

cobas e 411 Elecsys Assays Specifications



Chers utilisateurs, nous vous prions de trouver ci dessous les spécifications de répétabilité et reproductibilité pour les modules cobas e 411.

Dans cette mise à jour de Janvier 2023 ont été ajoutés :

- Les tests Elecsys®présentant un seuil de tolérance augmenté à la biotine : HSV-1 et 2, Anti-HCV II, Chagas, CMV IgG et IgG avidity, HTLV-I/II, ACTH, AFP, PIVKA-II et Vitamin active B12
- Les nouveaux tests Elecsys®FT4 IV, Anti-HAV II, Panel EBV (IgM, EBNA IgG, VCA IgG), Vitamin D Total III, AFP-L3, IGRA-SARS-CoV-2

| Les barres verticales dans les marges signalent les dernières modifications.

Utilisation des données :

Les colonnes 1 et 3, Specified repeatability (within-run precision) et Specified intermediate precision (within lab preci.) correspondent respectivement aux spécifications fournisseurs de répétabilité et de reproductibilité.

Les colonnes 2 et 4, Internal eval. Repeatability et Internal eval. Intermediate prec. présentent des résultats d'évaluations interne, ces données ne doivent pas être considérées comme des spécifications fournisseur.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
FT3 III	LEMUR - 3 pmol/L ≤ 0.15 pmol/L SD > 3 pmol/L to HEMR ≤ 5% CV	0.064 pmol/L SD 1.9, 1.4, 1.6, 0.8% CV	LEMUR - 3 pmol/L ≤ 0.25 pmol/L SD > 3 pmol/L to HEMR ≤ 8% CV	0.096 pmol/L 3.2, 2.4, 1.8, 1.1% CV
FT4 III	0.5 - 6 pmol/l ≤ 0.3 pmol/l SD > 6-100 pmol/l ≤ 5% CV	0.089 pmol/l SD 1.8, 1.7, 2.4, 1.6, 2.1% CV	0.5 - 6 pmol/l ≤ 0.5 pmol/l SD > 6-100 pmol/l ≤ 8% CV	0.166 pmol/l 3.5, 3, 5.9, 3, 3.4% CV
FT4 IV	LEMUR to 6 pmol/L ≤ 0.3 pmol/L SD > 6 pmol/L to HEMR ≤ 5% CV	0.040 pmol/L SD 1.1, 1.0, 1.3, 1.6% CV	LEMUR to 6 pmol/L ≤ 0.5 pmol/L SD > 6 pmol/L to HEMR ≤ 8% CV	0.089 pmol/l 2.0, 1.7, 2.4, 2.8% CV
T3	LEMUR - 0,7 nmol/l ≤ 0,040 nmol/l SD 0.7-1.2 nmol/l ≤ 6% CV 1.2-2.5 nmol/l ≤ 8% CV 2.5 nmol/l -HEMR ≤ 10% CV	0,028 nmol/l SD 5.1% CV 4.7, 4.8% CV 5.2, 6.5, 4.6% CV	LEMUR - 0,7 nmol/l ≤ 0,050 nmol/l SD 0.7-1.2 nmol/l 8% CV 1.2-2.5nmol/l 8% CV 2.5 nmol/l -HEoMR 11% CV	0,040 nmol/l SD 6.8% CV 5.7, 5.1% CV 7.3, 7.4, 6.4% CV
T4	LEMUR - 35 nmol/l ≤ 1.75 nmol/l SD 35-65 nmol/l ≤ 5% CV 65 nmol/l -HEMR ≤ 3% CV	0.232/0.394 nmol/L SD 2.6, 2.4% CV 1.6, 1.9, 2.3% CV	LEMUR - 35 nmol/l ≤ 2.45 nmol/l SD 35-65 nmol/l ≤ 7% CV 65-160 nmol/l ≤ 4% CV 160 nmol/l -HEMR ≤ 5% CV	0,810 / 1,11 nmol/l SD 5.5, 5.1% CV 3.9% CV 4.1, 4.0% CV
TSH	LEMUR -0.2 µU/ml ≤ 0.01 µIU/ml SD > 0.2-100 µIU/ml ≤ 5% CV	0.001, 0.003 µIU/ml SD 1.5, 1.2, 1.7% CV	LEMUR -0.2 µU/ml ≤ 0.02 µIU/ml SD > 0.2-100 µIU/ml ≤ 10% CV	0.001, 0.009 µIU/ml SD 4.7, 4.6, 4, 2.4, 3.8% CV

The system to system precision is defined as intermediate precision x 1.5 e.g.
6% intermediate precision = 9% system to system precision, when not specified for the test.

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
T-uptake	0.6-1.4 TBI 4% CV < 0.6 TBI (not specified) > 1.4 TBI (not specified)	2.2, 2.4, 3.3% CV 5.1% CV 0.7% CV	0.6-0.9 TBI 5% CV 0.9-1.4 TBI 4% CV < 0.6 TBI (not specified) > 1.4 TBI (not specified)	3.7, 2.7, 3.4% CV 11.7% CV 0.9% CV
Tg II	LEMUR – 0.5 ng/ml SD ≤ 0.04 ng/ml > 0.5 ng/ml - HEMR ≤ 8% CV	0.009 ng/ml SD 2.3, 1.3, 1.9, 1.7% CV	LEMUR – 0.5 ng/ml SD ≤ 0.05 ng/ml > 0.5 ng/ml - HEMR ≤ 10% CV	0.013 ng/ml SD 2.9, 1.8, 2.3, 2.2% CV
Calcitonin	LEMUR to 10 pg/mL SD ≤ 0.5 pg/mL > 10 pg/mL to HEMR CV ≤ 5.0 %	0.080 pg/mL SD 3.1, 2.4, 4.4% CV	LEMUR to 10 pg/mL SD ≤ 0.6 pg/mL > 10 pg/mL to HEMR CV ≤ 6.0 %	0.120 pg/mL SD 4.7, 4.6, 5.7% CV
Anti-Tg	50-75 IU/ml < 15% CV 75-1000 IU/ml < 8% CV 1000-2000 IU/ml < 13% CV > 2000 IU/ml < 18% CV	4.9% CV 5.5, 5.6, 5.1, 4.6% CV 6.5% CV 5.6% CV	50-75 IU/ml < 20% CV 75-1000 IU/ml < 10% CV 1000-2000 IU/ml < 15% CV > 2000 IU/ml < 20% CV	8.7% CV 7.2, 6.7, 7.2, 5.9% CV 8% CV 6.3% CV
Anti-TPO	15-40 IU/ml ≤ 10% CV > 40 IU/ml ≤ 7% CV	6, 8.8, 7.1% CV 3.4, 2.8% CV	15-40 IU/ml ≤ 15% CV > 40 IU/ml ≤ 10% CV	6.7, 11, 7.7% CV 4, 4.3% CV
Anti-TSHR	1.1-5 IU/l ≤ 0.3 IU/l SD ≥5-40 IU/l < 6% CV	0.097, 0.157, 0.112, 0.155 IU/l SD 1.5, 0.8, 2.2% CV	1.1-5 IU/l ≤ 0.35 IU/l SD ≥5-40 IU/l < 7% CV	0.17, 0.187, 0.173, 0.256 IU/L SD 1.8, 1.3, 2.8% CV
CK-MB	0.3-5 ng/ml 0.15 ng/ml SD >5-15 ng/ml ≤ 3% CV >15 ng/ml ≤ 5% CV	0.02, 0.06 ng/ml 1.3% CV 1.4, 1.2% CV	0.3-5 ng/ml 0.25 ng/ml SD >5-15 ng/ml ≤ 5% CV >15 ng/ml ≤ 10% CV	0.03, 0.1 ng/ml 2% CV 2.6, 2.0% CV
GDF-15	LEMUR-800 pg/mL ≤ 40 pg/mL SD > 800 pg/mL – HEMR ≤ 5% CV	10,2 pg/mL SD 2,3, 2,0, 1,4, 1,5, 1,6, 1,5% CV	LEMUR-800 pg/mL ≤ 80 pg/mL SD > 800 pg/mL – HEMR ≤ 10% CV	27,8 pg/mL SD 4,8, 4,6, 4,6, 4,8, 4,6, 4,4% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
Myoglobin STAT	15-50 ng/ml < 8% CV	2.1% CV	15-50 ng/ml < 10% CV	2.6% CV
	50-500 ng/ml < 5% CV	2.9, 1.3% CV	50-500 ng/ml < 6% CV	3.6, 1.6% CV
	> 500 ng/ml < 8% CV	2.9, 3.4, 5.3, 1.9% CV	> 500 ng/ml < 10% CV	3.8, 4.0, 6.7, 2.3% CV
proBNP II	LEMUR-50 pg/ml ≤ 5 pg/ml SD	1.7 pg/ml SD	LEMUR-50 pg/ml ≤ 6 pg/ml SD	2.95 pg/ml SD
	>50-100 pg/ml ≤ 10% CV	4.7% CV	>50-100 pg/ml ≤ 13% CV	7.8% CV
	>100-250 pg/ml ≤ 5% CV	2.4% CV	>100-250 pg/ml ≤ 8% CV	5.7% CV
	>250 pg/ml to HEMR ≤ 5% CV	2.1, 2.5, 2.3, 1.6, 2.3% CV	>250 pg/ml to HEMR ≤ 5% CV	4.3, 4.8, 4.6, 4.2, 4.7% CV
Troponin I STAT	0.1-0.2 ng/ml ≤ 25% CV		0.1-0.2 ng/ml ≤ 40% CV	
	0.2-0.4 ng/ml ≤ 10% CV	9.1, 4.8% CV	0.2-0.4 ng/ml ≤ 20% CV	16, 8.9% CV
	> 0.4 ng/ml ≤ 8% CV	3.3, 2.2, 4.2, 2.9% CV	> 0.4 ng/ml ≤ 8% CV	5.9, 5.3, 3.2, 6.7, 3.6% CV
Troponin T hs	LEMUR-< 14 pg/ml ≤ 0.7 pg/ml SD	0.65, 0.59 pg/ml SD	LEMUR-< 14 pg/ml ≤ 1.4 pg/ml SD	0.71, 0.63 pg/ml SD
	14-100 pg/ml ≤ 5% CV	3.8% CV	14-100 pg/ml ≤ 10% CV	3.9% CV
	> 100-HEMR ≤ 3% CV	2, 0.9, 1.6% CV	> 100-HEMR ≤ 6% CV	3.0, 1.5, 2.0% CV
Digoxin	< 2.2 ng/ml < 0.075 ng/ml SD	0.048, 0.045 ng/ml SD	< 2.2 ng/ml < 0.15 ng/ml SD	0.07, 0.066 ng/ml SD
	2.2-4 ng/ml < 3.5% CV	3.3% CV	2.2-4 ng/ml < 5.5% CV	4.1% CV
	> 4 ng/ml < 5% CV		>4 ng/ml < 7% CV	
Digitoxin	< 10 ng/ml < 8% CV	5.7% CV	< 10 ng/ml < 10% CV	6.5% CV
	10-40 ng/ml < 4% CV	2.6, 2.3% CV	10-40 ng/ml < 6% CV	3, 2.4% CV
	> 40 ng/ml < 6% CV	1.8, 1.7% CV	> 40 ng/ml < 8% CV	3, 2.6% CV
HCG STAT	LEMUR - 10 mIU/mL ≤ 0.4 mIU/mL SD	0.192 / 0.238 mIU/mL SD	LEMUR - 10 mIU/mL ≤ 0.56 mIU/mL SD	0.260 / 0.339 mIU/mL SD
	> 10 mIU/mL – HEMR ≤ 4% CV	1.8, 2.0, 2.2% CV	> 10 mIU/mL – HEMR ≤ 5.6% CV	4.1, 4.3, 4.7% CV
HCG+β	2-5 mIU/ml ≤ 9% CV	4.9% CV	2-5 mIU/ml ≤ 10% CV	5.9% CV
	5-10 mIU/ml ≤ 5% CV	1.9, 1.7% CV	5-10 mIU/ml ≤ 5% CV	2.9, 3.6, 2.9% CV
	> 10 mIU/ml ≤ 4% CV	3.3, 2.3, 1.3% CV	> 10 mIU/ml ≤ 5% CV	2.1, 2.7, 1.9% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
ACTH	LEMUR to 10 pg/mL SD ≤ 0.60 pg/mL > 10 pg/mL to HEMR CV ≤ 6.0 %	0.119 pg/mL SD 1.2, 1.1, 0.8, 1.0% CV	LEMUR to 10 pg/mL SD ≤ 0.76 pg/mL > 10 pg/mL to HEMR CV ≤ 7.6 %	0.156 pg/mL SD 1.8, 1.4, 1.5, 1.7% CV
AMH / AMH Plus	LEMUR- 0.5 ng/ml SD ≤ 0.025 ng/ml 0.5-1.0 ng/ml ≤ 5% CV 1.0-8.0 ng/ml ≤ 4% CV > 8.0 ng/ml – HEMR ≤ 3% CV	0.0008 ng/ml SD 1.3% CV 1.8% CV 1.2, 1.5% CV	LEMUR- 0.5 ng/ml SD ≤ 0.03 ng/ml 0.5-1.0 ng/ml ≤ 6% CV 1.0-8.0 ng/ml ≤ 5% CV 8.0 ng/ml - HEMR ≤ 5% CV	0.002 ng/ml SD 3.5% CV 3.7% CV 3.4, 3.7% CV
Androstenedione	LEMUR to 0.60 ng/mL SD ≤ 0.04 ng/mL > 0.60 ng/mL to HEMR CV ≤ 6.0 %	0.016 ng/mL / 0.461 ng/mL 0.966 ng/mL, 2,4% CV 3.39 ng/mL, 3,4% CV 5.77 ng/mL, 3,3% CV 9.00 ng/mL, 3,3% CV	LEMUR to 0.60 ng/mL SD ≤ 0.06 ng/mL > 0.60 ng/mL to HEMR CV ≤ 8.0 %	0.021 ng/mL, 0.461 ng/mL 0.966 ng/mL, 3,4% CV 3.39 ng/mL, 4,3% CV 5.77 ng/mL, 3,6% CV 9.00 ng/mL, 4,2% CV
Cortisol II serum	1.5-3 nmol/l ≤ 0.9 nmol/l SD >3-50 nmol/l ≤ 1.5 nmol/l SD >50-900 nmol/l ≤ 5% CV >900-1750 nmol/l ≤ 6% CV	0.2, 0.7 nmol/l SD 2.6, 1.9, 1.4% CV 1.8% CV	1.5-50 nmol/l ≤ 2.5 nmol/l SD >50-900 nmol/l ≤ 6% CV >900-1750 nmol/l ≤ 7% CV	0.39, 1.4 nmol/l 3.3, 3.2, 2.7, 2.7% CV 2.7% CV
Cortisol II saliva	1.5-3 nmol/l ≤ 0.9 nmol/l SD >3-50 nmol/l ≤ 1.5 nmol/l SD >50-900 nmol/l ≤ 5% CV >900-1750 nmol/l ≤ 6% CV	0.2, 0.35, 1.0, 0.4, 0.9 nmol/l 2.5% CV	1.5-50 nmol/l ≤ 2.5 nmol/l SD >50-900 nmol/l ≤ 6% CV >900-1750 nmol/l ≤ 7% CV	0.4, 0.7, 1.4 nmol/l 3.6% CV
DHEAS	50-1000 µg/dl < 5% CV	2.2, 2.8, 2.8, 2.4, 1.7% CV	50-1000 µg/dl < 7% CV	2.6, 3.1, 3.6, 4.7, 2.4% CV
Estradiol III	LoD-50 pg/ml ≤ 4 pg/ml SD > 50-200 pg/ml ≤ 7% CV > 200-3000 pg/ml ≤ 6% CV	2.2, 2.1 pg/ml SD 3.1, 3.5% CV 1.9, 2.4, 3.2% CV	LoD-50 pg/ml ≤ 6 pg/ml SD > 50-200 pg/ml ≤ 10% CV > 200-3000 pg/ml ≤ 8% CV	3, 3.1 pg/ml SD 3.4, 4.5% CV 2.5, 2.8, 3.5% CV
FSH	LEMUR to 20 mIU/mL SD ≤ 1 mIU/mL >20 mIU/mL-100mIU/mL CV ≤ 4.3 % >100 mIU/mL-200mIU/mL CV ≤ 3.5 %	0.021, 0.205 mIU/ml SD 1.3% CV 1.4, 1.8% CV	LEMUR to 20 mIU/mL SD ≤ 1.2 mIU/mL >20 mIU/mL-100mIU/mL CV ≤ 5.1 % >100 mIU/mL-200mIU/mL CV ≤ 6.0 %	0.055, 0.401 mIU/ml SD 3.2% CV 3.4, 4.1% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
LH	2-10 mU/ml ≤ 5% CV > 10-100 mU/ml ≤ 3% CV > 100-200 mU/ml ≤ 5% CV < 2 mU/ml (not specified)	1.1% CV 0.9, 0.8, 0.8% CV 1.8% CV	2-10 mU/ml ≤ 6% CV > 10-100 mU/ml ≤ 5% CV > 100-200 mU/ml ≤ 6% CV < 2 mU/ml (not specified)	2.0% CV 1.9, 2.0, 2.0% CV 5.2% CV
Progesterone III	0.05-0.5 ng/ml ≤ 0.1 ng/ml SD >0.5-1 ng/ml ≤ 12% CV >1 ng/ml ≤ 7% CV	0.026 ng/ml SD 3.3% CV 2.5, 1.2, 2.7% CV	0.05-0.5 ng/ml ≤ 0.15 ng/ml SD >0.5-1 ng/ml ≤ 14% CV >1 ng/ml ≤ 8% CV	0.051 ng/ml SD 10.4% CV 3.6, 4.2, 5.2% CV
Prolactin II	100-5000 µIU/ml ≤ 5% CV	4, 2.2, 2.8, 2, 3.3, 2.6% CV	100-5000 µIU/ml ≤ 6% CV	5, 3.6, 2.8, 3.7, 4.2, 3.4% CV
SHBG	5-200 nmol/l < 4% CV	2.2, 2.1, 2.4, 2.8% CV	5-200 nmol/l < 6% CV	2.6, 2.7, 2.8, 5.6% CV
Testosterone II	LEMUR – 0.15 ng/ml ≤ 0.015 ng/ml SD >0.15-0.5 ng/ml ≤ 10% CV >0.5-1 ng/ml ≤ 6% CV >1-3 ng/ml ≤ 5% CV >3-15 ng/ml ≤ 5% CV	0.008 ng/ml SD 2.7% CV 1.8% CV 1.6% CV 1.7% CV	LEMUR – 0.15 ng/ml ≤ 0.03 ng/ml SD >0.15-0.5 ng/ml ≤ 20% CV >0.5-1 ng/ml ≤ 8% CV >1-3 ng/ml ≤ 6% CV >3-15 ng/ml ≤ 6% CV	0.010 ng/ml SD 3.4% CV 2.3% CV 2.3% CV 1.8% CV
C-Peptide serum	0.5-20 ng/ml ≤ 5% CV	4.2, 2.4, 4.7% CV	0.5-20 ng/ml ≤ 6% CV	3.0, 5.0, 1.8% CV
C-Peptide urine	0.5-20 ng/ml ≤ 5% CV	1.6, 4.2, 2.9% CV	0.5-20 ng/ml ≤ 6% CV	4.2, 2.4, 1.8% CV
Insulin	5-10 µU/ml < 5% CV 10-300 µU/ml < 4% CV 300-1000 µU/ml < 5% CV	1.9% CV 1.5, 1.7, 1.9, 2.2, 1.9% 2% CV	5-10 µU/ml < 6% CV 10-300 µU/ml < 5% CV 300-1000 µU/ml < 6% CV	2.6% CV 2.5, 2.1, 2.8, 2.6, 2.3% CV 2.5% CV
PIGF	≤ 50 pg/ml ≤ 4 pg/ml SD ≥ 50 pg/ml ≤ 8% CV ≥ 200 pg/ml ≤ 6% CV ≥ 1000 pg/ml ≤ 6% CV	0.28 pg/ml SD 1, 0.8, 1% CV 0.8% CV 0.8, 0.9% CV	≤ 50 pg/ml ≤ 5 pg/ml SD ≥ 50 pg/ml ≤ 10% CV ≥ 200 pg/ml ≤ 8% CV ≥ 1000 pg/ml ≤ 8% CV	0.45 pg/ml SD 1.3, 1.4, 1.3% CV 1.3% CV 1, 2% CV
sFlt-1	≤ 25 pg/ml ≤ 2 pg/ml SD ≥ 25 pg/ml ≤ 8% CV ≥ 200 pg/ml ≤ 7% CV ≥ 10000 pg/ml ≤ 6% CV	1.6% CV 0.8, 1% CV 1, 1.2, 1% CV	≤ 25 pg/ml ≤ 3 pg/ml SD ≥ 25 pg/ml ≤ 12% CV ≥ 200 pg/ml ≤ 8% CV ≥ 10000 pg/ml ≤ 7% CV	4.3% CV 2.3, 2.3% CV 2.6, 2.9, 3.7% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
AFP	LEMUR to 4 IU/mL ≤ 0.4 IU/mL SD > 4 IU/mL to 60 IU/mL ≤ 4% CV > 60 IU/mL to HEMR ≤ 7% CV	0.097, 0.074 IU/mL SD 3.0, 2.7 % CV 2.6, 2.7, 2.2% CV	LEMUR to 4 IU/mL ≤ 0.4 IU/mL SD > 4 IU/mL to 60 IU/mL ≤ 7% CV > 60 IU/mL to HEMR ≤ 9% CV	0.131, 0.160 IU/mL SD 5.4, 5.4 % CV 4.9, 4.8, 5.1% CV
AFP-L3	LEMUR to 6 ng/mL ≤ 0.5 ng/mL SD 6.0 ng/mL to HEMR ≤ 8% CV	0.084, 0.109, 0.078, 0.109 ng/mL SD 2.3, 2.3, 2.1, 1.9% CV	LEMUR to 6 ng/mL ≤ 0.7 ng/mL SD 6.0 ng/mL to HEMR ≤ 12% CV	0.102, 0.136, 0.098, 0.142 ng/mL SD 3.2, 3.1, 2.8, 2.8% CV
Anti-p53	LoB-0.2 µg/ml ≤ 0.02 µg/ml SD > 0.2-10 µg/ml ≤ 3.5% CV > 10-100 µg/ml ≤ 4.5% CV	0.002 µg/ml SD 2% CV 1.2%, 1.2% CV	LoB-0.2 µg/ml ≤ 0.025 µg/ml SD > 0.2-10 µg/ml ≤ 6.5% CV > 10-100 µg/ml ≤ 7% CV	0.003 / 0.005 µg/ml SD 4.6% CV 4.5, 4.8% CV
CA 125 II	10 U/ml < 5% CV 35 U/ml 4% CV 60-100 U/ml 4% CV > 100 U/ml (not specified)	3.3% CV 1.9, 2.1% CV 2.1% CV 1.4% CV	10 U/ml < 6% CV 35 U/ml 4% CV 60-100 U/ml 4% CV > 100 U/ml (not specified)	4.2% CV 2.5, 3.1% CV 2.5% CV 2.7% CV
CA 15-3 II	10-50 U/ml < 4% CV 50-200 U/ml < 5%CV	1.6, 1.6% CV 2.7, 1.4, 1.9% CV	10-200 U/ml ≤ 6% CV	3, 3, 2.5, 1.8, 2.5% CV
CA 19-9	30-1000 U/ml < 5% CV < 30 U/ml (not specified)	2.9, 3.3, 2.9% CV 4.4, 3.6% CV	30 - 1000 U/ l < 9% CV < 30 U/ml (not specified)	3.8, 3.8, 2.9% CV 4.8, 4.1% CV
CA 72-4	LEMUR to 4 U/mL SD ≤ 0.2 U/mL >4 – 100 U/mL CV ≤ 5.0 % > 100 U/mL to HEMR CV ≤ 6.0 %	0.081 U/ml SD 1.5, 1.6% CV 1.9%, 1.6% CV	LEMUR to 4 U/mL SD ≤ 0.25 U/mL >4 – 100 U/mL CV ≤ 6.0 % > 100 U/mL to HEMR CV ≤ 8.0 %	0.157 U/ml SD 4.8, 4.6% CV 5.1, 5.8% CV
CEA	≤ 2 ng/ml ≤ 0.1 ng/ml SD 4.6 ng/ml ≤ 3% CV 10-50 ng/ml ≤ 5% CV 50-500 ng/ml ≤ 8% CV > 500 ng/ml (not specified)	0.11 ng/ml SD 2.5% CV 1.6, 1.7% CV 1.3% CV	≤ 2 ng/ml ≤ 0.15 ng/ml SD 4.6 ng/ml ≤ 6% CV 10-50 ng/ml ≤ 5% CV 50-500 ng/ml ≤ 8% CV > 500 ng/ml (not specified)	0.18 ng/ml SD 3.6% CV 2.3, 3% CV 2% CV
Cyfra 21-1	1-3 ng/ml ≤ 5% CV 3.1-10 ng/ml ≤ 3% CV > 10 ng/ml ≤ 5% CV	2.1% CV 2, 2% CV 1.6, 1.7% CV	1-3 ng/ml ≤ 7% CV 3.1-10 ng/ml ≤ 5% CV > 10 ng/ml ≤ 5% CV	4.7% CV 2.4, 3.3% CV 2.1, 3.1% CV

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HE4	< 30 pmol/l ≤ 3 pmol/l SD 30-150 pmol/l ≤ 5% CV 150-900 pmol/l ≤ 4% CV >900-1500 pmol/l ≤ 5% CV	0.5 pmol/l SD 1.8% CV 1.5, 1.6% CV 1.9% CV	< 30 pmol/l ≤ 3 pmol/l SD 30-150 pmol/l ≤ 7% CV 150-900 pmol/l ≤ 6% CV >900-1500 pmol/l ≤ 10% CV	0.8 pmol/l SD 2.8, 2.6% CV 3% CV 3.2% CV
NSE	15-100 ng/ml < 3% CV < 15 ng/ml (not specified)	2.8, 2.3% CV 2.1, 3.1, 2.1% CV	15-100 ng/ml < 5% CV < 15 ng/ml (not specified)	3.8, 4.4% CV 3, 4.4, 3.9% CV
PIVKA-II	LEMUR to 30 ng/ml ≤ 1.5 ng/ml SD > 30 ng/ml to HEMR ≤ 5% CV	0.161, 0.302, 0.644 ng/ml SD 2.6, 2.5, 2.5% CV	LEMUR to 30 ng/ml ≤ 2.25 ng/ml SD > 30 ng/ml to HEMR ≤ 7.5% CV	0.398, 0.904, 1.45 ng/ml SD 6.2, 5.9, 6.0% CV
ProGRP	LEMUR-60 pg/ml ≤ 3 pg/ml SD >60pg/ml – HEMR ≤ 5.4% CV	0.171, 0.574 pg/ml SD 0.7, 0.8, 0.9% CV	LEMUR-60 pg/ml ≤ 6 pg/ml SD >60pg/ml – HEMR ≤ 10.4% CV	0.281, 1.41 pg/ml SD 2.2, 2.1, 2.4% CV
free PSA	LEMUR-0.1 ng/ml ≤ 0.007 ng/ml SD > 0.1-0.4 ng/ml ≤ 7.4% CV > 0.4-50 ng/ml ≤ 5.4% CV	1.65, 1.64, 1.23, 1.14, 1% CV	LEMUR-0.1 ng/ml ≤ 0.01 ng/ml SD > 0.1-0.4 ng/ml ≤ 10.4% CV > 0.4-50 ng/ml ≤ 8.4% CV	4.71, 4.86, 4.19, 3.45, 3.42% CV
total PSA	LEMUR-≤ 0.1 ng/ml ≤ 0.007 ng/ml SD >0.1-≤ 1.0 ng/ml ≤ 7.4% CV >1-50 ng/ml ≤ 3.4% CV >50-100 ng/ml ≤ 5.4% CV	1.84% CV 2.51, 2.54, 2.27% CV 2.24% CV	LEMUR-≤ 0.1 ng/ml ≤ 0.010 ng/ml SD >0.1-≤ 1.0 ng/ml ≤ 10.4% CV >1-50 ng/ml ≤ 5.4% CV >50-100 ng/ml ≤ 8.4% CV	2.41% CV 2.93, 2.72, 2.89% CV 3.81% CV
S100	LEMUR-0.05 µg/L ≤ 0.005 µg/L SD >0.05-0.15 µg/L ≤ 3.0% CV >0.15 µg/L -HEMR ≤ 5.0% CV	0.002 µg/L SD 2.1 % CV 1.5, 1.4, 2.0% CV	LEMUR-0.05 µg/L ≤ 0.005 µg/L SD >0.05-0.15 µg/L ≤ 5.0% CV >0.15 µg/L -HEMR ≤ 7.0% CV	0.002 µg/L SD 3.6% CV 2.2, 2.2, 2.6% CV
SCC	LoD – 1.8 ng/ml SD ≤ 0.1 ng/ml > 1.8-5 ng/ml ≤ 5% CV >5-70 ng/ml ≤ 6.5% CV	0.022, 0.029 ng/ml SD 1.8, 1% CV 1.6, 1.1, 0.8% CV	LoD – 1.8 ng/ml SD ≤ 0.2 ng/ml > 1.8-70 ng/ml ≤ 10% CV	0.027, 0.033 ng/ml SD 2.5, 2, 1.8% CV
Free βhCG	LEMUR-15 IU/L ≤ 0.6 IU/l SD > 15 IU/L-HEMR ≤ 3% CV	0.012, 0.018, 0.23, 0.182 IU/l SD 2.3, 1.9, 1.8, 2.3% CV	LEMUR-15 IU/L ≤ 1 IU/l SD > 15 IU/L-HEMR ≤ 5% CV	0.019, 0.033, 0.012, 0.467, 0.422 IU/l SD 4.4, 5, 3.9, 4.2% CV
PAPP-A	LEMUR-50 mIU/l ≤ 2.5 mIU/l SD >50-2000 mIU/l ≤ 3.5% CV >2000 mIU/l-HEMR ≤ 3% CV	0.397 mIU/l SD 1.8, 1.6% CV 2.1% CV	LEMUR-50 mIU/l ≤ 4 mIU/l SD >50-2000 mIU/l ≤ 6% CV >2000 mIU/l-HEMR ≤ 5% CV	0.762 mIU/l SD 3.8, 3.6% CV 4.2, 3.9, 3.7% CV

The system to system precision is defined as intermediate precision x 1.5 e.g. 6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
Active B12	LEMUR to 20 pmol/L SD ≤ 0.8 pmol/L > 20 pmol/L to HEMR CV ≤ 4.0 %	0.093 pmol/L SD 1.7, 1.9, 2.1, 2.1% CV	LEMUR to 20 pmol/L SD ≤ 1.2 pmol/L > 20 pmol/L to HEMR CV ≤ 6.0 %	0.266 pmol/L SD 2.1, 2.5, 3.1, 3.0% CV
Vitamin B12 II	≤ 200 pg/ml ≤ 14 pg/ml SD > 200 pg/ml ≤ 7% CV	8.9 pg/ml SD 3.9, 2.1, 2.7% CV	≤ 200 pg/ml ≤ 24 pg/ml SD > 200 pg/ml ≤ 12% CV	13 pg/ml 5.4, 4.1, 3.2, 3.8% CV
Ferritin	10-40 ng/ml < 7% CV 50-400 ng/ml < 4% CV > 400 ng/ml (not specified)	3.5, 1.8, 2.1% CV 2.7, 1.8, 1.9% CV 2% CV	10-40 ng/ml < 7% CV 50-400 ng/ml < 7% CV > 400 ng/ml (not specified)	4.4, 2.9, 3.2% CV 3, 3.2, 2.2% CV 2.6% CV
Folate III	≤ 5 ng/ml < 0.35 ng/ml SD > 5 ng/ml < 7% CV	0.23, 0.24 ng/ml SD 5.7, 4.7 3.0, 4.3% CV	≤ 5 ng/ml < 1 ng/ml SD > 5 ng/ml < 12% CV	0.39, 0.45 ng/ml SD 6.4, 6.3, 7, 5% CV
Folate RBC	≤ 155 ng/ml ≤ 11 ng/ml SD > 155 ng/ml ≤ 7 % CV	5.2, 4.9 ng/ml SD 4.1, 3.3% CV	≤ 250 ng/ml ≤ 17.5 ng/ml SD > 250 ng/ml ≤ 7 % CV	8.7, 12.2 ng/ml SD 6.2, 4.7% CV

The system to system precision is defined as intermediate precision x 1.5 e.g.
6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
β-CrossLaps/ serum	LEMUR - ≤0.50 ng/ml ≤ 0.02 ng/mL SD >0.50ng/ml – HEMR ≤ 3.0% CV	0.003, 0.008 ng/ml SD 1.3, 1.4, 1.7% CV	LEMUR - ≤0.50 ng/ml ≤ 0.03 ng/mL SD >0.50ng/ml – HEMR ≤ 5.0% CV	0.004, 0.011 ng/ml SD 2.0, 2.0, 2.1% CV
N-MID Osteocalcin	1-10 ng/ml < 0.5 ng/ml SD 11-40 ng/ml < 5% CV 41-400 ng/ml < 3% CV	0.3 ng/ml SD 1.8, 4, 3.3, 2.5% CV 1.7, 1.4, 1.3, 1.2% CV	1-10 ng/ml < 0.8 ng/ml SD 11-40 ng/ml < 7% CV 41-400 ng/ml < 5% CV	0.33 ng/ml SD 3.1, 6.5, 3.8, 3.5% CV 2.3, 1.8, 1.8, 1.7% CV
PTH	11-75 pg/ml < 7% CV 76-1000 pg/ml <5% CV > 1000 pg/ml < 6% CV	4.1, 2.2, 2.7, 1.6% CV 1.9, 1.5% CV	11-75 pg/ml < 9% CV 76-1000 pg/ml <6% CV > 1000 pg/ml < 7% CV	6.2, 4.1, 6.5, 3.9% CV 2.6, 3% CV
PTH (1-84)	LEMUR to 25 pg/mL ≤ 1.2 pg/mL SD > 25 pg/mL to HEMR ≤ 4.5% CV	0.538, 0.604 pg/mL SD 1.1, 0.9, 1.2% CV	LEMUR to 25 pg/mL ≤ 1.5 pg/mL SD > 25 pg/mL to HEMR ≤ 6% CV	0.802, 0.853 pg/mL SD 2.0, 1.6, 1.7% SD
Total P1NP	< 50 µg/l < 5% CV 50-500 µg/l < 4% CV > 500 µg/l < 4% CV	3.5% CV 1.0, 0.8, 0.7% CV 1.3, 1.8, 2% CV	< 50 µg/l < 7% CV 50-500 µg/l < 5% CV > 500 µg/l < 6% CV	3.5% CV 1.8, 2% CV 3.9, 2.6, 5.5% CV
Vitamin D total III	LEMUR to 20 ng/ml ≤ 1.2 ng/ml SD > 20 ng/ml to HEMR ≤ 6% CV	1.10 ng/ml SD 5.4, 4.8, 3.8, 2.4% CV	LEMUR to 20 ng/ml ≤ 1.6 ng/ml SD > 20 ng/ml to HEMR ≤ 8% CV	1.25 ng/ml SD 5.9, 5.2, 3.8, 2.5% CV
hGH	0.7 ng/ml ≤ 0.04 ng/ml deviation > 0.7 – 50 ng/ml ≤ 6% CV	0.012 ng/ml SD 1.7, 2.6% CV	0.7 ng/ml ≤ 0.04 ng/ml deviation > 0.7 – 50 ng/ml ≤ 7% CV	0.003 ng/ml SD 0.7, 1.0% CV
IGF-1	7-40 ng/ml ≤ 1.6 ng/ml SD > 40 ng/ml ≤ 5% CV	1.24 ng/ml SD 2.2, 1.9, 3.1, 2.5, 2.3% CV	7-40 ng/ml ≤ 4 ng/ml SD > 40 ng/ml ≤ 10% CV	1.56 ng/ml SD 3.8, 4.0, 6.2, 3.9% CV
IGFBP-3	LEMUR – 150 ng/ml ≤ 6 ng/ml SD > 150 ng/ml to HEMR ≤ 4% CV	96.4 ng/ml SD 2.3, 1.9, 1.4, 1.8, 2, 1.7% CV	LEMUR – 150 ng/ml ≤ 7.5 ng/ml SD > 150 ng/ml to HEMR ≤ 5% CV	96.4 ng/ml SD 2.6, 2.5, 2.1, 1.9, 2.1% CV

The system to system precision is defined as intermediate precision x 1.5 e.g.

6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
IgE II	1-5 IU/ml < 9% CV	-	1-5 IU/ml < 10% CV	-
	6-250 IU/ml < 6% CV	2, 4.1% CV	6-250 IU/ml < 7% CV	3.7, 5.1% CV
	> 250 IU/ml < 5% CV	2.3, 2.4, 2.6, 2.4% CV	> 250 IU/ml < 8% CV	4, 3.8, 3.9, 4% CV
Anti-CCP	10-25 U/ml ≤ 2.5 U/ml SD	0.6, 1% CV	10-25 U/ml ≤ 3.8 U/ml SD	3, 3.1% CV
	25-200 U/ml ≤ 6% CV	1.4% CV	25-200 U/ml ≤ 8% CV	2.5% CV
	200-1000 U/ml ≤ 8% CV	2.3% CV	200-1000 U/ml ≤ 10% CV	4.5% CV
BRAHMS PCT	LoD-0.1 ng/ml ≤ +/- 0.01 ng/ml SD	0.005 ng/ml SD	LoD-0.1 ng/ml ≤ +/- 0.015 ng/ml SD	0.01 ng/ml SD
	> 0.1 ng/ml ≤ 10% CV	2.1, 1.3, 0.9% CV	> 0.1 ng/ml ≤ 15% CV	4.2, 4.9, 3.7, 4% CV
IL-6	LEMUR-25 pg/ml SD ≤ 5 pg/ml	0.768, 0.649, 0.565 pg/mL SD	LEMUR-25 pg/ml SD ≤ 5 pg/ml	0.916, 0.922, 1, 2.2pg/mL SD
	>25 pg/ml - HEMR ≤ 5% CV	1.3, 1.1% CV	>25 pg/ml - HEMR ≤ 7% CV	3.3, 3.0% CV
Cyclosporine	LoD - ≤ 90 ng/ml ≤ 7 ng/ml SD	2.45 ng/ml SD	LoD - ≤ 90 ng/ml ≤ 9 ng/ml	5.8 ng/ml
	> 90-2000 ng/ml ≤ 8% CV	3.1, 3.5, 3.2% CV	> 90-2000 ng/ml ≤ 10% CV	7, 6, 4.7% CV
Everolimus	LoD - 3 ng/ml ≤ +/- 0.24 ng/ml SD	0.134, 0.077 ng/ml SD	LoD - 3 ng/ml ≤ +/- 0.3 ng/ml SD	0.135, 0.14 ng/ml
	> 3-30 ng/ml ≤ 8% CV	2.8, 3.2, 2.6, 2.0% CV	> 3-30 ng/ml ≤ 10% CV	4.2, 3.7, 3.9, 4.1, 2.7% CV
Sirolimus	LoD - 3 ng/ml ≤ +/- 0.24 ng/ml SD	0.123, 0.149 ng/ml SD	LoD - 3 ng/ml ≤ +/- 0.3 ng/ml SD	0.13, 0.173 ng/ml SD
	> 3-30 ng/ml ≤ 8% CV	3.7, 2.4, 4.1, 2.4% CV	> 3-30 ng/ml ≤ 10% CV	4.2, 3.3, 4.1, 2.8% CV
Tacrolimus	0.5-3.5 ng/ml ≤ 0.25 ng/ml SD	0.064 ng/ml SD	0.5-3.5 ng/ml ≤ 0.35 ng/ml SD	0.182 ng/ml SD
	> 3.5 - 12 ng/ml ≤ 6% CV	2.5% CV	> 3.5 - 12 ng/ml ≤ 6% CV	5.6% CV
	>12-40 ng/ml ≤ 7% CV	2.6, 2.3% SV	>12-40 ng/ml ≤ 7% CV	3.3, 2.7% CV

The system to system precision is defined as intermediate precision x 1.5 e.g. 6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
β -Amyloid (1-42) CSF II	LEMR – 480 pg/ml \leq 24 pg/ml SD > 480 – 2000 pg/ml \leq 5% CV > 2000 pg/ml - HEMR \leq 8% CV	3,01 pg/ml SD 2.8, 2.5, 2.4, 2.5, 3.0% CV 4.2, 1.2% CV	LEMR – 480 pg/ml \leq 38 pg/ml SD > 480 – 2000 pg/ml \leq 8% CV > 2000 pg/ml - HEMR \leq 10% CV	7,28 pg/ml SD 5.6, 5.2, 5.6, 5.4, 4.9% CV 7.0, 4.7% CV
Phospho-Tau (181P) CSF	LEMR – 25 pg/ml \leq 1.3 pg/ml SD > 25 – 50 pg/ml \leq 5% CV > 50 pg/ml \leq 8% CV	0.262, 0.371 pg/ml SD 1.1, 1.0% CV 1.5, 1.0, 0.9% CV	LEMR – 25 pg/ml \leq 2 pg/ml SD > 25 – 50 pg/ml \leq 8% CV > 50 pg/ml \leq 10% CV	0.400, 0.662 pg/ml SD 1.5, 1.5% CV 2.8, 2.0, 2.0% CV
Total-Tau CSF	LEMR – 250 pg/ml \leq 13 pg/ml SD > 250 – 500 pg/ml \leq 5% CV > 500 pg/ml \leq 10% CV	1.09 pg/ml SD 1.1, 1.8, 1.0% CV 2.1, 1.1% CV	LEMR – 250 pg/ml \leq 20 pg/ml SD > 250 – 500 pg/ml \leq 8% CV > 500 pg/ml \leq 10% CV	6.77 pg/ml SD 6.5, 5.9, 6.5% CV 6.5, 7.2% CV

The system to system precision is defined as intermediate precision x 1.5 e.g. 6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
Anti-HAV II	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	0.9, 1.2% CV 0.011, 0.012, 0.0001 SD COI	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	1.3, 1.5% CV 0.016, 0.021, 0.0002 SD COI
Anti-HAV IgM	HS, neg ≤ 20% CV HS, weakly pos ≤ 7% CV HS, positive ≤ 5% CV	2% CV 3.4% CV 3.1% CV	HS, neg ≤ 20% CV HS, weakly pos ≤ 10% CV HS, positive ≤ 10% CV	3.8% CV 2.8% CV 5.4% CV
Anti-HBc II	COI > 1.0 ≤ 7.0 %CV COI ≤ 1.0 ≤ 0.07 COI SD	2.6% CV 0.023, 0.0001 SD COI	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	3.9% CV 0.042, 0.0003 SD COI
Anti-HBc IgM	HS, neg ≤ 5% CV HS, weakly pos ≤ 5% CV HS, positive ≤ 7% CV PC a-HBc IgM 1 ≤ 5% CV PC a-HBc IgM 2 ≤ 7% CV	2.2% CV 3.5% CV 3.7% CV 1.7% CV 4.5% CV	HS, neg ≤ 13% CV HS, weakly pos ≤ 8% CV HS, positive ≤ 10% CV PC a-HBc IgM 1 ≤ 10% CV PC a-HBc IgM 2 ≤ 13% CV	2.8% CV 1.8% CV 3.4% CV 3.3% CV 3.6% CV
Anti-HBe	HS, neg ≤ 5% CV HS, weakly pos ≤ 3% CV HS, positive ≤ 3% CV PC a-HBe 1 ≤ 5% CV PC a-HBe 2 ≤ 3% CV	2.4% CV 2.0% CV 3.0% CV 2.1% CV 2.1% CV	HS, neg ≤ 10% CV HS, weakly pos ≤ 5% CV HS, positive ≤ 5% CV PC a-HBe 1 ≤ 10% CV PC a-HBe 2 ≤ 5% CV	2.6% CV 2.2% CV 3.5% CV 2.0% CV 2.5% CV

HS = human sera

- no information

The system to system precision is defined as intermediate precision x 1.5 e.g.

6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
HBeAg	HS, neg ≤ 10% CV HS, weakly pos ≤ 5% CV HS, positive ≤ 5% CV PC HBeAg 1 ≤ 10% CV PC HBeAg 2 ≤ 5% CV	4.0% CV 4.0, 2.8% CV 6.6% CV 1.6% CV	HS, neg ≤ 10% CV HS, weakly pos - HS, positive ≤ 5% CV PC HBeAg 1 ≤ 10% CV PC HBeAg 2 ≤ 5% CV	4.0, 1.7% CV 4.9% CV 4.5% CV 1.7% CV
Anti-HBs II	≤ 5 IU/l ≤ 0.75 IU/l SD >5-≤10 IU/l SD ≤ 15% x mean >10 IU/l SD ≤ 5% x mean + 1 IU/l)	6.2% CV 3.8, 2.1, 2, 1.8, 1.7% CV	≤ 5 IU/l ≤ 1 IU/l SD >5-≤10 IU/l SD ≤ 20% x mean >10 IU/l SD ≤ 8% x mean + 1.2 IU/l)	8.3% CV 7.1, 4.8, 5.5, 5.4% CV
HBsAg II	≤ 0.70 COI ≤ 0.07 COI SD ≥ 0.7 COI ≤ 7% CV	0.026, 0.42 COI SD 2.2, 3.9, 1.5% CV	≤ 0.70 COI ≤ 0.1 COI SD ≥ 0.7 COI ≤ 10% CV	0.43, 0.144 COI SD 5.7, 1.1, 3.3% CV
HBsAg II quant II	LoD-5 IU/ml ≤ 0.4 IU/ml SD undiluted >5-130 IU/ml ≤ 8% CV undiluted > 130 IU/ml ≤ 10% CV undiluted	0.006, 0.069 IU/ml SD 2, 1.7, 2.8% CV 2.8% CV	LoD-5 IU/ml ≤ 0.5 IU/ml SD undiluted >5-130 IU/ml ≤ 10% CV undiluted > 130 IU/ml ≤ 12% CV undiluted	0.009, 0.099 IU/ml SD 4.1, 3.2, 4% CV 4.4% CV
Anti-HCV II	≤ 0.5 COI SD ≤ 0.1 COI 0.5-<1.0 COI SD ≤ 0.07 COI ≥ 1.0 COI ≤ 7% CV	0.002 COI SD 0.024, 0.022 COI SD 3.9, 3.7% CV	≤ 0.5 COI SD ≤ 0.12 COI 0.5-<1.0 COI SD ≤ 0.10 COI ≥ 1.0 COI ≤ 10% CV	0.002 COI SD 0.034, 0.045 COI SD 6.5, 5.1% CV
HIV Ag	HS, neg - HS, weakly pos ≤ 5 % CV HS, positive - PC HIV Ag 1 ≤ 10 % CV PC HIV Ag 2 ≤ 5 % CV	5.2% CV 2.7% CV 2.6% CV 6.6 % CV 2.0 % CV	HS, neg - HS, weakly pos - HS, positive - PC HIV Ag 1 ≤ 20 % CV PC HIV Ag 2 ≤ 10 % CV	7.1% CV 3.7% CV 4.1% CV 5.9% CV 5.0% CV

HS = human sera- no information

The system to system precision is defined as intermediate precision x 1.5 e.g. 6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)		Internal eval. repeatability	Specified intermediate precision (within lab precision)		Internal eval. Intermediate precision.
HIV combi PT	HS neg	SD ≤ 0.06	0.022 COI SD	HS neg	SD ≤ 0.09	0.041 COI SD
	Anti-HIV-1 pos.	≤ 6 % CV	2.4, 1.4% CV	Anti-HIV-1 pos.	≤ 10 % CV	3.0, 2.1% CV
	Anti-HIV-2 pos.	≤ 6 % CV	2.4% CV	Anti-HIV-2 pos.	≤ 10 % CV	3.6% CV
	HIV Ag pos.	≤ 6% CV	2.4% CV	HIV Ag pos.	≤ 10% CV	3.5% CV
HTLV-I/II	0 to 1.0 COI	SD ≤ 0.07 COI	0.003, 0.008, 0.007 COI SD	0 to 1.0 COI	SD ≤ 0.1 COI	0.010, 0.046, 0.041 COI SD
	COI > 1.0	≤ 5.5% CV	1.2, 2.0, 1.1% CV	COI > 1.0	≤ 7.5% CV	4.8, 5.4, 4.9% CV
Syphilis	COI < 1.00	SD ≤ 0.07 COI	0.001 COI SD	COI < 1.00	SD ≤ 0.1 COI	0.006 COI SD
	COI ≥ 1.00	≤ 5.5% CV	2.5, 2.7, 3.5, 3.3% CV	COI ≥ 1.00	≤ 7.5% CV	6.3, 6.7, 6.4, 5.7% CV
	(corresponds to 7% incl 95% conf. Interval)			(corresponds to 10% incl 95% conf. Interval)		
CMV IgG	LoD to ≤ 1.0 U/mL	≤ 0.06 U/mL SD	0.011, 0.039% CV	LoD to ≤ 1.0 U/mL	≤ 0.08 U/mL SD	0.017, 0.052% CV
	> 1.0 to 500 U/mL	≤ 6.0 % CV	1.5, 2.7, 1.5% CV	> 1.0 to 500 U/mL	≤ 8.0 % CV	2.8, 3.9, 3.1% CV
CMV IgG Avidity	Low avidity (<45.0 Avi%)	≤ 8% CV	2.0% CV	Low avidity (<45.0 Avi%)	≤ 10% CV	2.1% CV
	Gray zone (45.0-54.9 Avi%)	≤ 8% CV	3.6% CV	Gray zone (45.0-54.9 Avi%)	≤ 10% CV	3.8% CV
	High avidity (≥ 55.0 Avi %)	≤ 8% CV	1.6% CV	High avidity (≥ 55.0 Avi %)	≤ 10% CV	1.9% CV
CMV IGM	< 0.6 COI	≤ 0.06 COI SD	0.003, 0.002 COI SD	< 0.6 COI	≤ 0.06 COI SD	0.005, 0.004 COI SD
	> 0.6 COI	≤ 7% CV	1.5, 1.8% CV	> 0.6 COI	≤ 7% CV	5.3, 3.4, 3.1% CV
HSV-1 IgG	≤ 0.8 COI	≤ 0.1 SD	0.001 COI SD	≤ 0.8 COI	≤ 0.15 SD	0.001 COI SD
	> 0.8-2.0 COI	≤ 6% CV	0.9% CV	> 0.8-2.0 COI	≤ 8% CV	1.4% CV
	> 2 COI	≤ 8% CV	1.4% CV	> 2 COI	≤ 10% CV	1.9% CV
HSV-2 IgG	≤ 0.8 COI	≤ 0.1 SD	0.001 COI SD	≤ 0.8 COI	≤ 0.15 SD	0.002 COI SD
	> 0.8-2.0 COI	≤ 6% CV	1.3% CV	> 0.8-2.0 COI	≤ 8% CV	2.3% CV
	> 2 COI	≤ 8% CV	1.2% CV	> 2 COI	≤ 10% CV	1.9% CV

HS = human sera

- no information

The system to system precision is defined as intermediate precision x 1.5 e.g.

6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
Rubella IgG	< 5 IU/ml < 1 IU/ml SD > 5 IU/ml < 10% CV	0.075 IU/ml SD 1.9, 2.5, 1.6% CV	< 5 IU/ml < 1.1 IU/ml SD > 5 IU/ml < 12% CV	0.074 IU/ml SD 3.8, 3.4, 3.6% CV
Rubella IgM	HS neg: ≤ 7 % CV 2.4% CV HS, pos. ≤ 7 % CV 1.2, 1% CV PC Rub. IgM 1 ≤ 7 % CV 1.4% CV PC Rub. IgM 2 ≤ 7 % CV 1.1% CV	2.4% CV 1.2, 1% CV 1.4% CV 1.1% CV	HS neg: ≤ 10 % CV HS, pos. ≤ 10 % CV PC Rub. IgM 1 ≤ 10 % CV PC Rub. IgM 2 ≤ 10 % CV	3% CV 1.9, 4.1% CV 4.1% CV 4.1% CV
Toxo IgG	HS neg: ≤ 7 % CV HS, pos. ≤ 7 % CV PC Toxo IgG 1 ≤ 7 % CV PC Toxo IgG 2 ≤ 7 % CV	1.5, 1.3 % CV 1.6 % CV 2.1% CV	HS neg: ≤ 10 % CV HS, pos. ≤ 10 % CV PC Toxo IgG 1 ≤ 10 % CV PC Toxo IgG 2 ≤ 10 % CV	4.2, 5.3% CV 5.7% CV 3.0% CV
Toxo IgG Avidity	Low avidity samples ≤ 10 % CV Greyzone samples ≤ 8 % CV High-avidity samples ≤ 8 % CV	4.3, 7.3% CV 1.7% CV 0.6, 1% CV	n/a	n/a
Toxo IgM	HS neg: ≤ 7 % CV HS, pos. ≤ 7 % CV PC Toxo IgM 1 ≤ 7 % CV PC Toxo IgM 2 ≤ 7 % CV	1.9, 1.6% CV 2.5% CV 1.6% CV	HS neg: ≤ 10 % CV HS, pos. ≤ 10 % CV PC Toxo IgM 1 ≤ 10 % CV PC Toxo IgM 2 ≤ 10 % CV	4, 3.6 % CV 2.7% CV 3% CV

HS = human sera - no information

HS low pos/pos.: for anti-HIV 1, anti-HIV 2, HIV Ag determined (separate available in method sheet)

The system to system precision is defined as intermediate precision x 1.5 e.g.

6% intermediate precision = 9% system to system precision, when not specified for the test.

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)		Internal eval. repeatability	Specified intermediate precision (within lab precision)		Internal eval. Intermediate precision.
EBV IgM	< 1.0 COI ≥ 1.0 COI	SD ≤ 0.08 COI CV ≤ 8.0 %	0.002, 0,023 COI SD 1.6, 2.0, 2.1 % CV	< 1.0 COI ≥ 1.0 COI	SD ≤ 0.10 COI CV ≤ 10.0 %	0.005, 0.027 COI SD 2.0, 2.3, 3.0 % CV
EBV VCA IgG	COI <1.0 COI ≥ 1.0	SD ≤ 0.08 CV ≤ 8.0 %	0.026, 0.033 COI SD 2.50, 0.9, 1.5 % CV	COI <1.0 COI ≥ 1.0	SD ≤ 0.10 CV ≤ 10.0 %	0.046, 0.052 COI SD 3.80, 2.50, 2.70 % CV
EBV EBNA IgG	< 1.0 COI ≥1.0 COI	SD ≤ 0.08 COI CV ≤ 8.0 %	0.002, 0.031 SD COI 2.8, 3.1, 2.8 % CV	< 1.0 COI ≥1.0 COI	SD ≤ 0.10 COI CV ≤ 10.0 %	0.002, 0.038 SD COI 3.2, 3.6, 3.4 %
Chagas	< 1.0 COI ≥ 1.0 COI	≤ 0.08 COI SD ≤ 8% CV	0.001 COI SD 2, 2.7. 2.9% CV	< 1.0 COI ≥ 1.0 COI	≤ 0.1 COI SD ≤ 10% CV	0.002 COI SD 4.3, 3.9, 5.9% CV
ZIKA IgG	HS neg: HS, pos.	≤ n/a COI SD ≤ n/a % CV	0.008, 0.012 COI SD 2.4, 3.2, 1.6, 1.7, 1.9% CV	HS neg: HS, pos.	≤ n/a COI SD ≤ n/a % CV	0.011, 0.012 COI SD 3, 3.4, 2.5, 2.7% CV

HS = human sera - no information

cobas e 411 Elecsys Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate precision.
Anti-SARS-CoV-2	COI <1.0 SD ≤ 0.1 COI COI ≥1.0 CV ≤ 10 %	0.002, 0,001 COI SD 1.8, 2.8, 2.7, 1.6, 2.0% CV	COI <1.0 SD ≤ 0.12 COI COI ≥1.0 CV ≤ 12 %	0.003 COI SD 4.5, 4.7, 4.2, 5.0, 4.4 % CV
Anti-SARS-CoV-2 S	LEMUR- < 1.0 U/ml ≤ 0.1 U/ml SD ≥1.0-20 U/ml ≤ 10% CV >20 U/ml-HEMR ≤ 15% CV	0.014, 0.023 U/ml SD 2.3, 2.2% CV 2.9, 2.3, 1.6% CV	LEMUR- < 1.0 U/ml ≤ 0.12 U/ml SD ≥1.0-20 U/ml ≤ 12% CV >20 U/ml-HEMR ≤ 17% CV	0.016, 0.023 U/ml SD 2.6, 2.5% CV 2.9, 2.7, 1.9% CV
SARS-CoV-2 Antigen	COI <1.0 SD ≤ 0.1 COI COI ≥1.0 CV ≤ 10 %	0.022, 0,032 COI SD 5.3, 1.8, 2.4% CV	COI <1.0 SD ≤ 0.12 COI COI ≥1.0 CV ≤ 12 %	0.053 COI SD 5.8, 2.5, 3.1 % CV
IGRA SARS-CoV-2	0.07 – 1.0 IU/ml ≤ 0.05 IU/ml SD > 1 – 160 IU/ml ≤ 5% CV	0.006 IU/ml SD 0.8, 1.0, 1.2, 1.3% CV	0.07 – 1.0 IU/ml ≤ 0.07 IU/ml SD > 1 – 160 IU/ml ≤ 7% CV	0.016 IU/ml SD 2.5, 2.9, 3.1, 3.1 % CV

cobas e 411 Elecsys Assays Specifications



Used Documents:

Assay	Method sheet	Application report
FT3 III	0221/01	2_3_MS_AR_Summary_inclRec_FT3 III_V2_MethodSheet
FT4 III	1019/01	ARa_SummaryReport_ft4 III
FT4 IV	0522/01	2_3_MS_AR_Summary_inclRec_FT4 IV_MethodSheet
T3	0620/01	2_3_MS_AR_Summary_inclRec_T3_V2_MethodSheet
T4	0720/01	2_3_MS_AR_Summary_inclRec_T4_V2_MethodSheet
TSH	0419/01	2_3_AR_Summary TSH V2
T-uptake	0911/09	2tbk050a.xls (NCCLS precision)
Calcitonin	0221/01	2_3_MS_AR_Summary_inclRec_Calcitonin_V2_MethodSheet
Tg II	0620/01	2_3_MS_AR_Summary_inclRec_Tg II_V2_MethodSheet
Anti-Tg	0710/02	2atg050a.xls (NCCLS precision)
Anti-TPO	0811/02	2tpo050c.xls (NCCLS precision)
Anti-TSHR	1019/01	AR_Summary ATSHR V2
CK-MB STAT	0812/03	2_3AR01_Application Report Summary_CK-MB.doc
GDF-15	1020/01	2_3_MS_AR_Summary_inclRec_GDF-15_V2
Myoglobin STAT	0812/17	2myo050a.xls (NCCLS precision)
proBNP II	0321/01	2_3_MS_AR_Summary_inclRec_proBNP II_V2_MethodSheet
Troponin I STAT	0712/04	2_050a_EP5Precision_TNIstat.xls (CLSI precision)
Troponin T hs	0321/01	2_3_MS_AR_Summary_inclRec_TnThs_V2_MethodSheet_09315322190
Digoxin	0512/18	2dig050a.xls (NCCLS precision)
Digitoxin	0612/11	2dit050a.xls (NCCLS precision)
HCG STAT	0920/02	2_3_MS_AR_Summary_inclRec_HCGSTAT_V2_MethodSheet_v2.0
HCG+β	0412/15	2hb2050a.xls (NCCLS precision)
ACTH	0122/01	2_3_MS_AR_Summary_inclRec_ACTH_V2_MethodSheet
AMH	1020/01	2_3_MS_AR_Summary_inclRec_AMH_V2_MethodSheet_v2.0
AMH Plus	1020/01	2_3_MS_AR_Summary_inclRec_AMH Plus_V2_MethodSheet_v2.0
Androstenedione	0620/01	AR Summary: Androstenedione Version: 01-Oct-2019
Cortisol II	0615/01	Cortisol II Arx_SummaryReport
DHEA-S	0912/16	2dhe050a.xls (NCCLS precision)
Estradiol III	0605/02	2_3_ARc-Summary report_E2 III
FSH	0221/01	2_3_MS_AR_Summary_inclRec_FSH_V2_MethodSheet

cobas e 411 Elecsys Assays Specifications

Assay	Method sheet	Application report
LH	0412/18	2_lh050a.xls (NCCLS precision)
Progesterone III	0612/01	2_3_ARc-Summary report_PROGIII
Prolactin II	0312/05	2pro050a.xls (NCCLS precision)
SHBG	0512/10	2shg050a.xls (NCCLS precision)
Testosterone II	0321/01	2_3_MS_AR_Summary_inclRec_Testo II_V2_MethodSheet
C-Peptide	0412/08	2cpe050a.xls (NCCLS precision)
Insulin	0412/13	2in1050a.xls (NCCLS precision)
PIGF	0512/05	2PLGF050a.xls (CLSI precision)
sFlt-1	0512/05	2SFL050b.xls (CLSI precision)
AFP	1221/01	2_3_MS_AR_Summary_inclRec_AFP_V2_MethodSheet
AFP-L3	1022/01	3_MS_AR_Summary_inclRec_AFP-L3_MethodSheet
Anti-p53	0221/01	2_3_MS_AR_Summary_inclRec_Anti-p53_MethodSheet_v3.0
CA 125 II	1014/01	2125050a.xls (NCCLS precision)
CA 15-3 II	0512/16	2215050a.xls (NCCLS precision)
CA 19-9	0911/20	2192050a.xla (NCCLS precision)
CA 72-4	0221/01	2_3_MS_AR_Summary_inclRec_CA72-4_V2_MethodSheet
CEA	0512/20	2ce2050c.xls (NCCLS precision)
Cyfra 21-1	0812/15	2cyf050a.xls (NCCLS precision)
HE4	0612/05	2_AR01_SummaryReport_HE4.doc
NSE	0812/11	2nse050b.xls (NCCLS precision)
PIVKA-II	1221/01	2_3_MS_AR_Summary_inclRec_PIVKA-II_V2_MethodSheet
ProGRP	0720/01	2_3_MS_AR_Summary_inclRec_ProGRP_V2_MethodSheet_v2.0
free PSA	0819/01	Ara_summary_free PSA V2
total PSA	0819/01	Ara_summary_total PSA V2
S100	0220/01	2_3_MS_AR_Summary_inclRec_S100_V2_MethodSheet
SCC	0316/02	2_3_Arb_SummaryReport_SCC
Free β hCG	1019/01	AR_Summary free β hcg V2
PAPP-A	0819/01	AR_Summary PAPP-A V2
Active B12	1221/01	2_3_MS_AR_Summary_inclRec_Active B12_V2_MethodSheet
Vitamin B12 II	0715/02	2_3_Arc_SummaryReport_B12II
Ferritin	0312/12	2f2g050b.xls (NCCLS precision)

cobas e 411 Elecsys Assays Specifications

Assay	Method sheet	Application report
Folate III	0712/10	2Fo3050a.xls (NCCLS precision)
Folate RBC	1011/01	2_3_Ara_Summary Report_FolRBC.doc
β-CrossLaps/serum	0421/01	2_3_MS_AR_Summary_inclRec_βCrossLaps_V2_MethodSheet
hGH	0211/02	2_3_Ara_SummaryReport_hGH.doc
IGF-1	1117/01	2_3_ARd_SummaryReport v4 IGF-1
IGFBP-3	0718/01	Arb_SummaryReport IGFBP-3
N-MID Osteocalcin	1211/14	2oc050c.xls (NCCLS precision)
PTH STAT	1211/09	2PTH050a.xls (NCCLS precision)
PTH (1-84)	0521/01	2_3_MS_AR_Summary_inclRec_PTH(1-84)_V2_MethodSheet
total P1NP	0508/06	2P1_050a.xls (NCCLS precision)
Vitamin D total III	0322/01	2_3_MS_AR_Summary_inclRec_VITDT 3_MethodSheet
IgE II	0312/06	2ig2050b.xls (NCCLS precision)
Anti-CCP	0611/04	2acc050c.xls (NCCLS precision)
BRAHMS PCT	1119/01	AR_Summary PCT V2
IL-6	0920/01	2_3_MS_AR_Summary_inclRec_IL-6_V2_MethodSheet_v2.0
Cyclosporine	1113/02	2_3_AR01_SummaryReport_CSA.doc
Everolimus	0316/01	2_3_AR02_SummaryReport_EVL
Sirolimus	0316/01	2_3_AR02_SummaryReport_SLR
Tacrolimus	1013/02	2_3_AR01_SummaryReport_TCL.doc
β-Amyloid (1-42) CSF II	0521/01	2_3_MS_AR_Summary_inclRec_Abeta42 2_MethodSheet
Phospho-Tau (181P) CSF	0621/01	2_3_MS_AR_Summary_inclRec_pTau_V2_MethodSheet
Total-Tau CSF	0621/01	2_3_MS_AR_Summary_inclRec_tTau_V2_MethodSheet
Anti-HAV II	0322/03	2_3_MS_AR_Summary_inclRec_Anti-HAV II_MethodSheet
Anti-HAV IgM	1012/12	Precision from PEI report
Anti-HBc II	0521/01	2_3_MS_AR_Summary_inclRec_Anti-HBc II_V2_MethodSheet
Anti-HBc IgM	0212/14	Precision from PEI report
Anti-HBe	0610/13	Precision from PEI report
HBeAg	0610/15	Precision from PEI report

cobas e 411 Elecsys Assays Specifications

Assay	Method sheet	Application report
Anti-HBs II	1119/01	AR_Summary A-HBSII V2
HBsAg II	1019/01	AR_Summary HBsAg II V2
HBsAg II quant II	1019/01	AR_Summary_HBsAgIIQII
HSV-1 IgG	1221/01	2_3_MS_AR_Summary_inclRec_HSV-1 IgG_V2_MethodSheet
HBsAg Conf. Test	0812/22	Not available
Anti-HCV II	0222/01	2_3_MS_AR_Summary_inclRec_Anti-HCV II_V2_MethodSheet
Chagas	0622/02	2_3_MS_AR_Summary_inclRec_Chagas_V2
HIV Ag	0712/11	Precision from PEI report
HIV Ag Conf. Test	1108/09	na
HIV combi PT	1020/01	2_3_MS_AR_SummaryReport_inclRec_HIVcPT_V2_MethodSheet
HTLV-I/II	0222/01	2_3_MS_AR_Summary_inclRec_HTLV_V2_MethodSheet
Syphilis	0321/01	2_3_MS_AR_Summary_inclRec_Syphilis_V2_MethodSheet
CMV IgG	0122/01	2_3_MS_AR_Summary_inclRec_CMV IgG_V2_MethodSheet
CMV IgG Avidity	0122/01	2_3_MS_AR_Summary_inclRec_CMV IgG Avidity_V2_MethodSheet
CMV IgM	0712/05	2CMM050a.xls (NCCLS precision)
HSV-1 IgG	1221/01	2_3_MS_AR_Summary_inclRec_HSV-1 IgG_V2_MethodSheet
HSV-2 IgG	1221/01	2_3_MS_AR_Summary_inclRec_HSV-2 IgG_V2_MethodSheet
Rubella IgG	1012/06	Precision from internal evaluation report
Rubella IgM	1012/07	Precision from internal evaluation report
Toxo IgG	0612/10	Precision from internal evaluation report
Toxo IgG Avidity	0712/03	2_3_Ara_SummaryReport_ToxoIgG Avidity
Toxo IgM	1211/07	Precision from internal evaluation report
EBV IgM	0620/01	2_3_MS_AR_Summary_inclRec_EBV IgM_MethodSheet
EBV VCA IgG	0620/01	2_3_MS_AR_Summary_inclRec_EBV VCA IgG_MethodSheet
EBV EBNA IgG	0620/01	2_3_MS_AR_Summary_inclRec_EBV EBNA_MethodSheet
ZIKA IgG	0118/01	n/a
Anti-SARS-CoV-2	1220/04	2_3_MS_AR_Summary_inclRec_SARS-CoV2_MethodSheet
Anti-SARS-CoV-2 S	1020/01	2_3_MS_AR_Summary_inclRec_ACOV2S_MethodSheet.
SARS-CoV-2 Antigen	1220/01	2_3_MS_AR_Summary_inclRec_SARS-CoV-2 Antigen_MethodSheet
IGRA SARS-CoV-2	0822/02	2_3_MS_AR_Summary_inclRec_IGRA SARS-CoV-2_MethodSheet