

cobas e 601, cobas e 602 Assays Specifications

Chers utilisateurs, nous vous prions de trouver ci dessous les spécifications de répétabilité et reproductibilité pour les modules cobas e 601/e 602.

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

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

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

Utilisation des données :

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

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

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
FT3 III	LEMUR - 3 pmol/L \leq 0.15 pmol/L SD > 3 pmol/L to HEMR \leq 5% CV	0.067 pmol/l SD 2.1, 1.4, 1.3, 0.8% CV	LEMUR - 3 pmol/L \leq 0.25 pmol/L SD > 3 pmol/L to HEMR \leq 8% CV	0.081 pmol/l SD 2.5, 1.8, 1.5, 0.9% 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	0.5 - 6 pmol/l \leq 0.54 pmol/l SD > 6-100 pmol/l \leq 9% CV	0.156 pmol/l SD 1.7, 2.8, 2.0, 5.4, 1.8, 2.4 pmol/l CV
FT4 IV	LEMUR to 6 pmol/L \leq 0.3 pmol/L SD > 6 pmol/L to HEMR \leq 5% CV	0.077 pmol/LSD 1.4, 1.1, 0.9, 1.9% CV	LEMUR to 6 pmol/L \leq 0.5 pmol/L SD > 6 pmol/L to HEMR \leq 8% CV	0.100 pmol/l 1.8, 1.6, 1.9, 3.0% 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% CV >1.2 nmol/l-HEMR \leq 3% CV	0,020 nmol/l SD 2.5% CV 2.4, 1.7, 2.0 1.8, 2.1% CV	LEMUR - 0,7 nmol/l \leq 0,042 nmol/l SD >0.7-2.5 nmol/l 6% CV >2.5 nmol/l -HEoMR 7% CV	0,033 nmol/l SD 3.0, 3.1, 3.3% CV 2.3, 2.4, 2.4% CV	n/a	n/a
T4	LEMUR - 35 nmol/l \leq 1.75 nmol/l SD >35-65 nmol/l \leq 5% CV >65 nmol/l -HEMR \leq 3% CV	0.165/0.392 nmol/L SD 3.4% CV 2.2, 1.9, 2.5% 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	0,469 / 0,967 nmol/l SD 5.1% CV 4.3% CV 4.3, 4.2% 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	0.002, 0.004 μ U/ml SD 2, 1.3, 1.8, 2.2, 1.6, 1.5% CV	LEMUR -0.2 μ U/ml \leq 0.02 μ U/ml SD > 0.2-100 μ U/ml \leq 10% CV	0.002, 0.005 μ U/ml SD 2.7, 2.3, 2.5, 2.4% CV	LEMUR -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	0.6-1.4 TBI \leq 4% CV < 0.6 TBI (not specified) > 1.4 TBI (not specified)	2, 2.6, 0.8, 3.1% CV	0.6-0.9 TBI \leq 5% CV 0.9-1.4 TBI \leq 4% CV < 0.6 TBI (not specified) > 1.4 TBI (not specified)	4.9, 4.9% CV 2.4, 3.9% CV 1.5% CV	0.6-0.9 TBI \leq 6% CV 0.9-1.4 TBI \leq 5% CV < 0.6 TBI (not spec.) > 1.4 TBI (not spec.)	5.6% CV 3.7, 3.8, 2.5% CV 2% CV
Tg II	LEMUR - 0.5 ng/ml SD \leq 0.04 ng/ml > 0.5 ng/ml - HEMR \leq 8% CV	0.006 ng/ml SD 3.2, 1.8, 2.6, 2.2% CV	LEMUR - 0.5 ng/ml SD \leq 0.05 ng/ml > 0.5 ng/ml - HEMR \leq 10% CV	0.006 ng/ml SD 3.2, 2.2, 2.7, 2.6% CV	n/a	n/a
Calcitonin	LEMUR to 10 pg/mL SD \leq 0.5 pg/mL > 10 pg/mL to HEMR CV \leq 5.0 %	0.029 pg/ml SD 1.2, 3.1, 1.4, 2.9% CV	LEMUR to 10 pg/mL SD \leq 0.6 pg/mL > 10 pg/mL to HEMR CV \leq 6.0 %	0.065 pg/ml SD 2.3, 3.1, 2.3, 3.3% CV	n/a	n/a



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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Anti-TG	50-75 IU/ml < 15% CV 75-1000 IU/ml < 8% CV > 2000 IU/ml < 16% CV	4, 4.9% CV 3, 2.7, 1.3, 2% CV 1.3 1.6% CV	50-75 IU/ml < 20% CV 75-1000 IU/ml < 10% CV > 2000 IU/ml < 20% CV	6.3% CV 5.7, 3.2, 2.1% CV 3.4% CV	50-75 IU/ml < 25% CV 75-1000 IU/ml < 13% CV > 2000 IU/ml < 27% CV	4, 2.5, 3.6% CV 2.8, 3.3, 3.8% CV
Anti-TPO	15-40 IU/ml ≤ 10% CV > 40 IU/ml ≤ 7% CV	6, 3.3, 5.5% CV 5.1, 2.6, 2.7% CV	15-40 IU/ml ≤ 15% CV > 40 IU/ml ≤ 10% CV	9.2, 9.5% CV 4.3, 6.1, 4.2% CV	15-40 IU/ml ≤ 18% CV > 40 IU/ml ≤ 12% CV	5.3, 5.1% CV 1.5, 3.3, 2.4% CV
Anti-TSHR	1.1-5 IU/l ≤ 0.3 IU/l SD ≥5-40 IU/l < 6% CV	0.105, 0.14, 0.114, 0.145 IU/l SD 1.1, 0.8, 1.9% CV	1.1-5 IU/l ≤ 0.35 IU/l SD ≥5-40 IU/l < 7% CV	0.129, 0.161, 0.144, 0.178 IU/l SD 1.5, 1.3, 2.2% CV	n/a	n/a



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CK-MB	0.3-5 ng/ml 0.15 ng/ml SD >5-15 ng/ml ≤ 3% CV >15 ng/ml ≤ 5% CV	0.02, 0.04 ng/ml 0.7% CV 1.2, 1.0% CV	0.3-5 ng/ml 0.25 ng/ml SD >5-15 ng/ml ≤ 5% CV >15 ng/ml ≤ 10% CV	0.04 ng/ml SD 1.6% CV 1.6, 2.1% CV	0.3-5 ng/ml 0.3 ng/ml SD >5-15 ng/ml ≤ 6% CV >15 ng/ml ≤ 10% CV	0.04 ng/ml 1.1% CV 5.7, 3.2% CV
GDF-15	LEMR-800 pg/mL ≤ 40 pg/mL SD > 800 pg/mL – HEMR ≤ 5% CV	5,62 pg/mL SD 1.5, 1.1, 1.0, 1.2, 1.2% CV	LEMR-800 pg/mL ≤ 80 pg/mL SD > 800 pg/mL – HEMR ≤ 10% CV	10.1 pg/mL SD 1.8, 1.5, 1.4, 1.8, 1.6% CV	n/a	n/a
Myoglobin	15-50 ng/ml < 8% CV 50-500 ng/ml < 5% CV > 500 ng/ml < 8% CV	1.4, 1.3% CV 1.8, 1.7, 1.5% CV 2.6, 1.6, 2.5% CV	15-50 ng/ml < 10% CV 50-500 ng/ml < 6% CV > 500 ng/ml < 10% CV	2.3% CV 3.9, 5.2% CV 4.4, 7.1% CV	15-50 ng/ml < 10% CV 50-500 ng/ml < 7% CV > 500 ng/ml < 10% CV	2.4% CV 3.5, 3.4, 2.9% CV 3.8, 2.9, 5.1% CV
proBNP II	LEMR-50 pg/ml ≤ 5 pg/ml SD >50-100 pg/ml ≤ 10% CV >100-250 pg/ml ≤ 5% CV >250 pg/ml to HEMR ≤ 5% CV	1.63 pg/ml SD 2.9% CV 2.2% CV 2.7, 2.0, 1.9, 2.3, 1.8% CV	LEMR-50 pg/ml ≤ 6 pg/ml SD >50-100 pg/ml ≤ 13% CV >100-250 pg/ml ≤ 8% CV >250 pg/ml to HEMR ≤ 5% CV	2.4 pg/ml SD 4.8% CV 4.1% CV 3.8, 3.5, 3.3, 3.6, 3.9% CV	n/a	n/a
Troponin I	0.1-0.2 µg/l < 25 % CV 0.2-0.4 µg/l ≤ 10% CV > 0.4 µg/l ≤ 8% CV	14.2, 10% CV 5.3, 7% CV 5.2, 2.7, 2.6% CV	0.1-0.2 µg/l < 40 % CV 0.2-0.4 µg/l ≤ 20% CV* > 0.4 µg/l ≤ 8% CV * 10% above 0.3 µg/l	15.9, 13.4% CV 8.7, 8% CV 7.3, 4.7, 4.4% CV	0.1-0.2 µg/l < 40 % CV 0.2-0.4 µg/l ≤ 25% CV > 0.4 µg/l ≤ 12% CV	6.4% CV 4.4, 3.2, 2.3% CV 1.6, 1, 1.3% CV
Troponin T hs	LEMR-< 14 pg/ml ≤ 0.7 pg/ml SD 14-100 pg/ml ≤ 5% CV > 100-HEMR ≤ 3% CV	0.175 pg/ml SD 2.6, 1.9% CV 1.4, 2.0, 1.4% CV	LEMR-< 14 pg/ml ≤ 1.4 pg/ml SD 14-100 pg/ml ≤ 10% CV > 100-HEMR ≤ 6% CV	0.39 pg/ml SD 3.8, 3.3% CV 1.8, 2.4, 3.4% CV	n/a	n/a
Digoxin	< 0.8 ng/ml < 10% CV 0.8-4 ng/ml < 4% CV > 4 ng/ml < 5% CV	3.1, 4.9% CV 3.3, 1.3, 2.7% CV	< 0.8 ng/ml < 20% CV 0.8-4 ng/ml < 6% CV > 4 ng/ml < 7% CV	8.4% CV 3, 4.4, 3.8, 5.1% CV	< 0.8 ng/ml < 22% CV 0.8-4 ng/ml < 7% CV > 4 ng/ml < 9% CV	3.6, 2.6, 1.4% CV 2.2% CV
Digitoxin	< 10 ng/ml < 8% CV 10-40 ng/ml < 4% CV > 40 ng/ml < 6% CV	1.8, 2.3% CV 1.8, 2, 2.3% CV 1.7, 1.5% CV	< 10 ng/ml < 10% CV 10-40 ng/ml < 6% CV > 40 ng/ml < 8% CV	4% CV 2.8, 2.8, 2.6% CV 2.5% CV	< 10 ng/ml < 13% CV 10-40 ng/ml < 7% CV > 40 ng/ml < 10% CV	4.9, 3.1% CV 2.1, 2.4, 1.3% CV 1.5, 1, 0.6% CV
HCG+β	2-5 mIU/ml ≤ 9% CV 5-10 mIU/ml ≤ 4% CV > 10 mIU/ml ≤ 4 % CV	2.8, 2.5% CV 1.7, 2.7, 2.8% CV	2-5 mIU/ml ≤ 10% CV 5-10 mIU/ml ≤ 5% CV > 10 mIU/ml ≤ 5 % CV	7.4% CV 4.1, 3.4% CV 4.6, 4.6, 3.3% CV	2-5 mIU/ml ≤ 10% CV > 5 mIU/ml ≤ 6% CV	1.4, 1.6, 1.9% CV
HCG STAT	LEMR - 10 mIU/mL 0.4 mIU/mL SD > 10 mIU/mL – HEMR ≤ 4% CV	0,117 / 0,211 mIU/mL SD 1.2, 1.4, 1.4% CV	LEMR - 10 mIU/mL ≤ 0,56 mIU/mL SD > 10 mIU/mL – HEMR ≤ 5,6% CV	0,304 / 0,469 mIU/mL SD 3.7, 5.0, 3.4% CV	n/a	n/a



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ACTH	LEMUR to 10 pg/mL SD ≤ 0.60 pg/mL > 10 pg/mL to HEMR CV ≤ 6.0 %	0.102 pg/mL SD 1.3, 1.1, 1.0, 0.9% CV	LEMUR to 10 pg/mL SD ≤ 0.76 pg/mL > 10 pg/mL to HEMR CV ≤ 7.6 %	0.127 pg/mL SD 1.5, 1.3, 1.6, 1.7% CV	n/a	n/a
AMH / AMH Plus	LEMUR- 0.5 ng/ml SD ≤ 0.025 ng/ml >0.5-1.0 ng/ml ≤ 5% CV >1.0-8.0 ng/ml ≤ 4% CV >8.0 ng/ml – HEMR ≤ 3% CV	0.0007 ng/ml SD 1.3% CV 1.1% CV 1.7, 2.6% CV	LEMUR- 0.5 ng/ml SD ≤ 0.03 ng/ml >0.5-1.0 ng/ml ≤ 6% CV >1.0-8.0 ng/ml ≤ 5% CV >8.0 ng/ml - HEMR ≤ 5% CV	0.002 ng/ml SD 3.4% CV 3.9% CV 3.7, 3.5% CV	n/a	n/a
Androstenedione	LEoMR to 0.60 ng/mL SD ≤ 0.04 ng/mL > 0.60 ng/mL to HEoMR CV ≤ 6.0 %	0.013 ng/mL, 0.446 ng/mL 0.923 ng/mL, 1.8% CV 3.19 ng/mL, 2.4% CV 5.39 ng/mL, 1.8% CV 9.15 ng/mL, 2.1% CV	LEoMR to 0.60 ng/mL SD ≤ 0.06 ng/mL > 0.60 ng/mL to HEoMR CV ≤ 8.0 %	0.020 ng/mL, 0.446 ng/mL 0.923 ng/mL, 3.8% CV 3.19 ng/mL, 3.7% CV 5.39 ng/mL, 3.7% CV 9.15 ng/mL, 3.9% CV	n/a	n/a
Cortisol II serum	1.5-3 nmol/l ≤ 0.9 nmol/l SD >3-50 nmol/l ≤ 1.5 nmol/l SD >50-900 nmol/l ≤ 5% CV >900-1750 nmol/l ≤ 6% CV	0.2, 0.9 nmol/l SD 1.5, 1.7, 1.6% CV 1.6% CV	1.5-50 nmol/l ≤ 2.5 nmol/l SD >50-900 nmol/l ≤ 6% CV >900-1750 nmol/l ≤ 7% CV	0.4, 1.0 nmol/l SD 2.2, 2.3% CV 1.9% CV	1.5-50 nmol/l ≤ 3 nmol/l SD >50-900 nmol/l ≤ 8% CV >900-1750 nmol/l ≤ 9% CV	0.7 nmol/l SD 2.3, 2.9, 4% CV 3.2% CV



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Cortisol II saliva	1.5-3 nmol/l ≤ 0.9 nmol/l SD >3-50 nmol/l ≤ 1.5 nmol/l SD >50-900 nmol/l ≤ 5% CV >900-1750 nmol/l ≤ 6% CV	0.2 nmol/l SD 0.3, 0.7 nmol/l SD 1.7% CV	1.5-50 nmol/l ≤ 2.5 nmol/l SD >50-900 nmol/l ≤ 6% CV >900-1750 nmol/l ≤ 7% CV	0.4, 0.9 nmol/l SD 2.5% CV	1.5-50 nmol/l ≤ 3 nmol/l SD >50-900 nmol/l ≤ 8% CV >900-1750 nmol/l ≤ 9% CV	-
DHEAS	50-1000 µg/dl < 5% CV	2.6, 2.4, 2.3, 1.4% CV	50-1000 µg/dl < 7% CV	2.4, 2.2, 2.5, 2.7% CV	50-1000 µg/dl < 8% CV	1.6, 2.6, 1.5, 3.1% CV
Estradiol III	LoD-50 pg/ml ≤ 4 pg/ml SD > 50-200 pg/ml ≤ 7% CV > 200-3000 pg/ml ≤ 6% CV	1.9, 1.8 pg/ml SD 1.6, 2.4% CV 1.1, 1.9, 1.2% CV	LoD-50 pg/ml ≤ 6 pg/ml SD > 50-200 pg/ml ≤ 10% CV > 200-3000 pg/ml ≤ 8% CV	2.9, 2.7 pg/ml SD 2.5, 3.8% CV 1.9, 3.0% CV	LoD-50 pg/ml ≤ 7 pg/ml SD > 50-3000 pg/ml ≤ 12% CV	2.7 pg/ml SD 1.7, 3.1, 2% CV
FSH	LEMUR to 20 mIU/mL SD ≤ 1 mIU/mL >20-100mIU/mL CV ≤ 4.3 % >100-200mIU/mL CV ≤ 3.5 %	0.017, 0.162 mIU/ml SD 1.8% CV 1.2, 1.3% CV	LEMUR to 20 mIU/mL SD ≤ 1.2 mIU/mL >20-100mIU/mL CV ≤ 5.1 % >100-200mIU/mL CV ≤ 6.0 %	0.039, 0.358 mIU/ml SD 3.7% CV 3.9, 4.1% CV	n/a	n/a
LH	2-10 mU/ml ≤ 5% CV > 10-100 mU/ml ≤ 3% CV > 100-200 mU/ml ≤ 5% CV	1.2, 0.8, 1.4% CV 0.7, 0.6, 0.6% CV 0.9, 0.7% CV	2-10 mU/ml ≤ 6% CV > 10-100 mU/ml ≤ 5% CV > 100-200 mU/ml ≤ 6% CV	2.1, 2% CV 2.1, 1.7% CV 2.2% CV	2-10 mU/ml ≤ 7% CV > 10-100 mU/ml ≤ 7% CV > 100-200 mU/ml ≤ 6% CV	3.1, 2.2, 2.6% CV 1.9, 2.2, 2% CV 2.4% CV



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Progesterone III	0.05-0.5 ng/ml \leq 0.1 ng/ml SD >0.5-1 ng/ml \leq 12% CV >1 ng/ml \leq 7% CV	0.019 ng/ml SD 5.3% CV 2.5, 2.1, 1.2% CV	0.05-0.5 ng/ml \leq 0.15 ng/ml SD >0.5-1 ng/ml \leq 14% CV >1 ng/ml \leq 8% CV	0.036 ng/ml SD 8.2% CV 6.5, 3.3, 3.2% 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	0-005 ng/ml SD 10.8% CV 2.6, 1.8, 2.0% CV
Prolactin II	100-1000 μ U/ml \leq 5% CV	0.8, 1.7, 0.9, 0.8% CV	100-5000 μ U/ml \leq 6% CV	1.8, 1.4, 1.6, 1.4, 2% CV	100-5000 μ U/ml \leq 8% CV	3.8, 3.9, 2.5, 2.6% CV
SHBG	5-200 nmol/l < 4% CV	1.1, 1.3, 1.7% CV	5-200 nmol/l < 6% CV	1.8, 2.1, 4% CV	5-200 nmol/l < 8% CV	1.2, 1.4, 1.9, 2.7, 3.3% CV
Testosterone II	LEMUR – 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	0.008 ng/ml SD 4.4% CV 1.8% CV 1.2% CV 1.9% CV	LEMUR – 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	0.014 ng/ml SD 5.9% CV 3.2% CV 2.1% CV 3.0% CV	n/a	n/a
C-Peptide serum	0.5-20 ng/ml \leq 5% CV	0.6, 1.4, 1% CV	0.5-20 ng/ml \leq 6% CV	1.7, 1.8, 2.3% CV	0.5-20 ng/ml \leq 7% CV	2.1, 1.8, 1.2% CV
C-Peptide urine	0.5-20 ng/ml \leq 5% CV	0.8, 0.9, 1.3% CV	0.5-20 ng/ml \leq 6% CV	3.4, 4, 2.6% CV	0.5-20 ng/ml \leq 7% CV	na
Insulin	5-10 μ U/ml < 5% CV 10-300 μ U/ml < 4% CV 300-1000 μ U/ml < 5% CV	1.1, 1.5% CV 0.9, 0.8, 1.2% CV 0.7, 0.8% CV	5-10 μ U/ml < 6% CV 10-300 μ U/ml < 5% CV 300-1000 μ U/ml < 6% CV	4.9% CV 3.7, 3.4% CV 2.4% CV	5-10 μ U/ml < 7% CV 10-300 μ U/ml < 6% CV 300-1000 μ U/ml < 7% CV	2.4% CV 2.4, 2.9, 1.8% CV 2, 2.4% CV
PIGF	\leq 50 pg/ml \leq 4 pg/ml SD \geq 50 pg/ml \leq 8% CV \geq 200 pg/ml \leq 6% CV \geq 1000 pg/ml \leq 6% CV	0.19 pg/ml SD 3.2, 0.8, 0.8% CV 0.8% CV 0.8, 0.7, 1% CV	\leq 50 pg/ml \leq 5 pg/ml SD \geq 50 pg/ml \leq 10% CV \geq 200 pg/ml \leq 8% CV \geq 1000 pg/ml \leq 8% CV	0.41 pg/ml 4, 2, 1.9% CV 1.8% CV 2.1, 1.8, 2% CV	\leq 50 pg/ml \leq 6 pg/ml SD \geq 50 pg/ml \leq 12% CV \geq 200 pg/ml \leq 10% CV \geq 1000 pg/ml \leq 10% CV	0.22 pg/ml SD 2.3, 1.1% CV 1.9% CV 0.6, 0.8, 0.8% CV
sFlt-1	\leq 25 pg/ml \leq 2 pg/ml SD \geq 25 pg/ml \leq 8% CV \geq 200 pg/ml \leq 7% CV \geq 10000 pg/ml \leq 6% CV	1.3% CV 1.9, 1.8%, 1.7 CV 1.5, 1.5% CV	\leq 25 pg/ml \leq 3 pg/ml SD \geq 25 pg/ml \leq 12% CV \geq 200 pg/ml \leq 8% CV \geq 10000 pg/ml \leq 7% CV	3.2% CV 2.5, 3, 2.6% CV 3.4, 3.9% CV	\geq 25 pg/ml \leq 13% CV \geq 200 pg/ml \leq 12% CV \geq 10000 pg/ml \leq 11% CV	1.8, 1.7% CV 1.1, 1.7, 3, 2.7% CV 3.5, 2.3, 3.1% CV



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AFP	LEMUR 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	0.054, 0.051% CV 2.7, 3.1% CV 2.9, 3.0, 3.2% CV	LEMUR 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	0.080, 0.073% CV 3.5, 3.9% CV 3.6, 3.8, 3.9% CV	n/a	n/a
AFP-L3	LEMUR to 6 ng/mL ≤ 0.5 ng/mL SD 6.0 ng/mL to HEMR $\leq 8\%$ CV	0.084, 0.109, 0.078, 0.109 ng/mL SD 2.3, 2.3, 2.1, 1.9% CV	LEMUR to 6 ng/mL ≤ 0.7 ng/mL SD 6.0 ng/mL to HEMR $\leq 12\%$ CV	0.102, 0.136, 0.098, 0.142 ng/mL SD 3.2, 3.1, 2.8, 2.8% CV	n/a	n/a
Anti-p53	LoB-0.2 $\mu\text{g/ml}$ ≤ 0.02 $\mu\text{g/ml}$ SD > 0.2-10 $\mu\text{g/ml}$ $\leq 3.5\%$ CV > 10-100 $\mu\text{g/ml}$ $\leq 4.5\%$ CV	0.001, 0.002 $\mu\text{g/ml}$ SD 1.3% CV 1.2%, 0.9% CV	LoB-0.2 $\mu\text{g/ml}$ ≤ 0.025 $\mu\text{g/ml}$ SD > 0.2-10 $\mu\text{g/ml}$ $\leq 6.5\%$ CV > 10-100 $\mu\text{g/ml}$ $\leq 7\%$ CV	0.003 / 0.004 $\mu\text{g/ml}$ SD 3.3% CV 3.3, 2.9% CV	n/a	n/a
CA 125 II	10-25 U/ml $< 5\%$ CV 25-500 U/ml $< 4\%$ CV 500-5000 $< 10\%$ CV	0.9, 1.1% CV 0.8, 0.9, 1.1% CV 1.1, 1.6% CV	10-25 U/ml $< 6\%$ CV 25-500 U/ml $< 4\%$ CV 500-5000 $< 10\%$ CV	1.8% CV 1.6, 1.5, 1.7% CV 2.5% CV	10-500 U/ml $< 8\%$ CV 500-5000 $< 15\%$ CV	2. 1.5, 1.7% CV 2.2, 4% CV
CA 15-3 II	10-50 U/ml $< 4\%$ CV 50-200 U/ml $< 5\%$ CV	1.3, 1.2, 1.5% CV 1.4, 1.2, 1.5% CV	10-200 U/ml $\leq 6\%$ CV	4.2, 3.7, 3.2, 3.9, 5% CV	10-200 U/ml $\leq 8\%$ CV	1.3, 3.9, 2.2, 3.1, 4.2% CV
CA 19-9	30-1000 U/ml $< 5\%$ CV < 30 U/ml (not specified)	1.2, 1.1, 1.5% CV 2.1, 1.9% CV	30 - 1000 U/ml $< 9\%$ CV < 30 U/ml (not specified)	1.9, 2.4, 2.7% CV 2.6, 8.1% CV	30-1000 U/ml $< 10\%$ CV < 30 U/ml (not specified)	0.7, 3, 2.3% CV 2.8, 2.6% CV
CA 72-4	LEMUR to 4 U/mL SD ≤ 0.2 U/mL >4 - 100 U/mL CV $\leq 5.0\%$ > 100 U/mL to HEMR V $\leq 6.0\%$	0.044 U/ml SD 1.2, 1.2% CV 1.3%, 1.2% CV	LEMUR to 4 U/mL SD ≤ 0.25 U/mL >4 - 100 U/mL CV $\leq 6.0\%$ > 100 U/mL to HEMR CV $\leq 8.0\%$	0.116 U/ml SD 3.2, 3.4% CV 3.7%, 3.5% CV	n/a	n/a
CEA	2-10 ng/ml $\leq 3\%$ CV 10-50 ng/ml $\leq 2\%$ CV 50-500 ng/ml $\leq 3\%$ CV > 500 ng/ml (not spec.)	1.1, 1.3, 2.5% CV 2, 2% CV 2.2, 1% CV 1.3, 1.9% CV	2-10 ng/ml $\leq 6\%$ CV 10-50 ng/ml $\leq 5\%$ CV 50-500 ng/ml $\leq 8\%$ CV > 500 ng/ml (not spec.)	5.1, 4.7% CV 4.9% CV 4.6% CV 5% CV	2-10 ng/ml $\leq 7\%$ CV 10-50 ng/ml $\leq 6\%$ CV 50-500 ng/ml $\leq 9\%$ CV > 500 ng/ml (not spec.)	6.5, 5.7, 5.5% CV 3.5% CV 3.4, 4.8% CV 2.3, 3.1% CV



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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Cyfra 21-1	1-3 ng/ml ≤ 5% CV 3.1-10 ng/ml ≤ 3% CV > 10 ng/ml ≤ 5% CV	1.1., 1.5% CV 1.1, 1.4, 2.1% CV 0.6, 1, 1.6% CV	1-3 ng/ml ≤ 7% CV 3.1-10 ng/ml ≤ 5% CV > 10 ng/ml ≤ 5% CV	2.7% CV 2.6, 2.3% CV 1.9, 2% CV	1-3 ng/ml ≤ 8% CV 3.1-10 ng/ml ≤ 6% CV > 10 ng/ml ≤ 6% CV	1.9% CV 1.5, 2.5% CV 2.1, 1.9, 2.4% CV
HE4	< 30 pmol/l ≤ 3 pmol/l SD 30-150 pmol/l ≤ 5% CV 150-900 pmol/l ≤ 4% CV >900-1500 pmol/l ≤ 5% CV	0.5 pmol/l 1.8 % CV 1.5, 1.6% CV 1.9% CV	< 30 pmol/l ≤ 3 pmol/l SD 30-150 pmol/l ≤ 7% CV 150-900 pmol/l ≤ 6% CV >900-1500 pmol/l ≤ 10% CV	0.8 pmol/l SD 2.8% CV 2.6, 3.0 % CV 3.2% CV	30-150 pmol/l ≤ 10% CV 150-900 pmol/l ≤ 9% CV >900-1500 pmol/l ≤ 10% CV	0.7 % CV 0.9, 1.8% CV 1.6, 1.1% CV
NSE	15-100 ng/ml < 3% CV < 15 ng/ml (not specified)	0.9, 0.9,0.7% CV 1, 0.8% CV	15-100 ng/ml < 5% CV < 15 ng/ml (not specified)	1.6, 3.8% CV 1.8, 3.1% CV	15-100 ng/ml < 10% CV < 15 ng/ml (not specified)	5.8, 6.4, 5.2% CV 3, 11% CV
PIVKA-II	LEMUR to 30 ng/ml ≤ 1.5 ng/ml SD > 30 ng/ml to HEMR ≤ 5% CV	0.165, 0.309, 0.499, ng/ml SD 2.2, 1.7, 1.8% CV	LEMUR to 30 ng/ml ≤ 2.25 ng/ml SD > 30 ng/ml to HEMR ≤ 7.5% CV	0.34, 0.707, 1.1 ng/ml SD 4.2, 3.8, 3.7% CV	n/a	n/a

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
ProGRP	LEMUR-60 pg/ml \leq 3 pg/ml SD >60pg/ml – HEMR \leq 5.4% CV	0.270 pg/ml SD 0.9, 1.1, 0.9, 1.7% CV	LEMUR-60 pg/ml \leq 6 pg/ml SD >60pg/ml – HEMR \leq 10.4% CV	0.491 pg/ml SD 3.0, 3.7, 3.3, 3.8% CV	n/a	n/a
free PSA	LEMUR-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		LEMUR-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		n/a	n/a
total PSA	LEMUR- \leq 0.1 ng/ml \leq 0.007 ng/ml SD >0.1- \leq 1.0 ng/ml \leq 7.4% CV >1-50 ng/ml \leq 3.4% CV >50-100 ng/ml \leq 5.4% CV	1.4, 1.15, 1.66, 1.296, 1.39% CV	LEMUR- \leq 0.1 ng/ml \leq 0.010 ng/ml SD >0.1- \leq 1.0 ng/ml \leq 10.4% CV >1-50 ng/ml \leq 5.4% CV >50-100 ng/ml \leq 8.4% CV	3.17, 3.72, 2.74, 1.41, 1.58% CV	n/a	n/a
S100	LEMUR-0.05 μ g/L \leq 0.005 μ g/L SD >0.05-0.15 μ g/L \leq 3.0% CV >0.15 μ g/L -HEMR \leq 5.0% CV	0.0008 μ g/L SD 2.1, 1.8 % CV 1.3, 1.4% CV	LEMUR-0.05 μ g/L \leq 0.005 μ g/L SD >0.05-0.15 μ g/L \leq 5.0% CV >0.15 μ g/L -HEMR \leq 7.0% CV	0.001 μ g/L SD 3.4, 2.9% CV 2.7, 3.0% CV	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	0.020, 0.031 ng/ml SD 2.0, 0.9% CV 1.7, 1.4, 1.5% CV	LoD – 1.8 ng/ml SD \leq 0.2 ng/ml > 1.8-70 ng/ml \leq 10% CV	0.022, 0.033 ng/ml SD 2.5, 1.8, 2, 1.3% CV	LoD – 1.8 ng/ml SD \leq 0.2 ng/ml > 1.8-70 ng/ml \leq 12% CV	0.027, 0.035 ng/ml SD 1.3, 1.9, 2.4% CV
Free β hCG	LEMUR-15 IU/L \leq 0.6 IU/I SD > 15 IU/L-HEMR \leq 3% CV	0.014, 0.019, 0.011, 0.218, 0.234 IU/I SD 2.2, 2.6, 2.3, 2% CV	LEMUR-15 IU/L \leq 1 IU/I SD > 15 IU/L-HEMR \leq 5% CV	0.024, 0.032, 0.017, 0.38, 0.339 IU/I SD 3.6, 4.5, 4.2% CV	n/a	n/a
PAPP-A	LEMUR-50 mIU/I \leq 2.5 mIU/I SD >50-2000 mIU/I \leq 3.5% CV >2000 mIU/I-HEMR \leq 3% CV	0.888 mIU/I SD 1.4% CV 2.2, 2.1, 1.8, 1.9% CV	LEMUR-50 mIU/I \leq 4 mIU/I SD >50-2000 mIU/I \leq 6% CV >2000 mIU/I-HEMR \leq 5% CV	0.94 mIU/I SD 2.2, 2.1, 2.6% CV 2.5, 3.1, 2.9% CV	n/a	n/a
Active B12	LEMUR to 20 pmol/L SD \leq 0.8 pmol/L > 20 pmol/L to HEMR CV \leq 4.0 %	0.121 pmol/L SD 1.5, 1.4, 1.6, 1.4% CV	LEMUR to 20 pmol/L SD \leq 1.2 pmol/L > 20 pmol/L to HEMR CV \leq 6.0 %	0.380 pmol/I SD 2.5, 2.5, 2.5, 2.8% CV	n/a	n/a



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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Vitamin B12 II	≤ 200 pg/ml ≤ 14 pg/ml SD > 200 pg/ml ≤ 7% CV	5.9 pg/ml SD 2.3, 1.6, 1.3% CV	≤ 200 pg/ml ≤ 24 pg/ml SD > 200 pg/ml ≤ 12% CV	9 pg/ml SD 5.1, 3.4, 2.1% CV	≤ 200 pg/ml ≤ 28 pg/ml SD > 200 pg/ml ≤ 14% CV	9.4 pg/ml 3.7, 9.6, 1.5, 4.1% CV
Ferritin	10-40 ng/ml < 7% CV 50-400 ng/ml < 4% CV > 400 ng/ml (not specified)	3, 2.3, 2.9% CV 3.1, 2.9, 2.3% CV 3.6% CV	10-40 ng/ml < 7% CV 50-400 ng/ml < 7% CV > 400 ng/ml (not specified)	4.4, 4.3, 4% CV 4.3, 4.9, 4.4% CV 4.1% CV	10-40 ng/ml < 8% CV 50-400 ng/ml < 8% CV > 400 ng/ml (not specified)	3% CV 2.7, 3.4% CV 3.2, 4.7% CV
Folate III	≤ 5 ng/ml < 0.35 ng/ml SD > 5 ng/ml < 7% CV	0.2, 0.3 ng/ml SD 2.1, 2.3, 2.1, 2.5% CV	< 5 ng/ml < 0.6 ng/ml SD > 5 ng/ml < 10% CV	0.23 ng/ml SD 2.9, 4.7, 4.5, 5.7% CV	< 5 ng/ml < 0.6 ng/ml SD > 5 ng/ml < 12% CV	0.20, 0.27 ng/ml SD 3.2, 3.5, 4.4 % CV
Folate RBC	≤ 155 ng/ml ≤ 11 ng/ml SD > 155 ng/ml ≤ 7 % CV	5.3, 7.3 ng/ml 6.0, 5.5, 2.2% CV	≤ 250 ng/ml ≤ 17.5 ng/ml SD > 250 ng/ml ≤ 7 % CV	6.3, 12.4 ng/ml SD 5.9, 3.4% CV	≤ 155 ng/ml ≤ 19 ng/ml SD > 155 ng/ml ≤ 12 % CV	10.9 ng/ml SD 7.2, 3.3, 2.8% CV
β-CrossLaps/serum	LEMUR - ≤ 0.50 ng/ml ≤ 0.02 ng/mL SD > 0.50ng/ml – HEMR ≤ 3.0% CV	0.002, 0.008 ng/ml SD 1.5, 1.3, 1.2% CV	LEMUR - ≤ 0.50 ng/ml ≤ 0.03 ng/mL SD > 0.50ng/ml – HEMR ≤ 5.0% CV	0.002, 0.009 ng/ml SD 1.7, 1.4, 1.5% CV	n/a	n/a
N-MID Osteocalcin	1-10 ng/ml < 0.5 ng/ml SD 11-40 ng/ml < 5% CV 41-400 ng/ml < 3% CV	0.05, 0.05 ng/ml SD 0.7, 0.6, 0.5% CV 0.5, 1.2, 0.8% CV	1-10 ng/ml < 0.8 ng/ml SD 11-40 ng/ml < 7% CV 41-400 ng/ml < 5% CV	0.11 ng/ml SD 1.3, 1.4% CV 1.1, 1.2, 1.5% CV	1-10 ng/ml < 1 ng/ml SD 11-40 ng/ml < 8% CV 41-400 ng/ml < 6% CV	2.4, 2.4% CV 3, 2.1, 3.5% CV
PTH	11-75 pg/ml < 7% CV 76-1000 pg/ml < 5% CV > 1000 pg/ml < 6% CV	1.7, 1.1, 2% CV 0.8, 1.1% CV 0.6, 0.6% CV	11-75 pg/ml < 9% CV 76-1000 pg/ml < 6% CV > 1000 pg/ml < 7% CV	1.7, 3.4% CV 1.6, 2.8% CV 1.6% CV	11-75 pg/ml < 10% CV 76-1000 pg/ml < 7% CV > 1000 pg/ml < 8% CV	1.9, 2.3, 4.4% CV 1.6, 2.3, 2.1% CV 1.5, 1.1, 1.3% CV
PTH (1-84)	LEMUR to 25 pg/mL ≤ 1.2 pg/mL SD > 25 pg/mL to HEMR ≤ 4.5% CV	0.408, 0.462 pg/mL SD 1.5, 0.9, 1.2% CV	LEMUR to 25 pg/mL ≤ 1.5 pg/mL SD > 25 pg/mL to HEMR ≤ 6% CV	0.475, 0.585 pg/mL SD 1.6, 1.2, 1.3% CV	n/a	n/a
Total P1NP	< 50 µg/l < 5% CV 50-500 µg/l < 4% CV > 500 µg/l < 4% CV	2.9% CV 0.8% CV 2.1, 1.5, 1.1% CV	< 50 µg/l < 7% CV 50-500 µg/l < 5% CV > 500 µg/l < 6% CV	4.5, 3.8, 4% CV 4.6, 4.2% CV	< 50 µg/l < 10% CV 50-500 µg/l < 7% CV > 500 µg/l < 7% CV	3.9% CV 2.5, 3.3., 1.2% CV 1.6, 2.0, 1.9% CV
Vitamin D total III	LEMUR to 20 ng/ml ≤ 1.2 ng/ml SD > 20 ng/ml to HEMR ≤ 6% CV	0.905 ng/ml SD 4.4, 4.2, 2.3, 3.0%CV	LEMUR to 20 ng/ml ≤ 1.6 ng/ml SD > 20 ng/ml to HEMR ≤ 8% CV	1.2 ng/ml SD 6.0, 5.6, 3.7, 3.3% CV	n/a	n/a
hGH	0.7 ng/ml ≤ 0.04 ng/ml deviation > 0.7 – 50 ng/ml ≤ 6% CV	0.012 ng/ml dev. 1.7, 2.6% CV	0.7 ng/ml ≤ 0.04 ng/ml deviation > 0.7 – 50 ng/ml ≤ 7% CV	0.003 ng/ml dev. 0.7, 1% CV	0.7 ng/ml ≤ 0.04 ng/ml deviation > 0.7 – 50 ng/ml ≤ 8% CV	0.022 ng/ml dev. 4.3, 3% CV

na not available at the moment.



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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
IGF-1	7-40 ng/ml \leq 1.6 ng/ml SD > 40 ng/ml \leq 5% CV	0.298 ng/ml SD 1.4, 1.6, 3.5, 1.0% CV	7-40 ng/ml \leq 4 ng/ml SD > 40 ng/ml \leq 10% CV	0.518 ng/ml SD 2.7, 2.5, 4.6, 2.9% CV	7-40 ng/ml \leq 4.4 ng/ml SD > 40 ng/ml \leq 11% CV	0.489 ng/ml SD 1.4, 2.9, 3.4, 1.8% CV
IGFBP-3	LEMUR – 150 ng/ml \leq 6 ng/ml SD > 150 ng/ml to HEMR \leq 4% CV	102 ng/ml SD 2.0, 2.1, 1.9, 1.7, 1.5, 1.6% CV	LEMUR – 150 ng/ml \leq 7.5 ng/ml SD > 150 ng/ml to HEMR \leq 5% CV	102 ng/ml SD 2.5, 2.1, 2.4, 2% CV	LEMUR – 150 ng/ml \leq 15 ng/ml SD > 150 ng/ml to HEMR \leq 10% CV	n/a
IgE II	1-5 IU/ml $<$ 9% CV 6-250 IU/ml $<$ 6% CV >250 IU/ml $<$ 5% CV	1.4% CV 0.6% CV 0.7, 0.6, 0.7% CV	1-5 IU/ml $<$ 10% CV 6-250 IU/ml $<$ 7% CV >250 IU/ml $<$ 8% CV	- 2.7, 3.6, 2.8% CV 3.5, 3, 4.2% CV	1-5 IU/ml $<$ 11% CV 6-250 IU/ml $<$ 8% CV >250 IU/ml $<$ 9% CV	3.0, 4.9% CV 4.1, 4.3% CV 4.1% CV
Anti-CCP	10-25 U/ml \leq 2.5 U/ml SD 25-200 U/ml \leq 6% CV 200-1000 U/ml \leq 8% CV	0.24, 0.1 U/ml SD 1.4% CV 2.3% CV	10-25 U/ml \leq 3.8 U/ml SD 25-200 U/ml \leq 8% CV 200-1000 U/ml \leq 10% CV	0.7, 0.5 U/ml SD 2.5% CV 4.5% CV	10-25 U/ml \leq 4 U/ml SD 25-200 U/ml \leq 9% CV 200-1000 U/ml \leq 11% CV	2.7 U/ml SD 1.4, 7.2, 2.4% CV 1.4, 0.9, 2.7% CV
BRAHMS PCT	LoD-0.1 ng/ml \leq +/- 0.01 ng/ml SD > 0.1 ng/ml \leq 10% CV	0.006 ng/ml SD 1.8, 1.1, 2.6, 1.9% CV	LoD-0.1 ng/ml \leq +/- 0.015 ng/ml SD > 0.1 ng/ml \leq 15% CV	0.007 ng/ml SD 2.6, 1.6, 3.2, 2.3% CV	n/a	n/a
IL-6	LEMUR-25 pg/ml SD \leq 5 pg/ml >25 pg/ml - HEMR \leq 5% CV	0.269, 0.277, 0.384 pg/mL SD 1.7, 1.3% CV	LEMUR-25 pg/ml SD \leq 5 pg/ml >25 pg/ml - HEMR \leq 7% CV	0.472, 0.490, 0.979pg/mL SD 3.6, 3.0% CV	n/a	n/a
Cyclosporine	LoD - \leq 90 ng/ml \leq +/- 7 ng/ml > 90-2000 ng/ml \leq +/-8% CV	2.75 ng/ml SD 3, 3.1, 2.4% CV	LoD - \leq 90 ng/ml \leq +/- 9 ng/ml > 90-2000 ng/ml \leq +/-10% CV	4.12 ng/ml SD 5, 4.8, 5.8% CV	LoD - \leq 90 ng/ml \leq +/- 11 ng/ml > 90-2000 ng/ml \leq +/-12% CV	3.73 ng/ml SD 4.3, 1.5, 6.5% CV
Everolimus	LoD – 3 ng/ml \leq +/- 0.24 ng/ml SD > 3-30 ng/ml \leq 8% CV	0.1, 0.116 ng/ml SD 3.2, 2.6, 3.4% CV	LoD – 3 ng/ml \leq +/- 0.3 ng/ml SD > 3-30 ng/ml \leq 10% CV	0.12, 0.176 ng/ml SD 5.4, 4.1, 4.6% CV	LoD – 3 ng/ml \leq +/- 0.36 ng/ml SD > 3-30 ng/ml \leq 12% CV	0.077, 0.079 ng/ml SD 4.0, 1.8, 2.5% CV
Sirolimus	LoD – 3 ng/ml \leq +/- 0.24 ng/ml SD > 3-30 ng/ml \leq 8% CV	0.086, 0.133 ng/ml SD 4.2, 2.8, 2.1% CV	LoD – 3 ng/ml \leq +/- 0.3 ng/ml SD > 3-30 ng/ml \leq 10% CV	0.098, 0.181 ng/ml SD 5.4, 3.4, 4.9% CV	LoD – 3 ng/ml \leq +/- 0.36 ng/ml SD > 3-30 ng/ml \leq 12% CV	0.095, 0.187 ng/ml SD 0.9, 3.6, 2.8% CV



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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Tacrolimus	0.5-3.5 ng/ml \leq 0.25 ng/ml SD > 3.5 – 12 ng/ml \leq 6% CV >12-40 ng/ml \leq 7% CV	0.059 ng/ml SD 2.5% CV 1.9, 2.2% CV	0.5-3.5 ng/ml \leq 0.35 ng/ml SD > 3.5 – 12 ng/ml \leq 6% CV >12-40 ng/ml \leq 7% CV	0.124 ng/ml SD 3.9% CV 3.5, 5.1% CV	0.5-3.5 ng/ml \leq 0.45 ng/ml SD > 3.5 – 12 ng/ml \leq 9% CV >12-40 ng/ml \leq 10% CV	0.139 ng/ml SD 5.9% CV 2.4% CV
β -Amyloid (1-42) CSF	LEMUR – 480 pg/ml \leq 24 pg/ml SD > 480 – 2000 pg/ml \leq 5% CV > 2000 pg/ml – HEMR \leq 8% CV	2,23 pg/mL SD 2.0, 2.3, 1.5, 1.5, 1.7 % CV 4.8% CV	LEMUR – 480 pg/ml \leq 38 pg/ml SD > 480 – 2000 pg/ml \leq 8% CV > 2000 pg/ml – HEMR \leq 10% CV	6,71 pg/mL SD 3.6, 4.6, 4.2, 4.4, 5.9% CV 9.2% CV	n/a	n/a
Phospho-Tau (181P) CSF	LeMR – 25 pg/ml \leq 1.3 pg/ml SD > 25 – 50 pg/ml \leq 5% CV > 50 pg/ml \leq 8% CV	0.258, 0.359 pg/ml SD 1.1, 1.1% CV 1.1, 1.0, 1.2% CV	LEMUR – 25 pg/ml \leq 2 pg/ml SD > 25 – 50 pg/ml \leq 8% CV > 50 pg/ml \leq 10% CV	0.327, 0.539 pg/ml SD 1.7, 1.6% CV 2.3, 2.2, 2.2% CV	n/a	n/a
Total-Tau CSF	LEMUR – 250 pg/ml \leq 13 pg/ml SD > 250 – 500 pg/ml \leq 5% CV > 500 pg/ml \leq 10% CV	1.01 pg/ml SD 0.9, 1.2, 1.0% CV 1.0, 0.7% CV	LEMUR – 250 pg/ml \leq 20 pg/ml SD > 250 – 500 pg/ml \leq 8% CV > 500 pg/ml \leq 10% CV	4.69 pg/ml SD 4.6, 4.4, 4.8% CV 5.1, 5.6% CV	n/a	n/a



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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
Anti-HAV II	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	1.1, 1.1% CV 0.009, 0.009, 0.0002 SD COI	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	2.0, 1.9% CV 0.022, 0.020, 0.0002 SD COI	n/a	n/a
Anti-HAV IgM	HS, neg ≤ 20% CV HS, low pos ≤ 7% CV HS, positive ≤ 7% CV	1.2, 1.3 % CV 1.9, 2.1% CV 1.4, 2.3% CV	HS, neg ≤ 20% CV HS, low pos ≤ 10% CV HS, positive ≤ 10% CV	2.5% CV 5% CV 5.5% CV	HS, neg ≤ 28% CV HS, low pos ≤ 18% CV HS, positive ≤ 18% CV	3.6% CV 1.8% CV 1.6% CV
Anti-HBc II	COI > 1.0 ≤ 7.0 %CV COI ≤ 1.0 ≤ 0.07 COI SD	1.9% CV 0.029, 0.0001 SD COI	COI > 1.0 ≤ 10.0 %CV COI ≤ 1.0 ≤ 0.10 COI SD	3.1% CV 0.045, 0.0002 SD COI	n/a	n/a
Anti-HBc IgM	HS, neg ≤ 5% CV HS, low pos ≤ 5% CV HS, positive ≤ 7% CV	3.4, 3.4 % CV 2.4, 1.5% CV 1.6, 1.4% CV	HS, neg ≤ 13% CV HS, low pos ≤ 8% CV HS, positive ≤ 10% CV	3.9% CV 4.1% CV 3.3% CV	HS, neg ≤ 14% CV HS, low pos ≤ 9% CV HS, positive ≤ 11% CV	6% CV 3.8% CV 3.9% CV
Anti-HBe	HS, neg ≤ 10% CV HS, low pos ≤ 5% CV HS, positive ≤ 5% CV	4.1, 0.8% CV 3.9, 2.8% CV 2.7, 1.1% CV	HS, neg ≤ 10% CV HS, low pos ≤ 10% CV HS, positive ≤ 10% CV	4.8% CV 6.6% CV 5.5% CV	HS, neg ≤ 11% CV HS, low pos ≤ 11% CV HS, positive ≤ 16% CV	6.3% CV 5.9% CV 6.3% CV
HBeAg	HS, neg ≤ 10% CV HS, low pos ≤ 5% CV HS, positive ≤ 5% CV	3.2, 5.1% CV 0.8, 1.3% CV 0.5, 1.2% CV	HS, neg ≤ 25% CV HS, low pos ≤ 10% CV HS, positive ≤ 10% CV	11% CV 4.3% CV 5% CV	HS, neg ≤ 16% CV HS, low pos ≤ 11% CV HS, positive ≤ 11% CV	5% CV 3.3% CV 3.4% CV
Anti-HBs II	≤ 5 IU/I ≤ 0.75 IU/I SD >5-≤10 IU/I SD ≤ 15% x mean >10 IU/I SD ≤ 5% x mean + 1 IU/I)	4.7% CV 3.2, 2, 2.2, 1.7, 1.5% CV	≤ 5 IU/I ≤ 1 IU/I SD >5-≤10 IU/I SD ≤ 20% x mean >10 IU/I SD ≤ 8% x mean + 1.2 IU/I)	6.8% CV 4.4, 3.4, 3.9, 3.6% CV	≤ 5 IU/I ≤ 1.2 IU/I SD >5-≤10 IU/I ≤ 24% x mean >10 IU/I SD ≤ 9% x mean + 1.5 IU/I)	n/a

HS Human sera. - No information.

cobas e 601, cobas e 602 Assays Specifications

Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
HBsAg II	≤ 0.70 COI ≤ 0.07 COI SD ≥ 0.7 COI $\leq 7\%$ CV	0.036, 0.038 COI SD 2, 1.2, 2.1% CV	≤ 0.70 COI ≤ 0.1 COI SD ≥ 0.7 COI $\leq 10\%$ CV	0.82, 0.049 COI SD 6, 4, 3.5% CV	≤ 0.70 COI ≤ 0.13 COI SD ≥ 0.7 COI $\leq 13\%$ CV	n/a
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 undiluted	0.005, 0.087 IU/ml SD 1.7, 1.8, 2.9% CV 3.2% 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 undiluted	0.009, 0.105 COI SD 3.3, 2, 3.2% CV 4% CV	n/a	n/a
Anti-HCV II	≤ 0.5 COI SD ≤ 0.1 COI 0.5 - <1.0 COI SD ≤ 0.07 COI ≥ 1.0 COI $\leq 7\%$ CV	0.0004 SD COI 0.011 SD COI 0.8, 1.6, 1.4% CV	≤ 0.5 COI SD ≤ 0.12 COI 0.5 - <1.0 COI SD ≤ 0.10 COI ≥ 1.0 COI $\leq 10\%$ CV	0.0006 SD COI 0.025 SD COI 3.2, 2.0, 2.0% CV	n/a	n/a
HIV Ag	HS, neg - HS, low pos $\leq 5\%$ CV HS, positive - PC HIV Ag 1 $\leq 10\%$ CV PC HIV Ag 2 $\leq 5\%$ CV	7.6% CV 0.9% CV 4.1% CV 4.7% CV 1.6% CV	HS, neg - HS, low pos - HS, positive - PC HIV Ag 1 $\leq 20\%$ CV PC HIV Ag 2 $\leq 10\%$ CV	11.7% CV 4.8% CV 3.9% CV 5.4% CV 2.6% CV	n/a	n/a
HIV combi PT	HS neg SD ≤ 0.06 Anti-HIV-1 pos. $\leq 6\%$ CV Anti-HIV-2 pos. $\leq 6\%$ CV HIV Ag pos. $\leq 6\%$ CV	0.007 COI SD 2.3, 1.7% CV 2.8% CV 2.2% CV	HS neg SD ≤ 0.09 Anti-HIV-1 pos. $\leq 10\%$ CV Anti-HIV-2 pos. $\leq 10\%$ CV HIV Ag pos. $\leq 10\%$ CV	0.01 COI SD 3.0, 2.2% CV 3.6% CV 2.9% 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, 0.018, 0.018 COI SD 1.7, 2.1, 1.0% CV	0 to 1.0 COI SD ≤ 0.1 COI COI >1.0 $\leq 7.5\%$ CV	0.002, 0.026, 0.022 COI SD 2.4, 3.2, 2.8% CV	n/a	n/a
Syphilis	COI <1.00 SD ≤ 0.07 COI COI ≥ 1.00 $\leq 5.5\%$ CV (corresponds to 7% incl 95% conf. Interval)	0.001 COI SD 1.5, 2.4, 2.2, 1.8% CV	COI <1.00 SD ≤ 0.1 COI COI ≥ 1.00 $\leq 7.5\%$ CV (corresponds to 10% incl 95% conf. Interval)	0.006 COI SD 5.4, 6.3, 4.7, 4.4% CV	n/a	n/a

HS Human sera. - No information. n/a Not available at the moment.

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	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	0.010, 0.023% CV 2.0, 0.9, 1.3% CV	LoD to ≤ 1.0 U/mL ≤ 0.08 U/mL SD > 1.0 to 500 U/mL ≤ 8.0 % CV	0.011, 0.023% CV 4.6, 1.1, 1.6% 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	3.3% CV 2.3% CV 1.7% CV	Low avidity (<45.0 Avi%) ≤ 10 % CV Gray zone (45.0-54.9 Avi%) ≤ 10 % CV High avidity (≥ 55.0 Avi %) ≤ 10 % CV	3.4% CV 2.6% CV 1.9% CV	n/a	n/a
CMV IGM	< 0.6 COI ≤ 0.06 COI SD > 0.6 COI ≤ 7 % CV	0.002, 0.002 COI SD 1.6, 1.3% CV	< 0.6 COI ≤ 0.09 COI SD > 0.6 COI ≤ 10 % CV	0.010.01 COI SD 6.1, 4.9, 3.7% CV	< 0.6 COI ≤ 0.09 COI SD > 0.6 COI ≤ 10 % CV	0.01 COI SD 2.4, 2.3% CV
HSV-1 IgG	≤ 0.8 COI ≤ 0.1 COI SD > 0.8-2.0 COI ≤ 6 % CV > 2 COI ≤ 8 % CV	0.0004 COI SD 1.6% CV 0.8% CV	≤ 0.8 COI ≤ 0.15 COI SD > 0.8-2.0 COI ≤ 8 % CV > 2 COI ≤ 10 % CV	0.000 COI SD 4.1% CV 3.0% 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	0.0007 COI SD 1.3% CV 0.9% CV	≤ 0.8 COI ≤ 0.15 COI SD > 0.8-2.0 COI ≤ 8 % CV > 2 COI ≤ 10 % CV	0.001 COI SD 1.6% CV 1.3% CV	n/a	n/a
Rubella IgG	< 5 IU/ml < 1 IU/ml SD > 5 IU/ml < 10% CV	0.074 IU/ml SD 2.6, 1.1, 1% SD	< 5 IU/ml < 1.1 IU/ml SD > 5 IU/ml < 12% CV	0.15 IU/ml 3.3, 3.2, 3.3% CV	< 5 IU/ml < 1.1 IU/ml SD > 5 IU/ml < 15% CV	0.03, 0.12 IU/ml 2.2, 4.9% CV
Rubella IgM	HS neg: ≤ 7 % CV HS, pos. ≤ 7 % CV PC Rub. IgM 1 ≤ 7 % CV PC Rub. IgM 2 ≤ 7 % CV	1.9% CV 1, 1.2% CV 1.3% CV 1.3% CV	HS neg (0.25 COI) ≤ 25 % CV HS, pos. ≤ 10 % CV	11, 9.5% CV 3.4, 2.7% CV	≤ 13 % CV	6.1, 8, 8.1, 7, 8.4% CV
Toxo IgG	HS neg: ≤ 7 % CV HS, pos. ≤ 7 % CV PC Toxo IgG 1 ≤ 7 % CV PC Toxo IgG 2 ≤ 7 % CV	1.5, 1.3 % CV 1.6 % CV 2.1% CV	HS neg: ≤ 10 % CV HS, pos. ≤ 10 % CV PC Toxo IgG 1 ≤ 10 % CV PC Toxo IgG 2 ≤ 10 % CV	4.2, 5.3% CV 5.7% CV 3.0% CV	HS neg: ≤ 13 % CV HS, pos. ≤ 13 % CV PC Toxo IgG 1 ≤ 13 % CV PC Toxo IgG 2 ≤ 13 % CV	3.5% CV 8.9% CV
Toxo IgG Avidity	n/a	n/a	n/a	n/a	Low av. samples ≤ 10 % CV Greyzone samples ≤ 8 % CV High-av. samples ≤ 8 % CV	5.2, 8.7, 2.7% CV 1% CV 1.5, 0.5% CV
Toxo IgM	HS neg: ≤ 7 % CV HS, pos. ≤ 7 % CV PC Toxo IgM 1 ≤ 7 % CV PC Toxo IgM 2 ≤ 7 % CV	1.9, 1.6% CV 2.5% CV 1.6% CV	HS neg: ≤ 10 % CV HS, pos. ≤ 10 % CV PC Toxo IgM 1 ≤ 10 % CV PC Toxo IgM 2 ≤ 10 % CV	4, 3.6 % CV 2.7% CV 3% CV	HS neg: ≤ 13 % CV HS, pos. ≤ 13 % CV PC Toxo IgM 1 ≤ 13 % CV PC Toxo IgM 2 ≤ 13 % CV	2.0, 2.6% CV 4.3, 7.4% CV

n/a not available

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Elecsys Assay	Specified repeatability (within-run precision)	Internal eval. repeatability	Specified intermediate precision (within lab preci.)	Internal eval. Intermediate prec.	Specified intermodule precision	Internal eval. intermodule prec.
EBV IgM	< 1.0 COI SD ≤ 0.08 COI ≥ 1.0 COI CV ≤ 8.0 %	0.004 / 0.016 COI SD 2.0, 1.3, 2.2 % CV	< 1.0 COI SD ≤ 0.10 COI ≥ 1.0 COI CV ≤ 10.0 %	0.007, 0.022 COI 2.5, 2.0, 2.2 % CV	n/a	n/a
EBV VCA IgG	COI <1.0 SD ≤ 0.08 COI ≥ 1.0 CV ≤ 8.0 %	0.026, 0.033 COI 2.5, 0.9, 1.5 %	COI <1.0 SD ≤ 0.10 COI ≥ 1.0 CV ≤ 10.0 %	0.038, 0.052 COI 6.60, 3.20, 2.50, 2.40 %	n/a	n/a
EBV EBNA IgG	< 1.0 COI SD ≤ 0.08 COI ≥1.0 COI CV ≤ 8.0 %	0.0005, 0.011 SD COI 1.4, 1.8, 1.7 CV %	< 1.0 COI SD ≤ 0.10 COI ≥1.0 COI CV ≤ 10.0 %	0.0006, 0.020 SD COI 2.5, 2.6, 2.4 CV % @ 81.8 COI	n/a	n/a
Chagas	< 1.0 COI ≤ 0.08 COI SD ≥ 1.0 COI ≤ 8% CV	0.001 COI SD 2, 2.7. 2.9% CV	< 1.0 COI ≤ 0.1 COI SD ≥ 1.0 COI ≤ 10% CV	0.002 COI SD 4.3, 3.9, 5.9% CV	n/a	n/a
ZIKA IgG	HS neg: ≤ n/a COI SD HS, pos. ≤ n/a % CV	0.004, 0.005 COI SD 1.4, 1.5, 1.7, 1.3, 1.2% CV	HS neg: ≤ n/a COI SD HS, pos. ≤ n/a % CV	0.008, 0.009 COI SD 3, 2.8, 3.1, 2.5% CV	HS neg: ≤ n/a COI SD HS, pos. ≤ n/a % CV	n/a
Anti-SARS-CoV-2	COI <1.0 SD ≤ 0.1 COI COI ≥1.0 CV ≤ 10 %	0.001 COI SD 0.8, 1.1, 1.1, 0.9, 0.7% CV	COI <1.0 SD ≤ 0.12 COI COI ≥1.0 CV ≤ 12 %	0.003 COI SD 2.3, 2.7, 2.3, 2.4, 2.5% 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	0.007, 0.014 U/ml SD 1.8, 1.6% CV 1.4, 2.1, 1.8% CV	LEMUR-< 1.0 U/ml ≤ 0.12 U/ml SD ≥1.0-20 U/ml ≤ 12% CV >20 U/ml-HEMR ≤ 17% CV	0.016, 0.022 U/ml SD 3.2, 2.8% CV 2.7, 3.6, 2.8% CV	n/a	n/a
SARS-CoV-2 Antigen	COI <1.0 SD ≤ 0.1 COI COI ≥1.0 CV ≤ 10%	0.013, 0.017 COI SD 3.3, 2.3, 1.4% CV	COI <1.0 SD ≤ 0.12 COI COI ≥1.0 CV ≤ 12%	0.017, 0.019 COI SD 3.5, 2.9, 2.4 % CV		
IGRA SARS-CoV-2	0.07 – 1.0 IU/ml ≤ 0.05 IU/ml SD > 1 – 160 IU/ml ≤ 5% CV	0.006 IU/ml SD 0.8, 1.0, 1.2, 1.3% CV	0.07 – 1.0 IU/ml ≤ 0.07 IU/ml SD > 1 – 160 IU/ml ≤ 7% CV	0.016 IU/ml SD 2.5, 2.9, 3.1, 3.1 % CV	IGRA SARS-CoV-2	0.07 – 1.0 IU/ml ≤ 0.05 IU/ml SD > 1 – 160 IU/ml ≤ 5% CV

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Documents Used:

Assay	Method Sheet date / version	Application report
FT3 III	0221/01	2_3_MS_AR_Summary_inclRec_FT3 III_V2_MethodSheet
FT4 III	1019/01	ARa_SummaryReport_ft4 III
FT4 IV	0522/01	2_3_MS_AR_Summary_inclRec_FT4 IV_MethodSheet
T3	0620/01	2_3_MS_AR_Summary_inclRec_T3_V2_MethodSheet
T4	0720/01	2_3_MS_AR_Summary_inclRec_T4_V2_MethodSheet
TSH	0419/01	2_3_AR_Summary TSH V2
T-uptake	1111/18	3tup020a.xls/3tup031a.xls/3tup050a.xls
Tg II	0620/01	2_3_MS_AR_Summary_inclRec_Tg II_V2_MethodSheet
Tg Confirmatory Test	0912/04	
Anti-TG	0911/02	3atg020a.xls/3atg031a.xls/3atg050a.xls
Anti-TPO	0811/02	3atpo020b.xls/3atpo031b.xls/atpo050d.xls
Anti-TSHR	1019/01	AR_Summary ATSHR V2
Calcitonin	0221/01	2_3_MS_AR_Summary_inclRec_Calcitonin_V2_MethodSheet
CK-MB	0812/03	2_3AR01_Application Report Summary_CK-MB.doc
GDF-15	1020/01	2_3_MS_AR_Summary_inclRec_GDF-15_V2
Myoglobin	0812/14	3myo020a.xls/3myo031a.xls/3myo050a.xls
proBNP II	0321/01	2_3_MS_AR_Summary_inclRec_proBNP II_V2_MethodSheet_09315268190
Troponin I	0712/05	PSD / package insert / Tnl MP_E170_031x_InterModPrecision.xls
Troponin T hs	0321/01	2_3_MS_AR_Summary_inclRec_TnThs_V2_MethodSheet_09315322190
Digoxin	0512/18	3dig020b.xls/3dig031b.xls/3dig050b.xls
Digitoxin	0612/11	3dit020b.xls/3dit031b.xls/3dit050b.xls
HCG+β	0412/15	3hb2020b.xls/3hb2031a.xls/3hb2050a.xls
HCG STAT	0920/02	2_3_MS_AR_Summary_inclRec_HCGSTAT_V2_MethodSheet_v2.0
ACTH	0122/01	2_3_MS_AR_Summary_inclRec_ACTH_V2_MethodSheet
AMH	1020/01	2_3_MS_AR_Summary_inclRec_AMH_V2_MethodSheet_v2.0
AMH Plus	1020/01	2_3_MS_AR_Summary_inclRec_AMH Plus_V2_MethodSheet_v2.0
Androstenedione	0620/01	AR Summary: Androstenedione Version: 01-Oct-2019
Cortisol II	0615/01	Cortisol II Arx_SummaryReport
DHEA-S	0912/16	3dhe020a.xls/3dhe031a.xls/3dhe050a.xls
Estradiol III	0605/02	E2_3_ARc-Summary report_E2 III
FSH	0221/01	2_3_MS_AR_Summary_inclRec_FSH_V2_MethodSheet
LH	0412/18	3lh020a.xls/3lh031a.xls/3lh050a.xls

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Documents Used:

Assay	Method Sheet date / version	Application report
Progesterone III	0616/01	2_3_ARC-Summary report_PROGIII
Prolactin II	0312/05	3pro020a.xls/3pro050a.xls/3pro031a.xls
SHBG	0512/10	3shg020a.xls/3shg031a.xls/3shg050a.xls
Testosterone II	0321/01	2_3_MS_AR_Summary_inclRec_Testo II_V2_MethodSheet
C-Peptide	0412/08	3cpe020a.xls/3cpe050a.xls/3cpe031a.xls
Insulin	0412/13	3ins020a.xls/3ins031a.xls/3ins050a.xls
PIGF	0512/05	3PLG050a.xls/3PLG031a.xls
sFlt-1	0512/05	3SFL050b.xls/3SFL031a.xls
AFP	1221/01	2_3_MS_AR_Summary_inclRec_AFP_V2_MethodSheet
AFP-L3	1022/01	3_MS_AR_Summary_inclRec_AFP-L3_MethodSheet
Anti-p53	0221/01	2_3_MS_AR_Summary_inclRec_Anti-p53_MethodSheet_v3.0
CA 125 II	1014/01	3125020a.xls/3125031a.xls/3125050a.xls
CA 15-3 II	0512/16	3153020a.xls/3153031a.xls/3153050a.xls
CA 19-9	0911/20	3119020a.xls/3119031a.xls/3119050a.xls
CA 72-4	0221/01	2_3_MS_AR_Summary_inclRec_CA72-4_V2_MethodSheet
CEA	0512/20	3cea020a.xls/3cea031a.xls/3cea050a.xls
Cyfra 21-1	0812/15	3cyf020a.xls/3cyf031b.xls/3cyf050a.xls
HE4	0612/05	2_AR01_SummaryReport_HE4.doc
NSE	0812/11	3nse020a.xls/3nse031b.xls/3nse050a.xls
PIVKA-II	1221/01	2_3_MS_AR_Summary_inclRec_PIVKA-II_V2_MethodSheet
ProGRP	0720/01	2_3_MS_AR_Summary_inclRec_ProGRP_V2_MethodSheet_v2.0
free PSA	0819/01	Ara_summary_free PSA V2
total PSA	0819/01	Ara_summary_total PSA V2
S100	0220/01	2_3_MS_AR_Summary_inclRec_S100_V2_MethodSheet
SCC	0316/02	2_3ARb_SummaryReport_SCC.doc
Free βhCG	1019/01	AR_Summary free βhcg V2
PAPP-A	0819/01	AR_Summary PAPP-A V2
Active B12	1221/01	2_3_MS_AR_Summary_inclRec_Active B12_V2_MethodSheet
Vitamin B12 II	0715/02	2_3_Arc_SummaryReport_B12II
Ferritin	0312/12	3f2g020a.xls/3f2g050b.xls/3f2g031a.xls
Folate III	0712/10	3fo3020a.xls/3fo3031a.xls/3fo3050a.xls
Folate RBC	1011/01	2_3_Ara_Summary Report_FolRBC.doc
IgE II	0312/06	3ig2020a.xls/3ig2031a.xls/3ig2050a.xls

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Documents Used:

Assay	Method Sheet date / version	Application report
β-CrossLaps/serum	0421/01	2_3_MS_AR_Summary_inclRec_BCrossLaps_V2_MethodSheet
N-MID Osteocalcin	1211/14	3oc020b.xls/3oc031a.xls/3oc050b.xls
PTH	1012/22	3pth020b.xls/3pth031b.xls/3pth050c.xls
PTH (1-84)	0521/01	2_3_MS_AR_Summary_inclRec_PTH(1-84)_V2_MethodSheet
total P1NP	0812/09	3P1_020e.xls/3P1_031a.xls/3P1_050c.xls
Vitamin D total III	0322/01	2_3_MS_AR_Summary_inclRec_VITDT 3_MethodSheet
hGH	0211/02	2_3_Ara_SummaryReport_hGH.doc
IGF-1	1117/01	2_3_ARd_SummaryReport v4 IGF-1
IGFBP-3	0718/01	AR_Summary IGFBP-3
Anti-CCP	0611/04	3acc050b.xls/3acc031a.xls
BRAHMS PCT	1119/01	AR_Summary PCT V2
IL-6	0920/01	2_3_MS_AR_Summary_inclRec_IL-6_V2_MethodSheet_v2.0
Cyclosporine	1113/02	2_3_AR01_SummaryReport_CSA.doc
Everolimus	0316/01	2_3_AR01_SummaryReport_EVL.doc
Sirolimus	0316/01	2_3_AR02_SummaryReport_SRL.doc
Tacrolimus	1013/02	2_3_AR01_SummaryReport_TCL.doc
β-Amyloid (1-42) CSF II	0521/01	2_3_MS_AR_Summary_inclRec_Abeta42 2_MethodSheet
Phospho-Tau (181P) CSF	0621/01	2_3_MS_AR_Summary_inclRec_pTau_V2_MethodSheet
Total-Tau CSF	0621/01	2_3_MS_AR_Summary_inclRec_tTau_V2_MethodSheet
Anti-HAV II	0322/03	2_3_MS_AR_Summary_inclRec_Anti-HAV II_MethodSheet
Anti-HAV IgM	1012/12	3ham020a.xls/3ham031a.xls/3ham050a.xls
Anti-HBc II	0521/01	2_3_MS_AR_Summary_inclRec_Anti-HBc II_V2_MethodSheet
Anti-HBc IgM	0212/14	3hbm020a.xls/3hbm031a.xls/3hbm050a.xls
Anti-HBe	0610/13	3hbe020a.xls/3hbe031a.xls/3hbe050a.xls
HBeAg	0610/15	3eag020a.xls/3eag031a.xls/3eag050a.xls
Anti-HBs II	1119/01	AR_Summary A-HBSII V2
HBsAg II	1019/01	AR_Summary HBsAg II V2
HBsAg II quant II	1019/01	AR_Summary_HBsAgIIQII
HBsAg Confirmatory Test	0812/22	3_Arb_SummaryReport_Abeta42
Anti-HCV II	0222/01	2_3_MS_AR_Summary_inclRec_Anti-HCV II_V2_MethodSheet

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Documents Used:

Assay	Method Sheet date / version	Application report
Chagas	0622/02	2_3_MS_AR_Summary_inclRec_Chagas_V2
HIV Ag	0712/11	Precision from internal evaluation report
HIV Ag Conf. Test	1108/09	n/a
HIV combi PT	1020/01	2_3_MS_AR_SummaryReport_inclRec_HIVcPT_V2_MethodSheet
HTLV-I/II	0222/01	2_3_MS_AR_Summary_inclRec_HTLV_V2_MethodSheet
Syphilis	0321/01	2_3_MS_AR_Summary_inclRec_Syphilis_V2_MethodSheet
CMV IgG	0122/01	2_3_MS_AR_Summary_inclRec_CMV_IgG_V2_MethodSheet
CMV IgG Avidity	0122/01	2_3_MS_AR_Summary_inclRec_CMV_IgG_Avidity_V2_MethodSheet
CMV IgM	0712/05	3CMM050a.xls (NCCLS precision)
HSV-1 IgG	1221/01	2_3_MS_AR_Summary_inclRec_HSV-1_IgG_V2_MethodSheet
HSV-2 IgG	1221/01	2_3_MS_AR_Summary_inclRec_HSV-2_IgG_V2_MethodSheet
Rubella IgG	1012/06	Precision from internal evaluation report
Rubella IgM	1012/07	Precision from internal evaluation report
Toxo IgG	0612/10	Precision from internal evaluation report
Toxo IgG Avidity	0712/03	2_3_ARA-SummaryReport_ToxoIgG_Avidity
Toxo IgM	1211/07	Precision from internal evaluation report
EBV IgM	0620/01	2_3_MS_AR_Summary_inclRec_EBV_IgM_MethodSheet
EBV VCA IgG	0620/01	2_3_MS_AR_Summary_inclRec_EBV_VCA_IgG_MethodSheet
EBV EBNA IgG	0620/01	2_3_MS_AR_Summary_inclRec_EBV_EBNA_MethodSheet
Anti-SARS-CoV-2 S	1020/01	2_3_MS_AR_Summary_inclRec_ACOV2S_MethodSheet.
SARS-CoV-2 Antigen	1220/01	2_3_MS_AR_Summary_inclRec_SARS-CoV-2_Antigen_MethodSheet
IGRA SARS-CoV-2	0822/02	2_3_MS_AR_Summary_inclRec_IGRA_SARS-CoV-2_MethodSheet

STAT Tests (CK-MB STAT ect.) can only be used on cobas e 602 and cobas e 601.

For this document are the contents of the current Elecsys® Application Reports used. The used method sheet versions and Application Reports are listed above. Original datas are available in the corresponding method sheets and Application Reports.



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

LEMR = Low end measuring range

HEMR = High end measuring range

n/a = not available