only use Pancreatic elastase Calibrator: Cal0, Cal1, Cal2, Cal3, Cal4 and Cal5. Contain Pancreatic Elastase at diferent concentrations indicated on the label of each of the vials.

	Reference	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4	Calibrator 5
Conc.	0 µg/g	25 µg/g	50 µg/g	100 µg/g	200 µg/g	400 µg/g
Vol.	1000µL	1000µL	1000µL	1000µL	1000µL	1000µL

Reagents are ready to use. The frequency in the realization of the calibration curve must be established by the end user in the function of the criteria established for the clinical laboratory.

Note: See section quality control.

Analytical procedure

Measure range: 5.3 – 1250 µg hEL/g.

Procedure	Steps	
R1 addition	220 µL	0 s
Sample addition	10 µL	10 s
R2 addition	20µL	300 s
Blank measure	450 nm – 800 nm	310 s
Mainly measure	450 nm – 800 nm	610 s

*Dat obtained by Biolis 24i analyser (Tokio Boeki).

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INTERPRETATION OF RESULTS

Positive results: higher or equal than the Cut-off fixed by the clinical laboratory.

Recommended cut-off values: 100-200 µg of Pancreatic Elastase E1/g of stool for diagnostics

Positive results determine the normal level of Pancretic Elastase in stool samples.

Cut-off value of **Vitassay Pancreatic Elastase -Turbidimetric Assay**-:

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.

QUALITY CONTROL

Pancreatic Elastase C1 & C2 Controls are ready to use.

Pancreatic Elastase Control 1: is liquid control at a certain concentration of recombinant Pancreatic Elastase (lower than Control 2). Concentration is indicated on the label of the vial.

Pancreatic Elastase Control 2: is liquid control at a certain concentration of recombinant Pancreatic Elastase (higher than Control 1). Concentration is indicated on the label of the vial.

The use of controls at two different concentrations is recommended to verify test precision.

If the obtain results are out of the tolerance range, the equipment, the reagents or the technique must be reviewed. If the problems persists, stop using the reagents and contact your distribuitor.

LIMITATIONS

- **Vitassay Pancreatic Elastase -Turbidimetric Assay** should be only used in human stool samples.
- The quality of **Vitassay Pancreatic Elastase-Turbidimetric Assay** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Values in the range between 100-200 µg/g should be consider as mild to moderate pancreatic insufficiency, and they should be reviewed by the specialist.

EXPECTED VALUES

The reference range of less fecal elastase than 200 µg/g can be applied to both children and adults for the diagnosis of EPI. Some consider values less than 100 µg/g feces as diagnostic of severe EPI, with fecal elastase values between 100 and 200 µg/g to be indeterminate and difficult to interpret but in the face of other evidence, is suggestive of Chronic Pancreatitis. Values over 200 µg/g are normal.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

Detection limit: 1.07 µg hEL/g.

Prozone:

Lower concentrations of 10000 µg de hEL/g of stool do not show prozone effect and no false negative results have been observed. Studies using higher concentrations have not been carried out.

Within-Run Precision

	Low (25 µg/g)	Media (100 µg/g)	High (400 µg/g)
N	20	20	20
Media (µg/g)	25.0	101.9	390.6
DS (µg/g)	0.8	1.7	9.4
CV (%)	3	2	2

*Data obtained by the analyzer Biolis 24i (Tokio Boeki)

Cross reactivity:

No cross reactivity was detected against:

Porcine Elastase	*Pancreatic*	*None*

REFERENCES

1. Practical guide to exocrine pancreatic insufficiency – Breaking the myths. Struyvenberg, Maarten R.; Martin, Camila R.; Freedman Steven D. BMC Medicine (2017) 15:29 DOI 10.1186/s12916-017-0783-y.
2. Comparison of fecal elastase 1 for exocrine pancreatic insufficiency evaluation between ex-alcohilics and chronic pancreatitis patients. Mattar R,; Silva Lima G.A.; Zadrozny Gouvea da Costa M.; Kinoshita Silva-Etto J.; Guarita D.; CarrilhoF.J. Arq Gastroenterol v.51 no. 4-out/dez. 2014
3. Pancreatic function testing: Here to stay for the 21st century.John G Lieb II, Peter V Draganov, doi 10.3748/wig. 14.3149

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number
	Keep out of the sunlight		

ADAPTED EQUIPMENT

- Biolis 24i/Biolis 50i (Tokio Boeki)

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