External Quality Assessment Scheme

Hormones B Steroid and peptide hormones Round 1, 2023

Specimens

Please find enclosed 2 lyophilized serum samples S001 (B1), and S002 (B2), 3 mL each.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

See page 2.

Storage and use

Lyophilized samples are stable at +2 ... 8 °C until the closing date of the round.

Add 3.0 mL aqua to the samples. Ensure solubility and homogeneity. The reconstituted sample can be stored for 10 days at +2 to +8 ° C (C-peptide for 3 days). The sample can be stored frozen at -20 ° C for 4 weeks if the sample is frozen within 30 minutes after reconstitution. Thaw the sample shortly before analysis and mix until homogenous. Allow the sample to warm to room temperature before analysis.

Analyze both samples as patient samples.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S001



S002



2023-02-07

INSTRUCTIONS

Product no. 2301, 2301S, 1301 LQ732423011-012/NO

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi

The results should be reported no later than **February 27, 2023**.

Inquiries

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Examinations

Aldosterone

Androstendione

C-peptide

Cortisol

DHEAS

Estradiol

FSH

Gastrin

Growth hormone

Insulin

LH

Progesterone, 17-OH-progesterone Prolactin

SHBG

IGF-1

TBG

Testosterone and testosterone, free

Sample B2 Page: 1(5) Roche cobas e, Elecsys, & Modular... Roche Elecsys Cortisol 0030 e601 (X_{rot} nmol/l 30 nmol/l 1080 32 24 0 980 of res. No. of res 24 18 16 12 ġ 880 Sample 780 120 370 495 620 745 480 580 680 780 880 980 1080 680 Own result Own result analysed: 20.2.2023 analysed: 20.2.2023 580 Assigned value (X): 268 nmol/l, X_{rob} Assigned value (X): 704 nmol/l, X_{rob} Target limits (X ± 15%): 228 - 308 nmol/l Target limits (X ± 15%): 598 - 809 nmol/l CV% CV% 480 703.7 120 245 495 620 745 268.2 10.5 2.2 3.9 36 35.1 7.2 5.0 37 370 2.5 ΑII 262.3 17.9 6.8 78 ΑII 672.6 72.6 10.3 10.8 78 Sample B1 Previous results Conc./act. dependent performance Comments Round Sample Own Sample B1, Own group: 230 230 The standard uncertainty of the assigned value (Xrob) is 1.25 x standard error of the mean (SEM) and marked as 'u'. 273 1.9 0.5 23/01 HaD 360 268 HaF 360 704 665 -5.6 23/01 -1.1 Sample B2, Own group: 22/04 HbZ 360 164 172 5.2 12 The standard uncertainty of the assigned value (Xrob) is 1.25 22/04 HaF 360 714 794 11.1 2 1 x standard error of the mean (SEM) and marked as 'u'. 22/02 HbX 360 362 370 2.3 0.6 /lomu 22/02 HaF 360 699 686 -1.9 -0.4 21/06 Hbl 360 335 350 4.3 1.1 ⊒ E 21/06 HaF 360 691 725 5.0 1.1 115

-230

600

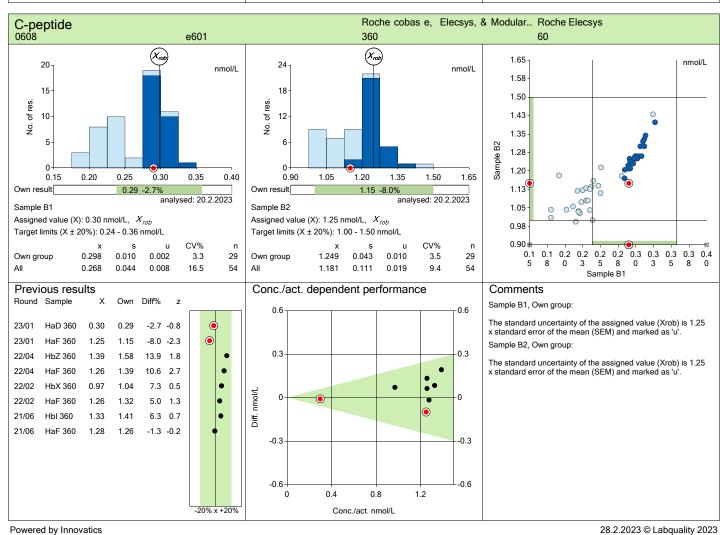
-230

-15% x +15%

200

400

Conc./act. nmol/l



Laboratory: XXXX

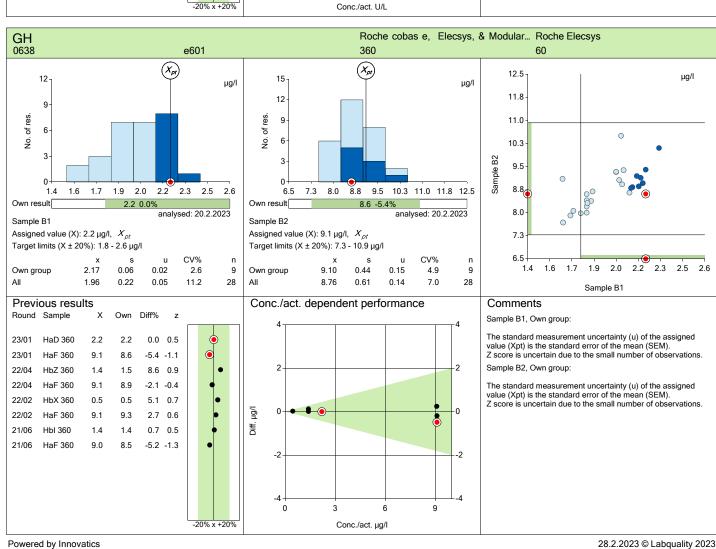
Laboratory: XXXX Sample B2 Page: 2(5) Roche cobas e, Elecsys, & Modular... Roche Elecsys **FSH** 0633 e601 U/L 36 U/L 47.0 30 24 of res. 43.5 of res. 18 16 ġ Š 40.0 36.5 Sam 3 2 44 5.0 62 26.0 29.5 33.0 36.5 40.0 33.00 Own result Own result analysed: 20.2.2023 analysed: 20.2.2023 29.5 Assigned value (X): 4.6 U/L, X_{rob} Assigned value (X): 36.1 U/L, X_{rob} Target limits (X ± 20%): 3.7 - 5.5 U/L Target limits (X ± 20%): 28.9 - 43.3 U/L CV% CV% 26.0 3.2 3.8 5.0 5.6 6.2 4.58 0.16 0.03 3.4 36 36.11 1.61 0.33 4.5 36 83 ΑII 4.53 0.22 0.03 82 ΑII 36.36 2.55 0.35 7.0 Sample B1 Previous results Conc./act. dependent performance Comments Round Sample Own Sample B1, Own group: 18 The standard uncertainty of the assigned value (Xrob) is 1.25 x standard error of the mean (SEM) and marked as 'u'. 23/01 HaD 360 4.6 4.4 -4.5 - 1.333.1 -8.3 23/01 HaF 360 36.1 -1.9 Sample B2, Own group: 22/04 HbZ 360 419 415 -12 -04 The standard uncertainty of the assigned value (Xrob) is 1.25 22/04 HaF 360 36.4 35.5 -25 -06 x standard error of the mean (SEM) and marked as 'u'. 22/02 HbX 360 4.0 4 0 0.4 0.1 22/02 HaF 360 36.7 37 1 0.9 0.2 Dĭ#. 21/06 Hbl 360 29.2 28.3 -3.1 -1.2 21/06 HaF 360 37.2 36.6 -1.7 -0.8 -9

20

40

-18

0



Laboratory: XXXX Sample B2 Page: 3(5) Roche cobas e, Elecsys, & Modular... Roche Elecsys IGF-1 0671 e601 (X_{pt}) 30.0 nmol/L nmol/L 27.5 10 of res. 25.0 ₽ 8 Š Š 22.5 0 9 20.0 Sam 17.5 10.0 12.5 15.0 17.5 20.0 22.5 25.0 27.5 30.0 11.0 14.0 17.0 20.0 23.0 26.0 29.0 32.0 35.0 Own result 16.6 -3.7 Own result 14.0 -11.8% analysed: 20.2.2023 analysed: 20.2.2023 15.0 Assigned value (X): 17.2 nmol/L, X_{pt} Assigned value (X): 15.9 nmol/L, X_{pt} 12.5 Target limits (X ± 20%): 12.7 - 19.1 nmol/L Target limits (X ± 20%): 13.8 - 20.6 nmol/L CV% 11.0 14.0 17.0 20.0 23.0 26.0 29.0 32.0 35.0 17.21 0.61 0.25 3.5 15.91 1.76 0.72 11.0 6 27 ΑII 18.54 2.63 0.63 14.2 27 ΑII 17.81 2.73 0.66 15.3 Sample B1 Previous results Conc./act. dependent performance Comments Round Sample Own Sample B1, Own group: 7.16 The standard measurement uncertainty (u) of the assigned value (Xpt) is the standard error of the mean (SEM). 23/01 HaD 360 17.2 16.6 -3.7 - 1.023/01 HaF 360 15.9 14.0 -11.8 -1.1 Z score is uncertain due to the small number of observations. 3.58 Sample B2, Own group: 22/04 HbZ 360 17.7 16.8 -52 The standard measurement uncertainty (u) of the assigned value (Xpt) is the standard error of the mean (SEM). 22/04 HaF 360 15.6 148 -49 22/02 HbX 360 15.8 16.0 1.3 0.4 The uncertainty (u) of the assigned value is not negligible, and evaluations could be affected. Z score is uncertain due to n 22/02 HaF 360 15.6 15.7 0.8 0.3 • the small number of observations. ΞĦ. -3.58 -3.58

-7.16

17.6

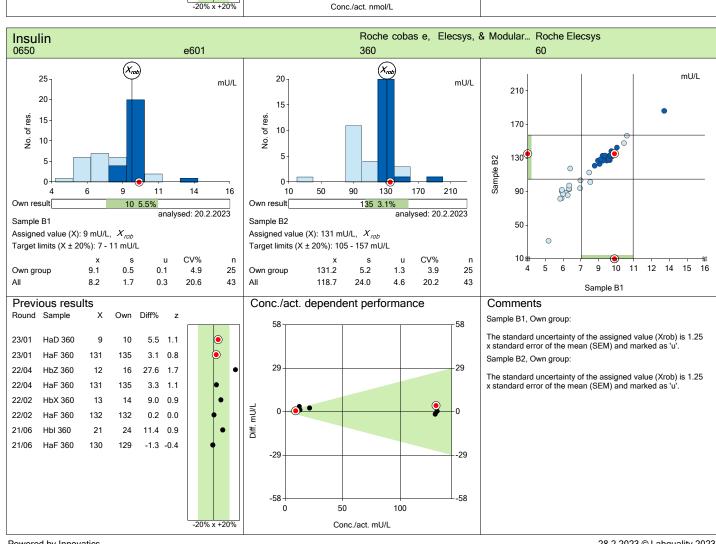
16.8

-7.16

-20% x +20%

15.2

16



Laboratory: XXXX Sample B2 Page: 4(5) Roche cobas e, Elecsys, & Modular... Roche Elecsys LH 0653 e601 (X_{rob}) 66.0 U/L U/L U/L 18 60.0 0 of res. No. of res. 12 0 54.0 ġ 6 Sample B2 48.0 0 54.0 2.0 2.7 3.4 4.1 4.8 5.5 30.0 36.0 42.0 48.0 66.0 42.0 Own result 4.5 -4.6% Own result 44.7 -12.1% analysed: 20.2.2023 analysed: 20.2.2023 0 36.0 Assigned value (X): 4.7 U/L, X_{rob} Assigned value (X): 50.8 U/L, X_{rob} Target limits (X ± 20%): 3.7 - 5.6 U/L Target limits (X ± 20%): 40.6 - 61.0 U/L CV% 30.0 4.8 5.5 4.69 0.05 50.81 2.22 2.0 2.7 3.4 4.1 0.23 4.9 34 Own group 0.48 4.4 34 3.72 1.01 0.14 27.2 80 All 45.91 7.72 1.09 16.8 79 ΑII Sample B1 Previous results Conc./act. dependent performance Comments Round Sample Own Diff% Sample B1, Own group: 22 The standard uncertainty of the assigned value (Xrob) is 1.25 x standard error of the mean (SEM) and marked as 'u'. 23/01 HaD 360 4.7 4.5 -4.6 -1.0 -12.1 -2.8 23/01 HaF 360 50.8 44.7 Sample B2, Own group: 11 17.4 22/04 HbZ 360 17.1 1.8 0.7 The standard uncertainty of the assigned value (Xrob) is 1.25 x standard error of the mean (SEM) and marked as 'u'. 22/04 HaF 360 50.8 51.0 0.5 0.2 22/02 HbX 360 4.4 4.5 1.6 0.5 <u>-</u> ೧ z 22/02 HaF 360 50.5 52.4 3.8 1.1 Dĭ# 21/06 Hbl 360 15.8 15.1 -4.5 -1.3 • 21/06 HaF 360 51.2 50.0 -2.3 -0.6 -11

20

Conc./act. U/L

-22

40

-22

-20% x +20%

0

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Hormone Determinations B 2023/1

Sample B1 Sample B2 Laboratory: XXXX Page: 5(5)

Participants

108 participants from 17 countries.

Report info

Assigned value (target value) calculation and its uncertainty

Your own result should be compared to others using the same method.

The assigned values (Xrob) are calculated according to the robust procedure described in the standard ISO 13528 (Statistical methods for use in proficiency testing by interlaboratory comparisons, Annex C, Algorithm A).

The standard uncertainty of the assigned value is expressed as 1.25 x the standard error of mean (SEM) and marked as "u" in numerical summary. Due to its iterative mode algorithm A

adds the uncertainty of the assigned value and with this factor we want to adjust uncertainty accordingly

In case there are 2-12 results in a method group, the robust calculation is not used but assigned values (Xpt) are means of the results where results deviating more than +/- 3*standard deviation from the median are removed. The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is too large (u > 0.1 * maximum allowable error) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

Please notice also that for groups that have only 1 result only the client's own result is shown. No target value (except for reference method values) is calculated, no target areas are shown.

Z score

In case there are 2-5 results in a method group, no z-score is calculated, and a text is printed on the report: "Due to the small number of results, the z score is not calculated." In case there are 6-12 results, the report has a text: "Z score is uncertain due to the small number of observations.

Results reported with < tai > -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" in LabScala User instructions (top right corner ?Help link).

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NUMERICAL SUMMARY

Hormone Determinations B 2023/01

Analyte Method group	х	med	s	CV%	u	Min	Max	Number
Sample B1								
Aldosterone, pmol/L								
Beckman Coulter Immunotech	159.2	159	25.2	15.9	17.9	141	177	2
DiaSorin Liaison	230.7	225	30.0	13.0	10.0	185	272	g
All	218.9	224	43.0	19.7	13.0	141	272	11
Androstenedione, nmol/L								
DiaSorin Liaison	4.16	4.3	0.29	7.0	0.17	3.8	4.4	3
DRG Diagnostics EIA	5.27	5.3	2.47	46.8	1.75	3.5	7.0	2
IBL ELISA	5.10	5.1	-	_	_	_	_	1
Mass spectrometry	3.89	3.9	1.39	35.9	0.99	2.9	4.9	2
Roche cobas e, Elecsys, & Modular E	2.90	2.9	0.14	4.7	0.08	2.8	3.0	3
Siemens Immulite 1000, 2000, 2500	4.90	4.9	0.69	14.1	0.40	4.2	5.6	3
Snibe Diagnostic Maglumi	4.99	5.0	-	-	-	-	-	1
All	4.22	4.3	1.17	27.7	0.30	2.8	7.0	15
Cortisol, nmol/l								
Abbott Alinity	248.8	250	14.3	5.7	3.6	209	271	25
Abbott Architect	249.7	256	12.0	4.8	6.9	236	257	3
DiaSorin Liaison	160.1	160	-	-	-	-	-	1
Mass spectrometry	266.0	266	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E	268.2	267	10.5	3.9	2.2	231	296	36
Siemens Advia Centaur & Atellica	298.9	283	34.1	11.4	11.4	259	360	9
Siemens Immulite 1000, 2000, 2500	244.7	245	22.3	9.1	15.7	229	260	2
Tosoh AIA	302.0	302	-	-	-	-	-	1
All	262.3	263	17.9	6.8	2.0	160	360	78
C-peptide, nmol/L								
Abbott Alinity	0.225	0.22	0.014	6.1	0.005	0.20	0.25	12
Abbott Architect	0.241	0.24	0.008	3.5	0.006	0.24	0.25	2
DiaSorin Liaison	0.324	0.32	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E	0.298	0.30	0.010	3.3	0.002	0.28	0.33	29
Siemens Advia Centaur & Atellica	0.239	0.24	0.022	9.1	0.008	0.22	0.28	7
Siemens Immulite 1000, 2000, 2500	0.186	0.19	0.008	4.3	0.006	0.18	0.19	2
Tosoh AIA	0.180	0.18	-	-	-	-	-	1
All	0.268	0.29	0.044	16.5	0.006	0.18	0.33	54
DHEAS, μmol/L								
Abbott Alinity	7.04	6.9	0.61	8.7	0.22	6.1	8.2	8
Abbott Architect Roche cobas e, Elecsys, &	6.73 7.97	6.7 8.0	0.59 0.35	8.7 4.3	0.41 0.11	6.3 7.5	7.1 8.6	2 15
Modular E Siemens Advia Centaur & Atellica	5.10	5.1	_	_	_	_	_	1
Siemens Immulite 1000, 2000, 2500	6.04	6.0	0.28	4.6	0.14	5.7	6.4	4
Tosoh AIA	8.05	8.1	-	-	-	-	-	1
All	7.35	7.6	0.95	12.9	0.17	5.1	8.6	31
Estradiol, nmol/L								
Abbott Alinity	0.316		0.031	9.8	0.009	0.28	0.39	19
Abbott Architect	0.308		0.029	9.3	0.013	0.28	0.36	5
Mass spectrometry	0.328	0.33	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E	0.321	0.32	0.017	5.2	0.004	0.28	0.37	33
Siemens Advia Centaur & Atellica	0.290	0.30		11.6	0.011	0.23	0.33	9
Siemens Dimension & Vista	0.290	0.29	0.015	5.1	0.011	0.28	0.30	2
Siemens Immulite 1000, 2000, 2500	0.179	0.18	-	-	-	-	-	1
Tosoh AIA	0.249	0.25	-	-	-	-	-	1

NUMERICAL SUMMARY Hormone Determinations B 2023/01, Sample B1

Analyte Method group	х	med	S	CV%	u	Min	Max	Number
Estradiol, nmol/L								
All	0.313	0.32	0.025	8.1	0.003	0.18	0.39	7′
FSH, U/L								
Abbott Alinity	4.51	4.5	0.20	4.3	0.05	4.2	5.0	25
Abbott Architect	4.39	4.4	0.29	6.6	0.13	4.0	4.7	5
Roche cobas e, Elecsys, & Modular E	4.58	4.6	0.16	3.4	0.03	4.1	4.9	36
Siemens Advia Centaur & Atellica	4.53	4.7	0.57	12.5	0.19	3.4	5.2	g
Siemens Dimension & Vista	4.40	4.4	0.20	4.5	0.12	4.2	4.6	3
Siemens Immulite 1000, 2000, 2500	4.22	4.3	0.19	4.6	0.11	4.0	4.3	3
Tosoh AIA	5.90	5.9	-	-	-	-	-	1
All	4.53	4.6	0.22	4.8	0.02	3.4	5.9	82
Gastrin, pmol/L								
Siemens Immulite 1000, 2000, 2500	9.9	10	1.0	10.0	0.4	8	11	8
All	9.9	10	1.1	11.4	0.4	8	11	8
GH, μg/l								
DiaSorin Liaison	1.71	1.7	0.08	4.8	0.05	1.6	1.8	3
IDS-iSYS	1.82	1.8	0.02	1.2	0.02	1.8	1.8	2
Roche cobas e, Elecsys, & Modular E	2.17	2.2	0.06	2.6	0.02	2.1	2.3	9
Siemens Immulite 1000, 2000, 2500	1.92	2.0	0.15	7.9	0.05	1.7	2.1	13
Tosoh AIA	1.64	1.6	-	-	-	-	-	1
All	1.96	2.0	0.22	11.2	0.04	1.6	2.3	28
IGF-1, nmol/L								
DiaSorin Liaison	23.51	23.5	1.55	6.6	0.69	21.8	26.0	5
DIAsource RIA	17.59	17.6	-	-	-	-	-	1
IDS-iSYS	21.88	21.9	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E	17.21	17.4	0.61	3.5	0.25	16.5	17.8	6
Siemens IGF-I Restandardized	17.54	17.5	1.54	8.8	0.52	15.0	20.7	14
All	18.54	17.7	2.63	14.2	0.51	15.0	26.0	27
Insulin, mU/L								
Abbott Alinity	6.1	6	0.3	4.2	0.1	6	6	10
Abbott Architect	7.6	8	0.5	6.7	0.4	7	8	2
DiaSorin Liaison	10.4	10	0.1	1.4	0.1	10	11	2
Roche cobas e, Elecsys, & Modular E	9.1	9	0.5	4.9	0.1	8	13	25
Siemens Advia Centaur & Atellica	7.5	8	0.4	5.8	0.3	7	8	2
Siemens Immulite 1000, 2000, 2500	5.0	5	-	-	-	-	-	1
Tosoh AIA	6.5	7	-	-	-	-	-	1
All	8.2	9	1.7	20.6	0.3	5	13	43
LH, U/L								
Abbott Alinity	2.71	2.7	0.12	4.3	0.03	2.5	3.5	23
Abbott Architect	2.88	2.9	0.15	5.0	0.07	2.7	3.1	5
Roche cobas e, Elecsys, & Modular E	4.69	4.7	0.23	4.9	0.05	3.6	5.1	34
Siemens Advia Centaur & Atellica	3.34	3.4	0.18	5.3	0.05	3.0	3.5	11
Siemens Dimension & Vista	3.37	3.3	0.12	3.4	0.07	3.3	3.5	3
Siemens Immulite 1000, 2000, 2500	3.90	4.0	0.16	4.0	0.09	3.7	4.0	3
Tosoh AIA	2.80	2.8	-	-	-	-	-	1
All	3.72	3.5	1.01	27.2	0.11	2.5	5.1	80
Prog, 17-OH, nmol/L								
Demeditec Diagnostics EIA	5.40	5.4	-	-	-	-	-	1
DIAsource RIA	4.10	4.1	4 00	-	-	- 4 -	-	1
DRG Diagnostics EIA	3.46	3.8	1.60	46.4	0.93	1.7	4.9	3

NUMERICAL SUMMARY Hormone Determinations B 2023/01, Sample B1

Analyte Method group	x	med	s	CV%	u	Min	Max	Number
Prog, 17-OH, nmol/L								
Mass spectrometry	2.66	2.7	0.06	2.4	0.04	2.6	2.7	
Novatec EIA	3.03	3.0	-	-	-	-	-	
Siemens Dimension	2.25	2.3	-	-	-	-	-	
Snibe Diagnostic Maglumi	3.30	3.3	-	-	-	-	-	
All	3.38	3.3	1.22	36.0	0.37	1.7	5.4	11
Progesterone, nmol/L								
Abbott Alinity	2.68	2.6	0.37	13.8	0.12	2.2	3.5	15
Abbott Architect	2.65	2.7	0.25	9.4	0.11	2.2	2.9	Ę
Roche cobas e, Elecsys, & Modular E	3.05	3.0	0.28	9.2	0.07	2.6	3.6	25
Siemens Advia Centaur & Atellica	2.83	2.8	0.25	8.7	0.09	2.5	3.3	12
Siemens Dimension & Vista	5.20	5.2	0.28	5.4	0.20	5.0	5.4	2
Siemens Immulite 1000, 2000, 2500	3.53	3.5	0.04	1.3	0.03	3.5	3.6	2
Tosoh AIA	3.37	3.4	-	-	-	-	-	1
All	2.93	2.9	0.38	13.1	0.05	2.2	5.4	62
Prolactin, mU/L								
Abbott Alinity	177.4	177	7.4	4.2	1.9	167	197	24
Abbott Architect	172.3	171	10.2	5.9	4.5	160	183	5
Brahms Kryptor	126.0	126	1.8	1.4	0.9	124	128	4
Roche cobas e, Elecsys, & Modular E	179.4	180	7.5	4.2	1.6	160	198	33
Siemens Advia Centaur & Atellica	130.0	127	7.4	5.7	2.6	121	141	13
Siemens Dimension & Vista	140.0	140	0.0	0.0	0.0	140	140	3
Siemens Immulite 1000, 2000, 2500	149.7	152	4.3	2.9	2.5	145	152	3
Tosoh AIA	200.0	200	-	-	-	-	-	1
All	167.6	174	22.6	13.5	2.4	121	200	86
SHBG, nmol/L								
Abbott Alinity	27.4	28	1.8	6.4	0.6	24	30	15
Abbott Architect	27.6	27	2.2	7.8	1.0	26	30	Ę
Roche cobas e, Elecsys, & Modular E	26.2	26	1.0	3.8	0.2	24	28	29
Siemens Advia Centaur & Atellica	26.3	27	1.8	6.7	0.6	24	30	9
Siemens Immulite 1000, 2000, 2500	22.1	22	-	-	-	-	-	•
Tosoh AIA	29.1	29	-	-	-	-	-	1
All	26.6	27	1.6	5.9	0.2	22	30	60
Testo, free, pmol/L								
Abbott Alinity	630.0	630	-	-	-	-	-	•
Calculated	393.0	393	-	-	-	-	-	1
DRG Diagnostics EIA	65.9	66	-	-	-	-	-	1
IDS-iSYS	51.2	51	-	-	-	-	-	1
Novatec EIA	125.3	125	-	-	-	-	-	1
All	253.1	125	285.6	112.9	127.7	51	630	
Testosterone, nmol/L								
Abbott Alinity	25.05	25.1	1.32	5.3	0.37	23.2	27.9	20
Abbott Architect	24.08	24.6	1.40	5.8	0.57	21.9	25.3	6
Mass spectrometry	23.03	23.0	1.41	6.1	0.63	21.2	24.5	Ę
Roche cobas e, Elecsys, & Modular E	23.83	23.7	0.86	3.6	0.20	22.7	39.3	28
Siemens Advia Centaur & Atellica	25.16	25.0	2.01	8.0	0.67	22.0	28.5	9
Siemens Immulite 1000, 2000, 2500	23.28	23.3	-	-	-	-	-	•
Tosoh AIA	27.50	27.5	-	-	-	-	-	
All	24.37	24.3	1.45	5.9	0.17	21.2	39.3	70

Sample B2

Aldosterone, pmol/L

NUMERICAL SUMMARY	Hormone Determinations	В	2023/01,	Sample B2
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Analyte Method group	х	med	S	CV%	u	Min	Max	Numbe
Aldosterone, pmol/L								
Beckman Coulter Immunotech	1,103.5	1,104	106.8	9.7	75.5	1,028	1,179	
DiaSorin Liaison	1,121.9	1,090	72.6	6.5	24.2	1,040	1,222	
All	1,118.6	1,090	83.4	7.5	25.1	1,028	1,222	1
ndrostenedione, nmol/L								
DiaSorin Liaison	21.51	22.1	1.42	6.6	0.82	19.9	22.5	
DRG Diagnostics EIA	17.62	17.6	0.64	3.6	0.45	17.2	18.1	
IBL ELISA	29.18	29.2	-	-	-	-	-	
Mass spectrometry	18.10	18.1	2.40	13.3	1.70	16.4	19.8	
Roche cobas e, Elecsys, & Modular E	16.31	16.0	0.68	4.2	0.40	15.8	17.1	
Siemens Immulite 1000, 2000, 2500 Snibe Diagnostic Maglumi	36.81 17.83	36.8 17.8	13.59 -	36.9 -	9.61	27.2 -	46.4 -	
All	20.43	18.9	5.08	24.9	1.36	15.8	46.4	1
ortisol, nmol/l								
Abbott Alinity	606.9	604	29.2	4.8	7.3	545	647	2
Abbott Architect	606.0	604	13.0	2.1	7.5	594	620	
DiaSorin Liaison	626.1	626	-	-	-	-	-	
Mass spectrometry	665.0	665	-	-	-	-	_	
Roche cobas e, Elecsys, & Modular E	703.7	701	35.1	5.0	7.2	618	790	3
Siemens Advia Centaur & Atellica	810.6	781	91.8	11.3	32.4	715	1,010	
Siemens Immulite 1000, 2000, 2500	608.3	608	21.5	3.5	15.2	593	624	
Tosoh AIA	757.5	758	-	-	-	-	-	
All	672.6	679	72.6	10.8	8.2	545	1,010	7
-peptide, nmol/L								
Abbott Alinity	1.098	1.10	0.057	5.2	0.021	1.03	1.21	1
Abbott Architect	1.133	1.13	0.010	0.9	0.007	1.13	1.14	
DiaSorin Liaison	1.430	1.43	-	-	-	-	-	
Roche cobas e, Elecsys, & Modular E	1.249	1.25	0.043	3.5	0.010	1.15	1.40	2
Siemens Advia Centaur & Atellica	1.062	1.04	0.067	6.3	0.025	0.99	1.18	
Siemens Immulite 1000, 2000, 2500	1.112	1.11	0.098	8.8	0.069	1.04	1.18	
Tosoh AIA	1.010	1.01	-	-	-	-	-	
All	1.181	1.21	0.111	9.4	0.015	0.99	1.43	5
HEAS, µmol/L								
Abbott Alinity	23.06	23.0	1.04	4.5	0.37	21.0	24.5	
Abbott Architect	22.76	22.8	1.63	7.2	1.15	21.6	23.9	
Roche cobas e, Elecsys, & Modular E	26.67	26.2	1.50	5.6	0.50	25.1	33.9	1
Siemens Advia Centaur & Atellica	18.40	18.4	-	-	-	-	-	
Siemens Immulite 1000, 2000, 2500	20.52	20.4	1.52	7.4	0.76	19.1	22.3	
Tosoh AIA	26.20	26.2	-	-	-	-	-	
All	24.43	24.8	2.99	12.2	0.55	18.4	33.9	3
stradiol, nmol/L								
Abbott Alinity	1.243	1.25	0.051	4.1	0.015	1.12	1.33	1
Abbott Architect	1.268	1.27	0.055	4.3	0.025	1.20	1.35	
Mass spectrometry	1.400	1.40	-	-	-	-	-	
Roche cobas e, Elecsys, & Modular E	1.557	1.55	0.056	3.6	0.012	1.45	1.75	3
Siemens Advia Centaur & Atellica	1.504	1.53	0.074	4.9	0.025	1.42	1.63	
Siemens Dimension & Vista	1.202	1.20	0.002	0.2	0.002	1.20	1.20	
Siemens Immulite 1000, 2000, 2500	1.130	1.13	-	-	-	-	-	
Tosoh AIA	1.461	1.46	-	-	-	-	-	
All	1.429	1.49	0.179	12.5	0.021	1.12	1.75	7

NUMERICAL SUMMARY Hormone Determinations B 2023/01, Sample B2

Analyte Method group	x	med	s	CV%	u	Min	Max	Number
FSH, U/L								
Abbott Alinity	36.18	36.1	1.76	4.9	0.44	32.5	38.8	25
Abbott Architect	36.26	35.8	3.65	10.1	1.63	30.8	40.0	5
Roche cobas e, Elecsys, & Modular E	36.11	36.2	1.61	4.5	0.33	32.1	40.2	36
Siemens Advia Centaur & Atellica	40.19	41.4	4.29	10.7	1.36	28.6	43.6	10
Siemens Dimension & Vista	34.00	33.9	0.95	2.8	0.55	33.1	35.0	3
Siemens Immulite 1000, 2000, 2500	31.57	31.1	1.46	4.6	0.84	30.4	33.2	3
Tosoh AIA	40.10	40.1	-	-	-	-	-	1
All	36.36	36.2	2.55	7.0	0.28	28.6	43.6	83
Gastrin, pmol/L								
Siemens Immulite 1000, 2000, 2500	10.7	11	1.0	9.4	0.4	9	12	8
All	10.8	11	1.0	9.5	0.4	9	12	8
GH, μg/l								
DiaSorin Liaison	8.00	7.9	0.37	4.6	0.21	7.7	8.4	3
IDS-iSYS	8.19	8.2	0.27	3.3	0.19	8.0	8.4	2
Roche cobas e, Elecsys, & Modular E	9.10	9.0	0.44	4.9	0.15	8.6	10.1	9
Siemens Immulite 1000, 2000, 2500	8.79	8.7	0.63	7.2	0.22	8.0	10.5	13
Tosoh AIA	9.10	9.1	-	-	-	-	-	1
All	8.76	8.8	0.61	7.0	0.12	7.7	10.5	28
IGF-1, nmol/L								
DiaSorin Liaison	22.29	22.5	1.64	7.4	0.73	20.2	24.4	5
DIAsource RIA	20.80	20.8	-	-	-	-	-	1
IDS-iSYS	19.91	19.9	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E	15.91	15.7	1.76	11.0	0.72	14.0	19.1	6
Siemens IGF-I Restandardized	16.88	16.8	1.29	7.6	0.43	15.0	20.0	14
All	17.81	17.0	2.73	15.3	0.52	14.0	24.4	27
Insulin, mU/L								
Abbott Alinity	89.2	90	5.1	5.7	1.6	82	97	10
Abbott Architect	97.8	98	5.2	5.4	3.7	94	102	2
DiaSorin Liaison	152.3	152	6.2	4.1	4.4	148	157	2
Roche cobas e, Elecsys, & Modular E	131.2	130	5.2	3.9	1.3	121	186	25
Siemens Advia Centaur & Atellica	108.2	108	6.6	6.1	4.7	104	113	2
Siemens Immulite 1000, 2000, 2500	31.5	32	-	-	-	-	-	1
Tosoh AIA	117.6	118	-	-	-	-	-	1
All	118.7	127	24.0	20.2	3.7	32	186	43
LH, U/L								
Abbott Alinity	36.73	36.7	1.15	3.1	0.31	35.0	40.4	22
Abbott Architect	38.83 50.81	39.2 51.0	1.44 2.22	3.7 4.4	0.64	37.3 44.7	40.8 54.1	5 34
Roche cobas e, Elecsys, & Modular E					0.48			
Siemens Advia Centaur & Atellica	48.12	48.0	2.13	4.4	0.64	44.9	51.0	11
Siemens Dimension & Vista	56.53	56.4	1.60	2.8	0.93	55.0	58.2	3
Siemens Immulite 1000, 2000, 2500 Tosoh AIA	51.72 46.70	50.7 46.7	4.61	8.9	2.66	47.7	56.8	3
All	46.70 45.91	40.7 47.7	- 7.72	16.8	0.87	35.0	- 58.2	79
	+0.71	41.1	1.12	10.0	V.01	33.0	JU.2	19
Prog, 17-OH, nmol/L Demeditec Diagnostics EIA	19.70	19.7	_	_	_	_	_	1
DIAsource RIA	17.45	17.5	_	_	-	_	-	1
DRG Diagnostics EIA	16.38	18.4	4.73	28.9	2.73	11.0	19.8	3
IBL ELISA	15.00	15.0	-			-	-	1
Mass spectrometry	14.31	14.3	2.40	16.8	1.70	12.6	16.0	2

NUMERICAL SUMMARY	Hormone Determinations	В	2023/01,	Sample B2
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Analyte Method group	x	med	s	CV%	u	Min	Max	Number
Prog, 17-OH, nmol/L								
Siemens Dimension	14.06	14.1	-	-	-	-	-	1
Snibe Diagnostic Maglumi	14.10	14.1	-	-	-	-	-	1
All	15.75	15.2	3.22	20.5	0.97	11.0	19.8	11
Progesterone, nmol/L								
Abbott Alinity	55.34	55.0	3.68	6.7	1.19	48.3	72.7	15
Abbott Architect	56.57	57.2	3.99	7.1	1.79	50.6	61.5	5
Roche cobas e, Elecsys, & Modular E	65.26	65.3	2.29	3.5	0.57	58.9	73.6	25
Siemens Advia Centaur & Atellica	43.38	42.9	1.37	3.2	0.41	41.9	46.0	11
Siemens Dimension & Vista	54.10	54.1	0.14	0.3	0.10	54.0	54.2	2
Siemens Immulite 1000, 2000, 2500	46.27	46.3	0.22	0.5	0.16	46.1	46.4	2
Tosoh AIA	75.50	75.5	-	-	-	-	-	1
All	57.52	58.0	10.35	18.0	1.33	41.9	75.5	61
Prolactin, mU/L								
Abbott Alinity	666.0	672	23.5	3.5	6.0	634	734	24
Abbott Architect	651.1	662	32.0	4.9	14.3	610	688	5
Brahms Kryptor	546.0	540	14.3	2.6	7.1	537	567	4
Roche cobas e, Elecsys, & Modular E	673.8	673	27.5	4.1	6.0	618	744	33
Siemens Advia Centaur & Atellica	508.0	490	35.6	7.0	12.9	475	571	12
Siemens Dimension & Vista	593.3	590	5.8	1.0	3.3	590	600	3
Siemens Immulite 1000, 2000, 2500	612.3	607	32.1	5.2	18.5	583	647	3
Tosoh AIA	718.0	718	-	-	-	-	-	1
All	644.9	658	57.5	8.9	6.2	475	744	85
SHBG, nmol/L								
Abbott Alinity	52.9	53	2.7	5.2	0.9	45	60	15
Abbott Architect	50.0	51	3.2	6.4	1.4	47	54	5
Roche cobas e, Elecsys, & Modular E	50.6	50	2.4	4.8	0.6	47	56	29
Siemens Advia Centaur & Atellica	52.6	52	3.8	7.3	1.3	47	61	9
Siemens Immulite 1000, 2000, 2500	43.7	44	-	-	-	-	-	1
Tosoh AIA	58.3	58	-	-	-	-	-	1
All	51.3	51	3.1	6.0	0.4	44	61	60
Testo, free, pmol/L								
Abbott Alinity	140.0	140	-	-	-	-	-	1
Calculated	124.9	125	-	-	-	-	-	1
DRG Diagnostics EIA	27.2	27	-	-	-	-	-	1
IDS-iSYS Novatec EIA	25.0 26.4	25 26	-	-	-	-	-	1
Roche cobas e, Elecsys, &	3.6	4	-	-	-	-	-	1
Modular E				4450	0- 4	_	440	
All	57.8	27	66.5	115.0	27.1	4	140	6
Testosterone, nmol/L	0.75	0.0	0.40	4.0	0.40	0.4	40.0	20
Abbott Alinity	9.75	9.8	0.42		0.12	9.1	10.8	20
Abbott Architect Mass spectrometry	9.66 9.88	9.7 10.0	0.28 0.62		0.11 0.28	9.2 9.1	10.0 10.5	6 5
Roche cobas e, Elecsys, &	9.88	10.0	0.02		0.28	9.1	11.0	28
Modular E								
Siemens Advia Centaur & Atellica	7.65	7.8	0.73	9.5	0.24	6.0	8.5	9
Siemens Immulite 1000, 2000, 2500 Tosoh AIA	10.90 13.40	10.9 13.4	-	-	-	-	-	1
All	9.76	9.8	0.60	6.2	0.07	6.0	13.4	70



NUMERICAL SUMMARY

Hormone Determinations B 2023/01, Sample B2

Analyte Method group x med s CV% u Min Max Number

Testosterone, nmol/L

Participants

108 participants from 17 countries.

Report info

Assigned value (target value) calculation and its uncertainty

Your own result should be compared to others using the same method.

The assigned values (Xrob) are calculated according to the robust procedure described in the standard ISO 13528 (Statistical methods for use in proficiency testing by interlaboratory comparisons, Annex C, Algorithm A).

The standard uncertainty of the assigned value is expressed as 1.25 x the standard error of mean (SEM) and marked as "u" in numerical summary. Due to its iterative mode algorithm A adds the uncertainty of the assigned value and with this factor we want to adjust uncertainty accordingly.

In case there are 2-12 results in a method group, the robust calculation is not used but assigned values (Xpt) are means of the results where results deviating more than \pm -3*standard deviation from the median are removed. The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is too large (u > 0.1 * maximum allowable error) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

Please notice also that for groups that have only 1 result only the client's own result is shown. No target value (except for reference method values) is calculated, no target areas are shown.

Z score

In case there are 2-5 results in a method group, no z-score is calculated, and a text is printed on the report: "Due to the small number of results, the z score is not calculated." In case there are 6-12 results, the report has a text: "Z score is uncertain due to the small number of observations."

Results reported with < tai > -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions (top right corner ?Help link).

External Quality Assessment Scheme

Hormones B Steroid and peptide hormones Round 1, 2023

Specimens

Sample S001/B1 (LQ732423011) and sample S002/B2 (LQ732423012) were lyophilized human serum samples.

Based on the previous tests and the results of this round, the samples are homogeneous, stable and suitable for the external quality assessment scheme.

The materials were sent without temperature control packaging.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific histogram and Global report. It is important to read the Final report first, because it contains important information of the samples and results in each round.

The samples have been used before on the round. The sample history can be seen in the client specific report with the histogram.

Comments – EQA Coordinator

In C-peptide, prolactin and progesterone, Siemens Advia Centaur & Atellica's level is the lowest in both samples, while Roche's level is the highest. In LH, in both samples, Abbott Alinity has the lowest level, while Roche has the highest level. The insulin level in Siemens Immulite is significantly lower than the other groups in sample S002/B2. The results of free testosterone with different methods differ from each other, just like in previous rounds.

Comments - Expert

The mean androstenedione concentration in sample B1 was in the adult reference range (x = 4.22 nmol/L, n = 15). The range of results of different methods was large, and the overall variation of the results was large (CV% = 27.7%). The consensus mean of sample B2 was very high and clearly above the adult reference range (x = 20.43 nmol/L, n = 14). Also in this sample, the overall variation of the results was very large (CV% = 24.9%).

The consensus mean of aldosterone in sample B1 was in the healthy reference range (x = 218.9 pmol/L, n = 11) and the overall variation in sample B1 was large (B1: CV% = 19.7%). The consensus mean of sample B2 in all participants was well above the adult reference range (x = 1118.6 pmol/L, n = 11). The overall variation in sample B2 was good (B2: CV% = 7.5%).

In DHEAS, the mean concentration of sample B1 was 7.35 μ mol/L, which was in the reference range for young adult men and women. In sample B2, on the other hand, the concentration was strongly elevated (24.43 μ mol/L). The overall variations in both samples were moderate (B1: CV% = 12.9%, n = 31, and B2: CV% = 12.2%, n = 30).

In estradiol, sample (B1) had estradiol levels of the female follicular/luteal phase for all methods (x = 0.313 nmol/L, n = 71) and sample B2 had a high level of estradiol for ovulation (x = 1.429 nmol/L, n = 72). The overall variation in sample B1 was good (CV% = 8.1%), but in sample B2 it was moderate (CV% = 12.5%). Siemens Immulite gave a lower result level in sample B1 than other methods.

2023-03-13

FINAL REPORT

Product no. 2301, 2301S

 Samples sent
 2023-02-07

 Round closed
 2023-02-27

 Final report
 2023-03-13

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

EQA Coordinator Päivi Ranta paivi.ranta@labquality.fi

Expert

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Mean cortisol results represented normal adult concentrations in sample B1. DiaSorin Liaison gave a lower result level at a low concentration than other methods. The results were slightly elevated in sample B2 compared to the reference range for adult cortisol. (B1: x = 262.3 nmol/L, n = 78 and B2: n = 672.6 nmol/L, n = 78). The overall variations of the methods and results were good and moderate (B1: n = 672.6 nmol/L, n = 78).

The mean concentrations of progesterone in sample B1 corresponded high follicular phase concentration (B1: x = 2.93 nmol/L), and the overall variation of the methods was moderately large (B1: x = 13.1%). Siemens Dimension & Vista gave a higher result level than other methods (5.20 nmol/l). In sample B2 the concentration of progesterone was high and corresponded to the women's luteal phase (B2: x = 57.52 nmol/L). All participants reported high luteal phase concentrations, but TOSOH AIA gave a higher result level than other methods (75.50 nmol/l). The overall variation of the methods was large (B2: CV% = 18.0%).

The concentration of 17OH-progesterone in sample B1 corresponded to the normal level of men (x = 3.38 nmol/L, n = 11). The overall variation of the methods was large, and the concentration varied largely between the groups (2.25 – 5.40 nmol/L, CV%=36.0 %). The concentration in sample B2 was elevated and clearly above the reference values (x = 15.75 nmol/L, n = 11). The overall variation of the methods was large (B2: CV% = 20.5 %).

In testosterone, the mean concentration of sample B1 was in the normal male concentration (x = 24.37 nmol/L, n = 70). The concentration of sample B2 corresponded to the lower limit of men's reference range (x = 9.76 nmol/L, n = 70). The Siemens Advia-Atellica user group received a lower mean compared to other groups. In both samples, the overall variation of the methods was good (B1: CV% = 5.9% and B2: CV% = 6.2%).

Free testosterone was reported by only five to six (5-6) laboratories. Because different methods used measured free testosterone levels differently, the concentrations of the samples obtained varied by 12-35 -fold and the total variations from the samples was consistent (CV% t were B1: 112.9% and B2: 115.0%). It is therefore not appropriate to compare the results with the different methods. The participants of the round can compare their own results with other laboratories that mainly use a similar method. In general, the testosterone and SHBG levels measured by reliable methods and the calculated free testosterone levels determined by them correlate with the results and result levels of known reference methods based on ultrafiltration or equilibrium dialysis.

End of report