Product information

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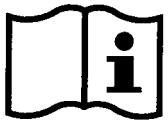

Useŕs Manual

C-Peptide ELISA

Enzyme immunoassay for the quantitative measurement of
C-Peptide in serum, plasma and urine

IVD

REF IB79101

Σ 96

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Contents

1 INTRODUCTION ..... **ERROR! BOOKMARK NOT DEFINED.**
2 PRINCIPLE OF THE TEST 3
3 WARNINGS AND PRECAUTIONS 4
4 REAGENTS 5
5 SAMPLE COLLECTION AND PREPARATION 6
6 ASSAY PROCEDURE 7
7 EXPECTED NORMAL VALUES 9
8 QUALITY CONTROL 9
9 PERFORMANCE CHARACTERISTICS 10
10 LIMITATIONS OF USE 10
11 LEGAL ASPECTS 11
12 REFERENCES / LITERATURE 12

SYMBOLS USED WITH IBL AMERICA ELISAS 13

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1 INTENDED USE

The **IBL AMERICA C-Peptide ELISA** is an enzyme immunoassay for the quantitative in vitro diagnostic measurement of C-Peptide in serum, plasma (EDTA-, heparin- or citrate plasma) and urine.

1.1 Summary and Explanation

Insulin is synthesized in the pancreatic beta cells as a 6000 mw component of an 86 amino acid polypeptide called proinsulin (1, 2, 3). Proinsulin is subsequently cleaved enzymatically, releasing insulin into the circulation along with a residual 3000 mw fragment called connection ("c") peptide, so named because it connects a and b chains of insulin within the proinsulin molecule (1, 2, 3, 4).

Human c-peptide, a 31 amino acid residue peptide, has a molecular mass of approximately 3000 daltons. C-peptide has no metabolic function. However, since c-peptide and insulin are secreted in equimolar amounts, the immunoassay of c-peptide permits the quantitation of insulin secretion (4, 5, 6).

This is the reason for the clinical interest of serum and urinary determinations of c-peptide. Moreover, c-peptide measurement has several advantages over immunoassays of insulin. The half-life of c-peptide in the circulation is between two and five times longer than that of insulin (7). Therefore, c-peptide levels are a more stable indicator of insulin secretion than the more rapidly changing levels of insulin. A very clear practical advantage of c-peptide measurement arising from its relative metabolic inertness as compared to insulin is that c-peptide levels in peripheral venous blood are about 5-6 times greater than insulin levels (3). Also, relative to an insulin assay, the c-peptide assay's advantage is its ability to distinguish endogenous from injected insulin.

Thus, low c-peptide levels are to be expected when insulin is diminished (as in insulin-dependent diabetes) or suppressed (as a normal response to exogenous insulin), whereas elevated c-peptide levels may result from the increased β-cell activity observed in insulinomas (3, 6, 9).

C-peptide has also been measured as an additional means for evaluating glucose tolerance and glibenclamide glucose tests (2, 3, 9, 10).

C-peptide levels are in many ways a better measurement of endogenous insulin secretion than peripheral insulin levels. C-peptide may be measured in either blood or urine (9). With improved sensitive c-peptide immunoassays, it is now possible to measure c-peptide values at extremely low levels. The clinical indications for c-peptide measurement include diagnosis of insulinoma and differentiation from factitious hypoglycemia, follow-up of pancreatectomy, and evaluation of viability of islet cell transplants (11, 12, 13). Recently, these indications have been dramatically expanded to permit evaluation of insulin dependence in maturity onset diabetes mellitus.

2 PRINCIPLE OF THE TEST

The IBL AMERICA C-Peptide ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding.

The microtiter wells are coated with anti-mouse antibody, which binds a monoclonal antibody directed towards a unique antigenic site on the C-Peptide molecule. Endogenous C-Peptide of a sample competes with a C-Peptide-horseradish peroxidase conjugate for binding to the coated antibody. After incubation the unbound conjugate is washed off.

The amount of bound peroxidase conjugate is inversely proportional to the concentration of C-Peptide in the sample. After addition of the substrate solution, the intensity of colour developed is inversely proportional to the concentration of C-Peptide in the sample.

3 WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only. For professional use only.
2. All reagents of this test kit which contain human serum or plasma have been tested and confirmed negative for HIV I/II, HBsAg and HCV by FDA approved procedures. All reagents, however, should be treated as potential biohazards in use and for disposal.
3. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
4. The microplate contains snap-off strips. Unused wells must be stored at 2 °C to 8 °C in the sealed foil pouch and used in the frame provided.
5. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
6. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
7. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
8. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
9. Allow the reagents to reach room temperature (21 °C – 26 °C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the samples will not be affected.
10. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
11. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
12. Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or samples may give false results.
13. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
14. Do not use reagents beyond expiry date as shown on the kit labels.
15. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiterplate readers.
16. Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.
17. Avoid contact with *Stop Solution* containing 1 N acidic solution. It may cause skin irritation and burns.
18. Some reagents contain Proclin 300, BND and/or MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
19. TMB substrate has an irritant effect on skin and mucosa. In case of possible contact, wash eyes with an abundant volume of water and skin with soap and abundant water. Wash contaminated objects before reusing them. If inhaled, take the person to open air.
20. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
21. For information on hazardous substances included in the kit please refer to Material Safety Data Sheets. Material Safety Data Sheets for this product are available upon request directly from IBL AMERICA.

4 REAGENTS

4.1 Reagents provided

1. **SORB MT** ***Microtiterwells***, 12 x 8 (break apart) strips, 96 wells; Wells coated with anti-mouse-antibody
2. **CAL 0 – 5** ***Standard (Standard 0-5)***, 6 vials, lyophilized, 0.75 mL.
   Concentrations: 0 – 16 ng/mL (see exact value on the vial label or on the Certificate of analysis).
   The standards are calibrated against WHO approved Reference material IRR C-Peptide, code 84/510. see „Preparation of Reagents“ Contain non-mercury preservative.
3. **SAM DIL** ***Sample Diluent***, 1 vial, 3 mL, ready to use, Contains non-mercury preservative.
4. **ANTISERUM Antiserum**, 1 vial, 7 mL, ready to use, monoclonal mouse anti C-Peptide antibody Contains non-mercury preservative.
5. **ENZ CONJ Enzyme Conjugate**, 1 vial, 14 mL, ready to use, biotinylated C-Peptide. Contains non-mercury preservative.
6. **ENZ COMP Enzyme Complex**, 1 vial, 14ml, ready to use, contains horseradish Peroxidase. Contains non-mercury preservative.
7. **SUB TMB Substrate Solution**, 1 vial, 14 mL, ready to use. TMB
8. **STOP SOLN Stop Solution**, 1 vial, 14 mL, ready to use
   contains 0.5 M H_2SO_4
   Avoid contact with the stop solution. It may cause skin irritations and burns.
9. **WASH SOLN 40x Wash Solution**, 1 vial, 30 mL (40X concentrated), see „Preparation of Reagents“

Note: Additional *Sample Diluent* for sample dilution is available upon request.

4.2 Materials required but not provided

- A microtiter plate calibrated reader (450 ± 10 nm)
- Calibrated variable precision micropipettes.
- Manual or automatic equipment for rinsing microtiter plates
- Absorbent paper.
- Distilled water
- Timer
- Semi logarithmic graph paper or software for data reduction

4.3 Storage Conditions

When stored at 2 °C to 8 °C unopened reagents will retain reactivity until expiration date. Do not use reagents beyond this date.
Opened reagents must be stored at 2 °C to 8 °C. Microtiter wells must be stored at 2 °C to 8 °C. Once the foil bag has been opened, care should be taken to close it tightly again. Open kits retain activity for 2 months if stored as described above.

4.4 Reagent Preparation

Bring all reagents and required number of strips to room temperature (20 °C to 26 °C)prior to use.

Standards

Reconstitute the lyophilized contents of each standard vial with 0.75 mL deionized water and let stand for 10 minutes in minimum. Mix several times before use.

Note: *The reconstituted standards are stable for 3 days at 2 °C to 8 °C.*
For longer storage the reconstituted standards should be aliquoted and stored at -20 °C.

Wash Solution

Add deionized water to the 40X concentrated Wash Solution.
Dilute 30mL of concentrated *Wash Solution* with 1170mL deionized water to a final volume of 1200mL.
The diluted Wash Solution is stable for 1 weeks at room temperature.

4.5 Disposal of the Kit

The disposal of the kit must be made according to the national regulations. Special information for this product is given in the Material Safety Data Sheet.

4.6 Damaged Test Kits

In case of any severe damage to the test kit or components, IBL AMERICA has to be informed in writing, at the latest, one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

5 SAMPLE COLLECTION AND PREPARATION

Serum, plasma (EDTA-, heparin- or citrate plasma) or urine can be used in this assay.
Note: Samples containing sodium azide should not be used in the assay. In general, it should be avoided to use haemolytic, icteric or lipaemic specimens. For further information refer to chapter *"Interfering substances"*

5.1 Sample Collection

Serum:
Collect blood by venipuncture (e.g. Sarstedt Monovette for serum), allow to clot, and separate serum by centrifugation at room temperature. Do not centrifuge before complete clotting has occurred. Patients receiving anticoagulant therapy may require increased clotting time.

Plasma:
Whole blood should be collected into centrifuge tubes containing anti-coagulant (e.g. Sarstedt Monovette with the appropriate plasma preparation) and centrifuged immediately after collection.

Urine:
The total volume of urine excreted during a 24 hour period should be collected and mixed in a single container.
Note: Samples should be stored at 2 °C - 8 °C during collection period and total volume collected should be recorded.

5.2 Sample Storage and Preparation

Serum / Plasma:
Samples should be capped and may be stored for up to 24 hours at 2 °C to 8 °C prior to assaying. Samples held for a longer time (up to 12 months) should be frozen only once at -20 °C prior to assay. Thawed samples should be inverted several times prior to testing.

Urine:
Aliquot a well-mixed sample to be used in the assay. Centrifuge sample to clear. Urine samples may be stored for up to 36 hours at 2 °C - 8 °C prior to assaying. Samples held for a longer time (up to 12 months) should be frozen only once at -20 °C prior to assay.

5.3 Sample Dilution

If in an initial assay, a specimen is found to contain more than the highest standard, the specimens can be diluted with *Sample Diluent* and reassayed as described in Assay Procedure.
For the calculation of the concentrations this dilution factor has to be taken into account.
Example:
a) dilution 1:10: 10 µL Serum + 90 µL *Sample Diluent* (mix thoroughly)
b) dilution 1:100: 10 µL dilution a) 1:10 + 90 µL *Sample Diluent* (mix thoroughly).

Urine Samples
Prior to use dilute urine samples **1:20** with *Sample Diluent*.

If the Sample Diluent included in the kit is insufficient, you can order additional *Sample Diluent* (40 mL vial) with REF: IB79101DIL

6 ASSAY PROCEDURE

6.1 General Remarks

- All reagents and specimens must be allowed to come to room temperature before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.
- Use new disposal plastic pipette tips for each standard, control or sample in order to avoid cross contamination.
- Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.

6.2 Test Procedure

Each run must include a standard curve.

1. Secure the desired number of Microtiter wells in the frame holder.
2. Dispense **100 µL** of each Standard, controls and samples with new disposable tips into appropriate wells.
3. Dispense **50 µL** Antiserum into each well
4. Dispense **100 µL** Enzyme Conjugate into each well.
   Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
5. Incubate for **60 minutes** at room temperature with shaking (500 - 600 rpm).
6. Briskly shake out the contents of the wells.
   Rinse the wells 3 times with diluted Wash Solution (400 µL per well). Strike the wells sharply on absorbent paper to remove residual droplets.
   Important note:
   The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!
7. Add **100 µL** of Enzyme Complex to each well.
8. Incubate for **30 minutes** at room temperature with shaking (500 - 600 rpm).
9. Briskly shake out the contents of the wells.
   Rinse the wells 3 times with diluted Wash Solution (400 µL per well). Strike the wells sharply on absorbent paper to remove residual droplets.
10. Add **100 µL** of Substrate Solution to each well.
11. Incubate for **20 minutes** at room temperature.
12. Stop the enzymatic reaction by adding **100 µL** of Stop Solution to each well.
13. Measure the optical density of the solution in each well at **450 nm (reading) and at 620 nm to 630 nm (background subtraction, recommended)** with a microtiter plate reader.
    It is recommended that the wells be read **within 10 minutes** after adding the *Stop Solution*.

6.3 Calculation of Results

1. Calculate the average absorbance values for each set of standards, controls and patient samples.
2. Using semi-logarithmic graph paper, construct a standard curve by plotting the mean absorbance obtained from each standard against its concentration with absorbance value on the vertical (Y) axis and concentration on the horizontal (X) axis.
3. Using the mean absorbance value for each sample determine the corresponding concentration from the standard curve.
4. Automated method: The results in the IFU have been calculated automatically using a 4 PL (4 Parameter Logistics) curve fit. 4 Parameter Logistics is the preferred method. Other data reduction functions may give slightly different results.
5. The concentration of the samples can be read directly from this standard curve. Samples with concentrations higher than that of the highest standard have to be further diluted or reported as > 16 ng/mL. For the calculation of the concentrations this dilution factor has to be taken into account.

6.3.1 Example of Typical Standard Curve

The following data is for demonstration only and **cannot** be used in place of data generations at the time of assay.

Standard	Optical Units (450 nm)
Standard 0 (0 ng/mL)	1.82
Standard 1 (0.2 ng/mL)	1.64
Standard 2 (0.7 ng/mL)	1.46
Standard 3 (2.0 ng/mL)	1.02
Standard 4 (6.0 ng/mL)	0.47
Standard 5 (16.0 ng/mL)	0.21

7 EXPECTED NORMAL VALUES

It is strongly recommended that each laboratory should determine its own normal and abnormal values.
In a study conducted with apparently normal healthy adults, using the IBL AMERICA C-Peptide ELISA the following values are observed:

	n	Mean ± 2SD
Serum (Post 12-hour Fasting)	60	0.5 – 3.2 ng/mL

	n	Range (min. – max.)	Mean	Median	5th Percentile	95th Percentile
Serum (females < 50 years)	42	0.1 – 5.8 ng/mL	1.0 ng/mL	0.7 ng/mL	0.2 ng/mL	3.9 ng/mL
Urine (males and females)	10	1 – 200 µg/day	108 µg/day	116 µg/day	5 µg/day	199 µg/day

8 QUALITY CONTROL

Good laboratory practice requires that controls be run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance.
It is recommended to use control samples according to state and federal regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels.
The controls and the corresponding results of the QC-Laboratory are stated in the QC certificate added to the kit. The values and ranges stated on the QC sheet always refer to the current kit lot and should be used for direct comparison of the results.
It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results.
Employ appropriate statistical methods for analysing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials patient results should be considered invalid.
In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods.
After checking the above mentioned items without finding any error contact your distributor or IBL AMERICA directly.

9 PERFORMANCE CHARACTERISTICS

9.1 Assay Dynamic Range

The range of the assay is between 0.06 – 16 ng/mL.

9.2 Specificity of Antibodies (Cross Reactivity)

The cross-reactivity of intact or split-Proinsulin is clinically not significant.

9.3 Sensitivity

The analytical sensitivity [Mean OD $_{(Standard\ 0)}$ – 2 x SD, n=20] was calculated to be 0.064 ng/mL

9.4 Reproducibility

9.4.1 Intra Assay

The within assay variability is shown below:

Sample	n	Mean (ng/mL)	CV (%)
1	20	0.48	6.5
2	20	2.30	6.7
3	20	3.86	5.1

9.4.2 Inter Assay

The between assay variability is shown below:

Sample	n	Mean (ng/mL)	CV (%)
1	12	0.42	9.3
2	12	2.05	9.9
3	12	4.23	8.4

9.4.3 Inter-Lot

The inter-assay (between-lots) variation was determined by measuring each sample 6 times with 3 different kit lots:

Sample	n	Mean (ng/mL)	CV (%)
1	21	1.86	4.8
2	21	5.05	3.2
3	21	13.9	2.9

9.5 Recovery

Samples have been spiked by adding C-Peptide solutions with known concentrations.
The recovery (%) was calculated by multiplying the ratio of measured and expected values with 100.

Sample		1	2	3	4	5	6
Sample Type		Serum	Serum	Serum	Urine	Urine	Urine
Concentration (ng/mL)		5.36	9.70	12.12	0.34	1.45	1.58
Average Recovery (%)		98.7	94.3	102.3	95.3	96.9	89.6
Range of Recovery (%)	from	96.5	87.3	88.1	85.4	88.7	85.4
	to	101.7	104.8	110.4	106.4	105.5	100.1

9.6 Linearity

Samples were measured undiluted and in serial dilutions with standard 0. The recovery (%) was calculated by multiplying the ratio of expected and measured values with 100.

Sample		1	2	3	4	5	6
Sample Type		Serum	Serum	Serum	Urine	Urine	Urine
Concentration (ng/mL)		6.10	9.90	13.25	8.70	9.20	13.90
Average Recovery (%)		107.6	107.2	102.0	97.1	99.1	97.9
Range of Recovery (%)	from	105.3	100.2	97.1	92.4	97.4	95.0
	to	110.6	112.8	105.1	100.2	102.2	103.6

10 LIMITATIONS OF USE

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the package insert instruction and with adherence to good laboratory practice. Any improper handling of samples or modification of this test might influence the results.

10.1 Interfering Substances

Haemoglobin (up to 4 mg/mL), Bilirubin (up to 0.5 mg/mL) and Triglyceride (up to 30 mg/mL) have no influence on the assay results.
A biotin concentration of up to 1200 ng/mL in a sample has no influence on the assay results.

10.2 Drug Interferences

Until today no substances (drugs) are known to us, which have an influence to the measurement of C-Peptide in a sample.

10.3 High-Dose-Hook Effect

A high dose hook effect is not known for competitive assays.

11 LEGAL ASPECTS

11.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test.
The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact IBL AMERICA.

11.2 Therapeutic Consequences

Therapeutic consequences should never be based on laboratory results alone even if all test results are in agreement with the items as stated under point 11.1. Any laboratory result is only a part of the total clinical picture of a patient. Only in cases where the laboratory results are in acceptable agreement with the overall clinical picture of the patient should therapeutic consequences be derived. The test result itself should never be the sole determinant for deriving any therapeutic consequences.

11.3 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.
Claims submitted due to customer misinterpretation of laboratory results subject to point 11.2. are also invalid. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

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SYMBOLS USED WITH IBL AMERICA ELISAS

Symbol	English	Deutsch	Français	Español	Italiano
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conforme aux normes européennes	Conformidad europea	Conformità europea
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instruc-tions d'utilisation	Consulte las Instruc-ciones	Consultare le istruzioni per l'uso
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Référence	Número de catálogo	No. di Cat.
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore