



Hu Pepsinogen I ELISA

KAPEPKT810

LOT : 090604/1



Human Pepsinogen I ELISA Kit

Enzyme Linked ImmunoSorbent Assay (ELISA) for the measurement of
Human Pepsinogen I Levels in Serum

KAPEPKT810

IN VITRO DIAGNOSTIC

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INTENDED USE

This ELISA (enzyme-linked immunosorbent assay) kit is intended for the quantitative determination of human pepsinogen I levels in serum. Determination of human serum pepsinogen I level would be a useful tool in the aid of diagnosing the functional states of acid secreting gastric mucosa.

SUMMARY OF PHYSIOLOGY

Pepsinogen consists of a single polypeptide chain of 375 amino acids with an average molecular weight of 42 kDa. Pepsinogen I is synthesized at gastric chief cells and mucous neck cells, while pepsinogen II is produced not only by gastric chief cells, mucous neck cells, but also by clear mucous cells of antrum, etc. The clinical applications of measuring pepsinogen I and pepsinogen II are of useful aid in diagnosing severe atrophic gastritis and stomach cancer. It was suggested that the measurement of serum pepsinogens served as a "serological biopsy" for predicting the presence of atrophic gastritis or superficial gastritis.

Atrophic Gastritis: It was found that a serum pepsinogen I level below 20 ng/ml was highly specific for severe atrophic gastritis. It is also observed that serum pepsinogen I levels fell with increasing severity of mucosal damage in atrophic gastritis. The diagnostic sensitivity and specificity of serum pepsinogen I level for advanced atrophic corpus gastritis are about 92% and 90% respectively. On the other hand, the decrease in serum pepsinogen I levels in patients with pernicious anemia and atrophic gastritis was found to be associated with normal or raised pepsinogen II levels. Therefore, a pepsinogen I/pepsinogen II ratio is significantly lower than those with superficial gastritis or normal remnant mucosa.

Stomach Cancer: Low serum pepsinogen I levels were found in patients with gastric cancer, with a threefold higher incidence. Other studies have concluded that low serum pepsinogen I levels may identify persons at increased risk for intestinal types of stomach cancer.

Duodenal Ulcer: A low serum pepsinogen I level can exclude a diagnosis of duodenal ulcer. Although a high pepsinogen I level has less clinical useful for establishing the diagnosis of a duodenal ulcer, the combination of hypergastrinemia and a highly elevated serum pepsinogen I strongly suggests the possibility of the Zollinger-Ellison syndrome.

ASSAY PRINCIPLE

This ELISA is designed, developed and produced for the quantitative measurement of human pepsinogen I level in serum samples. The assay utilizes the two-site "sandwich" technique with two selected monoclonal antibodies that bind to different epitopes of human pepsinogen I without any cross-reaction to human pepsinogen II.

Assay calibrators, controls and patient serum samples containing human pepsinogen I is added directly to the microtiter wells of a microplate that was coated with streptavidin. Simultaneously, a biotinylated antibody and a horseradish peroxidase conjugated antibody is added to each well. After the first incubation period, the streptavidin on the wall of the microtiter well captures the biotinylated antibody as well as immuno complexes in the form of "streptavidin – biotin-antibody – pepsinogen I – HRP-antibody". Unbound proteins as well as unbound HRP conjugated antibody in each microtiter well are removed in the subsequent washing step. The well is incubated with a substrate solution in a timed interval, the reaction is stopped and the developed colour is measured in a spectrophotometric microplate reader. The enzymatic activity of the detecting antibody bound to the pepsinogen I on the wall of the microtiter well is directly proportional to the amount of pepsinogen I in the sample. A calibrator curve is generated by plotting the absorbance versus the respective human pepsinogen I concentration for each calibrator on Point-to-Point, CubicSpline or 4-Parameter plot. The concentration of human pepsinogen I in test samples is determined directly from this calibrator curve.

REAGENTS: Preparation and Storage

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date.

Prior to use allow all reagents to come to room temperature. Reagents from different kit lot numbers should not be combined or interchanged.

1. | | |----| | UL | |----| Streptavidin Coated Microplate

One microplate with 12x8 strips (96 wells total) coated with streptavidin. The plate is framed and sealed in a foil Ziploc bag with a desiccant. This reagent should be stored at 2 – 8°C and is stable until the expiration date on the kit box.

2. | | | | |----|-----|------| | Ab | HRP | CONC | |----|-----|------| Detecting Antibody

One vial contains 0.6 mL concentrated horseradish peroxidase (HRP) conjugated anti-human pepsinogen I detecting antibody in a stabilized protein matrix. This reagent must be diluted with dilution buffer before use. This reagent should be stored at 2 – 8°C and is stable until the expiration date on the kit box.

3. | | | | |----|------|------| | Ab | BIOT | CONC | |----|------|------| Capture Antibody

One vial contains 0.6 mL concentrated biotinylated anti-human pepsinogen I capture antibody in a stabilized protein matrix. This reagent must be diluted with dilution buffer before use. This reagent should be stored at 2 – 8°C and is stable until the expiration date on the kit box.

4. | | | |-----|-----| | DIL | BUF | |-----|-----| Dilution buffer

One vial contains 12 mL ready to use buffer. It should be only used for detecting and capture antibody dilution according to the assay procedures. This reagent should be stored at 2 – 8°C and is stable until the expiration date on the kit box.

5. | | | | |------|------|------| | WASH | SOLN | CONC | |------|------|------| Washing buffer

One bottle contains 20 mL of a 30 fold concentrate. Before use the contents must be diluted with 580 mL of distilled water and mixed well. Upon dilution this yields a working wash solution containing a surfactant in phosphate buffered saline with a non-azide preservative. The diluted solution should be stored at room temperature and is stable until the expiration date on the kit box.

6. | | | |-------|-----| | CHROM | TMB | |-------|-----| TMB-Substrate solution

One bottle contains 12 mL of tetramethylbenzidine (TMB) with hydrogen peroxide. This reagent should be stored at 2 – 8°C and is stable until the expiration date on the kit box.

7. | | | |------|------| | STOP | SOLN | |------|------| Stop Solution

One bottle contains 12 mL of 0.5 M sulfuric acid. This reagent should be stored at 2 – 8°C or room temperature and is stable until the expiration date on the kit box.

8. | | | |-----|---| | CAL | N | |-----|---| Calibrators 0 - 5

Six vials each contains lyophilized human pepsinogen I in a bovine serum albumin based matrix with a non-azide preservative. **Refer to vial for exact concentration for each calibrator.** All the calibrators should be reconstituted with distilled water and stored at -20°C or below after the first use with up to 3 freeze cycles.

9. | | | |---------|---| | CONTROL | N | |---------|---| Controls 1 - 2

Two vials each contains lyophilized human pepsinogen I in a bovine serum albumin based matrix with a non-azide preservative. **Refer to vials for exact concentration range for each control.** Both controls should be reconstituted with distilled water and store at -20°C or below after the first use with up to 3 freeze cycles.

SAFETY PRECAUTIONS

For in vitro diagnostic use only.

The reagents must be used in research laboratory and is for in vitro diagnostic use only. Source material from which reagents of bovine serum albumin was derived in the contiguous 48 United States. It was obtained only from donor health animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this assay and handle these reagents as if they are potential infectious. Avoid contact with reagents containing TMB, hydrogen peroxide, or sulfuric acid. TMB may cause irritation to skin and mucous membranes and cause an allergic skin reaction. TMB is a suspected carcinogen. Sulfuric acid may cause severe irritation on contact with skin. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Precision single channel pipettes capable of delivering 20 µL, 25 µL, 100 µL, and 1000 µL, etc.
2. Repeating dispenser suitable for delivering 100 µL.
3. Disposable pipette tips suitable for above volume dispensing.
4. Disposable 12 x 75 mm or 13 x 100 glass tubes.
5. Disposable plastic 1000 mL bottle with caps.
6. Aluminum foil.
7. Deionized or distilled water.
8. Plastic microtiter well cover or polyethylene film.
9. ELISA multichannel wash bottle or automatic (semi-automatic) washing system.
10. Spectrophotometric microplate reader capable of reading absorbance at 450 nm.

SPECIMEN COLLECTION

Only 50 µL of human serum is required for human pepsinogen I measurement in duplicate. No special preparation of the individual is necessary prior to specimen collection. However, it is recommended drawing a 10 hour fasting serum sample for the test. Whole blood should be collected and must be allowed to clot for minimum 30 minutes at room temperature before the serum is separated by centrifugation (850 – 1500xg for 10 minutes). The serum should be separated from the clot within three hours of blood collection and transferred to a clean test tube. Serum samples should be stored at –20°C or below until measurement. Avoid repeated (more than three times) freezing and thawing of specimen.

ASSAY PROCEDURE

1. Reagent Preparation

- (1) Prior to use allow all reagents to come to room temperature. Reagents from different kit lot numbers should not be combined or interchanged.
- (2) Washing buffer must be diluted to working wash solution prior to use. Please see REAGENTS section for details.
- (3) Reconstitute all assay calibrators and controls by adding 1 mL of demineralized water to the vial of calibrator level 0 and 0.5 mL demineralized water to the vials of calibrator level 1 - 5 and control 1 & 2. Allow the calibrators and controls to sit undisturbed for 10 minutes, and then mix well by gentle vortexing. One must make sure that all solid is dissolved completely prior to use. These reconstituted calibrators and controls must be stored at - 20°C or below. Do not exceed 3 freeze-thaw cycles.

2. Assay Procedure

- (1) Place a sufficient number of streptavidin coated microwell strips in a holder to run calibrators, controls and unknown samples in duplicate.
- (2) Test Configuration

ROW	STRIP 1	STRIP 2	STRIP 3
A	CAL 0	CAL 4	SAMPLE 1
B	CAL 0	CAL 4	SAMPLE 1
C	CAL 1	CAL 5	SAMPLE 2
D	CAL 1	CAL 5	SAMPLE 2
E	CAL 2	C 1	SAMPLE 3
F	CAL 2	C 1	SAMPLE 3
G	CAL 3	C 2	
H	CAL 3	C 2	

- (3) Prepare working Detecting Antibody and Capture Antibody mixture by 1:21 fold dilution of the Pepsinogen I Detecting Antibody and the Pepsinogen I Capture Antibody with the dilution buffer. For each strip, 1 mL of dilution buffer is required (with the addition of 50 µL of Detecting Antibody and 50 µL Capture Antibody) in a clean test tube or vial. The table below shows the amount of antibody mix needed for a number of strips.

Strip no.	Dilution buffer	Detecting Antibody	Capture Antibody
1	1 mL	50 µL	50 µL
2	2 mL	100 µL	100 µL
3	3 mL	150 µL	150 µL
4	4 mL	200 µL	200 µL
5	5 mL	250 µL	250 µL
6	6 mL	300 µL	300 µL
7	7 mL	350 µL	350 µL
8	8 mL	400 µL	400 µL
9	9 mL	450 µL	450 µL
10	10 mL	500 µL	500 µL
11	11 mL	550 µL	550 µL
12	12 mL	600 µL	600 µL

Note: this antibody mix should be freshly prepared right before running the assay.

- (4) Add 25 µL of calibrators, controls and patient serum samples into the designated microwell.
- (5) Add 100 µL of above antibody mixture to each well
- (6) Mix gently and cover the plate with a plate sealer and with an aluminum foil to avoid exposure to light.
- (7) Incubate plate at room temperature for 1 hour.
- (8) Remove the aluminum foil and plate sealer. Aspirate the contents of each well. Wash each well 5 times by dispensing 350 µL of working wash solution into each well and then completely aspirate the contents. Alternatively, an automated microplate washer can be used.
- (9) Add 100 µL of TMB-Substrate solution into each well.
- (10) Cover the plate with a new plate sealer and with an aluminum foil to avoid exposure to light.
- (11) Incubate plate at room temperature for 20 minutes
- (12) Remove the aluminum foil and plate sealer. Add 100 µL of Stop Solution into each well. Mix gently.
- (13) Read the absorbance at 450 nm within 10 minutes in a microplate reader

PROCEDURAL NOTES

1. It is recommended that all calibrators, controls and unknown samples be assayed in duplicate. The average absorbance reading of each duplicate should be used for data reduction and the calculation of results.
2. Keep light sensitive reagents in the original bottles and avoid unnecessary exposure to the light.
3. Store any unused antibody coated strips in the foil Ziploc bag with desiccant to protect from moisture.
4. Careful technique and use of properly calibrated pipetting devices are necessary to ensure reproducibility of the test.
5. Incubation times or temperatures other than those stated in this insert may affect the results.
6. Avoid air bubbles in the microwell as this could result in lower binding efficiency and higher CV% of duplicate reading
7. All reagents should be mixed gently and thoroughly prior to use. Avoid foaming.

INTERPRETATION OF RESULTS

1. Calculate the average absorbance for each pair of duplicate test results.
2. Subtract the average absorbance of the CAL 0 (0 ng/mL) from the average absorbance of all other readings to obtain the corrected absorbance.
3. The calibration curve is generated by the corrected absorbance of all calibrators on the ordinate against the calibrator concentration on the abscissa using point-to-point or log-log paper. Appropriate computer assisted data reduction programs may also be used for the calculation of results.
4. It is recommended to use following curve fits: (1) Point-to-Point, or (2) 4-Parameter or (3) CubicSpline.

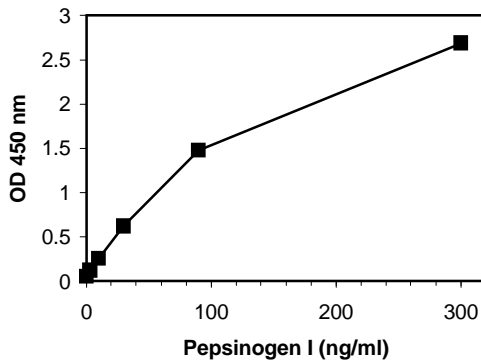
The human pepsinogen I concentrations for the controls and patient samples are read directly from the calibration curve using their respective corrected absorbance.

EXAMPLE DATA AND CALIBRATION CURVE

A typical absorbance data and the resulting calibration curve from human pepsinogen I ELISA are represented. **This curve should never be used instead of the real time calibration curve.**

Well I.D.	OD 450 nm Absorbance			Results ng/mL
	Readings	Average	Corrected	
0 ng/mL	0.053 0.050	0.052	0.000	
3 ng/mL	0.119 0.118	0.119	0.067	
10 ng/mL	0.262 0.246	0.254	0.128	
30 ng/mL	0.616 0.622	0.619	0.567	
90 ng/mL	1.565 1.387	1.476	1.424	
300 ng/mL	2.766 2.604	2.685	2.633	
Control 1	0.373 0.363	0.368	0.316	16.2 ng/mL
Control 2	1.692 1.587	1.640	1.588	118 ng/mL

Pepsinogen I Calibration Curve



EXPECTED VALUES

Seventy-three normal adult sera were measured with this human pepsinogen I ELISA. The expected normal range is listed in the following table with different percentile cut-off values. The median level of this population is 62.8 ng/mL.

Percentile Cut-off	Normal Range (ng/mL)
95%	25 – 200
90%	30 – 150
85%	40 – 120
80%	40 – 100

It is highly recommend that each laboratory should establish their own normal range for pepsinogen I based on local populations.

Patients with atrophic gastritis, as well as patients with stomach cancer would have a pepsinogen I level below 20 ng/mL. However, gastroendoscopy and tissue biopsy should be used as final and confirmative diagnostic method.

LIMITATION OF THE PROCEDURE

1. Since there is no Gold Calibrator available for human pepsinogen I measurement, the values of the calibrators were established by diluting a highly purified human pepsinogen I in a protein matrix.

2. If the measured sample concentration is higher than 300 ng/mL, it is recommended to measure a further diluted sample for a more accurate measurement.
3. If your microplate reader is unable to read beyond 2.0 at OD 450 nm, one can adjust the computer program for an assay without the calibrator level 5 from the calibrator set.
4. Bacterial or fungal contamination of serum specimens or reagents, or cross contamination between reagents may cause erroneous results.
5. Water deionized with polyester resins may inactivate the horseradish peroxidase enzyme.

QUALITY CONTROL

To assure the validity of the results, each assay should include adequate controls with known pepsinogen I levels. We recommend that all assays include the laboratory's own human serum based pepsinogen I controls in addition to those provided with these kits.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity of this human pepsinogen I ELISA is 0.1 ng/mL as determined by measuring the zero calibrator 16 times in the same assay and calculating the detection limit at 3 standard deviation above the pepsinogen I zero calibrator. The analytical sensitivity of the assay is approximately 0.5 ng/mL.

Specificity

This assay measures human pepsinogen I without any cross-reaction to human pepsinogen II.

Linearity

Two human serum samples were diluted with dilution buffer and assayed. The results, expressed in ng/mL, are as follows:

#	DILUTION	OBSERVED VALUE	EXPECTED VALUE	RECOVERY %
1	Neat	31.90	-	-
	1:2	16.21	15.95	102
	1:4	7.95	7.78	102
	1:8	3.73	3.99	93
	1:16	2.11	1.99	106
2	Neat	252.00	-	-
	1:2	125.27	126.00	99
	1:4	64.12	63.00	102
	1:8	31.25	31.50	99
	1:16	16.92	15.75	107

Precision

The intra-assay precision is validated by measuring two samples in a single assay with 20-replicate determinations.

Mean Pepsinogen I Value (ng/mL)	CV (%)
18.2	5.3
121.1	4.8

The inter-assay precision is validated by measuring two samples in duplicate in 12 individual assays.

Mean Pepsinogen I Value (ng/mL)	CV (%)
17.5	6.9
123.7	5.7

Recovery

Two patient samples were spiked with various amounts of human pepsinogen I and assayed. The results, expressed in ng/mL, are as follows:

#	Orig. Value	Amount Spiked	Observed Value	Expected Value	Recovery %
1	18.6	10	12.6	14.3	88
		30	25.1	24.3	103
		90	56.2	54.3	103
2	121.1	10	61.3	65.6	93
		30	70.9	75.6	94
		90	104.7	105.6	99

"Hook" Effect

It was determined that this pepsinogen I ELISA did not show any high dose "hook" effect up to 10,000 ng/mL of pepsinogen I.

REFERENCES

1. Kuipers EJ. In through the out door: serology for atrophic gastritis. *Eur J Gastroenterol Hepatol.* 2003 Aug;15(8):877-9.
2. Miki K, Morita M, Sasajima M, Hoshina R, Kanda E, Urita Y. Usefulness of gastric cancer screening using the serum pepsinogen test method. *Am J Gastroenterol.* 2003 Apr;98(4):735-9.
3. Miki K. [Serum pepsinogen I/II ratio test] *Nippon Rinsho.* 2003 Jan;61(1):92-5. Japanese.
4. So JB, Yeoh KG, Moochala S, Chachlani N, Ho J, Wong WK, Mack P, Goh PM. Serum pepsinogen levels in gastric cancer patients and their relationship with *Helicobacter pylori* infection: a prospective study. *Gastric Cancer.* 2002;5(4):228-32.
5. Korstanje A, den Hartog G, Biemond I, Lamers CB. The serological gastric biopsy: a non-endoscopic diagnostic approach in management of the dyspeptic patient: significance for primary care based on a survey of the literature. *Scand J Gastroenterol Suppl.* 2002;(236):22-6. Review.
6. Sipponen P, Harkonen M, Alanko A, Suovaniemi O. Diagnosis of atrophic gastritis from a serum sample. *Clin Lab.* 2002;48(9-10):505-15. Review.
7. Tabata H, Fuchigami T, Kobayashi H, Sakai Y, Nakanishi M, Tomioka K, Nakamura S, Matsumoto T, Fujishima M. Difference in degree of mucosal atrophy between elevated and depressed types of gastric epithelial tumors. *Scand J Gastroenterol.* 2001 Nov;36(11):1134-40.
8. Varis K, Sipponen P, Laxen F, Samloff IM, Huttunen JK, Taylor PR, Heinonen OP, Albanes D, Sande N, Virtamo J, Harkonen M. Implications of serum pepsinogen I in early endoscopic diagnosis of gastric cancer and dysplasia. Helsinki Gastritis Study Group. *Scand J Gastroenterol.* 2000 Sep;35(9):950-6.
9. Fernandez R, Vizoso F, Rodriguez JC, Merino AM, Gonzalez LO, Quintela I, Andicochea A, Truan N, Diez MC. Expression and prognostic significance of pepsinogen C in gastric carcinoma. *Ann Surg Oncol.* 2000 Aug;7(7):508-14.
10. Kalinovskii VP, Gamaiunova VB, Shumakov AP, Khanson KP. [Radioimmunoassay of serum pepsinogen I in chronic gastritis and stomach cancer] *Vopr Onkol.* 2000;46(2):153-5. Russian.
11. Shumakov AR, Fedorov SN, Kalinovskii VP, Khanson KP. [Evaluation of pepsinogen A expression in stomach cancer] *Vopr Onkol.* 1999;45(3):238-40. Russian.
12. Kitahara F, Kobayashi K, Sato T, Kojima Y, Araki T, Fujino MA. Accuracy of screening for gastric cancer using serum pepsinogen concentrations. *Gut.* 1999 May;44(5):693-7.
13. Samloff IM and Taggart RT. Pepsinogens, pepsins, and peptic ulcer. *Clinical and Investigative Medicine* 1987;10:215-221
14. Samloff IM. Slow moving protease and the seven pepsinogens. Electrophoretic demonstration of the existence of eight proteolytic fractions in human gastric mucosa. *Gastroenterology* 1969;57:659-669

Short Assay Procedure:

1. Add 25 µL of calibrators, controls and patient serum samples into the designated microwell.
 2. Add 100 µL of antibody mixture to each well
 3. Mix, cover and incubate the plate at room temperature for 1 hour.
 4. Wash each well 5 times
 5. Add 100 µL of TMB-Substrate solution into each of the wells.
 6. Cover and incubate plate at room temperature for 20 minutes
 7. Add 100 µL of Stop Solution into each of the wells.
 8. Read the absorbance at 450 nm
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Revision date: 2009-06-04

	<u>Used symbols</u>	<u>Symboles utilisés</u>
	Consult instructions for use	Consulter les instructions d'utilisation
	Storage temperature	Température de conservation
	Use by	Utiliser jusque
	Batch code	Numéro de lot
	Catalogue number	Référence de catalogue
	Control	Contrôle
	In vitro diagnostic medical device	Dispositif médical de diagnostic in vitro
	Manufacturer	Fabricant
	Contains sufficient for <n> tests	Contenu suffisant pour <n> tests
	Wash solution concentrated	Solution de lavage concentrée
	Zero calibrator	Calibreur zéro
	Calibrator #	Calibreur #
	Control #	Contrôle #
	Tracer	Traceur
	Tracer	Traceur
	Tracer concentrated	Traceur concentré
	Tracer concentrated	Traceur concentré
	Tubes	Tubes
	Incubation buffer	Tampon d'incubation
	Acetonitrile	Acétonitrile
	Serum	Sérum
	Specimen diluent	Diluant du spécimen
	Dilution buffer	Tampon de dilution
	Antiserum	Antisérum
	Immunoabsorbent	Immunoabsorbant
	Calibrator diluent	Diluant de calibrateur
	Reconstitution solution	Solution de reconstitution
	Polyethylene glycol	Glycol Polyéthylène
	Extraction solution	Solution d'extraction
	Elution solution	Solution d'élution
	Bond Elut Silica cartridges	Cartouches Bond Elut Silica
	Pre-treatment solution	Solution de pré-traitement
	Neutralization solution	Solution de neutralisation
	Tracer buffer	Tampon traceur
	Microtiterplate	Microplaque de titration
	HRP Conjugate	HRP Conjugué
	HRP Conjugate	HRP Conjugué
	HRP Conjugate concentrate	HRP Conjugué concentré
	HRP Conjugate concentrate	HRP Conjugué concentré
	Conjugate buffer	Tampon conjugué
	Chromogenic TMB concentrate	Chromogène TMB concentré
	Chromogenic TMB solution	Solution chromogène TMB
	Substrate buffer	Tampon substrat
	Stop solution	Solution d'arrêt
	Incubation serum	Sérum d'incubation
	Buffer	Tampon
	AP Conjugate	AP Conjugué
	Substrate PNPP	Tampon PNPP
	Biotin conjugate concentrate	Biotine conjugué concentré
	Avidine HRP concentrate	Avidine HRP concentré
	Assay buffer	Tampon de test
	Biotin conjugate	Biotine conjugué
	Specific Antibody	Anticorps spécifique
	Streptavidin HRP concentrate	Concentré streptavidine HRP
	Non-specific binding	Liant non spécifique
	2nd Antibody	Second anticorps
	Acidification Buffer	Tampon d'acidification

	<u>Gebruikte symbolen</u>	<u>Gebrauchte Symbolen</u>
	Raadpleeg de gebruiksaanwijzing	Gebrauchsanweisung beachten
	Bewaartemperatuur	Lagern bei
	Houdbaar tot	Verwendbar bis
	Lotnummer	Chargenbezeichnung
	Catalogusnummer	Bestellnummer
	Controle	Kontrolle
	Medisch hulpmiddel voor in-vitro diagnostiek	In Vitro Diagnostikum
	Fabrikant	Hersteller
	Inhoud voldoende voor <n> testen	Ausreichend für <n> Ansätze
	Wasoplossing, geconcentreerd	Waschlösung-Konzentrat
	Nulkalibrator	Null kalibrator
	Kalibrator #	Kalibrator #
	Controle #	Kontrolle #
	Tracer	Tracer
	Tracer	Tracer
	Tracer geconcentreerd	Tracer Konzentrat
	Tracer geconcentreerd	Tracer Konzentrat
	Buisjes	Röhrchen
	Incubatiebuffer	Inkubationspuffer
	Acetonitrile	Azetonitril
	Serum	Humanserum
	Specimen diluent	Probenverdünner
	Verdunningsbuffer	Verdünnungspuffer
	Antiserum	Antiserum
	Immunoabsorbent	Immunadsorbens
	Kalibratorverdunner	Kalibratorverdünnung
	Reconstitutieoplossing	Rekonstitutionslösung
	Polyethyleen glycol	Polyethylenglykol
	Extractieoplossing	Extraktionslösung
	Elutieoplossing	Eluierungslösung
	Bond Elut Silica kolom	Bond Elut Silikakartuschen
	Pre-behandelingsoplossing	Vorbehandlungslösung
	Neutralisatieoplossing	Neutralisierungslösung
	Tracerbuffer	Tracer-Puffer
	Microtiterplaat	Mikrotiterplatte
	HRP Conjuaat	HRP Conjugat
	HRP Conjuaat	HRP Conjugat
	HRP Conjuaat geconcentreerd	HRP Conjugat Konzentrat
	HRP Conjuaat geconcentreerd	HRP Conjugat Konzentrat
	Conjuaat buffer	Conjugatpuffer
	Chromogene TMB geconcentreerd	Chromogenes TMB Konzentrat
	Chromogene Oplossing TMB	Farblösung TMB
	Substraatbuffer	Substratpuffer
	Stopoplossing	Stopplösung
	Incubatieserum	Inkubationsserum
	Buffer	Puffer
	AP Conjuaat	AP Conjugat
	Substraat PNPP	Substrat PNPP
	Geconcentreerd Biotine conjuaat	Biotin-Conjugat-Konzentrat
	Geconcentreerd Avidine-HRP conjuaat	Avidin-HRP-Konzentrat
	Assay buffer	Assaypuffer
	Biotine conjuaat	Biotin-Conjugat
	Specifiek antilichaam	Spezifischer Antikörper
	Streptavidine-HRP concentraat	HRP Streptavidinkonzentrat
	Aspecifieke binding	Unspezifische Bindung
	2de antilichaam	Sekundärer Antikörper
	Verzuringbuffer	Ansäuerungspuffer

	<u>Simboli utilizzati</u>	<u>Símbolos utilizados</u>
	Consultare le istruzioni per l'uso	Consultar las instrucciones de uso
	Limitazioni di temperatura	Limitación de temperatura
	Utilizzare entro	Fecha de caducidad
	Numero di lotto	Código de lote
	Numero di catalogo	Número de catálogo
	Controllo	Control
	Dispositivo medico-diagnostico in vitro	Producto sanitario para diagnóstico in vitro
	Fabbricante	Fabricante
	Contenuto sufficiente per <n> saggi	Contenido suficiente para <n> ensayos
	Tampone di lavaggio concentrato	Solución de lavado concentrada
	Calibratore zero	Calibrador cero
	Standard #	Calibrador #
	Controllo #	Control #
	Marcato	Trazador
	Marcato	Trazador
	Marcato concentrato	Trazador concentrada
	Marcato concentrato	Trazador concentrada
	Provette	Tubos
	Tampone incubazione	Tampón de incubación
	Acetonitrile	Acetonitrilo
	Siero	Suero
	Diluente campione	Diluyente de Muestra
	Tampone diluizione	Tampón de dilución
	Antisiero	Antisuero
	Immunoassorbente	Immunoabsorbente
	Diluente calibratore	Diluyente de calibrador
	Soluzione di ricostituzione	Solución de Reconstitución
	Polietilenglicole	Glicol Polietileno
	Soluzione di estrazione	Solución de extracción
	Soluzione di eluizione	Solución de elución
	Cartucce di silice bond elut	Cartuchos Bond Elut Silica
	Soluzione di pretrattamento	Solución de Pre-tratamiento
	Soluzione di neutralizzazione	Solución de Neutralización
	Tracer Buffer	Tampón de trazador
	Piastra di microtitolazione	Placa de microvaloración
	HRP Coniugato	HRP Conjugado
	HRP Coniugato	HRP Conjugado
	HRP Coniugato concentrato	HRP Conjugado concentrada
	HRP Coniugato concentrato	HRP Conjugado concentrada
	Buffer coniugato	Tampón de Conjugado
	Cromogena TMB concentrato	Cromógena TMB concentrada
	Soluzione cromogena TMB	Solución Cromógena TMB
	Tampone substrato	Tampón de sustrato
	Soluzione di arresto	Solución de Parada
	Incubazione con siero	Suero de Incubación
	Buffer	Tampón
	AP Coniugato	AP Conjugado
	Substrato PNPP	Sustrato PNPP
	Concentrato coniugato con biotina	Concentrado de conjugado de biotina
	Concentrato avidina HRP	Concentrado avidina-HRP
	Soluzione tampone per test	Tampón de ensayo
	Coniugato con biotina	Conjugado de biotina
	Anticorpo Specifico	Anticuerpo específico
	Streptavidina-HRP concentrata	Estreptavidina-HRP Concentrado
	Legame non-specifico	Unión no específica
	2° Anticorpo	Segundo anticuerpo
	Tampone Acidificante	Tampón de Acidificación

	<u>Símbolos utilizados</u>	<u>Använda symboler</u>
	Consulte instruções de utilização	Läs instruktionerna före användning
	Temperatura de conservação	Förvaringstemperatur
	Utilizar antes de	Används av
	Código de lote	Lotnummer
	Número de catálogo	Katalognummer
	Controlo	Kontroll
	Dispositivo médico de diagnóstico in vitro	In vitro diagnostiskt kit
	Fabricante	Tillverkare
	Conteúdo suficiente para <n> testes	Innehållet räcker till <n> prover
	Solução de lavagem concentrada	Tvättlösning, koncentrerad
	Calibrador zero	Nollkalibrerare
	Calibrador #	Kalibrator #
	Controlo #	Kontroll #
	Marcador	Radioisotop, antigen
	Marcador	Radioisotop, antikropp
	Marcador concentrada	Radioisotop, antigen koncentrerad
	Marcador concentrada	Radioisotop, antikropp koncentrerad
	Tubos	Rör
	Tampão de incubação	Inkuberingsbuffert
	Acetonitrilo	Acetonitril
	Soro	Serum
	Diluidor de espécimes	Spädningsbuffert för prover
	Tampão de diluição	Spädningsbuffert
	Anti-soro	Antiserum
	Imunoadsorvente	Immunoadsorberare
	Diluyente do calibrador	Kalibratordiluent
	Solução de Reconstituição	Rekonstitutionslösning
	Poliétileno-glicol	Polyetylen glykol
	Solução de Extração	Extraktionslösning
	Solução de Eluição	Elueringslösning
	Cartuchos de sílica Bond Elut	Silikonpatroner för elueringsbindning
	Solução de pré-tratamento	Förbehandlingslösning
	Solução de neutralização	Neutraliseringslösning
	Tampão Marcador	Tracerbuffert
	Placa de micro titulação	Microtiterplatta
	HRP Conjugação	HRP-konjugat
	HRP Conjugação	HRP-konjugat
	HRP Conjugação concentrada	HRP-konjugat-koncentrat
	HRP Conjugação concentrada	HRP-konjugat-koncentrat
	Conjuge o tampão	Konjugatbuffert
	Cromogénica TMB concentrada	Kromogeniskt TMB-koncentrat
	Solução Cromogénica TMB	Kromogenisk TMB-lösning
	Tampão de substrato	Substratbuffert
	Solução de Paragem	Stopplösning
	Soro de incubação	Inkubationsserum
	Tampão	Buffert
	AP Conjugação	AP-konjugat
	Substrato PNPP	Substrat-PNPP
	Concentrado conjugado de biotina	Biotinkonjugat koncentrat
	Concentrado HRP de avidina	Avidin HRP-koncentrat
	Tampão de ensaio	Provbuffert
	Conjugado de biotina	Biotinkonjugat
	Anticorpo específico	-
	Estreptavidina HRP concentrado	-
	Ligações não específicas	-
	Anticorpo secundário	-
	Tampão de acidificação	-

	<u>Επεξήγηση συμβόλων</u>	<u>Anvendte symboler</u>
	Συμβουλευτείτε τις οδηγίες χρήσης	Læs brugsvejledningen
	Θερμοκρασία αποθήκευσης	Opbevaringstemperatur
	Ημερομηνία λήξης	Anvend inden
	Αριθμός παρτίδας	Batchkode
	Αριθμός καταλόγου	Katalognummer
	Πρότυπο ελέγχου	Kontrol
	In Vitro Διαγνωστικό Ιατροτεχνολογικό προϊόν	Medicinsk udstyr til in vitro-diagnosticering
	Κατασκευαστής	Fabrikant
	Περιεχόμενο επαρκές για «n» εξετάσεις	Indeholder nok til <n> test
	Συμπυκνωμένο διάλυμα έκπλυσης	Koncentreret vaskeopløsning
	Μηδενικός βαθμονομητής	Nul-kalibrator
	Βαθμονομητής #	Kalibrator nr.
	Ορός ελέγχου #	Kontrol nr.
	Ιζηθέτης	Markør
	Ιζηθέτης	Markør
	Χρωμογόνος Ιζηθέτης	Koncentreret markør
	Χρωμογόνος Ιζηθέτης	Koncentreret markør
	Σοληνάρια	Tuber
	Ρυθμιστικό διάλυμα επώασης	Inkubationsbuffer
	Ακετονιτρίλιο	Acetonitril
	Ορός	Serum
	Διάλυμα αραιώσης δειγμάτων	Prøvediluent
	Ρυθμιστικό διάλυμα αραιώσης	Fortyndingsbuffer
	Αντιορός	Antiserum
	Ανοσοπροσροφητικό	Immonoadsorbent
	Αραιωτικό βαθμονομητών	Kalibratordiluent
	Διάλυμα ανασύστασης	Rekonstitueringsopløsning
	Πολυαιθυλενογλυκόλη	Polyetylglykol
	Διάλυμα εκχύλισης	Ekstraktionsopløsning
	Διάλυμα έκλυσης	Elueringsopløsning
	Φύσιγγες πυριτίου Bond Elut	Patroner med bindingselueringssilica
	Διάλυμα προεπεξεργασίας	Forbehandlingsopløsning
	Διάλυμα εξουδετέρωσης	Neutraliseringsopløsning
	Ρυθμιστικό διάλυμα	Markørbuffer
	Πλάκα μικροτιτλοδότησης	Mikrotiterplade
	HRP Σύζευγμα	HRP-konjugat
	HRP Σύζευγμα	HRP-konjugat
	Χρωμογόνος HRP Σύζευγμα	HRP-konjugat-koncentreret
	Χρωμογόνος HRP Σύζευγμα	HRP-konjugat-koncentreret
	Ρυθμιστικό διάλυμα συζεύγματος	Konjugatbuffer
	Χρωμογόνος TMB	Kromogen TMB-koncentreret
	Διάλυμα χρωμογόνου TMB	Kromogen TMB-opløsning
	Ρυθμιστικό διάλυμα υποστρώματος	Substratbuffer
	Ανασχετικό αντιδραστήριο	Stopopløsning
	Ορός επώασης	Inkubationsserum
	Ρυθμιστικό διάλυμα	Buffer
	AP Σύζευγμα	AP-konjugat
	PNPP υποστρώματος	Substrat PNPP
	Συμπυκνωμένο αντιδραστήριο συζευγμένο με βιοτίνη	Biotin konjugat koncentrat
	Συμπυκνωμένο διάλυμα αβιδίνης-HRP	Avidin HRP koncentrat
	Ρυθμιστικό διάλυμα προσδιορισμού	Prøvebuffer
	αντιδραστήριο συζευγμένο με βιοτίνη	Biotin konjugat
	Ειδικό Αντίσωμα	-
	Συμπυκνωμένη στρεπταβιδίνη συνεξευγμένη με HRP	-
	μη-ειδική δέσμευση	-
	2ο Αντίσωμα	-
	Ρυθμιστικό Διάλυμα όξινο	-

	Stosowane symbole	Használt szimbólumok
	Przed zastosowaniem zapoznać się z instrukcją	Olvassa el a használati útmutatót
	Temperatura przechowywania	Tárolási hőmérséklet
	Zużyć przed	Lejárató idő
	Kod serii	Gyártási kód
	Numer katalogowy	Katalógus szám
	Kontrola	Kontrol
	Urządzenie medyczne do diagnostyki in vitro	In vitro diagnosztikai eszköz
	Producent	Gyártó
	Zawartość wystarczająca do <n> testów	Tartalma <n> teszt elvégzésére elegendő
	Roztwór płuczący stężony	Mosó folyadék koncentrátum
	Kalibrator zerowy	Zero kalibrátor
	Kalibrator nr	Kalibrátor #
	Kontrola nr	Kontrol #
	Znacznik izotopowy	Nyomjelző izotóp
	Znacznik izotopowy	Nyomjelző izotóp
	Znacznik izotopowy stężony	Nyomjelző izotóp koncentrátum
	Znacznik izotopowy stężony	Nyomjelző izotóp koncentrátum
	Probówki	Csővek
	Wymagana inkubacja buforu	Inkubáló puffer
	Acetonitryl	Acetonitril
	Surowica	Szérum
	Rozcieńczalnik próbki	Mintahígító
	Bufor do rozcieńczania	Hígító puffer
	Antysurowica	Antiszérum
	Immunoadsorbent	Immunadsorbens
	Rozcieńczalnik kalibratora	Kalibrátor hígító
	Roztwór do rozcieńczania	Mintaelőkészítő oldat
	Glikol poli(oksy)etylenowy	Polietylén glikol
	Roztwór ekstrakcyjny	Extraktív oldat
	Roztwór elucyjny	Eluáló oldat
	Kolumny krzemionkowe Bond Elut	Bond Elut Silica szilikagél patronok
	Roztwór do przygotowania wstępnego	Előkezelő oldat
	Roztwór neutralizujący	Semlegesítő oldat
	Bufor znacznika	Nyomjelző izotóp hígító puffer
	mikroplytka	Mikrotiter lemez
	Koniugat peroksydazy chrzanowej	HRP konjugátum
	Koniugat peroksydazy chrzanowej	HRP konjugátum
	Koncentrat koniugatu peroksydazy chrzanowej	HRP konjugátum koncentrátum
	Koncentrat koniugatu peroksydazy chrzanowej	HRP konjugátum koncentrátum
	Bufor do koniugacji	Konjugátum puffer
	Koncentrat chromogenu TMB (czterometrylobenzydyny)	Kromogén TMB koncentrátum
	Roztwór chromogenu TMB (czterometrylobenzydyny)	Kromogén TMB oldat
	Bufor substratu	Szubsztrát puffer
	Roztwór zatrzymujący reakcję	Stop oldat
	Wymagana inkubacja surowicy	Inkubációs szérum
	Bufor	Puffer
	Koniugat AP (fosfatazy alkalicznej)	AP konjugátum
	p-nitrofenylofosforan substratowy	Szubsztrát PNPP
	Koncentrat koniugatu biotyny	Biotin konjugátum koncentrátum
	Koncentrat peroksydazy chrzanowej z awidyną	Avidin HRP koncentrátum
	Bufor do oznaczania	Vizsgálati puffer
	Koniugatu biotyny	Biotin konjugátum
	Przeciwciało swoiste	Specifikus ellenanyag
	Koncentrat streptawidyny HRP	Sztreptawidin HRP koncentrátum
	Wiązanie nieswoiste	Nem-specifikus kötődés
	Drugie przeciwciało	Másodlagos ellenanyag
	Bufor zakwaszający	Savas puffer

	<u>Използвани символи</u>
	Вижте инструкцията за работа
	Температура на съхранение
	Използвайте с
LOT	Партиден код
REF	Каталожен номер
CONTROL	Контрол
IVD	Ин витро диагностично медицинско изделие
	Производител
	Съдържание достатъчно за <n> теста
WASH SOLN CONC	Концентриран измиващ разтвор
CAL 0	Нулев калибратор
CAL N	Калибратор #
CONTROL N	Контрол #
Ag 125I	Трейсър
Ab 125I	Трейсър
Ag 125I CONC	Концентриран маркер
Ab 125I CONC	Концентриран маркер
	Епруветки
INC BUF	Инкубационен буфер
ACETONITRILE	Ацетонитрил
SERUM	Серум
DIL SPE	Разредител за пробите
DIL BUF	Буфер за разреждане
ANTISERUM	Антисерум
IMMUNOABSORBENT	Имуноабсорбент
DIL CAL	Разредител за калибратора
REC SOLN	Пресъздаващ разтвор
PEG	Полиетилен гликол
EXTR SOLN	Екстрактов разтвор
ELU SOLN	Разтвор за елюиране
GEL	Силикагелни пълнители
PRE SOLN	Пред-лечебен разтвор
NEUTR SOLN	Неутрализиращ разтвор
TRACEUR BUF	Маркерен буфер
ULI	Микротигърна пластина
Ab HRP	HRP конюгат / Конюгат на хрянова пероксидаза
Ag HRP	HRP конюгат / Конюгат на хрянова пероксидаза
Ab HRP CONC	HRP конюгиран концентрат
Ag HRP CONC	HRP конюгиран концентрат
CONJ BUF	Буфер за конюгата
CHROM TMB CONC	Хромогенен ТМВ концентрат
CHROM TMB	Хромогенен ТМВ разтвор
SUB BUF	Субстратен буфер
STOP SOLN	Стоп разтвор
INC SER	Инкубационен серум
BUF	Буфер
Ab AP	AP конюгат / конюгат на алкална фосфатаза
SUB PNPP	Субстрат PNPP / пара нитрофенил фосфат
BIOT CONJ CONC	Биотин конюгиран концентрат
AVID HRP CONC	Авидин HRP концентрат
ASS BUF	Буфер за пробите
Ab BIOT	Биотин конюгат
Ab	специфично антитяло
SAV HRP CONC	стрептавидин HRP концентрат
NSB	не специфично свързване
2nd Ab	второ антитяло
ACID BUF	киселинизиращ буфер