Elecsys Insulin

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REF		Σ	SYSTEM
12017547122* 12017547214*	12017547500	100	**cobas e** 411 **cobas e** 601 **cobas e** 602

* Some kits shown may not be available in all countries.

English

System information

For **cobas e** 411 analyzer: test number 650
For **cobas e** 601 and **cobas e** 602 analyzers: Application Code Number 120

Intended use

Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various disorders of carbohydrate metabolism, including diabetes mellitus and hypoglycemia.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Summary

Insulin is a 51-residue peptide hormone with a molecular weight of 5808 Da. It is secreted by the β-cells of the islets of Langerhans in the pancreas, and passes into circulation via the portal vein and the liver. Insulin is generally released in pulses.[1,2]

The biologically active insulin molecule is monomeric and consists of two polypeptide chains, the 21 amino acid α-chain and the 30 amino acid β-chain joined by disulphide bridges. Insulin is the biosynthetic product of the single-chain precursor preproinsulin, which is subsequently cleaved to give proinsulin.[2,3,4,5] Specific proteases further cleave proinsulin to produce insulin and the connecting (C)-peptide which pass into the bloodstream simultaneously in equimolar concentrations. Circulating insulin has a half-life of 3-5 minutes and is preferentially retained and degraded in the liver. Therefore only about half of the insulin reaches the systemic circulation. Inactivation or excretion of proinsulin and C-peptide mainly takes place in the kidney and virtually none of the C-peptide is retained in the liver. As a result, C-peptide has a higher plasma concentration than insulin.[6]

The amino acid sequence of insulin is extremely well conserved, with the result that prior to the development of genetically engineered human insulin it was possible to successfully use porcine or bovine insulin in the therapy of diabetes mellitus.[7]

The action of insulin is mediated by specific receptors and primarily consists of facilitation of glucose uptake by the cells of the liver, fatty tissue and musculature; this is the basis of its hypoglycemic action.[2,8]

Serum insulin determinations are mainly performed on patients with symptoms of hypoglycemia and may be useful in classifying the different types of diabetes.[9,10] They are used to ascertain the glucose/insulin quotients and for clarification of questions concerning insulin secretion and β-cell function, e.g. in the evaluation of oral glucose tolerance tests or hunger provocation tests.[11]

A disorder in insulin metabolism can have a significant impact on a number of metabolic processes. Low concentrations of free, biologically active insulin can lead to the development of diabetes mellitus. Possible causes of this include destruction of the β-cells (type I diabetes), reduced activity of insulin or reduced pancreatic synthesis (type II), circulating antibodies to insulin, delayed release of insulin or the absence (or inadequacy) of insulin receptors.[12]

Conversely, autonomous, non-regulated insulin secretion is generally the cause of hypoglycemia. This condition is brought about by inhibition of gluconeogenesis, e.g. as a result of severe hepatic or renal failure, islet cell adenoma, or carcinoma. Hypoglycemia can, however, also be facilitated intentionally or unintentionally (factitious hypoglycemia).[10,13]

In certain individuals with reduced glucose tolerance, the metabolic state deteriorates towards diabetes mellitus over a period of time. Reduced glucose tolerance during pregnancy always requires treatment. The clearly elevated risk of mortality for the fetus necessitates intensive monitoring.[12]

The Elecsys Insulin assay employs two monoclonal antibodies which are specific for human insulin.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: Insulin from 20 µL sample, a biotinylated monoclonal insulin-specific antibody, and a monoclonal insulin-specific antibody labeled with a ruthenium complex[a)] 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 ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

The reagent rackpack is labeled as INSULIN.

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-insulin-Ab~biotin (gray cap), 1 bottle, 10 mL:
Biotinylated monoclonal anti-insulin antibody (mouse) 1 mg/L; MES[b)] buffer 50 mmol/L, pH 6.0; preservative.

R2 Anti-insulin-Ab~$Ru(bpy)_3^{2+}$ (black cap), 1 bottle, 10 mL:
Monoclonal anti-insulin antibody (mouse) labeled with ruthenium complex 1.75 mg/L; MES buffer 50 mmol/L, pH 6.0; preservative.

b) MES = 2-morpholino-ethane sulfonic acid

Precautions and warnings

For in vitro diagnostic use for health care 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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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

Warning

H317	May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.

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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: all countries: +49-621-7590, USA: 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	4 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, K_2-EDTA and K_3-EDTA plasma.

Criterion: Slope 0.9-1.1 + intercept within ≤ ± 0.8 µU/mL + coefficient of correlation ≥ 0.95.

Stable for 4 hours at 20-25 °C, 2 days at 2-8 °C, 6 months at -20 °C (± 5 °C). Freeze only once.

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.

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Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

- REF 12017504122, Insulin CalSet, for 4 x 1.0 mL
- REF 05341787190, PreciControl Multimarker, for 6 x 2.0 mL or REF 11731416190, PreciControl Universal, for 4 x 3.0 mL
- REF 11731416160, PreciControl Universal, for 4 x 3.0 mL (for USA) or REF 05341787160, PreciControl Multimarker, for 6 x 2.0 mL (for USA)
- General laboratory equipment
- **cobas e** analyzer

Additional materials for the **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 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution
- REF 11298500160, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution (for USA)

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 using the 1st IRP WHO Reference Standard 66/304 (NIBSC).

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

For quality control, use PreciControl Multimarker or PreciControl Universal.

In addition, other suitable control material can be used.

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.

Please note: Commercial controls may contain insulin of animal origin. When assessing results, the corresponding cross-reactivity of this test must be taken into account; see under "Analytical specificity".

Calculation

The analyzer automatically calculates the analyte concentration of each sample (either in µU/mL or pmol/L).

Conversion factors: µU/mL x 6.945 = pmol/L

pmol/L x 0.144 = µU/mL

Limitations - interference

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 1539 µmol/L or ≤ 90 mg/dL
Intralipid	≤ 1800 mg/dL
Biotin	≤ 246 nmol/L or ≤ 60 ng/mL
Rheumatoid factors	≤ 1200 IU/mL

Criterion: For concentrations of 0.2-2 µU/mL the deviation is ≤ 0.5 µU/mL. For concentrations > 2 µU/mL the deviation is ≤ 10 %.

Hemolysis interferes, as insulin-degrading peptidases are released from erythrocytes.[14]

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.

There is no high-dose hook effect at insulin concentrations up to 20000 µU/mL or 138900 pmol/L.

In vitro tests were performed on 20 commonly used pharmaceuticals. No interference with the assay was found.

Samples from patients treated with bovine, porcine or human insulin sometimes contain anti-insulin antibodies which can affect the test results.[15]

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

0.2-1000 µU/mL or 1.39-6945 pmol/L (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.2 µU/mL (< 1.39 pmol/L). Values above the measuring range are reported as > 1000 µU/mL (> 6945 pmol/L).

Lower limits of measurement

Lower detection limit of the test

Lower detection limit: 0.2 µU/mL (1.39 pmol/L)

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

Dilution

Not necessary due to the broad measuring range.

Expected values

Studies with the Elecsys Insulin assay conducted in a clinical center in Germany with samples from 57 healthy, fasting individuals gave the following results (5^{th}-95^{th} percentile range):

2.6-24.9 µU/mL (17.8-173 pmol/L)

Status: Elecsys Insulin MCE, study No.: B99P027 of 29 March 2001.

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

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); repeatability on MODULAR ANALYTICS E170 analyzer, n = 21. The following results were obtained:

cobas e 411 analyzer					
			Repeatability		
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
Human serum 1	6.36	44.2	0.122	0.847	1.9
Human serum 2	20.9	145	0.391	2.71	1.9
Human serum 3	747	5188	15.1	105	2.0

cobas e 411 analyzer					
			Intermediate precision		
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
Human serum 1	6.36	44.2	0.163	1.11	2.6
Human serum 2	20.9	145	0.593	4.10	2.8
Human serum 3	747	5188	18.6	129	2.5

cobas e 601 and **cobas e** 602 analyzers					
	Repeatability				
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
Human serum 1	5.93	41.2	0.09	0.62	1.5
Human serum 2	14.5	101	0.13	0.92	0.9
Human serum 3	49.9	346	0.58	4.05	1.2
Human serum 4	399	2768	3.32	23.1	0.8

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cobas e 601 and **cobas e** 602 analyzers					
	Intermediate precision				
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
Human serum 1	6.85	47.6	0.336	2.33	4.9
Human serum 2	16.7	116	0.616	4.28	3.7
Human serum 3	55.1	383	1.86	12.9	3.4
Human serum 4	425	2949	10.0	69.6	2.4

Precision was determined using Elecsys reagents 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		
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
PreciControl MM[c)]1	23.7	165	0.270	1.88	1.1
PreciControl MM2	81.7	567	1.14	7.92	1.4

c) MM = Multimarker

cobas e 411 analyzer					
			Intermediate precision		
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
PreciControl MM1	23.7	165	0.834	5.79	3.5
PreciControl MM2	81.7	567	3.04	21.1	3.7

cobas e 601 and **cobas e** 602 analyzers					
			Repeatability		
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
PreciControl MM1	21.9	152	0.712	4.94	3.2
PreciControl MM2	74.3	516	2.72	18.9	3.7

cobas e 601 and **cobas e** 602 analyzers					
			Intermediate precision		
Sample	Mean		SD		CV
	µU/mL	pmol/L	µU/mL	pmol/L	%
PreciControl MM1	21.9	152	0.926	6.43	4.2
PreciControl MM2	74.3	516	3.42	23.8	4.6

Method comparison

a) A comparison of the Elecsys Insulin assay (y) with the Enzymun-Test Insulin method (x) using clinical samples gave the following correlations (µU/mL):

Number of samples measured: 99

Passing/Bablok[16]	Linear regression
y = 1.00x - 1.16	y = 0.92x + 0.59
τ = 0.844	r = 0.958

The sample concentrations were between approximately 3.9 and 80 µU/mL (approximately 27 and 550 pmol/L).

b) A comparison of the Elecsys Insulin assay (y) with a commercially available Insulin test (x) using clinical samples gave the following correlations (µU/mL):

Number of samples measured: 99

Passing/Bablok[16]	Linear regression
y = 0.89x - 0.62	y = 0.93x - 1.02
τ = 0.935	r = 0.981

The sample concentrations were between approximately 1 and 118 µU/mL (approximately 7 and 820 pmol/L).

Analytical specificity

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

	Concentration tested	Cross-reactivity %
Bovine insulin	17360 pmol/L	25.0
Porcine insulin	8334 pmol/L	19.2
Human proinsulin	1000 ng/mL	0.05
C-peptide	100 ng/mL	n.d.[d)]
Glucagon	1000 pg/mL	n.d.
Somatostatin	100 pg/mL	n.d.
Insulin-like growth factor I	6579 pmol/L	0.04

d) n.d. = not detectable

Results for cross-reactivity with recombinant insulin analogs in a number of insulin methods have been published for example by two groups in France and the USA.[15,17,18] The following results were published by Owen et al.[17] for the Elecsys Insulin assay:

Insulin lispro, insulin aspart, and insulin glargine were each tested in concentrations of 30, 100, 300, and 1000 mIU/L in the absence of insulin. The results obtained were below the detection limit of the Elecsys Insulin assay (< 0.2 µU/mL or < 1.39 pmol/L) at all the concentrations tested.

Moreover, these results also correlate with those published earlier by Sapin et al. for insulin lispro.[15]

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

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

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 dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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