


REF			SYSTEM
11732234122	11732234500	100	<b>cobas e 411</b> <b>cobas e 601</b> <b>cobas e 602</b>

## English

### System information

For **cobas e 411** analyzer: test number 140

For **cobas e 601** and **cobas e 602** analyzers: Application Code Number 020

### Intended use

Immunoassay for the in vitro quantitative determination of luteinizing hormone in human serum and plasma.

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

### Summary

Luteinizing hormone (LH) measurements, performed with this assay, in human serum and plasma are used as an aid in diagnosis of the hypothalamic-pituitary-gonadal system, assessment of the primary cause of female and male infertility.

LH is a glycoprotein hormone with a heterodimeric structure, consisting of an  $\alpha$ - and a  $\beta$ -subunit, where the  $\alpha$  subunit is commonly shared with other hormones in the glycoprotein family. Hypothalamic gonadotropin-releasing hormone (GnRH) directs the pituitary to synthesize and secrete LH in a pulsatile pattern. LH together with follicle-stimulating hormone (FSH) control the functional activity of the gonads and synthesis of sex steroids.<sup>1,2,3</sup> Pituitary gonadotropin secretion is controlled by feedback from the gonadotropic hormones. In women, estrogen regulates LH secretion, and in men, testosterone regulates LH release.<sup>1</sup>

In women, LH acts together with FSH to regulate the menstrual cycle. The highest LH-concentrations occur during the mid-cycle peak to induce ovulation and to assist in the formation of corpus luteum promoting progesterone secretion.<sup>1</sup> In men, LH stimulates the development and functional activity of Leydig cells that produce testosterone.<sup>1,4</sup>

Determination of LH concentration is used in the elucidation of dysfunctions within the hypothalamus-pituitary-gonadal system. In women the determination of LH in conjunction with FSH is utilized for the indications such as congenital diseases with chromosome aberrations (e.g. Turner's syndrome) and infertility related conditions such as clarifying causes of amenorrhea, menopausal syndrome, polycystic ovary syndrome (PCOS). In men, measurement of LH is used for the assessment of male reproductive abnormalities leading to lowered levels of circulating testosterone (primary or secondary hypogonadism).<sup>1,2,3,4</sup>

The Elecsys LH assay employs two monoclonal antibodies specifically directed against human LH. The two specific antibodies used recognize particular conformations, with the biotinylated antibodies detecting an epitope constructed from both subunits whereas the antibody with the ruthenium complex<sup>a)</sup> label detects an epitope from the  $\beta$ -subunit. As a result, the Elecsys LH assay shows negligible cross-reactivity with FSH, TSH, hCG, hGH, and hPL.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ( $\text{Ru}(\text{bpy})_3^{2+}$ )

### Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 20  $\mu\text{L}$  of sample, a biotinylated monoclonal LH-specific antibody, and a monoclonal LH-specific antibody labeled with a ruthenium complex 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.

### Reagents - working solutions

The reagent rackpack is labeled as LH.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL:  
Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 Anti-LH-Ab~biotin (gray cap), 1 bottle, 10 mL:  
Biotinylated monoclonal anti-LH antibody (mouse) 2.0 mg/L; TRIS buffer 50 mmol/L, pH 8.0; preservative.
- R2 Anti-LH-Ab~ $\text{Ru}(\text{bpy})_3^{2+}$  (black cap), 1 bottle, 10 mL:  
Monoclonal anti-LH antibody (mouse) labeled with ruthenium complex 0.3 mg/L; TRIS buffer 50 mmol/L, pH 8.0; preservative.

### 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.

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 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: all countries: +49-621-7590

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, K<sub>2</sub>-EDTA and K<sub>3</sub>-EDTA plasma.

Criterion: Slope 0.9-1.1 + intercept within  $\pm 0.3$  mIU/mL + coefficient of correlation  $\geq 0.95$ .

Stable for 5 days at 20-25 °C, 14 days at 2-8 °C, 6 months at -20 °C ( $\pm 5$  °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.

## Materials provided

See "Reagents – working solutions" section for reagents.

## Materials required (but not provided)

- [REF] 03561097190, LH CalSet II, for 4 x 1.0 mL
- [REF] 09557423190, LH CalSet II, for 4 x 1.0 mL
- [REF] 11731416190, PreciControl Universal, for 4 x 3.0 mL
- 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

## 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 2nd International Standard (NIBSC) 80/552.

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.

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 Universal 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 (either in mIU/mL or IU/L).

## 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	$\leq 1129 \mu\text{mol/L}$ or $\leq 66 \text{ mg/dL}$
Hemoglobin	$\leq 0.621 \text{ mmol/L}$ or $\leq 1000 \text{ mg/dL}$
Intralipid	$\leq 1900 \text{ mg/dL}$
Biotin	$\leq 205 \text{ nmol/L}$ or $\leq 50 \text{ ng/mL}$
Rheumatoid factors	$\leq 1500 \text{ IU/mL}$



# Elecsys LH



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 [navifyportal.roche.com](https://navifyportal.roche.com) for definition of symbols used):

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

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

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