Elecsys Cortisol III Urine

cobas®

Calculation

The analyzer automatically calculates the analyte concentration of each sample (either in nmol/L, µg/dL or µg/L).

Conversion factors:

nmol/L x 0.03625 = µg/dL

nmol/L x 0.3625 = µg/L

µg/dL x 27.586 = nmol/L

µg/L x 2.7586 = nmol/L

Manual calculation for urinary free cortisol, cortisol excretion over 24 hours (cortisol concentration/24 h): Multiply the analyzer results by the volume of the 24-hour urine (L/24 h). When the analyzer result is given in µg/dL, multiply it again by 10 in order to achieve a result given in µg/24 h.

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	≤ 1130 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.621 mmol/L or ≤ 1000 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 14735 nmol/L or ≤ 3600 ng/mL
Rheumatoid factors	≤ 1200 IU/mL
IgG	≤ 7.0 g/dL
IgA	≤ 1.6 g/dL
IgM	≤ 1.0 g/dL
Human serum albumin	≤ 4.9 g/dL
Creatinine	≤ 5 mmol/L
Glucose	≤ 5 mmol/L
NaCl	≤ 750 mmol/L
Urea	≤ 350 mmol/L

Criterion: For concentrations of 7.5-42 nmol/L the deviation is ≤ 4.2 nmol/L. For concentrations > 42-500 nmol/L the deviation is ≤ 10 %.

Pharmaceutical substances

In vitro tests were performed on 12 commonly used pharmaceuticals. No interference with the assay was found.

At concentrations corresponding to the daily therapeutic dose, the special drugs prednisolone and hydrocortisone caused elevated concentrations of cortisol.
For the special drug 6-methylprednisolone, no interference was observed for concentrations ≤ 0.157 mg/dL.

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

Special drugs

Drug	Concentration tested mg/dL
Amlodipine	0.008
Betamethasone	0.0345
Beclomethasone	0.000631
Budenoside	0.00063
Canrenone	0.075
Dexamethasone	1.20
Fludrocortisone	0.120
Fluticasone propionate	0.0003
HCT (hydrochlorothiazide)	0.113
Lisinopril	0.025
Losartan potassium	0.092
Metformin	1.20
Metoprolol	0.150
Mometasone	0.000045
Prednisone	0.010
Spironolactone	0.0555
Triamterene	0.059
Valsartan	1.17
Verapamil	0.160
Triamcinolone	0.003
Atorvastatin	0.075
Danazol	0.030
Diclofenac	2.40
β-Sitosterol	1.00

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.

Pregnancy, contraceptives and estrogen therapy give rise to elevated cortisol concentrations.
During metyrapon tests, 11-deoxycortisol levels are elevated. Falsely elevated cortisol values may be determined due to cross-reactivity (see section "Analytical specificity").
Patients suffering from 21-hydroxylase deficiency exhibit elevated 21-deoxycortisol levels and this can also give rise to falsely elevated cortisol results.

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

7.50-500 nmol/L or 0.272-18.1 µg/dL (defined by the Limit of Detection and the maximum of the master curve). Values below the Limit of Detection are reported as < 7.50 nmol/L (< 0.272 µg/dL). Values above the measuring range are reported as > 500 nmol/L (> 18.1 µg/dL).

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 4.00 nmol/L (0.145 µg/dL)

Limit of Detection = 7.50 nmol/L (0.272 µg/dL)

Limit of Quantitation = 10.0 nmol/L (0.363 µg/dL)

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 defined as the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error of ≤ 30 %.

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The sample concentrations were between 20.7 and 482 nmol/L or 0.750 and 17.5 µg/dL (Elecsys Cortisol III Urine assay).

Analytical specificity

For the urine application of the Elecsys Cortisol III Urine assay, the following cross-reactivities (in %) were found at the respective cross-reactant concentration, tested with a cortisol concentration of approximately 17 nmol/L (0.6 µg/dL):

Cross-reactant	Concentration tested µg/dL	Cross-reactivity %
11-Deoxycorticosterone	100	0.174
11-Deoxycortisol	50	24.3
17α-Hydroxyprogesterone	1000	0.412
21-Deoxycortisol	100	2.33
Corticosterone	750	0.368
Cortisone	500	1.49
Androstenedione	100	n. d.[e)]
DHEAS	1000	n. d.
DHEA	1000	n. d.
Progesterone	1000	0.00930
Testosterone	1000	n. d.
Estradiol	1000	n. d.
Estriol	1000	n. d.
Estrone	1000	n. d.
Aldosterone	1000	n. d.
Pregnenolone	1000	n. d.
17α-Hydroxypregnenolone	1000	0.0417
11β-Hydroxyprogesterone	1000	0.0173
Pregnanetriol	1000	n. d.
6α-Hydroxycortisol	100	n. d.
6β-Hydroxycortisol	100	0.0698
Cortisol-21 glucuronide	1000	0.0301
Allotetrahydrocortisol	10	11.3
Cortisol-21-sulfate	1000	n. d.
β-Cortol	1000	n. d.
β-Cortolone	1000	n. d.
Pregnanediol	1000	n. d.
Tetrahydrocortisol	10	n. d.

e) n. d. = not detectable

References

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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

CE 0123

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