

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 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) et Vitamin D Total III, AFP-L3, IGRA-SARS-CoV-2 et HCV Duo

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	LEMUR 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	LEMUR 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	LEMUR 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	LEMUR 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	LEMUR-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	LEMUR-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	LEMUR-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	LEMUR-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	LEMUR-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/I \leq 0.3 IU/I SD \geq 5-40 IU/I < 6% CV	0.115, 0.14, 0.131, 0.146 IU/I SD 1.4, 1.3, 2% CV	1.1-5 IU/I \leq 0.35 IU/I SD \geq 5-40 IU/I < 7% CV	0.194, 0.199, 0.21, 0.229 IU/I SD 1.9, 1.7, 2.6% CV	1.1-5 IU/I \leq 0.5 IU/I SD \geq 5-40 IU/I < 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	LEMUR-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	LEMUR-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	LEMUR 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	LEMUR 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	LEMUR 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	LEMUR 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	LEMUR-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	LEMUR-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	LEMUR 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	LEMUR 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	LEMUR-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	LEMUR-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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Androstenedione	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	-	-
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	LEMUR 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	LEMUR 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 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 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	LEMUR 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	LEMUR 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	LEMUR to 4 IU/mL \leq 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	LEMUR to 4 IU/mL \leq 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	LEMUR to 6 ng/mL \leq 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	LEMUR to 6 ng/mL \leq 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 \leq 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 \leq 1.0 U/ml SD >10 U/ml \leq 8% CV	0.054, 0.065 U/ml SD 1.9, 2.8, 2.4% CV	LoD-10 U/ml \leq 1.2 U/ml SD >10 U/ml \leq 12% CV	0.132 U/ml SD 1.8, 4.1, 6.7, 1.4% CV
CA 15-3 II	LoD-15 U/ml \leq 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 \leq 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 \leq 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 \leq 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 \leq 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 \leq 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	LEMUR to 4 U/ml \leq 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	LEMUR to 4 U/ml \leq 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 \leq 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 \leq 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 \leq 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	LEMUR-1 ng/ml \leq +/- 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	LEMUR-1 ng/ml \leq +/- 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	LEMUR-1 ng/ml \leq +/- 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

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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.
HE4	LoD-30 pmol/l ≤ 3 pmol/l SD >30-1500 pmol/l ≤ 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 ≤ 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 ≤ 10% CV	1.5, 3.3, 2.7, 1.6, 1.7% CV
PIVKA-II	LEMUR to 30 ng/ml ≤ 1.5 ng/ml SD > 30 ng/ml to HEMR ≤ 5% CV	0.112, 0.215, 0.314 ng/ml SD 1.4, 1.0, 1.3% CV	LEMUR to 30 ng/ml ≤ 2.25 ng/ml SD > 30 ng/ml to HEMR ≤ 7.5% CV	0.511, 1.19, 1.57 ng/ml SD 5.1, 4.3, 4.2% CV	n/a	n/a
ProGRP	LEMUR-60 pg/ml ≤ 3 pg/ml SD > 60 pg/ml - HEMR ≤ 5.4% CV	0.292, 0.417 pg/ml SD 1.6, 1.6, 1.1% CV	LEMUR-60 pg/ml ≤ 6 pg/ml SD > 60 pg/ml - HEMR ≤ 10.4% CV	0.334, 0.447 pg/ml SD 1.9, 1.9, 1.8% CV	n/a	n/a
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	0.0025 ng/ml SD 1.8% CV 1.4, 1, 1.2, 1.1, 1.3% 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	0.003 ng/ml SD 3.6% CV 2.1, 2.3, 1.8, 1.9, 2% CV	n/a	n/a
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	0.001, 0.001 ng/ml SD 1.1% CV 0.9, 1.3, 1.4, 1.6% CV 1.8% CV	LEMUR-≤ 0.1 ng/ml ≤ 0.010 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	0.001, 0.002 ng/ml SD 2.3% CV 1.5, 1.9, 2.2, 2.4% CV 2.1% 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 ≤ 0.1 ng/ml > 1.8-5 ng/ml ≤ 5% CV > 5-70 ng/ml ≤ 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 ≤ 0.2 ng/ml > 1.8-70 ng/ml ≤ 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 ≤ 0.2 ng/ml > 1.8-70 ng/ml ≤ 10% CV	0.0225, 0.0427 ng/ml SD 1.6, 1.1, 1.5% 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	0.001, 0.002 µg/ml SD 1.2% CV 0.9%, 0.7% 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	0.002 / 0.002 µg/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	LEMUR-15 IU/L ≤ 0.6 IU/L SD > 15 IU/L-HEMR $\leq 3\%$ CV	0.008, 0.129 IU/L SD 1.4, 1.6, 1.8, 1.5% CV	LEMUR-15 IU/L ≤ 1 IU/L SD > 15 IU/L-HEMR $\leq 5\%$ CV	0.008, 0.134 IU/L SD 1.7, 1.9, 2.1, 1.6% CV	n/a	n/a
PAPP-A	LEMUR-50 mIU/l ≤ 2.5 mIU/l SD >50-2000 mIU/l $\leq 3.5\%$ CV >2000 mIU/l-HEMR $\leq 3\%$ CV	0.419, 0.491 mIU/l SD 1.7, 1.3% CV 1.6, 1.7, 2.4, 1.3% CV	LEMUR-50 mIU/l ≤ 4 mIU/l SD >50-2000 mIU/l $\leq 6\%$ CV >2000 mIU/l-HEMR $\leq 5\%$ CV	0.575, 0.74 mIU/l SD 2, 1.6% CV 2.3, 2.6, 3.2, 1.8, 1.6% CV	n/a	n/a
Active B12	LEMUR 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	LEMUR to 20 pmol/L SD ≤ 1.2 pmol/L > 20 pmol/L to HEMR CV $\leq 6.0\%$	0.231 pmol/l SD 2.4, 2.4, 2.5, 2.4% CV	n/a	n/a
B12 II	LEMUR-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	LEMUR-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	LEMUR- 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	LEMUR-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	LEMUR-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	LEMUR-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	LEMUR-5 ng/ml \leq 0.35 ng/ml SD > 5 ng/ml \leq 7% CV	0.19, 0.233, 0.226, 0.188 ng/ml SD 2.9, 3.0, 2.2% CV	LEMUR-5 ng/ml \leq 0.6 ng/ml SD > 5 ng/ml \leq 12% CV	0.195, 0.237, 0.236, 0.199 ng/ml SD 3.2, 2.6% SD	LEMUR-5 ng/ml \leq 0.6 ng/ml SD > 5 ng/ml \leq 12% CV	0.065, 0.096, 0.144, 0.117 ng/ml SD 1.9, 3.6% CV
Folate RBC	LEMUR-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	LEMUR-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	LEMUR-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	LEMUR 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	LEMUR 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	LoEMR-15 pg/ml \leq 0.9 pg/ml SD \geq 15 pg/ml \leq 6% CV	0.283 pg/ml SD 1.5, 0.7, 0.9, 0.8, 2.4 % CV	LoEMR-15 pg/ml \leq 1.2 pg/ml SD \geq 15 pg/ml \leq 8% CV	0.422 pg/ml SD 2.2, 5.6, 1.8 1.6, 2.8, 1.3, 1.5% CV	LoEMR-15 pg/ml \leq 1.5 pg/ml SD \geq 15 pg/ml \leq 10% CV	3.9, 2.4, 1.9, 1, 0.9, 3.5, 2.1, 2.0% CV
PTH (1-84)	LEMUR 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	LEMUR 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	LEMUR - 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	LEMUR - 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	LEMUR - 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	LEMUR - 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	LEMUR - 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

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.
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

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.
HBeAg	≤ 0.5 COI ≤ 0.10 COI SD $0.5 < x < 1$ COI ≤ 0.07 COI SD $1.0 \leq x \leq 1.5$ COI $\leq 7\%$ CV > 1.5 COI $\leq 8\%$ CV	0.004 COI SD 1.6% CV 1.5, 0.9% CV	≤ 0.5 COI ≤ 0.12 COI SD $0.5 < x < 1$ COI ≤ 0.10 COI SD $1.0 \leq x \leq 1.5$ COI $\leq 10\%$ CV > 1.5 COI $\leq 10\%$ CV	0.004 COI SD 3.1% CV 2.8, 2.4% CV	≤ 0.5 COI ≤ 0.13 COI SD $0.5 < x < 1$ COI ≤ 0.11 COI SD $1.0 \leq x \leq 1.5$ COI $\leq 11\%$ CV > 1.5 COI $\leq 11\%$ CV	0.005 COI SD 0.028 COI SD 2.4, 2.6% CV 3.5, 3.9% CV
Anti-HBs II	≤ 5 IU/l ≤ 0.75 IU/l SD $>5-\leq 10$ IU/l SD $\leq 15\%$ x mean >10 IU/l SD $\leq 5\%$ x mean + 1 IU/l)	4.6% CV 4.3, 2.4, 1.6% CV	≤ 5 IU/l ≤ 1 IU/l SD $>5-\leq 10$ IU/l SD $\leq 20\%$ x mean >10 IU/l SD $\leq 8\%$ x mean + 1.2 IU/l)	6.9% CV 6.9, 3.9, 4.6, 3.6% CV	≤ 5 IU/l ≤ 1.2 IU/l SD $>5-\leq 10$ IU/l $\leq 24\%$ x mean >10 IU/l SD $\leq 9\%$ x mean + 1.5 IU/l)	
HBsAg II	≤ 0.70 COI ≤ 0.07 COI SD ≥ 0.7 COI $\leq 7\%$ CV	0.038, 0.03 COI SD 3.5, 2.4, 2.2% CV	≤ 0.70 COI ≤ 0.1 COI SD ≥ 0.7 COI $\leq 10\%$ CV	0.048, 0.035 COI SD 4.3, 3.4% CV	≤ 0.70 COI ≤ 0.13 COI SD ≥ 0.7 COI $\leq 13\%$ CV	n/a
HBsAg II Auto Confirm	<0.81 COI SD ≤ 0.08 ≥ 0.81 COI 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 COI SD ≤ 0.12 ≥ 0.81 COI 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

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.
HBsAg II quant II	LoD-5 IU/ml \leq 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 \leq 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 \leq 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	\leq 0.5 COI SD \leq 0.10 COI 0.5-<1.0 COI SD \leq 0.07 COI \geq 1.0 COI \leq 7% CV	0.0005 SD COI 0.012 SD COI 1.2, 1.4, 1.0% CV	\leq 0.5 COI SD \leq 0.12 COI 0.5-<1.0 COI SD \leq 0.10 COI \geq 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
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 \leq 0.08 COI SD \geq 1.0 COI \leq 8% CV	0.001, 0.012 COI SD 1, 1.4, 0.9% CV	< 1.0 COI \leq 0.08 COI SD \geq 1.0 COI \leq 8% CV	0.001 COI SD 1.6, 2.4, 1.7% CV	< 1.0 COI \leq 0.08 COI SD \geq 1.0 COI \leq 8% CV	0.002, 0.008, 0.013 COI SD 0.9, 1.4, 1.1% CV
HIV Duo	Neg \leq 0.1 COI SD Pos \leq 6% CV	0.006 COI SD 1.7, 1.6, 1.6, 1.5, 1.4% CV	Neg \leq 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 \leq 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 \leq 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<1.0 \leq 0.07 COI SD COI \geq 1.0 \leq 5.5% CV	0.00192 COI SD 1.6, 2.4, 2.9, 2.5% CV	COI<1.0 \leq 0.1 COI SD COI \geq 1.0 \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 $\leq 6.0\%$ 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 $\leq 8.0\%$ 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%) $\leq 8\%$ CV Gray zone (45.0-54.9 Avi%) $\leq 8\%$ CV High avidity (≥ 55.0 Avi %) $\leq 8\%$ CV	3.1% CV 2.4% CV 1.3% CV	Low avidity (<45.0 Avi%) $\leq 10\%$ CV Gray zone (45.0-54.9 Avi%) $\leq 10\%$ CV High avidity (≥ 55.0 Avi %) $\leq 10\%$ 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 $\leq 7\%$ 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 $\leq 10\%$ 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 $\leq 12\%$ CV	
HSV-1 IgG	≤ 0.8 COI ≤ 0.1 COI SD > 0.8-2.0 COI $\leq 6\%$ CV > 2 COI $\leq 8\%$ CV	0.0003 COI SD 1.6% CV 1.5% CV	≤ 0.8 COI ≤ 0.15 COI SD > 0.8-2.0 COI $\leq 8\%$ CV > 2 COI $\leq 10\%$ 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 $\leq 6\%$ CV > 2 COI $\leq 8\%$ CV	0.001 COI SD 1.2% CV 1.7% CV	≤ 0.8 COI ≤ 0.15 COI SD > 0.8-2.0 COI $\leq 8\%$ CV > 2 COI $\leq 10\%$ 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 $\leq 8\%$ 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 $\leq 9\%$ 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 $\leq 14\%$ 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 $\leq 5.5\%$ CV	0.003 COI SD 0.9, 1.2% SD	≤ 0.5 COI ≤ 0.04 COI SD > 0.5 COI $\leq 8\%$ CV	0.009, 0.10 COI SD 1.5, 1.7, 1.6% CV	≤ 0.5 COI ≤ 0.065 COI SD > 0.5 COI $\leq 13\%$ CV	0.014 COI SD 8.6, 7.9, 4.6, 10.9, 11.4% 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.
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	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, 0.015 U/mL SD 2.1, 1.3% CV 1.4, 1.6, 0.9% CV	LEMUR-< 1.0 U/ml ≤ 0.12 U/ml SD ≥1.0 – 20 U/ml ≤ 12% CV >20 U/ml - HEMR ≤ 17% CV	0.014, 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

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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_Digitoxin
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
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_Testo II_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	Ara_SummaryReport_tPSA V2
S100	n/a
SCC	4_Ara_SummaryReport_SCC
Anti-p53	4_6_MS_AR_Summary_inclRec_Anti-p53_MethodSheet
Free hCG	Ar_SummaryReport_fhCG V2
PAPP-A	Ar_SummaryReport_PAPP-A V2

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Documents Used:

Assay	Application report
Active B12	4_6_MS_AR_Summary_inclRec_Active B12_V2_MethodSheet
Vitamin B12 II	4_Arb_SummaryReport_B12 II
Ferritin	4_Ara_SummaryReport_Ferritin
Folate III	4_Arb_SummaryReport_Fol III
Folate RBC	4_Arb_SummaryReport_Fol RBC
IgE II	4_Ara_SummaryReport_IGEII
β -CrossLaps/serum	4_6_MS_AR_Summary_inclRec_βCrossLaps_V2_MethodSheet
Osteocalcin	4_Ara_SummaryReport_N_MID Osteocalcin
PTH	4_Ara_SummaryReport_PTH
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

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Documents Used:

Assay	Application report
Anti-HBc IgM	4_Ard_SummaryReport Anti-HBc IgM
Anti-HBe	4_Ara_SummaryReport Anti-HBe
HBeAg	4_Arf_SummaryReport HBeAg
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_Ard_SummaryReport_Chagas
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

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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.

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