Elecsys Vitamin D total III

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REF		Σ	SYSTEM
			cobas e 411
09038078190	09038078500	100	**cobas e** 601
			cobas e 602

English

System information

For **cobas e** 411 analyzer: test number 2200
For **cobas e** 601 and **cobas e** 602 analyzers: Application Code Number 800

Intended use

Binding assay for the in vitro quantitative determination of total 25-hydroxyvitamin D in human serum and plasma. This assay is to be used as an aid in the assessment of vitamin D sufficiency.

The electrochemiluminescence binding assay is intended for use on **cobas e** immunoassay analyzers.

Summary

Vitamin D is a fat-soluble steroid hormone precursor that is mainly produced in the skin by exposure to sunlight. Vitamin D is biologically inert and must undergo two successive hydroxylations in the liver and kidney to become the biologically active 1,25-dihydroxyvitamin D.[1]

The two most important forms of vitamin D are vitamin D_3 (cholecalciferol) and vitamin D_2 (ergocalciferol). In contrast to vitamin D_3, the human body cannot produce vitamin D_2 which is taken up with fortified food or given by supplements. In blood vitamin D_3 and D_2 are bound to the vitamin D binding protein (VDBP) and transported to the liver where both are hydroxylated to form 25-hydroxyvitamin D. It is commonly agreed that 25-hydroxyvitamin D is the metabolite to determine the overall vitamin D status as it is the major storage form of vitamin D in the human body. This primary circulating form of vitamin D is biologically inactive with levels approximately 1000-fold greater than the circulating 1,25-dihydroxyvitamin D. The half-life of circulating 25-hydroxyvitamin D is 2-3 weeks.

Most of the 25-hydroxyvitamin D, measurable in blood circulation, is 25-hydroxyvitamin D_3 whereas 25-hydroxyvitamin D_2 reaches measurable levels only in patients taking vitamin D_2 supplements.[2,3,4] Vitamin D_2 is considered to be less effective.[5]

The most abundant product of 25-hydroxyvitamin D catabolism by 24-hydroxylase (CYP24A1) is 24,25-dihydroxyvitamin D.[6] It accounts for 2-20 % of the total circulating 25-hydroxyvitamin D, has a half-life of approximately 7 days and is present in blood circulation at concentrations of up to approximately 10 nmol/L.[6,7,8]

Vitamin D is essential for bone health. In children, severe deficiency leads to bone-malformation, known as rickets. Milder degrees of insufficiency are believed to cause reduced efficiency in the utilization of dietary calcium.[9] Vitamin D deficiency causes muscle weakness; in elderly, the risk of falling has been attributed to the effect of vitamin D on muscle function.[10] Vitamin D deficiency is a common cause of secondary hyperparathyroidism.[11,12] Elevations of parathyroid hormone levels, especially in elderly vitamin D deficient adults can result in osteomalacia, increased bone turnover, reduced bone mass and risk of bone fractures.[13] Low 25-hydroxyvitamin D concentrations are also associated with lower bone mineral density.[14] In conjunction with other clinical data, the results may be used as an aid in the assessment of bone metabolism.

So far, vitamin D has been shown to affect expression of over 200 different genes. Insufficiency has been linked to diabetes, different forms of cancer, cardiovascular disease, autoimmune diseases, respiratory diseases and innate immunity.[2]

The Elecsys Vitamin D total III assay employs a vitamin D binding protein labeled with a ruthenium complex[a)] as capture protein to bind 25-hydroxyvitamin D_3 and 25-hydroxyvitamin D_2. Cross-reactivity to 24,25-dihydroxyvitamin D is blocked by a specific monoclonal antibody.

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

Test principle

Competition principle. Total duration of assay: 27 minutes.

- 1st incubation: By incubating the sample (15 µL) with pretreatment reagent 1 and 2, bound 25-hydroxyvitamin D is released from the VDBP.
- 2nd incubation: By incubating the pretreated sample with the ruthenium labeled vitamin D binding protein, a complex between the 25-hydroxyvitamin D and the ruthenylated VDBP is formed. A specific unlabeled antibody binds to 24,25-dihydroxyvitamin D present in the sample and inhibits cross-reactivity to this vitamin D metabolite.
- 3rd incubation: After addition of streptavidin-coated microparticles and 25-hydroxyvitamin D labeled with biotin, unbound ruthenylated labeled vitamin D binding proteins become occupied. A complex consisting of the ruthenylated vitamin D binding protein and the biotinylated 25-hydroxyvitamin D is formed and 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 (M, R1, R2) and the pretreatment reagents (PT1, PT2) are labeled as VITDT 3.

PT1 Pretreatment reagent 1 (white cap), 1 bottle, 4 mL:
Dithiothreitol 1 g/L, pH 5.5.

PT2 Pretreatment reagent 2 (gray cap), 1 bottle, 4 mL:
Sodium hydroxide 57.5 g/L.

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

R1 Vitamin D binding protein-Ru/$(bpy)_3^{2+}$(gray cap), 1 bottle, 9 mL:
Ruthenium labeled vitamin D binding protein 150 µg/L; bis-tris propane buffer 200 mmol/L; albumin (human) 25 g/L; pH 7.5; preservative.

R2 25-hydroxyvitamin D~biotin (black cap), 1 bottle, 8.5 mL:
Biotinylated 25-hydroxyvitamin D 20 µg/L; bis-tris propane buffer 200 mmol/L; pH 8.6; 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:

Danger

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

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H317	May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[15,16]

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	56 days (8 weeks)
on the analyzers	28 days (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- and K_3-EDTA plasma.

Plasma tubes containing separating gel can be used.

Criterion: Slope 0.9-1.1 + coefficient of correlation ≥ 0.95 and within a bias ≤ ± 15 % at the medical decision point (30 ng/mL).

Stable for 8 hours at 20-25 °C, 4 days at 2-8 °C, 24 weeks 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.

Adapt preanalytics protocol if required.

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 09038116190, CalSet Vitamin D total III, for 4 x 1.0 mL
- REF 09038124190, PreciControl Vitamin D total III, for 6 x 1.0 mL
- REF 11732277122, Diluent Universal, 2 x 16 mL sample diluent or
  REF 03183971122, Diluent Universal, 2 x 36 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 03004899190, PreClean M, 5 x 600 mL detection cleaning solution
- 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.

cobas e 601 and **cobas e** 602 analyzers: PreClean M solution is necessary.

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 internal standards which are traceable to the ID-LC-MS/MS 25-hydroxyvitamin D Reference Measurement Procedure.[17,18] The ID-LC-MS/MS is traceable to the National Institute of Standards and Technology Standard Reference Material 2972.[19]

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 3 months (12 weeks) 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 Vitamin D total III.

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.

Calculation

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

Conversion factors: nmol/L x 0.40 = ng/mL

ng/mL x 2.50 = nmol/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	≤ 1129 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.373 mmol/L or ≤ 600 mg/dL
Intralipid	≤ 300 mg/dL
Biotin	≤ 2456 nmol/L or ≤ 600 ng/mL
Rheumatoid factors	≤ 1200 IU/mL

Criterion: ± 2.5 ng/mL of initial value for samples ≤ 20.0 ng/mL, within ± 10 % of initial value for samples > 20.0 ng/mL to 50.0 ng/mL and within ± 15 % of initial value for samples > 50.0 ng/mL.

The assay result is not affected in samples with biotin concentrations up to 600 ng/mL (2456 nmol/L). Some studies have shown that serum concentrations of biotin can reach up to 355 ng/mL within the first hour after biotin ingestion for subjects consuming supplements of 20 mg biotin per day.[20] Concentrations up to 1160 ng/mL have been described after a single dose of 300 mg biotin used in controlled settings.[21]

If the biotin threshold for the assay is exceeded the result will have a positive bias (e.g. 2.63 ng/mL at 930 ng/mL).

Pharmaceutical substances

In vitro tests were performed on 17 commonly used pharmaceuticals. No interference with the assay was found.

In addition, the following special drugs were tested. No interference with the assay was found.

Special drugs

Drug	Concentration tested mg/L
EinsAlpha (alfacalcidol)	0.0018
ZEMPLAR (paricalcitol)	0.0012
Rocaltrol (calcitriol)	0.0010

Drug interferences are measured based on recommendations given in CLSI guidelines EP07 and EP37 and other published literature. Effects of concentrations exceeding these recommendations have not been characterized.

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

3.00-120 ng/mL or 7.50-300 nmol/L (defined by the Limit of Detection and the maximum of the master curve). Values below the Limit of Detection are reported as < 3.00 ng/mL (< 7.50 nmol/L). Values above the measuring range are reported as > 120 ng/mL (> 300 nmol/L) or up to 240 ng/mL (600 nmol/L) for 2-fold diluted samples.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 2.0 ng/mL (5.0 nmol/L)

Limit of Detection = 3.0 ng/mL (7.5 nmol/L)

Limit of Quantitation = 6.0 ng/mL (15.0 nmol/L)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

Dilution

Samples with 25-hydroxyvitamin D concentrations above the measuring range can be manually diluted with Diluent Universal or a suitable human serum with a low analyte concentration. The recommended dilution is 1:2. The concentration of the diluted sample must be ≥ 40 ng/mL (≥ 100 nmol/L). After manual dilution, multiply the results by the dilution factor 2. The endogenous analyte concentration of the human serum used for dilution has to be taken into account.

Expected values

Due to different standardizations between methods, result variation may arise.

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

Clinical assessment should be taken into consideration when interpreting results. It should be taken into consideration that differences in 25-hydroxyvitamin D levels may exist with respect to gender, age, season, geographical latitude and ethnic groups.[22,23]

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Currently there is no standard definition of the optimal vitamin D status. Most experts agree that vitamin D deficiency should be defined as 25-hydroxyvitamin D of ≤ 20 ng/mL (≤ 50 nmol/L).[22] Vitamin D insufficiency is recognized as 21-29 ng/mL.[22] Similarly, the US National Kidney Foundation considers levels < 30 ng/mL to be insufficient or deficient.[24] The preferred level for 25-hydroxyvitamin D by many experts is now recommended to be ≥ 30 ng/mL (≥ 75 nmol/L).[22,23,25,26] Other clinical references may show different values.

A reference range study was conducted with samples from apparently healthy donors from the United States. Samples were collected from southern, middle and northern sites in summer and winter. There were approximately equal numbers of males and females, and approximately 30 % of the donors had dark complexion. The age range was 22 to 79 years.
The values given are for information only and may vary from other published data.

			Season			
	All (n = 463)		Summer (n = 245)		Winter (n = 218)	
Unit	ng/mL	nmol/L	ng/mL	nmol/L	ng/mL	nmol/L
Mean	26.6	66.5	29.2	73.1	23.6	59.1
Median	25.7	64.1	27.7	69.2	22.8	57.1
2.5th percentile	10.2	25.4	12.5	31.3	9.38	23.5
97.5th percentile	49.4	123	52.4	131	44.1	110

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, samples and controls in a protocol (EP05-A3) 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
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS[b)] 1	14.7	36.8	1.10	2.75	7.5
HS 2	22.2	55.5	1.19	2.98	5.4
HS 3	35.8	89.5	1.73	4.33	4.8
HS 4	59.3	148	2.28	5.70	3.8
HS 5	109	273	2.59	6.48	2.4
PC[c)] Vitamin D total III 1	23.7	59.3	1.29	3.23	5.4
PC Vitamin D total III 2	42.9	107	1.68	4.20	3.9

b) HS = human serum

c) PC = PreciControl

cobas e 411 analyzer					
			Intermediate precision		
Sample	Mean		SD		CV
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS 1	14.7	36.8	1.25	3.13	8.5
HS 2	22.2	55.5	1.31	3.28	5.9
HS 3	35.8	89.5	1.88	4.70	5.2
HS 4	59.3	148	2.28	5.70	3.8
HS 5	109	273	2.77	6.93	2.5
PC Vitamin D total III 1	23.7	59.3	1.34	3.35	5.7
PC Vitamin D total III 2	42.9	107	1.99	4.98	4.6

cobas e 601 and **cobas e** 602 analyzers					
			Repeatability		
Sample	Mean		SD		CV
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS 1	12.3	30.8	0.905	2.26	7.4
HS 2	28.7	71.8	1.28	3.20	4.4
HS 3	33.0	82.5	1.39	3.48	4.2
HS 4	61.0	153	1.39	3.48	2.3
HS 5	112	280	3.37	8.43	3.0
PC Vitamin D total III 1	23.0	57.5	1.27	3.18	5.5
PC Vitamin D total III 2	41.9	105	1.52	3.80	3.6

cobas e 601 and **cobas e** 602 analyzers					
			Intermediate precision		
Sample	Mean		SD		CV
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS 1	12.3	30.8	1.20	3.00	9.8
HS 2	28.7	71.8	1.74	4.35	6.0
HS 3	33.0	82.5	1.85	4.63	5.6
HS 4	61.0	153	2.23	5.58	3.7
HS 5	112	280	3.65	9.13	3.3
PC Vitamin D total III 1	23.0	57.5	1.49	3.73	6.5
PC Vitamin D total III 2	41.9	105	1.87	4.68	4.5

Method comparison

A comparison of the Elecsys Vitamin D total III assay (y) using the CDC Verification Samples with concentrations assigned by the CDC Vitamin D Reference Laboratory by ID-LC-MS/MS (x) gave the following correlations (ng/mL):

Number of samples measured: 157

Deming[27,28]	Passing Bablok[29]
y = 0.981x + 0.795	y = 0.979x + 0.675
r = 0.982	r = 0.908

The sample concentrations were between 5.64 ng/mL (14.1 nmol/L) and 118 ng/mL (295 nmol/L).

Analytical specificity

A study was performed based on guidance from CLSI EP07-A2 to evaluate the cross-reactivity of the assay with other vitamin D metabolites. Samples containing the cross-reactants were prepared at three 25-hydroxyvitamin D concentrations (approximately 25, 40 and 60 ng/mL). The % cross-reactivity was calculated for each sample using the equation below and normalized to the cross-reactivity of 25-hydroxyvitamin D_3.[30]

$$\%\ \text{cross-reactivity} = \frac{(\text{mean conc. of spiked sample} - \text{mean conc. of unspiked sample})}{\text{spiked concentration}} \times 100\ \%$$

The mean results from this study are summarized in the following table:

Cross-reactant	**Concentration added ng/mL**	**Mean cross-reactivity %**
25-hydroxyvitamin D_3	50	100
25-hydroxyvitamin D_2	50	105.0
24,25-dihydroxyvitamin D_3	100	8.1
3-epi-25-hydroxyvitamin D_3	50	122.4
3-epi-25-hydroxyvitamin D_2	50	103.6

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Cross-reactant	Concentration added ng/mL	Mean cross-reactivity %
1,25-dihydroxyvitamin D_3	100	n. d.[d)]
1,25-dihydroxyvitamin D_2	100	0.4
Vitamin D_3	1000	0.8
Vitamin D_2	1000	0.7

d) n. d. = not detectable

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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

Elecsys Vitamin D total III

cobas®

CE 0123

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