

Elecsys C-Peptide

cobas®

REF		Σ	SYSTEM
03184897190	03184897501	100	cobas e 411 cobas e 601 cobas e 602

English

For use in the USA only

System information

For **cobas e 411** analyzer: test number 070

For **cobas e 601** and **cobas e 602** analyzers: Application Code Number 186

Intended use

Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine.

The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion.

The **electrochemiluminescence immunoassay "ECLIA"** is intended for use on **cobas e** immunoassay analyzers.

Summary

C-peptide is a single chain 31-amino acid (AA 33-63) connecting (C) polypeptide with a molecular weight of approximately 3021 daltons.^{1,2}

In the process of biosynthesis of insulin the C-peptide is formed as a by-product together with insulin by the proteolytic cleavage of the precursor molecule proinsulin, stored in secretory granules in the Golgi complex of the pancreatic β -cells. Proinsulin in turn was cleaved from preproinsulin.^{2,3}

C-peptide fulfills an important function in the assembly of the 2-chain insulin (A- and B-chain) structure and the formation of the 2 disulfide bonds within the proinsulin molecule. Insulin and C-peptide are secreted in equimolar amounts and released into circulation via the portal vein.⁴ As half of the insulin, but almost none of the C-peptide is extracted in the liver, C-peptide has a longer half-life (about 35 minutes) than insulin; 5 to 10 times higher concentration of C-peptide persist in the peripheral circulation, and these levels fluctuate less than insulin.^{2,3,4}

The liver does not extract C-peptide, which is removed from the circulation by the kidneys and degraded, with a fraction excreted unchanged in the urine. The concentration in urine is about 20-50 fold higher than in serum. C-peptide concentrations are therefore elevated in renal disease.^{1,2,3}

In the past, C-Peptide has been considered biologically inactive. However, recent studies have demonstrated that it is capable of eliciting molecular and physiological effects suggesting that C-peptide is in fact a bioactive peptide. There is evidence that C-peptide replacement, together with insulin administration, may prevent the development or retard the progression of long-term complications in type 1 diabetes.^{5,6,7,8,9,10}

Measurements of C-peptide, insulin and glucose are used as an aid in the differential diagnosis of hypoglycemia (factitious hypoglycemia and hypoglycemia caused by hyperinsulinism) to ensure an appropriate management and therapy of the patients. To quantify the endogenous insulin secretion, C-peptide is measured basally, after fasting and after stimulation and suppression tests. Due to high prevalence of endogenous anti-insulin antibodies C-peptide concentrations reflect the endogenous pancreatic insulin secretion more reliably in insulin-treated diabetics than the levels of insulin itself. Measurements of C-peptide may therefore be an aid in the assessment of a residual β -cell function in the early stages of type-1 diabetes mellitus and for the differential diagnosis of latent autoimmune diabetes of adults (LADA) and type-2 diabetes.^{2,3,11,12,13,14}

C-peptide measurements are also used to assess the success of islet transplantation and for monitoring after pancreatotomy.^{2,3}

Urine C-peptide is measured when a continuous assessment of β -cell function is desired or frequent blood sampling is not practical (e.g. in children).² C-peptide excretion in urine has been used to assess pancreatic function in gestational diabetes, and in patients with unstable glycemic control in insulin-dependent diabetes mellitus (IDDM).^{15,16}

Although testing for C-peptide is not requested for the routine monitoring of diabetes, it is a valuable tool for the individual therapeutic decisions which are essential for an optimal long-term metabolic control.^{17,18}

Elevated C-peptide levels may result from increased β -cell activity observed in hyperinsulinism, from renal insufficiency, and obesity.²

Correlation was also found between higher C-peptide levels and increasing hyperlipoproteinaemia and hypertension.¹⁹

Decreased C-peptide levels are observed in: starvation, factitious hypoglycemia, hypoinsulinism (NIDDM, IDDM), Addison's disease and after radical pancreatectomy.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 20 μ L of sample, a biotinylated monoclonal C-peptide-specific antibody, and a monoclonal C-peptide-specific antibody labeled with a ruthenium complex^{a)} react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode or e-barcode.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)₃²⁺)

Reagents - working solutions

The reagent rackpack is labeled as CPEPTID.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 Anti-C-peptide-Ab~biotin (gray cap), 1 bottle, 9 mL: Biotinylated monoclonal anti-C-peptide antibody (mouse) 1 mg/L, phosphate buffer 50 mmol/L, pH 6.0; preservative.
- R2 Anti-C-peptide-Ab~Ru(bpy)₃²⁺ (black cap), 1 bottle, 9 mL: Monoclonal anti-C-peptide antibody (mouse) labeled with ruthenium complex 0.4 mg/L; phosphate buffer 50 mmol/L, pH 6.0; preservative.

Precautions and warnings

For in vitro diagnostic use for healthcare professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H317

May cause an allergic skin reaction.

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Prevention:

- P261 Avoid breathing mist or vapours.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves.

Response:

- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

- P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: 1-800-428-2336

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

The reagents in the kit have been assembled into a ready-for-use unit that cannot be separated.

All information required for correct operation is read in from the respective reagent barcodes.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the Elecsys reagent kit **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	12 weeks
on the analyzers	8 weeks

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin and K₃-EDTA plasma.

Criterion: Recovery within 90-110 % of serum value or slope 0.9-1.1 + coefficient of correlation > 0.95.

24 h Urine, 1:10 prediluted with Diluent MultiAssay.

Stability of the serum and 24 h urine samples: 4 hours at 15-25 °C, 24 hours at 2-8 °C, 30 days at -20 °C (± 5 °C). Freeze only once.²⁰

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Do not use heat-inactivated samples.

Do not use samples and controls stabilized with azide.

Ensure the samples, calibrators and controls are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the

responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- REF 05341787160, PreciControl Multimarker, for 6 x 2.0 mL
- REF 03184919190, C-Peptide CalSet, for 4 x 1.0 mL
- REF 03609987190, Diluent MultiAssay, 2 x 16 mL sample diluent
- General laboratory equipment

- cobas e** analyzer

Additional materials for **cobas e** 411 analyzer:

- REF 11662988122, ProCell, 6 x 380 mL system buffer
- REF 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- REF 11930346122, Elecsys SysWash, 1 x 500 mL washwater additive
- REF 11933159001, Adapter for SysClean
- REF 11706802001, AssayCup, 60 x 60 reaction cups
- REF 11706799001, AssayTip, 30 x 120 pipette tips
- REF 11800507001, Clean-Liner

Additional materials for **cobas e** 601 and **cobas e** 602 analyzers:

- REF 04880340190, ProCell M, 2 x 2 L system buffer
- REF 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- REF 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- REF 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- REF 12102137001, AssayTip/AssayCup, 48 magazines x 84 reaction cups or pipette tips, waste bags
- REF 03023150001, WasteLiner, waste bags
- REF 03027651001, SysClean Adapter M

Additional materials for all analyzers:

- REF 11298500160, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use. Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Calibration

Traceability: This method has been standardized against the WHO International Reference Reagent for C-peptide of human insulin for immunoassay, IRR, code 84/510, established 1986, from the National Institute for Biological Standards and Control (NIBSC).²¹

Every Elecsys reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

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Renewed calibration is recommended as follows:

- after 1 month (28 days) when using the same reagent lot
- after 7 days (when using the same reagent kit on the analyzer)
- as required: e.g. quality control findings outside the defined limits

Quality control

Use PreciControl Multimer or other suitable controls for routine quality control procedures.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

The analyzer automatically calculates the analyte concentration of each sample in nmol/L, ng/mL or pmol/L (selectable).

Conversion factors:

$$\begin{aligned} \text{ng/mL } (\mu\text{g/L}) \times 0.33333 &= \text{nmol/L} \\ \text{ng/mL} \times 333.33 &= \text{pmol/L} \\ \text{nmol/L} \times 3.0 &= \text{ng/mL} \\ \text{pmol/L} \times 0.003 &= \text{ng/mL} \end{aligned}$$

Limitations - interference

The assay is unaffected by icterus (bilirubin < 855 $\mu\text{mol/L}$ or < 50 mg/dL), hemolysis (Hb < 0.186 mmol/L or < 0.3 g/dL), lipemia (Intralipid < 2000 mg/dL) and biotin (< 246 nmol/L or < 60 ng/mL).

Criterion: Recovery within $\pm 10\%$ of initial value.

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

No interference was observed from rheumatoid factors up to a concentration of 1200 IU/mL.

There is no high-dose hook effect at C-peptide concentrations up to 60 nmol/L (180 ng/mL).

In vitro tests were performed on 17 commonly used pharmaceuticals in serum and 13 commonly used pharmaceuticals in urine. No interference with the assay was found.

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Limits and ranges

Measuring range

Serum and plasma: 0.003-13.3 nmol/L or 0.010-40.0 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.003 nmol/L (< 0.010 ng/mL). Values above the measuring range are reported as > 13.3 nmol/L (> 40.0 ng/mL) (or up to 133 nmol/L or 400 ng/mL for 10-fold diluted samples).

Urine: 0.030-133 nmol/L or 0.100-400 ng/mL (defined by the lower detection limit and the maximum of the master curve for urine prediluted 1:10 with Diluent MultiAssay). Values below the lower detection limit are reported as < 0.030 nmol/L (< 0.100 ng/mL). Values above the measuring range are reported as > 133 nmol/L (> 400 ng/mL) or retested in a higher dilution of the sample.

Lower limits of measurement

Lower detection limit of the test

Lower detection limit: 0.003 nmol/L (0.010 ng/mL)

The Lower Detection Limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 2 standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 21).

Dilution

Serum and plasma: Although the necessity for dilutions is unlikely due to the high measuring range samples with C-peptide concentrations above the measuring range can be diluted with Diluent MultiAssay. The recommended dilution is 1:10 (either automatically by the analyzers or manually). The concentration of the diluted sample must be > 1.3 nmol/L (> 4 ng/mL).

After manual dilution, multiply the result by the dilution factor.

After dilution by the analyzers, the software automatically takes the dilution into account when calculating the sample concentration.

Urine: All urine samples must be prediluted 1:10 with Diluent MultiAssay before measurement. After dilution by the analyzers, the software automatically takes the dilution into account when calculating the sample concentration. Urine samples with C-peptide concentrations above the measuring range can be retested using a 1:20 or higher dilution with Diluent MultiAssay either automatically by the analyzers or manually. The concentration of the diluted sample must be > 1.3 nmol/L (> 4 ng/mL).

After manual dilution, multiply the result by the dilution factor.

After dilution by the analyzers, the software automatically takes the dilution into account when calculating the sample concentration.

Expected values

Studies with the Elecsys C-Peptide assay were performed using serum samples from apparently healthy fasting males and females, and 24 h urine samples from apparently healthy individuals.

The following results were obtained:

	N	Median	5 th -95 th percentile	Unit
C-peptide in serum/plasma	96	1.96	1.1-4.4	ng/mL
		0.65	0.37-1.47	nmol/L
C-peptide in 24 h urine	79	54.8	17.2-181	$\mu\text{g}/24\text{ h}$
		18.3	5.74-60.3	nmol/24 h

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Serum and plasma:

Precision was determined using Elecsys reagents and pooled human sera in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute): 6 times daily for 10 days (n = 60); human serum 3 at 1 day 5 times (n = 59); repeatability on MODULAR ANALYTICS E170 analyzer (n = 21). The following results were obtained:

cobas e 411 analyzer					
			Repeatability		
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Master calibrator 3	0.302	0.907	0.005	0.015	1.6
Human serum 2	0.606	1.82	0.028	0.084	4.6
Human serum 3	1.90	5.69	0.034	0.103	1.8
Human serum 4	5.57	16.7	0.212	0.637	3.8
Human serum 5	8.05	24.1	0.105	0.315	1.3

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cobas e 411 analyzer					
			Intermediate precision		
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Master calibrator 3	0.302	0.907	0.007	0.021	2.4
Human serum 2	0.606	1.82	0.030	0.090	5.0
Human serum 3	1.90	5.69	0.042	0.126	2.2
Human serum 4	5.57	16.7	0.209	0.627	3.8
Human serum 5	8.05	24.1	0.141	0.424	1.8

cobas e 601 and cobas e 602 analyzers					
	Repeatability				
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Master calibrator 3	0.33	0.98	0.002	0.005	0.6
Human serum 2	0.643	1.93	0.003	0.009	0.5
Human serum 3	2.00	6.01	0.019	0.056	0.9
Human serum 4	5.99	18.0	0.054	0.163	0.9
Human serum 5	8.59	25.8	0.126	0.378	1.5

cobas e 601 and cobas e 602 analyzers					
	Intermediate precision				
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Master calibrator 3	0.307	0.922	0.006	0.017	1.9
Human serum 2	0.615	1.84	0.010	0.030	1.6
Human serum 3	1.92	5.75	0.044	0.132	2.3

Precision was determined using Elecsys reagents, samples and controls in a protocol (EP5-A2) of the CLSI (Clinical and Laboratory Standards Institute): 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

cobas e 411 analyzer					
			Repeatability		
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
PreciControl MM ^{b)} 1	0.667	2.00	0.006	0.018	0.9
PreciControl MM2	3.33	9.98	0.043	0.129	1.3

b) MM = Multimarker

cobas e 411 analyzer					
			Intermediate precision		
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
PreciControl MM1	0.667	2.00	0.016	0.047	2.3
PreciControl MM2	3.33	9.98	0.091	0.272	2.7

cobas e 601 and cobas e 602 analyzers					
			Repeatability		
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
PreciControl MM1	0.650	1.95	0.020	0.059	3.0
PreciControl MM2	3.24	9.72	0.104	0.312	3.2

cobas e 601 and cobas e 602 analyzers					
			Intermediate precision		
Serum sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
PreciControl MM1	0.650	1.95	0.028	0.084	4.3
PreciControl MM2	3.24	9.72	0.151	0.453	4.7

Urine:

Precision was determined using Elecsys reagents, native and spiked human urine; repeatability (n = 21), intermediate precision: 1-fold determination in 10 runs (n = 10); predilution by the analyzer. The following results were obtained:

cobas e 411 analyzer					
	Repeatability				
Urine sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Urine 1	5.38	16.1	0.158	0.475	2.9
Urine 2	8.92	26.8	0.141	0.428	1.6
Urine 3	12.8	38.4	0.515	1.54	4.0
Urine 4	54.1	162	0.888	2.67	1.6
Urine 5	78.3	235	1.70	5.09	2.2

cobas e 411 analyzer					
	Intermediate precision				
Urine sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Urine 1	5.33	16.0	0.214	0.64	4.0
Urine 2	9.06	27.2	0.222	0.67	2.4
Urine 3	12.9	38.7	0.237	0.71	1.8
Urine 4	53.5	160	1.95	5.86	3.6
Urine 5	76.4	229	1.32	3.97	1.7

cobas e 601 and cobas e 602 analyzers					
	Repeatability				
Urine sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Urine 1	5.55	16.7	0.045	0.13	0.8
Urine 2	9.48	28.4	0.087	0.26	0.9
Urine 3	13.1	39.2	0.081	0.24	0.6
Urine 4	58.9	177	0.454	1.36	0.8
Urine 5	81.8	246	1.09	3.28	1.3

cobas e 601 and cobas e 602 analyzers					
	Intermediate precision				
Urine sample	Mean		SD		CV
	nmol/L	ng/mL	nmol/L	ng/mL	%
Urine 1	5.82	17.5	0.197	0.59	3.4
Urine 2	9.64	28.9	0.385	1.15	4.0
Urine 3	13.9	41.8	0.366	1.10	2.6
Urine 4	58.6	176	1.74	5.22	3.0
Urine 5	83.0	249	1.53	4.60	1.8

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Method comparison

Serum

A comparison of the Elecsys C-Peptide assay (y) with a commercially available C-peptide assay (x) using clinical serum samples gave the following correlations:

Number of samples measured: 266

Passing/Bablok ²²	Linear regression
$y = 1.07x + 0.026$	$y = 1.11x - 0.149$
$r = 0.962$	$r = 0.996$

The sample concentrations were between 0.157 and 7.26 nmol/L or 0.470 and 21.8 ng/mL.

Urine

A comparison of the Elecsys C-Peptide assay (y) with a commercially available C-peptide assay (x) using clinical urine samples gave the following correlations:

Number of samples measured: 72

Passing/Bablok ²²	Linear regression
$y = 0.95x - 0.823$	$y = 1.02x - 3.69$
$r = 0.921$	$r = 0.992$

The sample concentrations were between 0.223 and 173 nmol/L or 0.670 and 518 ng/mL.

Analytical specificity

For the monoclonal antibodies used, the following cross-reactivities were found:

Substance	Concentration tested µg/mL	Cross-reactivity %
Proinsulin, human ^{c)}	0.10	32.5
Insulin, human ^{d)}	8.66	0.005
Insulin, porcine ^{e)}	7.50	n.d. ^{f)}
Insulin, bovine ^{g)}	7.69	n.d.
Somatomedin (Insulin-like growth factor 1 - IGF-I)	1.0	n.d.
Human Growth Hormone	10.0	n.d.
Glucagon	10.0	n.d.

c) WHO preparation 84/611

d) WHO preparation 66/304

e) WHO preparation 86/690

f) n.d. = not detectable

g) WHO preparation 83/511

The Elecsys C-Peptide assay uses 2 monoclonal antibodies specifically directed against human C-peptide. The antibodies show cross-reactivity with the C-chain of human proinsulin and presumably with partially processed proinsulins (split products). The concentrations of proinsulin and split products of fasting healthy subjects are 100 times lower than the C-peptide concentrations and therefore the cross-reactivity is of no clinical significance. In patients with insulinoma, the proinsulin concentrations are reported as up to 60-fold higher than those from fasting healthy subjects.^{23,24}

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For further information, please refer to the appropriate user guide or operator's manual for the analyzer concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

Elecsys C-Peptide



Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

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	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume for reconstitution
	Global Trade Item Number

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