

# Vitamin D total II

cobas®

REF		SYSTEM
07464215 190	100	MODULAR ANALYTICS E170 cobas e 411 cobas e 601 cobas e 602

## English

### Intended use

This assay is intended for the 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 Elecsys and **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.<sup>1</sup>

The two most important forms of vitamin D are vitamin D<sub>3</sub> (cholecalciferol) and vitamin D<sub>2</sub> (ergocalciferol). In contrast to vitamin D<sub>3</sub>, the human body cannot produce vitamin D<sub>2</sub> which is taken up with fortified food or given by supplements. In human plasma vitamin D<sub>3</sub> and D<sub>2</sub> are bound to the vitamin D binding protein 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 serum, is 25-hydroxyvitamin D<sub>3</sub> whereas 25-hydroxyvitamin D<sub>2</sub> reaches measurable levels only in patients taking vitamin D<sub>2</sub> supplements.<sup>2,3,4</sup> Vitamin D<sub>2</sub> is considered to be less effective.<sup>5</sup>

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

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.<sup>9</sup> Vitamin D deficiency causes muscle weakness; in elderly, the risk of falling has been attributed to the effect of vitamin D on muscle function.<sup>10</sup> Vitamin D deficiency is a common cause of secondary hyperparathyroidism.<sup>11,12</sup> 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.<sup>13</sup> Low 25-hydroxyvitamin D concentrations are also associated with lower bone mineral density.<sup>14</sup> 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 and innate immunity.<sup>2</sup>

The Elecsys Vitamin D total II assay employs a vitamin D binding protein (VDBP) labeled with a ruthenium complex<sup>a)</sup> as capture protein to bind 25-hydroxyvitamin D<sub>3</sub> and 25-hydroxyvitamin D<sub>2</sub>. Cross-reactivity to 24,25-dihydroxyvitamin D is blocked by a specific monoclonal antibody.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)<sub>3</sub><sup>2+</sup>)

### Test principle

Competition principle. Total duration of assay: 27 minutes.

- 1st incubation: By incubating the sample (20 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 VitDII.

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 28 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)<sub>3</sub><sup>2+</sup> (gray cap), 1 bottle, 6.5 mL:

Ruthenium labeled vitamin D binding protein 100 µg/L; bis-tris propane buffer 100 mmol/L; albumin (human) 40 g/L; pH 6.4; preservative.

R2 25-hydroxyvitamin D~biotin (black cap), 1 bottle, 6.5 mL:

Biotinylated 25-hydroxyvitamin D 140 µg/L; bis-tris propane buffer 100 mmol/L; pH 8.6; preservative.

### Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. 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.

### Prevention:

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

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P301 + P330 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  
+ P331

P303 + P361 IF ON SKIN (or hair): Take off immediately all contaminated  
+ P353 clothing. Rinse skin with water/shower.

P304 + P340 IF INHALED: Remove person to fresh air and keep  
+ P310 comfortable for breathing.  
Immediately call a POISON CENTER/ doctor

P305 + P351 IF IN EYES: Rinse cautiously with water for several  
+ P338 minutes. Remove contact lenses, if present and easy to do.  
+ P310 Continue rinsing. Immediately call a POISON CENTER/  
doctor.

P390 Absorb spillage to prevent material damage.

Product safety labeling primarily 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 applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

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.<sup>15,16</sup>

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

Plasma tubes containing separating gel can be used.

Criterion: Method comparison serum versus plasma, slope 0.9-1.1 + intercept within  $\pm 3$  ng/mL + coefficient of correlation  $\geq 0.95$ .

Serum, Li-heparin, K<sub>2</sub>- and K<sub>3</sub>-EDTA plasma: 25-hydroxyvitamin D is stable for 8 hours at 20-25 °C, 4 days at 2-8 °C, 24 weeks at -20 °C ( $\pm 5$  °C).

Freeze only once.

The stability of 25-hydroxyvitamin D found with the Elecsys Vitamin D total II assay is in line with earlier studies using a vitamin D binding protein assay and mass spectrometry.<sup>17</sup>

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] 07464240190, Vitamin D total II CalSet, for 4 x 1.0 mL
- [REF] 07464266190, PreciControl Vitamin D total II, 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
- MODULAR ANALYTICS E170 or **cobas e** analyzer

Accessories 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

Accessories for MODULAR ANALYTICS E170, **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

Accessories 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 (except for the **cobas e** 602 analyzer).

MODULAR ANALYTICS E170, **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.

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## 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.<sup>18,19</sup> The ID-LC-MS/MS is traceable to the National Institute of Standards and Technology Standard Reference Material 2972.<sup>20</sup>

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). 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 II.

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:

$$\text{nmol/L} \times 0.40 = \text{ng/mL}$$

$$\text{ng/mL} \times 2.50 = \text{nmol/L}$$

## 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	≤ 123 nmol/L or ≤ 30 ng/mL

Criterion: ± 2.0 ng/mL of initial value for samples ≤ 20 ng/mL and within ± 10 % of initial value for samples > 20 ng/mL.

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.

### Pharmaceutical substances

In vitro tests were performed on 16 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)	0.003
ZEMPLAR (paricalcitol)	0.002

Drug	Concentration tested mg/L
Rocaltrol (calcitriol)	0.0017

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

3-100 ng/mL or 7.5-250 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 ng/mL (< 7.5 nmol/L). Values above the measuring range are reported as > 100 ng/mL (> 250 nmol/L).

### Lower limits of measurement

*Limit of Blank, Limit of Detection and Limit of Quantitation*

Limit of Blank = 2 ng/mL (5 nmol/L)

Limit of Detection = 3 ng/mL (7.5 nmol/L)

Limit of Quantitation = 5 ng/mL (12.5 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 95<sup>th</sup> percentile value from  $n \geq 60$  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. Clinical assessment should be taken into consideration when interpreting results.

### Health based reference values (recommended for use):

Currently there is no standard definition of the optimal vitamin D status. Many specialists consider the commonly used population based reference values too low. Health based reference values are recommended to replace population based reference values.<sup>21</sup>

Most experts agree that vitamin D deficiency should be defined as 25-hydroxyvitamin D of ≤ 20 ng/mL (≤ 50 nmol/L).<sup>22</sup> Vitamin D insufficiency is recognized as 21-29 ng/mL.<sup>22</sup> Similarly, the US National Kidney Foundation considers levels < 30 ng/mL to be insufficient or deficient.<sup>23</sup>

The preferred level for 25-hydroxyvitamin D by many experts is now recommended to be ≥ 30 ng/mL (≥ 75 nmol/L).<sup>22,24,25,26</sup>

### Reference values measured in an apparently healthy population:

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.<sup>22,24</sup>

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

*Population based reference ranges should not be taken as clinical cutoff to recommend or dissuade from vitamin D supplementation. Guidance for supplementation should be taken from recent literature.<sup>22,23</sup>*

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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 21 to 88 years.

The values given are for information only and may vary from other published data.

	Season					
	All (n = 400)		Summer (n = 197)		Winter (n = 203)	
Unit	ng/mL	nmol/L	ng/mL	nmol/L	ng/mL	nmol/L
Mean	25.7	64.3	28.9	72.3	22.6	56.5
2.5 <sup>th</sup> percentile	7.61	19.0	11.1	27.8	5.65	14.1
97.5 <sup>th</sup> percentile	55.5	139	60.3	151	52.3	131

## 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 <sup>b)</sup> 1	11.1	27.8	0.725	1.81	6.6
HS 2	20.8	52.0	0.849	2.12	4.1
HS 3	25.6	64.0	0.774	1.94	3.0
HS 4	47.5	119	0.749	1.87	1.6
HS 5	92.6	232	1.76	4.40	1.9
PC <sup>c)</sup> Vitamin D total II 1	15.4	38.5	0.748	1.87	4.8
PC Vitamin D total II 2	29.1	72.8	1.04	2.60	3.6

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	11.1	27.8	0.965	2.41	8.7
HS 2	20.8	52.0	1.09	2.73	5.2
HS 3	25.6	64.0	1.43	3.58	5.6
HS 4	47.5	119	1.77	4.43	3.7
HS 5	92.6	232	2.40	6.00	2.6
PC Vitamin D total II 1	15.4	38.5	1.30	3.25	8.4
PC Vitamin D total II 2	29.1	72.8	1.56	3.90	5.4

MODULAR ANALYTICS E170, <b>cobas e</b> 601 and <b>cobas e</b> 602 analyzers					
			Repeatability		
Sample	Mean		SD		CV
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS 1	10.5	26.3	0.783	1.96	7.4

MODULAR ANALYTICS E170, <b>cobas e 601</b> and <b>cobas e 602</b> analyzers					
Sample			Repeatability		
	Mean		SD		CV
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS 2	21.1	52.8	0.968	2.42	4.6
HS 3	24.9	62.3	0.973	2.43	3.9
HS 4	54.9	137	1.72	4.30	3.1
HS 5	94.3	236	2.65	6.63	2.8
PC Vitamin D total II 1	15.9	39.8	0.919	2.30	5.8
PC Vitamin D total II 2	29.4	73.5	1.24	3.10	4.2

MODULAR ANALYTICS E170, <b>cobas e</b> 601 and <b>cobas e</b> 602 analyzers					
			Intermediate precision		
Sample	Mean		SD		CV
	ng/mL	nmol/L	ng/mL	nmol/L	%
HS 1	10.5	26.3	0.934	2.34	8.9
HS 2	21.1	52.8	1.24	3.10	5.9
HS 3	24.9	62.3	1.23	3.08	4.9
HS 4	54.9	137	2.09	5.23	3.8
HS 5	94.3	236	3.59	8.98	3.8
PC Vitamin D total II 1	15.9	39.8	1.15	2.88	7.2
PC Vitamin D total II 2	29.4	73.5	1.46	3.65	5.0

## Method comparison

A comparison of the Elecsys Vitamin D total II assay (y) using samples measured with ID-LC-MS/MS 25-hydroxyvitamin D Reference Measurement Procedure (x) gave the following correlations (ng/mL):

Number of samples measured: 111

Deming<sup>27,28</sup>

$$y = 0.954x - 0.707$$

$$r = 0.982$$

Passing Bablok<sup>29</sup>

$$y = 0.937x - 0.360$$

$$r = 0.902$$

The sample concentrations were between approximately 5.6 ng/mL (14 nmol/L) and 93 ng/mL (233 nmol/L).

## Analytical specificity

The specificity was assessed at 50 % B<sub>0</sub> and the results are summarized in the following table:

Cross-reactant	Cross-reactivity %
25-hydroxyvitamin D <sub>3</sub>	100
25-hydroxyvitamin D <sub>2</sub>	94
24,25-dihydroxyvitamin D <sub>3</sub>	13
C3-epimer of 25-hydroxyvitamin D <sub>3</sub>	109
C3-epimer of 25-hydroxyvitamin D <sub>2</sub>	83
1,25-dihydroxyvitamin D <sub>3</sub>	n. d. <sup>d)</sup>
1,25-dihydroxyvitamin D <sub>2</sub>	n. d.
Vitamin D <sub>3</sub>	n. d.
Vitamin D <sub>2</sub>	n. d.

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, the product information 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.

## Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

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

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