

REF			SYSTEM
03052001190	03052001500	100	cobas e 411 cobas e 601 cobas e 602

English

System information

For **cobas e 411** analyzer: test number 750
 For **cobas e 601** and **cobas e 602** analyzers: Application Code Number 146

Intended use

Immunoassay for the in vitro quantitative determination of sex hormone-binding globulin in human serum and plasma.

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

Summary

Sex hormone-binding globulin (SHBG) measurements, performed with this assay, in human serum and plasma are used as an aid in diagnosis of conditions associated with altered androgen levels, such as hyperandrogenism and hypogonadism.

SHBG is the blood transport protein for testosterone, estradiol (E2) and other steroids. It is produced mainly, but not exclusively, by the liver and its synthesis is regulated by metabolic as well as endocrine factors. In healthy individuals, body composition and in particular the ratio of fat to lean mass, is one of the main factors determining circulating levels of SHBG.¹ Body weight, body-mass-index (BMI) and waist-to-hip ratio (WHR) correlate inversely with SHBG levels.² Metabolic and hormonal changes throughout life are reflected in fluctuations in SHBG levels.^{1,2}

SHBG exists as a homodimeric glycoprotein composed of two identical subunits. Dimerization is required for the integrity of a single steroid binding site per dimer.³ SHBG has low binding capacity but a very high binding affinity for steroids, showing highest affinities for dihydrotestosterone, testosterone, androstenediol, and estradiol (E2).^{4,5} Besides transportation, SHBG regulates the bioavailability of sex-steroids via control of their respective metabolic clearance rates and their access to target tissues.^{5,6} The SHBG-binding sites are mainly occupied by testosterone, thus SHBG serum concentrations are major determinant of the total testosterone concentrations. Only a small percentage (2 to 3 %) of testosterone circulates in the bloodstream freely, the majority is either strongly bound to SHBG, or weakly bound to non-specific proteins like albumin. In men, 44 % to 65 % of testosterone is bound to SHBG while in women, the percentages range from 66 % to 78 %. In addition, SHBG levels are about two times lower in men than women.^{1,5} In women, circulating estradiol is mainly present in a form bound to SHBG but the affinity of SHBG for estradiol is about five times lower than its affinity for testosterone.^{4,5,6}

The free and non-specifically bound plasma hormone levels generally reflect the clinical situation more accurately than total plasma hormone levels. Serum SHBG and testosterone measurements have been used in algorithms to calculate free testosterone levels in patients with suspected hyperandrogenism or hypoandrogenism.⁶ The estimated amount of free testosterone can be calculated by performing the ratio of total testosterone (T) to SHBG which provides the so-called free androgen index or free testosterone index [% FAI or FTI = (100 T/SHBG)]. By additionally taking into account the non-specifically albumin-bound testosterone, it is possible to calculate the bioavailable testosterone, which is the sum of free testosterone (non-SHBG bound testosterone) and the albumin-bound testosterone fraction, calculated via the association constant to albumin.⁷ Free and bioavailable testosterone are also referred to as non-SHBG-bound testosterone.⁸ Similar calculations can be performed for E2, to explain how serum SHBG levels contribute to abnormal estrogen exposures, especially in postmenopausal women.^{6,9}

Clinical conditions of androgen excess (hyperandrogenemia) or conditions where the effect of androgen on its target organs is excessive, are associated with decreased SHBG serum levels. In clinical conditions where androgen levels are normal, but clinical symptoms indicate androgen in excess, low SHBG titer can be an important indicator of an excessive/chronic androgenic action.¹⁰ Low SHBG is one of the typical features of polycystic ovary syndrome (PCOS).^{1,2} Diagnosis of PCOS can involve assessment of SHBG levels to define biochemical hyperandrogenism upon calculation of the free androgen index.¹¹

Decreased SHBG levels may be associated with: inflammation processes (indicator of response to anti-inflammatory treatment), cardiovascular disease (risk factor), type 2 diabetes and breast cancer.^{11,12,13,14,15,16,17} Decreased SHBG concentrations are often seen in patients with hypothyroidism, obesity, and acromegaly.^{10,12,18}

Clinical conditions of androgen deficiency, such as male hypogonadism, are usually associated with low total testosterone or low testosterone action. Evaluation of SHBG levels is particularly recommended in the presence of conditions that alter SHBG levels, or when total testosterone is in the borderline range.^{19,20,21}

High serum SHBG concentrations have been proposed to be associated with change of diet resulting in loss of weight.^{22,23} Elderly men, late postmenopausal women, patients with hyperthyroidism and patients with cirrhosis also often show an increase in SHBG levels.^{2,24} Pregnant women have markedly higher SHBG serum concentrations due to their increased estrogen production. Specific medications, such as oral contraceptives or antiepileptic drugs can increase SHBG levels.² Hormone therapy in postmenopausal women modulates SHBG levels, depending on regimens and routes of administration.^{25,26,27}

The Elecsys SHBG assay employs two monoclonal antibodies specifically directed against human SHBG. Cross-reactivity with α_1 -fetoprotein (AFP), corticosteroid binding globulin (CBG), dihydrotestosterone (DHT), E2, fibrinogen, human immunoglobulin A (IgA), human immunoglobulin G (IgG), plasminogen, thyroxine binding globulin (TBG), testosterone, thyroglobulin (Tg), transferrin, and thyrotropin (TSH) is negligible.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 10 μ L of sample, a biotinylated monoclonal SHBG-specific antibody, and a monoclonal SHBG-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)₃²⁺)

Reagents - working solutions

The reagent rackpack is labeled as SHBG.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 Anti-SHBG-Ab~biotin (gray cap), 1 bottle, 10 mL:
Biotinylated monoclonal anti-SHBG antibody (mouse) 1.25 mg/L;
phosphate buffer 100 mmol/L, pH 7.2; preservative.
- R2 Anti-SHBG-Ab~Ru(bpy)₃²⁺ (black cap), 1 bottle, 10 mL:
Monoclonal anti-SHBG antibody (mouse) labeled with ruthenium complex 1.25 mg/L; phosphate buffer 100 mmol/L, pH 7.2; 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	7 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, or lithium heparin plasma.

Do not use EDTA plasma.

Criterion: Recovery within 90-110 % of serum value or slope 0.9-1.1 + intercept within $\pm 2x$ analytical sensitivity (LDL) + coefficient of correlation > 0.95 .

Stable for 3 days at 2-8 °C, 1 month at -20 °C (± 5 °C). Freeze only once.²⁸

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] 03052028190, SHBG CalSet, for 4 x 1.0 mL
- [REF] 11731416190, PreciControl Universal, for 4 x 3.0 mL
- [REF] 03609987190, Diluent MultiAssay, 2 x 16 mL sample diluent
- 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 1st International Standard for SHBG from the National Institute for Biological Standards and Control (NIBSC) code 95/560.

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 nmol/L, µg/mL or mg/L (selectable).

Conversion factors: nmol/L x 0.095 = µg/mL (mg/L)

µg/mL (mg/L) x 10.53 = nmol/L

Limitations - interference

The assay is unaffected by icterus (bilirubin < 1026 µmol/L or < 60 mg/dL), hemolysis (Hb < 1.8 mmol/L or < 2.9 g/dL), lipemia (Intralipid < 2700 mg/dL) and biotin (< 246 nmol/L or < 60 ng/mL).

Criterion: Recovery within ± 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 1160 IU/mL.

There is no high-dose hook effect at SHBG concentrations up to 1000 nmol/L.

In vitro tests were performed on 16 commonly used pharmaceuticals. 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

0.350-200 nmol/L (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.350 nmol/L. Values above the measuring range are reported as > 200 nmol/L (or up to 2000 nmol/L for 10-fold diluted samples).

Lower limits of measurement

Lower detection limit of the test

Lower detection limit: 0.350 nmol/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

Samples with SHBG 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 > 20 nmol/L.

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

The following table shows the results obtained from a group of 415 males and 343 females using the Elecsys SHBG assay. All subjects were apparently healthy, non-obese (BMI, body mass index ≤ 30), non-pregnant adults without intake of any contraceptive or relevant prescription drugs (study number CIM 000669). Blood samples (fasting) were taken between 6.30 am and 2.00 pm. This clinical study focusing on the Elecsys Testosterone II assay included measurements in parallel using the Elecsys SHBG assay. Please refer to the Elecsys Testosterone II package insert for SHBG values in combination with testosterone.

SHBG

	SHBG (nmol/L)		
	N	Median	5-95 th percentiles
Males (20-49 years)	241	33.2	18.3-54.1
Males (≥ 50 years)	174	40.6	20.6-76.7
Females (20-49 years)	166	67.8	32.4-128
Females (≥ 50 years)	177	62.4	27.1-128

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, pooled human sera and controls 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					
Sample	Mean nmol/L	Repeatability		Intermediate precision	
		SD nmol/L	CV %	SD nmol/L	CV %
Human serum 1	14.1	0.30	2.1	0.39	2.7
Human serum 2	44.2	1.05	2.4	1.24	2.8
Human serum 3	204	5.61	2.7	11.4	5.6
PreciControl U ^{b)} 1	34.9	0.76	2.2	0.92	2.6
PreciControl U2	19.0	0.41	2.2	0.52	2.7

b) U = Universal

cobas e 601 and cobas e 602 analyzers						
Sample	Repeatability			Intermediate precision		
	Mean nmol/L	SD nmol/L	CV %	Mean nmol/L	SD nmol/L	CV %
Human serum 1	14.9	0.17	1.1	13.7	0.24	1.8
Human serum 2	45.7	0.60	1.3	42.0	0.89	2.1
Human serum 3	219	3.76	1.7	189	7.58	4.0
PreciControl U1	35.3	0.46	1.3	33.1	0.63	1.9
PreciControl U2	19.2	0.21	1.1	18.1	0.42	2.3

Method comparison

A comparison of the Elecsys SHBG assay (y) with a commercially available SHBG test (x) using clinical samples gave the following correlations:

Number of samples measured: 109

Passing/Bablok ²⁹	Linear regression
$y = 1.17x - 3.26$	$y = 1.15x - 1.82$
$r = 0.909$	$r = 0.981$

The sample concentrations were between 11.2 and 155 nmol/L.

Analytical specificity

For the monoclonal antibodies used, non-detectable cross-reactivities were found for the following substances:

AFP, CBG, DHT, estradiol, fibrinogen, human IgA, human IgG, plasminogen, TBG, testosterone, Tg, transferrin, and TSH.

References

- Hammond GL, Wu TS, Simard M. Evolving utility of sex hormone-binding globulin measurements in clinical medicine. *Curr Opin Endocrinol Diabetes Obes.* 2012 Jun;19(3):183-9.
- Thaler MA, Seifert-Klauss V, Luppa PB. The biomarker sex hormone-binding globulin - from established applications to emerging trends in clinical medicine. *Best Pract Res Clin Endocrinol Metab.* 2015 Oct;29(5):749-60.
- Avvakumov GV, Cherkasov A, Muller YA, et al. Structural analyses of sex hormone-binding globulin reveal novel ligands and function. *Mol Cell Endocrinol.* 2010 Mar 5;316(1):13-23.
- Dunn JF, Nisula BC, Rodbard D. Transport of steroid hormones: binding of 21 endogenous steroids to both testosterone-binding globulin and corticosteroid-binding globulin in human plasma. *J Clin Endocrinol Metab.* 1981 Jul;53(1):58-68.
- Nerenz RD, Boh B. Reproductive endocrinology and related disorders. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, editors. *Tietz Textbook of Laboratory Medicine*, Saunders Elsevier, Philadelphia, 7th edition, 2023, chapter 58, p. 846-884.e11.
- Hammond GL. Plasma steroid-binding proteins: primary gatekeepers of steroid hormone action. *J Endocrinol.* 2016 Jul;230(1):R13-25.
- Vermeulen A, Verdonck L, Kaufman JM. A critical evaluation of simple methods for the estimation of free testosterone in serum. *J Clin Endocrinol Metab.* 1999 Oct;84(10):3666-72.
- Trost LW, Mulhall JP. Challenges in Testosterone Measurement, Data Interpretation, and Methodological Appraisal of Interventional Trials. *J Sex Med.* 2016 Jul;13(7):1029-46.
- Rosner W. Free estradiol and sex hormone-binding globulin. *Steroids* 2015;99:113-116.
- Pugeat M, Crave JC, Tournaire J, et al. Clinical utility of sex hormone binding globulin measurement. *Horm Res* 1996;45:148-155.
- Teede HJ, Tay CT, Laven JJE, et al. Recommendations From the 2023 International Evidence-based Guideline for the Assessment and Management of Polycystic Ovary Syndrome. *J Clin Endocrinol Metab.* 2023 Aug 15:dgad463.
- Simó R, Sáez-López C, Barbosa-Desongles A, et al. Novel insights in SHBG regulation and clinical implications. *Trends in Endocrinol Metab* 2015;26(7):376-383.
- Maggio M, Cattabiani C, Lauretani F, et al. SHBG and endothelial function in older subjects. *Int J of Cardiology* 2013;168(3):2825-2830.
- Calderon-Margalit R, Schwartz S.M, Wellons MF. Prospective Association of Serum Androgens and Sex Hormone-Binding Globulin with Subclinical Cardiovascular Disease in Young Adult Women: The "Coronary Artery Risk Development in Young Adults" Women's Study. *J Clin Endocrinol Metab* 2010;95(9):4424-4431.
- Hedderson MM, Xu F, Darbinian JA, et al. Prepregnancy SHBG Concentrations and Risk for Subsequently Developing Gestational Diabetes Mellitus. *Diabetes Care* 2014;37(5):1296-1303.
- Soriguer F, Rubio-Martín E, Fernández D, et al. Testosterone, SHBG and risk of type 2 diabetes in the second evaluation of the Pizarra cohort study. *Eur J Clin Invest* 2012;42(1):79-85.
- Fortunati N, Catalano MG, Boccuzzi G, et al. Sex Hormone-Binding (SHBG), estradiol and breast cancer. *J Mol Cell Endocrinol* 2010;316(1):86-92.
- Anderson DC. Sex-hormone-binding globulin. *Clin Endocrinol (Oxf).* 1974 Jan;3(1):69-96.
- Yeap BB, Grossmann M, McLachlan RI, et al. Endocrine Society of Australia position statement on male hypogonadism (part 1): assessment and indications for testosterone therapy. *Med J Aust.* 2016 Aug 15;205(4):173-8.
- Al-Sharefi A, Quinton R. Current National and International Guidelines for the Management of Male Hypogonadism: Helping Clinicians to Navigate Variation in Diagnostic Criteria and Treatment Recommendations. *Endocrinol Metab (Seoul).* 2020 Sep;35(3):526-540.
- Jayasena CN, Anderson RA, Llahana S, et al. Society for Endocrinology guidelines for testosterone replacement therapy in male hypogonadism. *Clin Endocrinol (Oxf).* 2022 Feb;96(2):200-219.
- Duggan C, Tapsoba JD, Stanczyk F, et al. Long-term weight loss maintenance, sex steroid hormones, and sex hormone-binding globulin. *Menopause.* 2019 Apr;26(4):417-422.
- Campbell KL, Foster-Schubert KE, Alfano CM, et al. Reduced-calorie dietary weight loss, exercise, and sex hormones in postmenopausal women: randomized controlled trial. *J Clin Oncol.* 2012 Jul 1;30(19):2314-26.
- Aribas E, Kavousi M, Laven JSE, et al. Aging, Cardiovascular Risk, and SHBG Levels in Men and Women From the General Population. *J Clin Endocrinol Metab.* 2021 Sep 27;106(10):2890-2900.
- Hofling M, Carlström K, Svane G, et al. Different effects of tibolone and continuous combined estrogen plus progestogen hormone therapy on sex hormone binding globulin and free testosterone levels--an association with mammographic density. *Gynecol Endocrinol.* 2005 Feb;20(2):110-5.
- Lu DH, Zhou SY, Xu LZ. Association between hormone replacement therapy and sex hormones in postmenopausal women: a systematic review and meta-analysis. *Eur Rev Med Pharmacol Sci.* 2023 Jun;27(11):5264-5279.
- Marina L, Sojat AS, Maseroli E, et al. Hormonal profile of menopausal women receiving androgen replacement therapy: a meta-analysis. *J Endocrinol Invest.* 2020 Jun;43(6):717-735.
- Wu AHB. *Tietz Clinical Guide To Laboratory Tests*, 4th Edition, WB Saunders Co, 2006: 982 pp.
- Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. *J Clin Chem Clin Biochem* 1988 Nov;26(11):783-790.

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).

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 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

Elecsys SHBG



GTIN

Global Trade Item Number

COBAS, NAVIFY, ELECSYS and PRECICONTROL are trademarks of Roche. INTRALIPID is a trademark of Fresenius Kabi AB.

All other product names and trademarks are the property of their respective owners.

Additions, deletions or changes are indicated by a change bar in the margin.

© 2023, Roche Diagnostics



Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

+800 5505 6606

