

cobas e 801, cobas e 402 Assays Specifications



Chers utilisateurs, nous vous prions de trouver ci dessous les spécifications de répétabilité et reproductibilité pour les modules cobas e 801/e 402.

Dans cette mise à jour de Janvier 2025 ont été ajoutés:

- Les tests Elecsys® présentant un seuil de tolérance augmenté à la biotine: Folate III, PTH
- Les nouveaux tests Elecsys® Cortisol III Urine, Interferon Gamma, Anti HEV IgG et IgM, HBeAg quant

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.

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab prec.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
FT3 III	LEMR to 4 pmol/l $\leq$ 0.2 pmol/l SD >4 pmol/l to HEMR $\leq$ 5% CV	0.085, 0.096 pmol/l SD 1.9, 1.3, 0.9 % CV	LEMR to 4 pmol/l $\leq$ 0.32 pmol/l SD >4 pmol/l to HEMR $\leq$ 8% CV	0.086, 0.102 pmol/l SD 1.9, 1.3, 1.0% CV	n/a	n/a
FT4 III	0.5 – 6 pmol/l $\leq$ 0.3 pmol/l SD > 6-100 pmol/l $\leq$ 5% CV	0.103 pmol/l SD 2.4, 2.2, 1.5, 2.6, 2% CV	0.5 – 6 pmol/l $\leq$ 0.5 pmol/l SD > 6-100 pmol/l $\leq$ 8% CV	0.131 pmol/l SD 2.6, 2.4, 2.5, 3.6, 2.1% CV	n/a	n/a
FT4 IV	LEMR to 6 pmol/L $\leq$ 0.3 pmol/L SD > 6 pmol/L to HEMR $\leq$ 5% CV	0.0795 pmol/L SD 1.7, 1.1, 1.5, 3.3% CV	LEMR to 6 pmol/L $\leq$ 0.5 pmol/L SD > 6 pmol/L to HEMR $\leq$ 8% CV	0.130 pmol/l 2.6, 2.4, 2.9, 4.6% CV	n/a	n/a
T3	LEMR-0.7 nmol/l $\leq$ 0.028 nmol/l SD >0.7-1.2 nmol/l $\leq$ 4.0% CV >1.2 nmol/l -HEMR $\leq$ 3.0% CV	0.0239 nmol/l SD 2.5, 1.8, 1.7, 1.5% CV	LEMR-0.7 nmol/l $\leq$ 0.042 nmol/l SD >0.7-2.5 nmol/l $\leq$ 6% CV >2.5 nmol/l-HEMR $\leq$ 7% CV	0.0331 nmol/l SD 3.1% CV 2.1, 2.1, 1.9% CV	n/a	n/a
T4	LEMR-35 nmol/l $\leq$ 1.75 nmol/l SD >35-65 nmol/l $\leq$ 5.0% CV >65 nmol/l-HEMR $\leq$ 3.0% CV	0.217, 0.344 nmol/l SD 2.7% CV 2.2, 2.5, 2.0% CV	LEMR-35 nmol/l $\leq$ 2.45 nmol/l SD >35-65 nmol/l $\leq$ 7% CV >65-160 nmol/l $\leq$ 4% CV >160 nmol/l-HEMR $\leq$ 5% CV	0.472, 0.856 nmol/l SD 4.4% CV 4.4% CV 3.9, 3.6% CV	n/a	n/a
TSH	LEMR-0.2 μ U/ml $\leq$ 0.01 μ U/ml SD > 0.2-100 μ U/ml $\leq$ 5% CV	0.001, 0.002 μ U/ml SD 1.1, 0.7, 0.8, 1% CV	LoD-0.2 μ U/ml $\leq$ 0.02 μ U/ml SD > 0.2-100 μ U/ml $\leq$ 10% CV	0.002, 0.004 μ U/ml SD 1.8, 2.2, 4, 1.5, 1.6% CV	LoD-0.2 μ U/ml $\leq$ 0.02 μ U/ml SD > 0.2-100 μ U/ml $\leq$ 11% CV	n/a
T-uptake	0.2-0.6 TBI $\leq$ 0.03 TBI SD > 0.6 -0.9 TBI $\leq$ 5% CV > 0.9-1.4 TBI $\leq$ 4% CV	0.014, 0.013 TBI SD 1% CV 0.9, 0.4, 0.7% CV	0.2-0.6 TBI $\leq$ 0.03 TBI SD > 0.6 -0.9 TBI $\leq$ 5% CV > 0.9-1.4 TBI $\leq$ 4% CV	0.017, 0.015 TBI SD 1.1, 1.3% CV 0.9, 0.4, 0.8% CV	0.2-0.6 TBI $\leq$ 0.04 TBI SD > 0.6 -0.9 TBI $\leq$ 7% CV > 0.9-1.4 TBI $\leq$ 5% CV	0.0145 TBI SD 1.0, 1.2% CV 1.3, 0.8, 0.5, 0.7% CV

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Tg II	LEMUR-0.5 ng/ml $\leq$ 0.04 ng/ml SD > 0.5 ng/ml – HEMR $\leq$ 8% CV	0.003 ng/ml SD 2.4, 1.4, 1.8, 1.6% CV	LEMUR-0.5 ng/ml $\leq$ 0.05 ng/ml SD > 0.5 ng/ml - HEMR $\leq$ 10% CV	0.005 ng/ml SD 2.7, 1.8, 2.2, 1.9% CV	n/a	n/a
Calcitonin	LEMUR to 10 pg/ml $\leq$ 0.5 pg/ml SD > 10 pg/ml to HEMR $\leq$ 5% CV	0.040 pg/ml SD 3.6, 1.8, 1.6% CV	LEMUR to 10 pg/ml $\leq$ 0.6 pg/ml SD > 10 pg/ml to HEMR $\leq$ 6% CV	0.054 pg/ml SD 3.8, 2.5, 5.3 % CV	n/a	n/a
Anti-TG	LoD-75 IU/ml $\leq$ 6 IU/ml 75-1000 IU/ml $\leq$ 8% CV 1000-2000 IU/ml $\leq$ 13% CV > 2000 IU/ml < 18% CV	1.24, 1.86 IU/ml SD 3.2, 3.5, 4.5% CV 5.1% CV 5.8, 4.2, 6.5% CV	LoD-75 IU/ml $\leq$ 7.5 IU/ml 75-1000 IU/ml $\leq$ 10% CV 1000-2000 IU/ml $\leq$ 15% CV > 2000 IU/ml < 20% CV	3.38, 3.32 IU/ml SD 6.0, 7.6, 6.9% CV 5.8, 6.3% CV 7.1, 9.6% CV	LoD-75 IU/ml $\leq$ 9.75 IU/ml 75-1000 IU/ml $\leq$ 13% CV > 1000 IU/ml < 27% CV	1.26, 0.96 IU/ml SD 2.7, 3.4% CV 1.8, 2.7% CV
Anti-TPO	LoD-40 IU/ml $\leq$ 3.2 IU/ml SD > 40 IU/ml $\leq$ 8% CV	1.14, 1.21, 1.49 IU/ml SD 3.0, 4.2, 4.8% CV	LoD-40 IU/ml $\leq$ 4.8 IU/ml SD > 40 IU/ml $\leq$ 12% CV	1.9, 2.6, 1.7 IU/ml SD 4.9, 5.5, 6.6% CV	LoD-40 IU/ml $\leq$ 6 IU/ml SD > 40 IU/ml $\leq$ 15% CV	2.65, 2.07 IU/ml SD 1.9, 2.9, 4.3% CV
Anti-TSHR	1.1-5 IU/l $\leq$ 0.3 IU/l SD $\geq$ 5-40 IU/l < 6% CV	0.115, 0.14, 0.131, 0.146 IU/l SD 1.4, 1.3, 2% CV	1.1-5 IU/l $\leq$ 0.35 IU/l SD $\geq$ 5-40 IU/l < 7% CV	0.194, 0.199, 0.21, 0.229 IU/l SD 1.9, 1.7, 2.6% CV	1.1-5 IU/l $\leq$ 0.5 IU/l SD $\geq$ 5-40 IU/l < 10% CV	n/a

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CK-MB	LoD-5 ng/ml $\leq$ 0.15 ng/ml SD >5-15 ng/ml $\leq$ 3% CV >15 ng/ml $\leq$ 5% CV	0.033, 0.093 ng/ml SD 1.8, 2.2% CV 1.6, 2.2% CV	LoD-5 ng/ml $\leq$ 0.25 ng/ml SD >5-15 ng/ml $\leq$ 5% CV >15 ng/ml $\leq$ 10% CV	0.048, 0.141 ng/ml SD 2.9, 4% CV 2.4, 3.4, 4.9% CV	LoD-5 ng/ml $\leq$ 0.3 ng/ml SD >5-15 ng/ml $\leq$ 6% CV >15 ng/ml $\leq$ 10% CV	0.044 ng/ml SD 2.3, 1.3, 2.1% CV 2.2, 3, 2.5% CV
GDF-15	LEMR-800 pg/mL $\leq$ 40 pg/mL SD > 800 pg/mL - HEMR $\leq$ 5% CV	7.87 pg/ml SD 1.3, 1.2, 1.1, 1.2, 1.3% CV	LEMR-800 pg/mL $\leq$ 80 pg/mL SD > 800 pg/mL - HEMR $\leq$ 10% CV	11.3 pg/ml SD 2.2, 2.0, 2.0, 2.3, 1.8% CV	n/a	n/a
Myoglobin	LoD-50 ng/ml $\leq$ 2.5 ng/ml SD >50-500 ng/ml $\leq$ 5% CV > 500 ng/ml $\leq$ 8% CV	0.686, 0.86 ng/ml SD 1.5, 1.1% CV 1.5, 1.7, 1.2% CV	LoD-50 ng/ml $\leq$ 3 ng/ml SD >50-500 ng/ml $\leq$ 6% CV > 500 ng/ml $\leq$ 10% CV	0.7, 0.935 ng/ml SD 1.7, 1.4% CV 1.6, 2.1, 2.4, 2.3, 1.6% CV	LoD-50 ng/ml $\leq$ 3.5 ng/ml SD >50-500 ng/ml $\leq$ 7% CV > 500 ng/ml $\leq$ 10% CV	0.45 ng/ml SD 0.7, 0.9, 1.3% CV 1.5, 2.8, 1.0% CV
proBNP II	LEMR to 50 pg/ml $\leq$ 5 pg/ml SD > 50 – 100 pg/ml $\leq$ 10% CV > 100-250 pg/ml $\leq$ 5% CV > 250 pg/ml to HEMR $\leq$ 5% CV	1.87 pg/ml 2.8% CV 2.0% CV 2.1, 1.7, 2.0, 1.7, 2.2% CV	LEMR to 50 pg/ml $\leq$ 6 pg/ml SD > 50 – 100 pg/ml $\leq$ 13% CV > 100-250 pg/ml $\leq$ 8% CV > 250 pg/ml to HEMR $\leq$ 5% CV	2.52 pg/ml SD 4.0% CV 3.4% CV 3.2, 3.0, 3.5, 3.4, 3.4% CV	n/a	n/a
Troponin I	LoD-0.3 ng/ml $\leq$ 0.024 ng/ml SD > 0.3 ng/ml $\leq$ 8% CV	0.005 ng/ml SD 2.1, 1.4, 1.3, 1.5% CV	LoD-0.3 ng/ml $\leq$ 0.03 ng/ml SD > 0.3 ng/ml $\leq$ 10% CV	0.013 ng/ml SD 2.8, 1.7, 1.6, 2.0 1.8% CV	LoD-0.3 ng/ml $\leq$ 0.036 ng/ml SD > 0.3 ng/ml $\leq$ 12% CV	0.009 ng/ml SD 1, 1.7, 0.6, 1.6, 1.1, 0.8% CV
Troponin T hs	LEMR to <14 pg/ml $\leq$ 0.7 pg/ml SD 14-100 pg/ml $\leq$ 5% CV > 100 pg/ml to HEMR $\leq$ 3% CV	0.45, 0.52 pg/ml SD 2.4% CV 2.2, 2.5, 2.1% CV	LEMR to <14 pg/ml $\leq$ 1.4 pg/ml SD 14-100 pg/ml $\leq$ 10% CV > 100 pg/ml to HEMR $\leq$ 6% CV	0.65, 0.63 pg/ml SD 3.6% CV 3.4, 4.0, 4.6% CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Digitoxin	LoD - <10 ng/ml ≤ 0.8 ng/ml SD ≥10-40 ng/ml ≤ 4% CV ≥ 40 ng/ml ≤ 6% CV	0.184, 0.256 ng/ml 1.8, 2.4, 1.7% CV 1.6% CV	LoD - <10 ng/ml ≤ 1.0 ng/ml SD ≥10-40 ng/ml ≤ 6% CV ≥ 40 ng/ml ≤ 8% CV	0.302, 0.366 ng/ml SD 3, 2.8% CV 2.7% CV	LoD - <10 ng/ml ≤ 1.5 ng/ml SD ≥10-40 ng/ml ≤ 9% CV ≥ 40 ng/ml ≤ 12% CV	0.223 ng/ml SD 3, 1.8, 3.8, 2.1% CV 1.5, 2.5% CV
Digoxin	LoD – 0.8 ng/ml ≤ 0.04 ng/ml SD > 0.8-4 ng/ml ≤ 5% CV > 4 ng/ml ≤ 6% CV	0.024 0.027 ng/ml SD 3.6, 2.0, 2.7, 2.3% CV 1.9% CV	LoD – 0.8 ng/ml ≤ 0.06 ng/ml SD > 0.8-4 ng/ml ≤ 7% CV > 4 ng/ml ≤ 9% CV	0.027, 0.029 ng/ml SD 3.9, 2.2, 3, 2.5% CV 2.6% CV	LoD – 0.8 ng/ml ≤ 0.07 ng/ml SD > 0.8-4 ng/ml ≤ 8% CV > 4 ng/ml ≤ 10% CV	0.0184 ng/ml SD 2.4, 4.8, 1.3, 3.7, 2.9% CV 1.9% CV
HCG+β	LoX-5 mIU/ml ≤ 0.225 mIU/ml SD >5-10000 mIU/ml ≤ 4.5% CV	0.0473 mIU/ml SD 2.8, 2.4, 2.1, 2.93.0 % CV	LoX-5 mIU/ml ≤ 0.275 mIU/ml SD >5-10000 mIU/ml ≤ 5.5% CV	0.0713 mIU/ml SD 4.3, 3.8, 4.4, 5.0, 3.5% CV	LoX-5 mIU/ml ≤ 0.325 mIU/ml SD >5-10000 mIU/ml ≤ 6.5% CV	0.058 mIU/ml SD 2.8, 1.5, 0.9, 0.7, 1.4, 2.1% CV
hCG STAT	LEMR-10 mIU/ml ≤ 0.4 mIU/ml SD > 10 mIU/ml - HEMR ≤ 4% CV	0.122, 0.0969 mIU/ml SD 1.5, 1.9, 1.5% CV	LEMR-10 mIU/ml ≤ 0.56 mIU/ml SD > 10 mIU/ml – HEMR ≤ 5.6% CV	0.164. 0.153 mIU/ml SD 3.6, 3.5, 3.4% CV	n/a	n/a
ACTH	LEMR to 10 pg/mL SD ≤ 0.60 pg/mL > 10 pg/mL to HEMR CV ≤ 6.0 %	0.170 pg/mL SD 1.3, 1.3, 1.1, 1.0% CV	LEMR to 10 pg/mL SD ≤ 0.76 pg/mL > 10 pg/mL to HEMR CV ≤ 7.6 %	0.272 pg/mL SD 2.9, 2.9, 2.8, 3.2% CV	n/a	n/a
AMH / AMH Plus	LEMR-0.5 ng/ml ≤ 0.025 ng/ml SD >0.5-1 ng/ml ≤ 5% CV >1-8 ng/ml ≤ 4% CV > 8 ng/ml - HEMR ≤ 3% CV	0.001 ng/ml SD 1.5% CV 1.5% CV 1.4, 1.9% CV	LEMR-0.5 ng/ml ≤ 0.03 ng/ml SD >0.5-1 ng/ml ≤ 6% CV >1-8 ng/ml ≤ 5% CV > 8 ng/ml - HEMR ≤ 5% CV	0,0019 ng/ml SD 2.8% CV 3.6% CV 3.7, 3.2% CV	n/a	n/a

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Androsten edione	LEoMR to 0.60 ng/mL SD ≤ 0.04 ng/mL > 0.60 ng/mL to HEoMR CV ≤ 6.0 %	0.014 ng/mL, 0.435 ng/mL 0.900 ng/mL, 2.3 % 3.12 ng/mL, 2.9 % 5.33 ng/mL, 3.2 % 9.15 ng/mL, 3.4 %	LEoMR to 0.60 ng/mL SD ≤ 0.06 ng/mL > 0.60 ng/mL to HEoMR CV ≤ 8.0 %	0.019 ng/mL, 0.435 ng/mL 0.900 ng/mL, 3.4 % 3.12 ng/mL, 3.7 % 5.33 ng/mL, 3.7 % 9.15 ng/mL, 4.5 %	n/a	n/a
Cortisol II serum	LoD-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	0.123 nmol/l SD 0.366 nmol/l SD 1.1, 1.6, 1.4% CV 1.4% CV	LoD-50 nmol/l ≤ 2.5 nmol/l SD >50-900 nmol/l ≤ 6% CV >900-1750 nmol/l ≤ 7% CV	0.163, 0.581 nmol/l SD 1.8, 2.1, 1.7% CV 2.1% CV	LoD-50 nmol/l ≤ 3 nmol/l SD >50-900 nmol/l ≤ 8% CV >900-1750 nmol/l ≤ 9% CV	0.133, 0.723 nmol/l SD 2.3, 2.8, 1.4, 1.2% CV 2.3% CV
Cortisol II saliva	LoD-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	0.094 nmol/l SD 0.145, 0.219, 0.408 nmol/l SD 1.3% CV	LoD-50 nmol/l ≤ 2.5 nmol/l SD >50-900 nmol/l ≤ 6% CV >900-1750 nmol/l ≤ 7% CV	0.149, 0.202, 0.630, 0.795 nmol/l SD 1.9% CV	-	-
Cortisol III Urine	LEMR to 35 nmol/L ≤ 1.75 nmol/L SD > 35 nmol/L to HEMR ≤ 5% CV	0.341 nmol/L SD 2.7, 2.3, 2.0, 2.1% CV	LEMR to 35 nmol/L ≤ 2.1 nmol/L SD > 35 nmol/L to HEMR ≤ 6% CV	0.492 nmol/L SD 3.8, 2.9, 3.2, 3.2% CV	n/a	n/a
DHEAS	0.2-50 µg/dl ≤ +/- 2.5 µg/dl SD > 50-1000 µg/dl ≤ 5% CV	0.160, 0.539 µg/dl SD 3.7, 3.5, 3.6, 3.4, 3.2% CV	0.2-50 µg/dl ≤ +/- 3.5 µg/dl SD > 50-1000 µg/dl ≤ 7% CV	0.174, 0.667 µg/dl SD 4.9, 4.2, 5.1, 4, 4.6% CV	0.2-50 µg/dl ≤ +/- 4 µg/dl SD > 50-1000 µg/dl ≤ 8% CV	1.3 µg/dl SD 4.3, 2.9, 4.6, 7.2, 1.95, 0.7% CV
Estradiol III	LoD-50 pg/ml ≤ 4 pg/ml SD > 50-200 pg/ml ≤ 7% CV > 200-3000 pg/ml ≤ 6% CV	1.56 pg/ml SD 1.4, 2% CV 1.2, 2.4, 1.6% CV	LoD-50 pg/ml ≤ 6 pg/ml SD > 50-200 pg/ml ≤ 10% CV > 200-3000 pg/ml ≤ 8% CV	2.3 pg/ml SD 1.8, 2.6% CV 1.9, 2, 1.7% CV	LoD-50 pg/ml ≤ 7 pg/ml SD > 50-3000 pg/ml ≤ 12% CV	1.32 pg/ml SD 1.3, 1.2, 0.8, 1.6, 2.4, 1.3% CV

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FSH	LEMR to 20 mIU/ml $\leq$ 1 mIU/ml SD > 20-100 mIU/ml $\leq$ 4.3% CV > 100-200 mIU/ml $\leq$ 3.5% CV	0.010, 0.139 mIU/ml SD 2.1% CV 1.4, 1.6% CV	LEMR to 20 mIU/ml $\leq$ 1.2 mIU/ml SD > 20-100 mIU/ml $\leq$ 5.1% CV > 100-200 mIU/ml $\leq$ 6% CV	0.040, 0.326 mIU/ml SD 3.8% CV 3.3, 3.5% CV	n/a	n/a
LH	LoD-20 mU/ml $\leq$ 1 mIU/ml SD > 20-100 mU/ml $\leq$ 5% CV > 100-200 mU/ml $\leq$ 4% CV	0.021, 0.12 mIU/ml SD 1.0, 1.3% CV 1.1, 0.9% CV	LoD-20 mU/ml $\leq$ 1.4 mIU/ml SD > 20-100 mU/ml $\leq$ 6% CV > 100-200 mU/ml $\leq$ 5% CV	0.023, 0.0177 mIU/ml SD 1.1, 2.1% CV 1.3, 1.2% CV	LoD-20 mU/ml $\leq$ 1.6 mIU/ml SD > 20-100 mU/ml $\leq$ 7% CV > 100-200 mU/ml $\leq$ 6% CV	0.0276, 0.224 mIU/ml SD 4.7, 1.3% CV 1.4, 1.7% CV
Progesterone III	LoD-0.5 ng/ml $\leq$ 0.08 ng/ml SD >0.5-1 ng/ml $\leq$ 10% CV >1 ng/ml $\leq$ 6% CV	0.0111 ng/ml SD 4.2 % CV 1.1, 1.4, 2.0, 2.7% CV	LoD-0.5 ng/ml $\leq$ 0.12 ng/ml SD >0.5-1 ng/ml $\leq$ 11.5% CV >1 ng/ml $\leq$ 7% CV	0.236 ng/ml SD 6.2% CV 3.3, 1.7, 2.8, 2.0% CV	0.05-0.5 ng/ml $\leq$ 0.2 ng/ml SD >0.5-1 ng/ml $\leq$ 16% CV >1 ng/ml $\leq$ 9% CV	0.0272 ng/ml SD 5% CV 3.6, 3.3, 3.4, 2.4, 1.7% CV
Prolactin II	LoD-50 μ IU/ml $\leq$ 5 μ IU/ml SD > 50-100 μ IU/ml $\leq$ 5% CV > 100 μ IU/ml $\leq$ 6% CV	0.269 μ IU/ml SD 3.1 % CV 1.8, 2.4, 2.1, 2.0% CV	LoD-50 μ IU/ml $\leq$ 6 μ IU/ml SD > 50-100 μ IU/ml $\leq$ 12% CV > 100 μ IU/ml $\leq$ 7% CV	0.313 μ IU/ml SD 3.8% CV 2.9, 3.5, 2.6, 4.4% CV	LoD-50 μ IU/ml $\leq$ 7 μ IU/ml SD > 50-100 μ IU/ml $\leq$ 14% CV > 100 μ IU/ml $\leq$ 8% CV	3.8% CV 2.7, 2.9, 3.5, 2.6, 4.4% CV
SHBG	LoD-20 nmol/l +/- 1 nmol/l SD >20-200 nmol/l $\leq$ 4% CV	0.0732, 0.16 nmol/l SD 1.7, 2.2, 3.1, 1.9% CV	LoD-20 nmol/l +/- 1.4 nmol/l SD >20-200 nmol/l $\leq$ 6% CV	0.105, 0.236 nmol/l SD 2.4, 2.9, 3.8, 2.6, 2.4% CV	LoD-20 nmol/l +/- 2 nmol/l SD >20-200 nmol/l $\leq$ 8% CV	0.305, 0.389 nmol/l SD 2.4, 4.6, 2, 2.1% CV

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Testosterone II	LEMR to 0.15 ng/ml $\leq$ 0.015 ng/ml SD > 0.15 – 0.5 ng/ml $\leq$ 10% CV > 0.5-1 ng/ml $\leq$ 6% CV > 1-3 ng/ml $\leq$ 5% CV >3-15 ng/ml $\leq$ 5% CV	0.006 ng/ml SD 3.0% CV 1.6% CV 1.5% CV 1.7% CV	LEMR to 0.15 ng/ml $\leq$ 0.03 ng/ml SD > 0.15 – 0.5 ng/ml $\leq$ 20% CV > 0.5-1 ng/ml $\leq$ 8% CV > 1-3 ng/ml $\leq$ 6% CV >3-15 ng/ml $\leq$ 6% CV	0.012 ng/ml SD 4.7% CV 3.2% CV 2.2% CV 2.2% CV	LoD-0.15 ng/ml $\leq$ 0.06 ng/ml SD > 0.15 – 0.5 ng/ml $\leq$ 20% CV > 0.5-1 ng/ml $\leq$ 10% CV 1-15 ng/ml $\leq$ 8% CV	0.007 ng/ml SD 4.3% CV 1.3% CV 1.8, 3.6, 1.8, 2.2% CV
C-Peptide serum	LoD-0.5 ng/ml $\leq$ 0.15 ng/ml SD 0.5-40 ng/ml $\leq$ 5% CV	0.004 ng/ml SD 0.9, 2.0, 2.8% CV	LoD-0.5 ng/ml $\leq$ 0.2 ng/ml SD 0.5-40 ng/ml $\leq$ 6% CV	0.004 ng/ml SD 2.3, 3.6, 2.6% CV	LoD-0.5 ng/ml $\leq$ 0.3 ng/ml SD 0.5-40 ng/ml $\leq$ 8% CV	0.01 ng/ml SD 0.9, 2.0, 1.5% CV
C-Peptide urine	0.2-0.5 ng/ml $\leq$ 0.15 ng/ml SD 0.5-40 ng/ml $\leq$ 5% CV	0.059 ng/ml SD 3.8, 1.4, 3.0% CV	0.2-0.5 ng/ml $\leq$ 0.2 ng/ml SD 0.5-40 ng/ml $\leq$ 6% CV	0.067 ng/ml SD 4.8, 2.9, 3.3% CV	-	-
Insulin	LoD-10 μ U/ml $<$ 0.5 μ U/ml SD >10-1000 μ U/ml $<$ 5% CV	0.141 μ U/ml SD 1.4, 0.8, 1.1, 1.0 % CV	LoD-10 μ U/ml $<$ 0.6 μ U/ml SD >10-1000 μ U/ml $<$ 6% CV	0.172 μ U/ml SD 2.1, 1.4, 1.6, 1.5, 2.0% CV	LoD-10 μ U/ml $<$ 0.7 μ U/ml SD >10-1000 μ U/ml $<$ 7% CV	0.214 μ U/ml SD 1.4, 2.2, 2.3, 4.3, 1.8% CV
PIGF	LoD -50 pg/ml $\leq$ 4 pg/ml SD > 50-200 pg/ml $\leq$ 8% CV > 200 pg/ml $\leq$ 6% CV	0.226 pg/ml SD 1.3% CV 1.0, 1.4, 1.3% CV	$\leq$ LoD -50 pg/ml $\leq$ 5 pg/ml SD > 50-200 pg/ml $\leq$ 10% CV > 200 pg/ml $\leq$ 8% CV	0.351 pg/ml SD 1.9% CV 1.5, 1.8, 2.3, 1.5% CV	LoD -50 pg/ml $\leq$ 6 pg/ml SD > 50-200 pg/ml $\leq$ 12% CV > 200 pg/ml $\leq$ 10% CV	0.331 pg/ml SD 1.8, 0.8% CV 1.3, 1.6, 2.2, 1.3% CV
sFlt-1	LoD-25 pg/ml $\leq$ 2 pg/ml SD $\geq$ 25-200 pg/ml $\leq$ 8% CV $\geq$ 200-10000 pg/ml $\leq$ 7% CV $\geq$ 10000 pg/ml $\leq$ 6% CV	1.47 pg/ml SD 3.8, 2.4% CV 1.9, 2% CV 2.5, 4.2% CV	LoD-25 pg/ml $\leq$ 3 pg/ml SD $\geq$ 25-200 pg/ml $\leq$ 12% CV $\geq$ 200-10000 pg/ml $\leq$ 8% CV $\geq$ 10000 pg/ml $\leq$ 7% CV	1.62 pg/ml SD 4, 3.5% CV 3.1, 3.6% CV 4.3, 6.1% CV	LoD-25 pg/ml $\leq$ 3.25 pg/ml SD $\geq$ 25-200 pg/ml $\leq$ 13% CV $\geq$ 200-10000 pg/ml $\leq$ 12% CV $\geq$ 10000 pg/ml $\leq$ 11% CV	1.5, 1.8% CV 1, 1.3% CV 1.3, 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 prec.	Specified intermodule precision	Internal eval. intermodule prec.
AFP	LEMR to 4 IU/mL ≤ 0.4 IU/mL SD > 4 IU/mL to 60 IU/mL $\leq 4\%$ CV > 60 IU/mL to HEMR $\leq 7\%$ CV	0.0783, 0.0731% CV 1.6, 2.4% CV 1.8, 1.6, 1.9% CV	LEMR to 4 IU/mL ≤ 0.4 IU/mL SD > 4 IU/mL to 60 IU/mL $\leq 7\%$ CV > 60 IU/mL to HEMR $\leq 9\%$ CV	0.0840, 0.0756% CV 2.4, 2.8% CV 2.4, 2.3, 2.4% CV	n/a	n/a
AFP-L3	LEMR to 6 ng/mL ≤ 0.5 ng/mL SD 6.0 ng/mL to HEMR $\leq 8\%$ CV	0.108, 0.153, 0.147, 0.211 ng/mL SD 5.9, 5.9, 3.9, 4.6% CV	LEMR to 6 ng/mL ≤ 0.7 ng/mL SD 6.0 ng/mL to HEMR $\leq 12\%$ CV	0.136, 0.157, 0.168, 0.236 ng/mL SD 6.6, 5.9, 4.5, 4.9% CV	n/a	n/a
CA 125 II	LoD-10 U/ml ≤ 0.8 U/ml SD >10 U/ml $\leq 6\%$ CV	0.043, 0.046 U/ml SD 1.1, 1.5, 1.6% CV	LoD-10 U/ml ≤ 1.0 U/ml SD >10 U/ml $< 8\%$ CV	0.054, 0.065 U/ml SD 1.9, 2.8, 2.4% CV	LoD-10 U/ml ≤ 1.2 U/ml SD >10 U/ml $< 12\%$ CV	0.132 U/ml SD 1.8, 4.1, 6.7, 1.4% CV
CA 15-3 II	LoD-15 U/ml ≤ 0.8 U/ml SD > 15-50 U/ml $\leq 5\%$ CV > 50 U/ml $\leq 6.5\%$ CV	0.11 U/ml SD 2, 1.3% CV 4.5, 2.9, 1.5% CV	LoD-15 U/ml ≤ 1.2 U/ml SD > 15 U/ml $\leq 7.5\%$ CV	0.305 U/ml SD 2.7, 3.4, 5.0% SD	LoD-15 U/ml ≤ 1.5 U/ml SD > 15 U/ml $\leq 10\%$ CV	0.256 U/ml SD 2.1, 3.4, 4.0% CV
CA 19-9	LoD-30 U/ml ≤ 1.5 U/ml SD 30-1000 U/ml $\leq 5\%$ CV	0.106, 0.278, 0.143 U/ml SD 1.1, 1.3, 1.2% CV	LoD-30 U/ml ≤ 2.7 U/ml SD 30-1000 U/ml $\leq 9\%$ CV	0.119, 0.361, 0.173 U/ml SD 1.3, 1.7, 1.4% CV	LoD-30 U/ml ≤ 3 U/ml SD 30-1000 U/ml $\leq 10\%$ CV	0.382, 0.503, 0.45 U/ml SD 1.3, 1.4, 2.5% CV
CA 72-4	LEMR to 4 U/ml ≤ 0.2 U/ml SD > 4-100 U/ml $\leq 5\%$ CV > 100 U/ml to HEMR $\leq 6\%$ CV	0.51 U/ml SD 1.5, 2.0% CV 1.0, 1.4% CV	LEMR to 4 U/ml ≤ 0.25 U/ml SD > 4-100 U/ml $\leq 6\%$ CV > 100 U/ml to HEMR $\leq 8\%$ CV	0.112 U/ml SD 2.6, 2.6% CV 1.8, 1.9% CV	n/a	n/a
CEA	LoB-5 ng/ml ≤ 0.5 ng/ml SD >5-1000 ng/ml $\leq 6.5\%$ CV	0.021, 0.049, 0.066, 0.078 ng/ml SD 2.1, 2.2, 1.6% CV	LoB-10 ng/ml ≤ 1 ng/ml SD >10-1000 ng/ml $\leq 10.5\%$ CV	0.023, 0.058, 0.103 ng/ml SD 2.3, 2.1, 1.8% CV	LoB-10 ng/ml ≤ 1.2 ng/ml SD >10-1000 ng/ml $\leq 12.5\%$ CV	0.064, 0.049 ng/ml SD 1.1, 1.2, 3.0% CV
Cyfra 21-1	LEMR-1 ng/ml $\leq \pm 0.08$ ng/ml SD >1-10 ng/ml $\leq 4.5\%$ CV > 10 ng/ml $\leq 5.5\%$ CV	0.026 ng/ml 1.2, 1.4% CV 1, 1.3, 1.4, 0.9, 1.2% CV	LEMR-1 ng/ml $\leq \pm 0.1$ ng/ml SD >1-10 ng/ml $\leq 6.5\%$ CV > 10 ng/ml $\leq 7\%$ CV	0.03 ng/ml SD 1.4, 1.8% CV 1.1, 1.5, 1.6, 1.3, 1.4% CV	LEMR-1 ng/ml $\leq \pm 0.12$ ng/ml SD >1-10 ng/ml $\leq 8\%$ CV > 10 ng/ml $\leq 10\%$ CV	0.057, 0.0275 ng/ml SD 1.9, 2% CV 1.6, 1.2% CV
HE4	LoD-30 pmol/l ≤ 3 pmol/l SD >30-1500 pmol/l $\leq 5\%$ CV	0.16, 0.332 pmol/l SD 2.1, 0.9, 2.4, 1.0, 0.7% CV	LoD-30 pmol/l ≤ 3 pmol/l SD >30-1500 pmol/l $\leq 7\%$ CV	0.21, 0.374 pmol/l SD 2.4, 1.2, 1.1, 1.2% CV	LoD-30 pmol/l ≤ 5 pmol/l SD >30-1500 pmol/l $\leq 10\%$ CV	1.5, 3.3, 2.7, 1.6, 1.7% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
NSE	0.075-15 ng/ml $\leq$ +/- 0.6 ng/ml SD > 15-300 ng/ml $\leq$ 4% CV	0.028, 0.029, 0.176, 0.182 ng/ml SD 1.3, 1.6, 1.4, 1.5% CV	0.075-15 ng/ml $\leq$ +/- 1 ng/ml SD > 15-300 ng/ml $\leq$ 6.5% CV	0.017, 0.015, 0.16, 0.139 ng/ml SD 0.9, 1.3, 1.2, 1% CV	0.075-15 ng/ml $\leq$ +/- 1.5 ng/ml SD > 15-300 ng/ml $\leq$ 10% CV	0.0097, 0.293, 0.185 ng/ml SD 1.7, 1.8% CV
PIVKA-II	LEMR to 30 ng/ml $\leq$ 1.5 ng/ml SD > 30 ng/ml to HEMR $\leq$ 5% CV	0.112, 0.215, 0.314 ng/ml SD 1.4, 1.0, 1.3% CV	LEMR to 30 ng/ml $\leq$ 2.25 ng/ml SD > 30 ng/ml to HEMR $\leq$ 7.5% CV	0.511, 1.19, 1.57 ng/ml SD 5.1, 4.3, 4.2% CV	n/a	n/a
ProGRP	LEMR-60 pg/ml $\leq$ 3 pg/ml SD > 60 pg/ml - HEMR $\leq$ 5.4% CV	0.292, 0.417 pg/ml SD 1.6, 1.6, 1.1% CV	LEMR-60 pg/ml $\leq$ 6 pg/ml SD > 60 pg/ml - HEMR $\leq$ 10.4% CV	0.334, 0.447 pg/ml SD 1.9, 1.9, 1.8% CV	n/a	n/a
free PSA	LEMR-0.1 ng/ml $\leq$ 0.007 ng/ml SD > 0.1-0.4 ng/ml $\leq$ 7.4% CV > 0.4-50 ng/ml $\leq$ 5.4% CV	0.0025 ng/ml SD 1.8% CV 1.4, 1, 1.2, 1.1, 1.3% CV	LEMR-0.1 ng/ml $\leq$ 0.01 ng/ml SD > 0.1-0.4 ng/ml $\leq$ 10.4% CV > 0.4-50 ng/ml $\leq$ 8.4% CV	0.003 ng/ml SD 3.6% CV 2.1, 2.3, 1.8, 1.9, 2% CV	n/a	n/a
total PSA	LEMR- $\leq$ 0.1 ng/ml $\leq$ 0.007 ng/ml SD >0.1- $\leq$ 1.0 ng/ml $\leq$ 7.4% CV >1- $\leq$ 50 ng/ml $\leq$ 3.4% CV >50-100 ng/ml $\leq$ 5.4% CV	0.001 ng/ml SD 3.1% CV 2.0, 0.6, 2.9% CV 0.7, 4.5% CV	LEMR- $\leq$ 0.1 ng/ml $\leq$ 0.010 ng/ml SD >0.1- $\leq$ 1.0 ng/ml $\leq$ 10.4% CV >1- $\leq$ 50 ng/ml $\leq$ 5.4% CV >50-100 ng/ml $\leq$ 8.4% CV	0.001ng/ml SD 3.2% CV 2.3, 1.5, 3.0% CV 1.5, 4.5% CV	n/a	n/a
S100	n/a	n/a	n/a	n/a	n/a	n/a
SCC	LoD-1.8 ng/ml SD $\leq$ 0.1 ng/ml > 1.8-5 ng/ml $\leq$ 5% CV > 5-70 ng/ml $\leq$ 6.5% CV	0.024, 0.019 ng/ml SD 1.9, 1.6, 2.0% CV 1.1, 0.9, 1.3% CV	LoD-1.8 ng/ml SD $\leq$ 0.2 ng/ml > 1.8-70 ng/ml $\leq$ 10% CV	0.026, 0.02 ng/ml SD 2, 2.9, 2.7% CV 1.4, 1.2, 1.5, 1.7% CV	LoD-1.8 ng/ml SD $\leq$ 0.2 ng/ml > 1.8-70 ng/ml $\leq$ 10% CV	0.0225, 0.0427 ng/ml SD 1.6, 1.1, 1.5% CV
Anti-p53	LoB-0.2 μ g/ml $\leq$ 0.02 μ g/ml SD > 0.2-10 μ g/ml $\leq$ 3.5% CV > 10-100 μ g/ml $\leq$ 4.5% CV	0.001, 0.002 μ g/ml SD 1.2% CV 0.9%, 0.7% CV	LoB-0.2 μ g/ml $\leq$ 0.025 μ g/ml SD > 0.2-10 μ g/ml $\leq$ 6.5% CV > 10-100 μ g/ml $\leq$ 7% CV	0.002 / 0.002 μ g/ml SD 2.2% CV 1.5, 1.9% CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Free β hCG	LEMR-15 IU/L ≤ 0.6 IU/I SD > 15 IU/L-HEMR $\leq 3\%$ CV	0.008, 0.129 IU/L SD 1.4, 1.6, 1.8, 1.5% CV	LEMR-15 IU/L ≤ 1 IU/I SD > 15 IU/L-HEMR $\leq 5\%$ CV	0.008, 0.134 IU/I SD 1.7, 1.9, 2.1, 1.6% CV	n/a	n/a
PAPP-A	LEMR-50 mIU/I ≤ 2.5 mIU/I SD >50-2000 mIU/I $\leq 3.5\%$ CV >2000 mIU/I-HEMR $\leq 3\%$ CV	0.419, 0.491 mIU/I SD 1.7, 1.3% CV 1.6, 1.7, 2.4, 1.3% CV	LEMR-50 mIU/I ≤ 4 mIU/I SD >50-2000 mIU/I $\leq 6\%$ CV >2000 mIU/I-HEMR $\leq 5\%$ CV	0.575, 0.74 mIU/I SD 2, 1.6% CV 2.3, 2.6, 3.2, 1.8, 1.6% CV	n/a	n/a
Active B12	LEMR to 20 pmol/L SD ≤ 0.8 pmol/L > 20 pmol/L to HEMR CV $\leq 4.0\%$	0.106 pmol/L SD 1.9, 1.7, 1.8, 1.5% CV	LEMR to 20 pmol/L SD ≤ 1.2 pmol/L > 20 pmol/L to HEMR CV $\leq 6.0\%$	0.231 pmol/I SD 2.4, 2.4, 2.5, 2.4% CV	n/a	n/a
B12 II	LEMR-200 pg/ml ≤ 11 pg/ml SD > 200 pg/ml $\leq 5.5\%$ CV	9.45, 8.5 pg/ml SD 3.9, 1.2, 1.1, 4.1, 2.3% CV	LEMR-200 pg/ml ≤ 19 pg/ml SD > 200 pg/ml $\leq 9.5\%$ CV	10.6, 9.74 pg/ml SD 4.5, 1.8, 2.4, 4.8, 2.6% CV	LEMR- 200 pg/ml ≤ 24 pg/ml SD > 200 pg/ml $\leq 12\%$ CV	7.88, 9.86, 7.07 pg/ml SD 1.4, 1.6, 3.4, 2.1% CV
Ferritin	LEMR-25 ng/ml $\leq +/- 1$ ng/ml SD > 25 pg/ml $\leq 4\%$ CV	0.115, 0.054, 0.458 ng/ml SD 1.5, 2.6, 2.8, 1.5, 1.1, 1.3, 1.9% CV	LEMR-25 ng/ml $\leq +/- 1.75$ ng/ml SD > 25 pg/ml $\leq 7\%$ CV	0.127, 0.0625, 0.62 ng/ml SD 2.6, 4, 4.4, 2.4, 3.7% CV	LEMR-25 ng/ml $\leq +/- 2$ ng/ml SD > 25 pg/ml $\leq 8\%$ CV	0.115, 0.385, 0.227 ng/ml SD 1.6, 1, 3.7, 1.8% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Folate III	LEMR to 5 ng/ml $\leq$ 0.35 ng/ml SD > 5 ng/ml to HEMR $\leq$ 7% CV	0.148, 0.197, 0.169 ng/ml SD 3.7, 3.2 % CV	LEMR to 5 ng/ml $\leq$ 0.6 ng/ml SD > 5 ng/ml to HEMR $\leq$ 12% CV	0.172, 0.215, 0.197 ng/ml SD 4.1, 3.4 % CV	n/a	n/a
Folate RBC	LEMR-155 ng/ml $\leq$ 12.4 ng/ml SD > 155 ng/ml $\leq$ 8 % CV	9.31 ng/ml SD 5.7, 6.1, 3.0, 3.6% CV	LEMR-250 ng/ml $\leq$ 20 ng/ml SD > 250 ng/ml $\leq$ 8 % CV	10, 10.4, 12.4 ng/ml SD 4.0, 4.2% CV	LEMR-155 ng/ml $\leq$ 19 ng/ml SD > 155 ng/ml $\leq$ 12 % CV	6.53 ng/ml SD 1.4, 3.4, 2.0, 10.3% CV
β -CrossLaps/ serum	LEMR to $\leq$ 0.50 ng/ml $\leq$ 0.02 ng/ml SD > 0.50 ng/ml to HEMR $\leq$ 3 % CV	0.003, 0.011 ng/ml SD 2.2, 1.6, 2.0% CV	LEMR to $\leq$ 0.50 ng/ml $\leq$ 0.03 ng/ml SD > 0.50 ng/ml to HEMR $\leq$ 5 % CV	0.003, 0.014 ng/ml SD 2.4, 1.9, 2.5% CV	n/a	n/a
N-MID Osteocalcin	LoEMR-20 ng/ml $\leq$ 0.8 ng/ml SD > 20 ng/ml-HiEMR $\leq$ 3% CV	0.096, 0.139 ng/ml SD 1.5, 1.4, 1.6, 0.7, 0.8% CV	LoEMR-20 ng/ml $\leq$ 1 ng/ml SD > 20 ng/ml-HiEMR $\leq$ 4% CV	0.14, 0.179 ng/ml SD 2.2, 2.4, 2.2, 1, 1.3% CV	LoEMR-20 ng/ml $\leq$ 1.2 ng/ml SD > 20 ng/ml-HiEMR $\leq$ 4.5% CV	0.079, 0.075 ng/ml SD 0.6, 1.5, 1.7, 0.8, 2.0% CV
PTH	LEMR to 15 pg/ml $\leq$ 0.8 pg/ml SD >15 pg/ml to HEMR $\leq$ 5% CV	0.159 pg/ml SD 1.7, 1.2, 1.3, 1.0 % CV	LEMR to 15 pg/ml $\leq$ 1.0 pg/ml SD >15 pg/ml to HEMR $\leq$ 6.5% CV	0.236 pg/ml SD 2.3, 1.7, 1.9, 1.8 % CV	n/a	n/a
PTH (1-84)	LEMR to 25 pg/ml $\leq$ 1.2 pg/ml SD > 25 pg/ml to HEMR $\leq$ 4.5% CV	0.390, 0.342 pg/ml SD 1.3, 1.4, 1.3% CV	LEMR to 25 pg/ml $\leq$ 1.5 pg/ml SD > 25 pg/ml to HEMR $\leq$ 6% CV	0.465, 0.388 pg/ml SD 1.7, 2.0, 1.7% CV	n/a	n/a
Total P1NP	LoD $\leq$ 15 ng/ml $\leq$ 0.9 ng/ml SD > 15-1200 ng/ml $\leq$ 6 % CV	0.137 ng/ml SD 1.6, 1.8, 2.0, 3.5, 1.6, 1.8% CV	LoD $\leq$ 15 ng/ml $\leq$ 1.1 ng/ml SD > 15-1200 ng/ml $\leq$ 7 % CV	0.144 ng/ml SD 2, 2.4, 2.3, 3.8, 2.1% CV	LoD $\leq$ 15 ng/ml $\leq$ 1.4 ng/ml SD > 15-1200 ng/ml $\leq$ 9 % CV	0.427 ng/ml SD 2, 2.3, 1.4, 3.5, 1.7, 1.4% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Vitamin D total III	LEMUR to 20 ng/ml $\leq$ 1.2 ng/ml SD > 20 ng/ml to HEMR $\leq$ 6% CV	0.498, 0.483 ng/ml SD 3.0, 1.6, 1.3%CV	LEMUR to 20 ng/ml $\leq$ 1.6 ng/ml SD > 20 ng/ml to HEMR $\leq$ 8% CV	0.698, 0.883 ng/ml SD 3.9, 2.4, 1.5% CV	n/a	n/a
hGH	LoD-0.7 ng/ml $\leq$ 0.04 ng/ml SD > 0.7 – 50 ng/ml $\leq$ 6% CV	0.002 ng/ml SD 2.8, 1.3, 2.2, 0.6, 0.8% CV	LoD-0.7 ng/ml $\leq$ 0.04 ng/ml SD > 0.7 – 50 ng/ml $\leq$ 7% CV	0.003, 0.002 ng/ml SD 3, 1.7, 2.5, 1.1% CV	LoD-0.7 ng/ml $\leq$ 0.04 ng/ml SD > 0.7 – 50 ng/ml $\leq$ 8% CV	0.004 ng/ml SD 2.9, 2.1, 1.7, 1.9% CV
IGF-1	LEMUR – 40 ng/ml $\leq$ 1.6 ng/ml SD > 40 ng/ml to HEMR $\leq$ 4% CV	0.475 ng/ml SD 1.1, 1.7, 1.3, 3.5, 1, 0.9% CV	LEMUR – 40 ng/ml $\leq$ 4 ng/ml SD > 40 ng/ml to HEMR $\leq$ 10% CV	0.551 ng/ml SD 1.7, 2.7, 1.8, 3.9, 1.4, 1.2% CV	LEMUR – 40 ng/ml $\leq$ 4.4 ng/ml SD > 40 ng/ml to HEMR $\leq$ 11% CV	n/a
IGFBP-3	LEMUR – 150 ng/ml $\leq$ 6 ng/ml SD > 150 ng/ml to HEMR $\leq$ 4% CV	105 ng/ml SD 2.2, 2.1, 3.2, 2.6, 1.9% CV	LEMUR – 150 ng/ml $\leq$ 7.5 ng/ml SD > 150 ng/ml to HEMR $\leq$ 5% CV	105 ng/ml SD 2.8, 2.3, 3.8, 2.1% CV	LEMUR – 150 ng/ml $\leq$ 15 ng/ml SD > 150 ng/ml to HEMR $\leq$ 10% CV	84.9 ng/ml SD 2.1, 2.2, 2.5, 2.7% CV
IgE II	LeMR-3 IU/ml $\leq$ 0.14 IU/ml SD > 3 IU/ml $\leq$ 4.5% CV	0.017, 0.03 IU/ml SD 1.6, 1.7, 2.1, 2.6% CV	LeMR-3 IU/ml $\leq$ 0.18 IU/ml SD > 3 IU/ml $\leq$ 6% CV	0.02, 0.049 IU/ml SD 2.3, 3.0, 3.7, 2.2% CV	LeMR-3 IU/ml $\leq$ 0.27 IU/ml SD > 3 IU/ml $\leq$ 7% CV	0.03 IU/ml SD 2.4, 1.3, 1.9, 2.0% CV
Anti-CCP	LoX-17 U/ml $\leq$ 2.5 U/ml SD > 17-200 U/ml $\leq$ 6% CV > 200-1000 U/ml $\leq$ 8% CV	0.202, 0.189 U/ml SD 1.4, 1.3, 1.6, 0.9% CV 1.2, 1.9% CV	LoX-17 U/ml $\leq$ 4 U/ml SD > 17-200 U/ml $\leq$ 8% CV > 200-1000 U/ml $\leq$ 10% CV	0.291, 0.261 U/ml SD 1.8, 1.5, 2.4, 1.7% CV 1.3, 1.9% CV	LoX-17 U/ml $\leq$ 4 U/ml SD > 17-200 U/ml $\leq$ 10% CV > 200-1000 U/ml $\leq$ 11% CV	0.422 U/ml SD 1.1, 0.5, 1% CV 2.3, 1.1% CV
BRAHMS PCT	LoD-0.1 ng/ml $\leq$ +/- 0.01 ng/ml SD > 0.1 ng/ml $\leq$ 10% CV	0.002 ng/ml SD 6.9, 1.8, 1.4, 2.1, 0.9% CV	LoD-0.1 ng/ml $\leq$ +/- 0.015 ng/ml SD > 0.1 ng/ml $\leq$ 15% CV	0.004 ng/ml SD 7.9, 2, 1.5, 2.4, 1% CV	LoD-0.1 ng/ml $\leq$ +/- 0.02 ng/ml SD > 0.1 ng/ml $\leq$ 20% CV	n/a
IL-6	LEMUR-25 pg/ml $\leq$ 2 pg/ml SD > 25 pg/ml – HEMR $\leq$ 5% CV	0.141, 0.179, 0.321 pg/ml SD 0.6, 1.0% CV	LEMUR-25 pg/ml $\leq$ 2 pg/ml SD > 25 pg/ml – HEMR $\leq$ 7% CV	0.180, 0.209, 0.360 pg/ml SD 1.2, 1.3% CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Cyclosporine	LoD - ≤ 90 ng/ml ≤ 7 ng/ml SD > 90-2000 ng/ml $\leq 8\%$ CV	1.33, 1.96 ng/ml SD 2, 2.9, 2.2, 1.5, 1.6% CV	LoD - ≤ 90 ng/ml ≤ 9 ng/ml SD > 90-2000 ng/ml $\leq 10\%$ CV	2.22, 2.87 ng/ml SD 2.8, 3.4, 2.7, 2.1, 1.8, 2.2% CV	LoD - ≤ 90 ng/ml ≤ 11 ng/ml SD > 90-2000 ng/ml $\leq 12\%$ CV	1.32, 1.77 ng/ml SD 2.4, 1.7, 2.6, 2.1, 1.9% CV
Everolimus	LoX-3 ng/ml ≤ 0.24 ng/ml SD > 3-30 ng/ml $\leq 8\%$ CV	0.068, 0.102 ng/ml SD 3, 2.5, 3.5, 3.1% CV	LoX-3 ng/ml ≤ 0.3 ng/ml SD > 3-30 ng/ml $\leq 10\%$ CV	0.081, 0.129 ng/ml SD 4.3, 4.0, 4.6, 3.9% CV	LoD-3 ng/ml ≤ 0.36 ng/ml SD > 3-30 ng/ml $\leq 12\%$ CV	0.033 ng/ml SD 1.7, 3.1, 1.4, 3, 1.2% CV
Sirolimus	LoX - 3 ng/ml ≤ 0.24 ng/ml SD > 3-30 ng/ml $\leq 8\%$ CV	0.062 ng/ml SD 3.8, 3.3, 4.2, 3.8, 3.4, 2.7, 3% CV	LoX - 3 ng/ml ≤ 0.3 ng/ml SD > 3-30 ng/ml $\leq 10\%$ CV	0.0867 ng/ml SD 5.7, 4.4, 4.5, 3.7, 3.8, 4.6% CV	LoX - 3 ng/ml ≤ 0.36 ng/ml SD > 3-30 ng/ml $\leq 12\%$ CV	0.0674, 0.074 ng/ml SD 3.4, 2.3, 3.0, 3.9, 3.1, 2.2% CV
Tacrolimus	LoX-3.5 ng/ml ≤ 0.25 ng/ml SD > 3.5-12 ng/ml $\leq 5\%$ CV >12 ng/ml-HeMR $\leq 7\%$ CV	0.056, 0.065 ng/ml SD 3.1, 2.2% CV 2.7, 2.4, 2.1% CV	LoX-3.5 ng/ml ≤ 0.35 ng/ml SD > 3.5-12 ng/ml $\leq 6\%$ CV >12 ng/ml-HeMR $\leq 7\%$ CV	0.069, 0.079 ng/ml SD 3.3, 3.8, 2.9% CV 3.6, 3.1, 2.5% CV	LoX-3.5 ng/ml ≤ 0.45 ng/ml SD > 3.5-12 ng/ml $\leq 9\%$ CV >12 ng/ml-HeMR $\leq 10\%$ CV	0.033, 0.042 ng/ml SD 1.3, 3.8% CV 2.2, 2.6, 1.3% CV
β -Amyloid (1-42) CSF	LEM - 480 pg/ml ≤ 24 pg/ml SD > 480 - 2000 pg/ml $\leq 5\%$ CV > 2000 pg/ml - HEMR $\leq 8\%$ CV	1.53, 1.83 pg/mL SD 2.0, 2.1, 2.0, 1.9, 2.2 % CV 4.0, 0.9% CV	LEM - 480 pg/ml ≤ 38 pg/ml SD > 480 - 2000 pg/ml $\leq 8\%$ CV > 2000 pg/ml - HEMR $\leq 10\%$ CV	2.44, 3.17 pg/mL SD 2.8, 2.8, 2.9, 2.7, 3.0 % CV 5.9, 1.2% CV	n/a	n/a
Phospho-Tau (181P) CSF	LeMR - 25 pg/ml ≤ 1.3 pg/ml SD > 25 - 50 pg/ml $\leq 5\%$ CV > 50 pg/ml $\leq 8\%$ CV	0.161, 0.268 pg/ml SD 1.0, 1.0% CV 1.3, 1.3% CV	LEM - 25 pg/ml ≤ 2 pg/ml SD > 25 - 50 pg/ml $\leq 8\%$ CV > 50 pg/ml $\leq 10\%$ CV	0.238, 0.441 pg/ml SD 1.3, 1.4% CV 1.8, 2.6% CV	n/a	n/a
Total-Tau CSF	LEM - 250 pg/ml ≤ 13 pg/ml SD > 250 - 500 pg/ml $\leq 5\%$ CV > 500 pg/ml $\leq 10\%$ CV	0.727, 1.64 pg/ml SD 0.8, 0.8% CV 0.9, 0.9, 1.2% CV	LEM - 250 pg/ml ≤ 20 pg/ml SD > 250 - 500 pg/ml $\leq 8\%$ CV > 500 pg/ml $\leq 10\%$ CV	0.965, 2.62 pg/ml SD 1.2, 1.2% CV 1.2, 1.2, 1.3% CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Anti-HAV II	COI > 1.0 ≤ 8.0 %CV COI ≤ 1.0 ≤ 0.08 COI SD	0.9, 1.1% CV 0.010, 0.009, 0.0001 SD COI	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	2.0, 2.2% CV 0.023, 0.023, 0.0001 SD COI	n/a	n/a
Anti-HAV IgM	< 0.8 COI ≤ 0.06 COI SD ≥ 0.8-1.2 COI ≤ 7% CV ≥ 1.2 COI ≤ 5% CV	0.006, 0.005 COI SD 2% CV 1.8, 2.2% CV	< 0.8 COI ≤ 0.07 COI SD ≥ 0.8-1.2 COI ≤ 10% CV ≥ 1.2 COI ≤ 10% CV	0.0067, 0.005 COI SD 2.1% CV 2.3, 2.4% CV	< 0.8 COI ≤ 0.08 COI SD ≥ 0.8-1.2 COI ≤ 13% CV ≥ 1.2 COI ≤ 13% CV	0.006 COI SD 2.5% CV 3.3, 2.4% CV
Anti-HBc II	≤ 1.0 COI ≤ 0.07 COI SD > 1.0 COI ≤ 7 % CV	0.017, 0.0001, COI SD 1.5% CV	≤ 1.0 COI ≤ 0.10 COI SD > 1.0 COI ≤ 10 % CV	0.029, 0.0001 COI SD 1.7% CV	n/a	n/a
Anti-HBc IgM	Neg ≤ 0.08 COI SD Weakly pos. ≤ 8% CV Pos ≤ 8% CV	0.001 COI SD 3% CV 2.6, 3.1% CV	Neg ≤ 0.10 COI SD Weakly pos. ≤ 10% CV Pos ≤ 10% CV	0.001 COI SD 3.3% CV 3.4, 3.2% CV	Neg ≤ 0.15 COI SD Weakly pos. ≤ 15% CV Pos ≤ 15% CV	0.001, 0.043 COI SD 5.1% CV 5.7, 2.7% CV
Anti-HBe	< 0.5 COI ≤ 0.07 COI SD 0.5-1.0 COI ≤ 0.10 COI SD > 1 COI ≤ 10% CV	0.005 COI SD 0.01, 0.008 COI SD 1.3% CV	< 0.5 COI ≤ 0.08 COI SD 0.5-1.0 COI ≤ 0.12 COI SD > 1 COI ≤ 12% CV	0.007 COI SD 0.014, 0.01 COI SD 1.4, 1.5% CV	< 0.5 COI ≤ 0.09 COI SD 0.5-1.0 COI ≤ 0.13 COI SD > 1 COI ≤ 13% CV	0.007 COI SD 0.019, 0.016, 0.01 COI SD 1.7, 1.5, 1.3% CV

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
HBeAg	$\leq 0.5 \text{ COI} \leq 0.10 \text{ COI SD}$ $0.5 < x < 1 \text{ COI} \leq 0.07 \text{ COI SD}$ $1.0 \leq x \leq 1.5 \text{ COI} \leq 7\% \text{ CV}$ $> 1.5 \text{ COI} \leq 8\% \text{ CV}$	0.004 COI SD 1.6% CV 1.5, 0.9% CV	$\leq 0.5 \text{ COI} \leq 0.12 \text{ COI SD}$ $0.5 < x < 1 \text{ COI} \leq 0.10 \text{ COI SD}$ $1.0 \leq x \leq 1.5 \text{ COI} \leq 10\% \text{ CV}$ $> 1.5 \text{ COI} \leq 10\% \text{ CV}$	0.004 COI SD 3.1% CV 2.8, 2.4% CV	$\leq 0.5 \text{ COI} \leq 0.13 \text{ COI SD}$ $0.5 < x < 1 \text{ COI} \leq 0.11 \text{ COI SD}$ $1.0 \leq x \leq 1.5 \text{ COI} \leq 11\% \text{ CV}$ $> 1.5 \text{ COI} \leq 11\% \text{ CV}$	0.005 COI SD 0.028 COI SD 2.4, 2.6% CV 3.5, 3.9% CV
HBeAg quant	LEMR to 0.30 IU/ml $\leq 0.025 \text{ IU/ml SD}$ 0.30 IU/mL to HEMR $\leq 8\% \text{ CV}$	0.008 IU/ml SD 3.2, 3.0, 3.2, 2.9, 3.0, 3.1 %CV	LEMR to 0.30 IU/ml $\leq 0.03 \text{ IU/ml SD}$ 0.30 IU/mL to HEMR $\leq 10\% \text{ CV}$	0.017 IU/ml SD 7.1, 7.5, 6.3, 6.0, 5.6, 5.8 %CV	n/a	n/a
Anti-HBs II	$\leq 5 \text{ IU/l} \leq 0.75 \text{ IU/l SD}$ $>5\text{-}\leq 10 \text{ IU/l} \text{ SD} \leq 15\% \times \text{mean}$ $>10 \text{ IU/l} \text{ SD} \leq 5\% \times \text{mean} + 1 \text{ IU/l}$	4.6% CV 4.3, 2.4, 1.6% CV	$\leq 5 \text{ IU/l} \leq 1 \text{ IU/l SD}$ $>5\text{-}\leq 10 \text{ IU/l} \text{ SD} \leq 20\% \times \text{mean}$ $>10 \text{ IU/l} \text{ SD} \leq 8\% \times \text{mean} + 1.2 \text{ IU/l}$	6.9% CV 6.9, 3.9, 4.6, 3.6% CV	$\leq 5 \text{ IU/l} \leq 1.2 \text{ IU/l SD}$ $>5\text{-}\leq 10 \text{ IU/l} \leq 24\% \times \text{mean}$ $>10 \text{ IU/l} \text{ SD} \leq 9\% \times \text{mean} + 1.5 \text{ IU/l}$	
HBsAg II	$\leq 0.70 \text{ COI} \leq 0.07 \text{ COI SD}$ $\geq 0.7 \text{ COI} \leq 7\% \text{ CV}$	0.038, 0.03 COI SD 3.5, 2.4, 2.2% CV	$\leq 0.70 \text{ COI} \leq 0.1 \text{ COI SD}$ $\geq 0.7 \text{ COI} \leq 10\% \text{ CV}$	0.048, 0.035 COI SD 4.3, 3.4% CV	$\leq 0.70 \text{ COI} \leq 0.13 \text{ COI SD}$ $\geq 0.7 \text{ COI} \leq 13\% \text{ CV}$	n/a
HBsAg II Auto Confirm	$<0.81 \text{ COI} \text{ SD} \leq 0.08$ $\geq 0.81 \text{ COI} \text{ CV} \leq 8.0 \%$	Control reaction 66.5 COI, 3.7% CV 29.5 COI, 2.9% CV 3.44 COI, 2.6% CV 2494 COI, 2.5% CV 0.997 COI, 4.5% CV Confirmatory reaction 0.027 COI, 0.294 COI 0.031 COI, 0.311 COI 0.037 COI, 0.577 COI 1.77 COI, 6.4% CV 0.321 COI, 0.029 COI	$<0.81 \text{ COI} \text{ SD} \leq 0.12$ $\geq 0.81 \text{ COI} \text{ CV} \leq 13.0 \%$	Control reaction 66.5 COI, 4.0 % CV 29.5 COI, 3.0 % CV 3.44 COI, 3.9% CV 2494 COI, 5.2% CV 0.997 COI, 7.5% CV Confirmatory reaction 0.032 COI, 0.294 COI 0.035 COI, 0.311 COI 0.038 COI, 0.577 COI 1.77 COI, 7.3% CV 0.034 COI, 0.321 COI	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
HBsAg II quant II	LoD-5 IU/ml ≤ 0.4 IU/ml SD undiluted >5-130 IU/ml $\leq 8\%$ CV undiluted > 130 IU/ml $\leq 10\%$ CV diluted (up to 1:900)	0.002, 0.035 IU/ml 1, 2.3% CV 1.8% CV	LoD-5 IU/ml ≤ 0.5 IU/ml SD undiluted >5-130 IU/ml $\leq 10\%$ CV undiluted > 130 IU/ml $\leq 12\%$ CV diluted (up to 1:900)	0.003, 0.072 IU/ml SD 2.1, 2.2, 2.9% CV 2.9% CV	LoD-5 IU/ml ≤ 0.6 IU/ml SD undiluted >5-130 IU/ml $\leq 14\%$ CV undiluted > 130 IU/ml $\leq 14\%$ CV diluted (up to 1:900)	0.0025, 0.043, 0.049 IU/ml SD 1.8, 2.0, 1.7, 3.3% CV 3.2, 2.3% CV
Anti-HCV II	≤ 0.5 COI SD ≤ 0.10 COI 0.5-<1.0 COI SD ≤ 0.07 COI ≥ 1.0 COI $\leq 7\%$ CV	0.0005 SD COI 0.012 SD COI 1.2, 1.4, 1.0% CV	≤ 0.5 COI SD ≤ 0.12 COI 0.5-<1.0 COI SD ≤ 0.10 COI ≥ 1.0 COI $\leq 10\%$ CV	0.0005 SD COI 0.016 SD COI 1.9, 2.3, 1.3% CV	n/a	n/a
Anti-HEV IgG	LEMR to 0.2 U/ml ≤ 0.01 U/ml SD > 0.2 U/ml to HEMR $\leq 5\%$ CV	0.0009, 0.0013, 0.0016 U/ml SD 1.1, 1.0, 1.0 % CV	LEMR to 0.2 U/ml ≤ 0.014 U/ml SD > 0.2 U/ml to HEMR $\leq 7\%$ CV	0.0010, 0.0014, 0.0021 U/ml SD 1.2, 1.1, 1.2 % CV	n/a	n/a
Anti-HEV IgM	HS, neg (< 1.0COI) ≤ 0.08 SD HS, positive (≥ 1.0 COI) $\leq 8\%$ CV	0.003, 0.011 COI SD 1.7, 2.2, 1.8% CV	HS, neg (< 1.0COI) ≤ 0.10 SD HS, positive (≥ 1.0 COI) $\leq 10\%$ CV	0.008, 0.03 COI SD 5.1, 6.1, 6.1% CV	n/a	n/a
HCV-Duo	HCVAG < 1.0 COI SD 0.07 COI 1.0 COI 7% CV AHCV < 1.0 COI SD 0.07 COI 1.0 COI 7% CV	0.0453, 0.0387, 0.0422 SD COI 2.6, 3.7, 2.0 % CV 0.00148, 0.00842, 0.0133 2.0, 4.2, 1.5 %	HCVAG < 1.0 COI SD 0.1 COI 1.0 COI 10% CV AHCV < 1.0 COI SD 0.1 COI 1.0 COI 10% CV	0.0457, 0.0542, 0.0514 SD COI 4.5, 4.8, 4.0% CV 0.00159, 0.0144, 0.0318 3.4, 4.3, 3.3	n/a	n/a
Chagas	< 1.0 COI ≤ 0.08 COI SD ≥ 1.0 COI $\leq 8\%$ CV	0.001 COI SD 2.0, 1.6% CV	< 1.0 COI ≤ 0.1 COI SD ≥ 1.0 COI $\leq 10\%$ CV	0.001 COI SD 3.4, 3.3% CV	n/a	n/a
HIV Duo	Neg ≤ 0.1 COI SD Pos $\leq 6\%$ CV	0.006 COI SD 1.7, 1.6, 1.6, 1.5, 1.4% CV	Neg ≤ 0.1 COI SD Pos $\leq 8\%$ CV	0.008 COI SD 2.8, 3.4, 3.2, 3.6, 3.5% CV	n/a	n/a
HTLV-I/II	0 to 1.0 COI SD ≤ 0.07 COI COI > 1.0 $\leq 5.5\%$ CV	0.001, 0.013, 0.012 COI SD 1.3, 1.4, 1.9% CV	0 to 1.0 COI SD ≤ 0.1 COI COI > 1.0 $\leq 7.5\%$ CV	0.002, 0.023, 0.020 COI SD 2.4, 2.8, 3.1% CV	n/a	n/a
Syphilis	COI<1.00 ≤ 0.07 COI SD COI $\geq$ 1.00 $\leq 5.5\%$ CV	0.00192 COI SD 1.6, 2.4, 2.9, 2.5% CV	COI<1.00 ≤ 0.1 COI SD COI $\geq$ 1.00 $\leq 7.5\%$ CV	0.00210 COI SD 2.4, 3.1, 3.6, 3.6% CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
CMV IgG	LoD to ≤ 1.0 U/mL ≤ 0.06 U/mL SD > 1.0 to 500 U/mL ≤ 6.0 % CV	0.006, 0.022% CV 2.0, 1.4, 1.0% CV	LoD to ≤ 1.0 U/mL ≤ 0.08 U/mL SD > 1.0 to 500 U/mL ≤ 8.0 % CV	0.008, 0.029% CV 2.4, 1.8, 1.9% CV	n/a	n/a
CMV IgG Avidity	Low avidity (<45.0 Avi%) ≤ 8 % CV Gray zone (45.0-54.9 Avi%) ≤ 8 % CV High avidity (≥ 55.0 Avi %) ≤ 8 % CV	3.1% CV 2.4% CV 1.3% CV	Low avidity (<45.0 Avi%) ≤ 10 % CV Gray zone (45.0-54.9 Avi%) ≤ 10 % CV High avidity (≥ 55.0 Avi %) ≤ 10 % CV	3.2% CV 2.4% CV 1.5% CV	n/a	n/a
CMV IGM	< 1.0 COI ≤ 0.07 COI SD ≥ 1.0 COI ≤ 7 % CV	0.002, 0.011, 0.002 COI SD 1.6, 1.0, 1.9% CV	< 1.0 COI ≤ 0.1 COI SD ≥ 1.0 COI ≤ 10 % CV	0.006, 0.015, 0.006 COI SD 1.8, 1.4, 2.2% CV	< 1.0 COI ≤ 0.12 COI SD ≥ 1.0 COI ≤ 12 % CV	
HSV-1 IgG	≤ 0.8 COI ≤ 0.1 COI SD > 0.8-2.0 COI ≤ 6 % CV > 2 COI ≤ 8 % CV	0.0003 COI SD 1.6% CV 1.5% CV	≤ 0.8 COI ≤ 0.15 COI SD > 0.8-2.0 COI ≤ 8 % CV > 2 COI ≤ 10 % CV	0.0004 COI SD 2.1% CV 2.3% CV	n/a	n/a
HSV-2 IgG	≤ 0.8 COI ≤ 0.1 COI SD > 0.8-2.0 COI ≤ 6 % CV > 2 COI ≤ 8 % CV	0.001 COI SD 1.2% CV 1.7% CV	≤ 0.8 COI ≤ 0.15 COI SD > 0.8-2.0 COI ≤ 8 % CV > 2 COI ≤ 10 % CV	0.001 COI SD 2.6% CV 2.7% CV	n/a	n/a
Rubella IgG	< 10 IU/ml ≤ 0.8 IU/ml SD ≥ 10 IU/ml ≤ 8 % CV	0.064, 0.096 IU/ml SD 3.5, 2.2, 2.9% CV	< 10 IU/ml ≤ 0.9 IU/ml SD ≥ 10 IU/ml ≤ 9 % CV	0.084, 0.155 IU/ml SD 4.6, 3.9, 4.2% CV	≤ 5 IU/ml ≤ 1.3 IU/ml SD > 5 IU/ml ≤ 14 % CV	0.157, 0.167 IU/ml SD 4.7, 1.6, 1.8, 3.1% CV
Rubella IgM	≤ 0.5 COI ≤ 0.028 COI SD > 0.5 COI ≤ 5.5 % CV	0.003 COI SD 0.9, 1.2% SD	≤ 0.5 COI ≤ 0.04 COI SD > 0.5 COI ≤ 8 % CV	0.009, 0.10 COI SD 1.5, 1.7, 1.6% CV	≤ 0.5 COI ≤ 0.065 COI SD > 0.5 COI ≤ 13 % CV	0.014 COI SD 8.6, 7.9, 4.6, 10.9, 11.4% CV

cobas e 801, cobas e 402 Assays Specifications



Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Toxo IgG	< 3 IU/ml ≤ 0.21 IU/ml SD ≥ 3 IU/ml ≤ 7% CV	0.034, 0.044 IU/ml SD 1.7, 2.6, 1.3% CV	< 3 IU/ml ≤ 0.3 IU/ml SD ≥ 3 IU/ml ≤ 10% CV	0.045, 0.056 IU/ml 2.7, 3.8, 2.2% CV	< 3 IU/ml ≤ 0.39 IU/ml SD ≥ 3 IU/ml ≤ 13% CV	0.0363, 0.0289, 0.0354 IU/ml SD 1.1, 2, 1.8, 0.9% CV
Toxo IgG Avidity	< 70 Avi% ≤ 10% CV 70 ≤ x < 80 Avi% ≤ 8% CV ≥ 80 Avi% ≤ 8% CV	3.4, 2.8% CV 0.9% CV 0.4, 0.5% CV	< 70 Avi% ≤ 12% CV 70 ≤ x < 80 Avi% ≤ 10% CV ≥ 80 Avi% ≤ 10% CV	5.4, 3.1% CV 1.1% CV 0.4, 0.6% CV	< 70 Avi% ≤ 15% CV 70 ≤ x < 80 Avi% ≤ 13% CV ≥ 80 Avi% ≤ 13% CV	3.6, 1.6, 3.1% CV 1.0, 0.4% CV 0.5, 0.4% CV
Toxo IgM	< 1.0 COI ≤ 0.07 COI SD ≥ 1.0 COI ≤ 7% CV	0.002, 0.003 COI SD 0.9, 1.0% CV	< 1.0 COI ≤ 0.1 COI SD ≥ 1.0 COI ≤ 10% CV	0.003 COI SD 1.3, 1.5, 2.3% CV	< 1.0 COI ≤ 0.13 COI SD ≥ 1.0 COI ≤ 13% CV	0.004, 0.014, 0.008 COI SD 2.3, 2.0, 2.1, 1.4% CV
EBV IgM	< 1.0 COI SD ≤ 0.08 COI ≥ 1.0 COI CV ≤ 8.0 %	0.002, 0.012 COI SD 1.6, 1.0, 1.2 % CV	< 1.0 COI SD ≤ 0.10 ≥ 1.0 COI CV ≤ 10.0 %	0.023, 0.023 COI SD 0.023, 0.028, 0.364 % CV	n/a	n/a
EBV VCA IgG	COI < 1.0 SD ≤ 0.08 COI ≥ 1.0 CV ≤ 8.0 %	0.025, 0.026 COI SD 3.00, 2.10, 1.40, 1.20 % CV	COI < 1.0 SD ≤ 0.10 COI ≥ 1.0 CV ≤ 10.0 %	0.035, 0.035 COI SD 4.20, 3.30, 3.30, 2.60 % CV	n/a	n/a
EBV EBNA IgG	< 1.0 COI SD ≤ 0.08 COI ≥ 1.0 COI CV ≤ 8.0 %	0.001, 0.013 COI SD 1.2, 2.7, 1.4 CV %	< 1.0 COI SD ≤ 0.10 ≥ 1.0 COI CV ≤ 10.0 %	0.001, 0.025 COI SD 2.9, 3.5, 2.6 % CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab precision)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Anti-SARS-CoV-2	<1.0 COI ≤ 0.1 COI SD ≥1.0 COI ≤ 10 % CV	0.002, 0.001 COI SD 1.5, 1.3, 1.6, 1.7, 1.6 % CV	<1.0 COI ≤ 0.12 COI SD ≥1.0 COI ≤ 12 % CV	0.003 , 0.003 COI SD 2.1, 2.2, 2.3, 2.3, 2.6 % CV	n/a	n/a
Anti-SARS-CoV-2 S	LEMR- < 1.0 U/ml ≤ 0.1 U/ml SD ≥1.0 – 20 U/ml ≤ 10% CV >20 U/ml - HEMR ≤ 15% CV	0.014, 0.015 U/mL SD 2.1, 1.3% CV 1.4, 1.6, 0.9% CV	LEMR- < 1.0 U/ml ≤ 0.12 U/ml SD ≥1.0 – 20 U/ml ≤ 12% CV >20 U/ml - HEMR ≤ 17% CV	0.014, 0.015 U/mL SD 2.4, 1.6% CV 1.4, 2.0, 1.4% CV	n/a	n/a
SARS-CoV-2 Antigen	<1.0 COI ≤ 0.1 COI SD ≥1.0 COI ≤ 10 % CV	0.021, 0.014 COI SD 5.2, 1.4, 1.6% CV	<1.0 COI ≤ 0.12 COI SD ≥1.0 COI ≤ 12 % CV	0.022 , 0.018 COI SD 5.7, 2.0, 2.2% CV	n/a	n/a
IGRA SARS-CoV-2	0.07 – 1.0 IU/ml ≤ 0.05 IU/ml SD > 1 – 160 IU/ml ≤ 5% CV	0.005 IU/ml SD 1.0, 1.0, 1.4, 0.9 % CV	0.07 – 1.0 IU/ml ≤ 0.07 IU/ml SD > 1 – 160 IU/ml ≤ 7% CV	0.008 IU/ml SD 1.6, 1.5, 1.7, 1.4 % CV	n/a	n/a
Interferon Gamma	0.07 – 1.0 IU/ml ≤ 0.05 IU/ml SD > 1.0 – 160 IU/ml ≤ 5% CV	0.005 IU/ml SD 1.0, 1.0, 1.4, 0.9 % CV	0.07 – 1.0 IU/ml ≤ 0.07 IU/ml SD > 1.0 – 160 IU/ml ≤ 7% CV	0.008 IU/ml SD 1.6, 1.5, 1.7, 1.4 % CV	n/a	n/a

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Documents Used:

Assay	Application report
FT3 III	4_6_MS_AR_Summary_inclRec_FT3 III_V2_MethodSheet
FT4 III	4_Ar_SummaryReport_FT4III
FT4 IV	4_6_MS_AR_Summary_inclRec_FT4 IV_MethodSheet
T3	4_MS_AR_Summary_inclRec_T3_V2_MethodSheet
T4	4_6_MS_AR_Summary_inclRec_T4_V2_MethodSheet
TSH	4_Are_SummaryReport_TSH V2
T-uptake	4_Ara_SummaryReport_T-Uptake
Tg II	4_6_MS_AR_Summary_inclRec_Tg II_V2_MethodSheet
Anti-TG	4_Arc_SummaryReport_ATG
Anti-TPO	4_Ara_SummaryReport_ATPO
Anti-TSHR	AR_Summary_ATSHR V2
Calcitonin	4_6_MS_AR_Summary_inclRec_Calcitonin_V2_MethodSheet
CK-MB	4_ArdSummaryReport_CK-MB_9min
GDF-15	4_6_MS_AR_Summary_inclRec_GDF-15_V2_MethodSheet
Myoglobin	4_Ara_SummaryReport_Myoglobin
proBNP II	4_6_MS_AR_Summary_inclRec_proBNP II_V2_proBNP II STAT_V2_MethodSheet
Troponin I	4_Ara_SummaryReport_TNI
Troponin T hs	4_6_MS_AR_Summary_inclRec_TnThs_V2_TnThs STAT_V2_MethodSheet
Digoxin	4_Ara_SummaryReport_Digoxin
Digitoxin	4_Ard_SummaryReport_Digoxin
HCG+β	4_Ara_SummaryReport_HCG-BETA
HCG STAT	4_6_MS_AR_Summary_inclRec_HCGSTAT_V2_MethodSheet
ACTH	4_6_MS_AR_Summary_inclRec_ACTH_V2_MethodSheet
AMH	4_MS_AR_Summary_inclRec_AMH_V2_MethodSheet_v2.0
AMH Plus	4_MS_AR_Summary_inclRec_AMH Plus_V2_MethodSheet_v2.0
Androstenedione	4_MS_AR_Summary_inclRec_ASD_MethodSheet
Cortisol II	4_Are_SummaryReport_Cortisol II
Cortisol III Urine	4_6_MS_AR_Summary_inclRec_CORT III_MethodSheet
DHEA-S	4_Ara_SummaryReport_DHEA-S

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Documents Used:

Assay	Application report
Estradiol III	4_Ard_SummaryReport_Estradiol
FSH	4_6_MS_AR_Summary_inclRec_FSH_V2_MethodSheet
LH	4_Arf_SummaryReport_LH
Progesterone III	4_Ard_SummaryReport_ProgIII
Prolactin II	4_Ard_SummaryReport_Prolactin
SHBG	4_Ara_SummaryReport_SHBG
Testosterone II	4_6_MS_AR_Summary_inclRec_Testosterone_V2_MethodSheet
C-Peptide	4_Ard_SummaryReport_C-Peptide
Insulin	4_Ard_SummaryReport_Insulin
PIGF	4_Ara_SummaryReport_PIGF
sFlt-1	4_Ara_SummaryReport_sFlt-1
AFP	4_6_MS_AR_Summary_inclRec_AFP_V2_MethodSheet
AFP-L3	4_6_MS_AR_Summary_inclRec_AFP-L3_MethodSheet
CA 125 II	4_Arb_SummaryReport_CA125
CA 15-3 II	4_Ara_SummaryReport_CA15-3
CA 19-9	4_Ard_SummaryReport_CA19-9
CA 72-4	4_6_MS_AR_Summary_inclRec_CA72-4_V2_MethodSheet
CEA	4_Ard_SummaryReport_CEA
Cyfra 21-1	4_Ara_SummaryReport_Cyfra 21-1
HE4	4_Ard_SummaryReport_HE4
NSE	4_Ard_SummaryReport_NSE
PIVKA-II	4_6_MS_AR_Summary_inclRec_PIVKA-II_V2_MethodSheet
ProGRP	4_MS_AR_Summary_inclRec_ProGRP_V2_MethodSheet
free PSA	Ara_SummaryReport_fPSA V2
total PSA	4_6_MS_AR_Summary_inclRec_TPSA_V2_MethodSheet
S100	n/a
SCC	4_Ara_SummaryReport_SCC
Anti-p53	4_6_MS_AR_Summary_inclRec_Anti-p53_MethodSheet
Free hCG	Ar_SummaryReport_fβhCG V2
PAPP-A	Ar_SummaryReport_PAPP-A V2
Active B12	4_6_MS_AR_Summary_inclRec_Active B12_V2_MethodSheet
Vitamin B12 II	4_Arb_SummaryReport_B12 II

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Documents Used:

Assay	Application report
Ferritin	4_Ara_SummaryReport_Ferritin
Folate III	4_6_MS_AR_Summary_inclRec_Folate III_V3_Folate RBC_V2_MethodSheet
Folate RBC	4_Arb_SummaryReport_Fol RBC
IgE II	4_Ara_SummaryReport_IGEII
β -CrossLaps/serum	4_6_MS_AR_Summary_inclRec_ β CrossLaps_V2_MethodSheet
Osteocalcin	4_Ara_SummaryReport_N_MID Osteocalcin
PTH	4_6_MS_AR_Summary_inclRec_PTH_V2_PTH STAT_V2_MethodSheet
PTH (1-84)	4_6_MS_AR_Summary_inclRec_PTH(1-84)_V2_MethodSheet
total P1NP	4_Ara_SummaryReport_tP1NP
Vitamin D total III	4_6_MS_AR_Summary_inclRec_VITDT 3_MethodSheet
hGH	4_Ard_SummaryReport_hGH
IGF-1	Ara_Summary_IGF-1
IGFBP-3	Ara_Summary_IGFBP-3
Anti-CCP	4_Ard_SummaryReport_ACCP
BRAHMS PCT	Ar_SummaryReport_PCT V2
IL-6	4_MS_AR_Summary_inclRec_IL-6_V2_MethodSheet_v2.0
Cyclosporine	4_Ard_SummaryReport_CSA
Everolimus	4_Ara_SummaryReport_EVL
Sirolimus	4_Ara_Summary Report_SRL
Tacrolimus	4_Ara_Summary Report_TCL
β -Amyloid (1-42) CSF II	4_6_MS_AR_Summary_inclRec_Abeta42 2_MethodSheet
Phospho-Tau (181P) CSF	4_6_MS_AR_Summary_inclRec_pTau_V2_MethodSheet
Total-Tau CSF	4_6_MS_AR_Summary_inclRec_tTau_V2_MethodSheet
Anti-HAV II	4_6_MS_AR_Summary_inclRec_Anti-HAV II_MethodSheet
Anti-HAV IgM	4_Ara_SummaryReport Anti-HAV IgM
Anti-HBc II	4_6_MS_AR_Summary_inclRec_Anti-HBc II_V2_MethodSheet
Anti-HBc IgM	4_Ard_SummaryReport Anti-HBc IgM
Anti-HBe	4_Ara_SummaryReport Anti-HBe
HBeAg	4_Arf_SummaryReport HBeAg
HBeAg quant	4_6_MS_AR_Summary_inclRec_HBeAg_quant_MethodSheet

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Documents Used:

Assay	Application report
Anti-HBs II	Ar_SummaryReport_Anti-HBsII V2
HBsAg II	Ar_SummaryReport HBsAg II V2
HBsAg II Auto Confirm	AR Summary: Elecsys HBsAg II Auto Confirm
HBsAg II quant II	Ar_SummaryReport_HBsAgIIQII
Anti-HCV II	4_6_MS_AR_Summary_inclRec_Anti-HCV II_V2_MethodSheet
HCV-Duo	4_6_MS_AR_Summary_inclRec_HCV Duo_MethodSheet
Chagas	4_6_MS_AR_Summary_inclRec_Chagas_V2
Anti-HEV IgG	4_6_MS_AR_Summary_inclRec_Anti-HEV IgG_MethodSheet
Anti-HEV IgM	4_6_MS_AR_Summary_inclRecAnti-HEV IgM_MethodSheet = ab V2.0
HIV Duo	4_MS_AR_Summary_inclRec_HIV Duo_V2_MethodSheet
HTLV-I/II	4_6_MS_AR_Summary_inclRec_HTLV_V2_MethodSheet
Syphilis	4_6_MS_AR_Summary_inclRec_Syphilis_V2_MethodSheet
CMV IgG	4_6_MS_AR_Summary_inclRec_CMV IgG_V2_MethodSheet
CMV IgG Avidity	4_6_MS_AR_Summary_inclRec_CMV IgG Avidity_V2_MethodSheet
CMV IgM	4_Ara_Summary Report_CMV IgM
HSV-1 IgG	4_6_MS_AR_Summary_inclRec_HSV-1 IgG_V2_MethodSheet
HSV-2 IgG	4_6_MS_AR_Summary_inclRec_HSV-2 IgG_V2_MethodSheet
Rubella IgG	4_Ard_SummaryReport_Rubella IgG
Rubella IgM	4_Ard_SummaryReport_Rubella IgM
Toxo IgG	4_Ard_SummaryReport_Toxo IgG
Toxo IgG Avidity	4_Ard_SummaryReport_Toxo IgG Avi
Toxo IgM	4_Ard_SummaryReport_Toxo IgM
EBV IgM	4_MS_AR_Summary_inclRec_EBV IgM_MethodSheet
EBV VCA IgG	4_MS_AR_Summary_inclRec_EBV VCA IgG_Method
EBV EBNA IgG	4_MS_AR_Summary_inclRec_EBV EBNA_MethodSheet
Anti-SARS-CoV-2	4_MS_AR_Summary_inclRec_SARS-CoV2_MethodSheet
Anti-SARS-CoV-2 S	4_MS_AR_Summary_inclRec_ACOV2S_MethodSheet
SARS-CoV-2 Antigen	4_MS_AR_Summary_inclRec_SARS-CoV-2 Antigen_MethodSheet
IGRA SARS-CoV-2	4_6_MS_AR_Summary_inclRec_IGRA SARS-CoV-2_MethodSheet
Interferon Gamma	4_5_6_MS_AR_Summary_inclRec_IFNG_MethodSheet

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For this document are the contents of the cobas e 801 assay specific Application Reports used. The used Application Reports are listed above. Original datas are available in the corresponding Application Reports.

The same precision specifications apply to cobas e 801 and cobas e 402. The measured data from the cobas e 801 (master instrument) are included in the list, comparable to the corresponding method sheets.

The measured data from cobas e 402 can be found in the application report.

Several products are available in US as US versions with the same or different cat.no., and / or ACN or other specifications e.g. measuring range.

LEMR = Low end measuring range

HEMR = High end measuring range

n/a = not available