LABQUALITY

External Quality Assessment Scheme

Prostate specific antigen
Round 1, 2023

Specimens
Please find enclosed 2 liquid pooled human sera samples S001 and S002, each 1 mL. No preservatives are added.

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
Total PSA
Free PSA
Complexed PSA
Free/total PSA ratio

Storage and use
Samples are ready to use. Please analyse the samples as soon as possible. If you analyse the samples later than on the day of the sample arrival, please store them frozen. A little before analysing, thaw, allow the samples to reach the room temperature and mix until homogenous. Analyse 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
LQ741123011

S002
LQ741123012

2023-02-06

INSTRUCTIONS

Product no. 2226
LQ741123011-012/FI
Subcontracting: Sample preparation, sample pretesting

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

The results should be reported no later than **March 2, 2023**.

Inquiries
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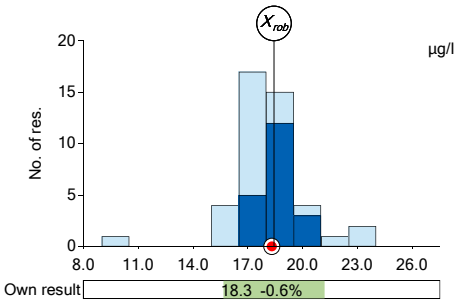
FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

PSA

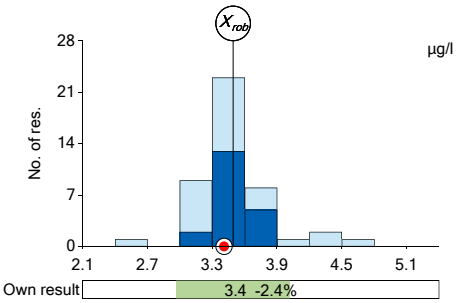
0059	Cobas	360	767
		Roche cobas e, Elecsys, & Modular...	Roche cobas e411



Own result 18.3 -0.6%
analysed: 1.3.2023

Sample 001
Assigned value (X): 18.4 µg/l, X_{rob}
Target limits (X ± 15%): 15.7 - 21.2 µg/l

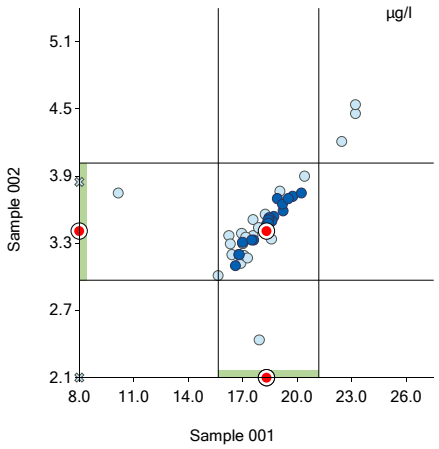
	x	s	u	CV%	n
Own group	18.42	1.01	0.28	5.5	20
All	18.01	1.39	0.26	7.7	44



Own result 3.4 -2.4%
analysed: 1.3.2023

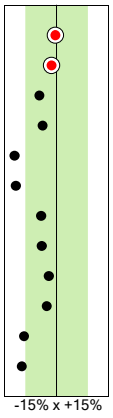
Sample 002
Assigned value (X): 3.5 µg/l, X_{rob}
Target limits (X ± 15%): 3.0 - 4.0 µg/l

	x	s	u	CV%	n
Own group	3.49	0.18	0.05	5.2	20
All	3.46	0.27	0.05	7.7	45

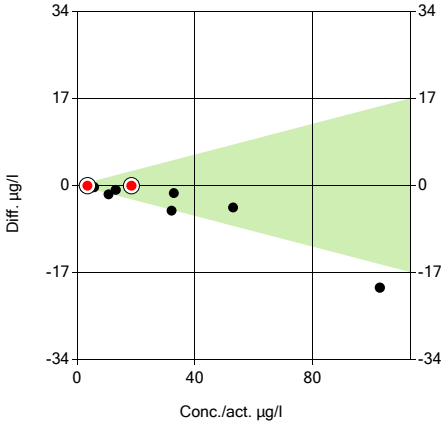


Previous results

Round	Sample	X	Own	Diff%	z
23/01	PaK 360	18.4	18.3	-0.6	-0.1
23/01	PaL 360	3.5	3.4	-2.4	-0.5
22/04	PaI 360	52.9	48.6	-8.2	-1.4
22/04	PaJ 360	5.7	5.4	-6.6	-1.2
22/03	PaG 360	2.6	2.1	-20.1	-2.5
22/03	PaH 360	102.8	82.8	-19.5	-2.7
22/02	PaE 360	4.2	3.9	-7.4	-1.5
22/02	PaF 360	13.1	12.2	-7.1	-1.3
22/01	PaC 360	4.0	3.8	-3.7	-1.1
22/01	PaD 360	32.8	31.3	-4.7	-1.4
21/03	PaZ 360	32.0	27.1	-15.5	-3.0
21/03	PaY 360	10.7	8.9	-16.6	-2.6
21/02	PaV 360	4.4	4.3	-3.1	-0.9



Conc./act. dependent performance



Comments

Sample 001, Own group:

The standard uncertainty of the assigned value (Xrob) is 1.25 x standard error of the mean (SEM) and marked as 'u'.

Sample 002, Own group:

The standard uncertainty of the assigned value (Xrob) is 1.25 x standard error of the mean (SEM) and marked as 'u'.

Participants

34 participants from 9 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).

NUMERICAL SUMMARY **Prostate specific antigen 2023/01**

Analyte / Method group	x	med	s	CV%	u	Min	Max	Number
Sample 001								
PSA, µg/l								
Abbott Architect	17.90	17.9	0.66	3.7	0.38	17.3	18.6	3
Autobio AutoLumo	17.31	17.0	1.21	7.0	0.60	16.2	19.0	4
bioMerieux Vidas	22.45	22.5	-	-	-	-	-	1
Brahms Kryptor	23.20	23.2	0.00	0.0	0.00	23.2	23.2	2
maccura	16.14	17.2	2.79	17.3	1.06	10.2	18.2	7
Roche cobas e, Elecsys, & Modular E	18.42	18.4	1.01	5.5	0.28	16.6	20.2	20
Siemens Advia Centaur & Atellica	17.44	17.0	1.35	7.7	0.51	16.4	20.4	7
All	**18.01**	**18.1**	**1.39**	**7.7**	**0.21**	**10.2**	**23.2**	**44**
PSA free, µg/L								
Abbott Architect	1.420	1.42	-	-	-	-	-	1
Brahms Kryptor	1.730	1.73	0.042	2.5	0.030	1.70	1.76	2
Roche cobas e, Elecsys, & Modular E	1.451	1.47	0.093	6.4	0.033	1.28	1.58	8
Siemens Advia Centaur & Atellica	1.665	1.67	0.064	3.8	0.045	1.62	1.71	2
Siemens Dimension & Vista	1.360	1.36	-	-	-	-	-	1
All	**1.513**	**1.48**	**0.163**	**10.8**	**0.044**	**1.28**	**1.76**	**14**
PSA free/total, %								
Abbott Architect	8.00	8.0	-	-	-	-	-	1
Brahms Kryptor	7.45	7.5	0.21	2.8	0.15	7.3	7.6	2
Calculated	8.00	8.0	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E	7.58	7.6	0.18	2.4	0.08	7.3	7.8	5
All	**7.64**	**7.6**	**0.29**	**3.8**	**0.10**	**7.3**	**8.0**	**9**
PSA, complexed, µg/L								
Roche cobas e, Elecsys, & Modular E	16.87	17.3	1.19	7.1	0.69	15.5	17.8	3
Siemens Dimension & Vista	26.78	26.8	-	-	-	-	-	1
All	**19.35**	**17.6**	**5.72**	**29.6**	**2.86**	**15.5**	**26.8**	**4**
Sample 002								
PSA, µg/l								
Abbott Architect	3.32	3.3	0.14	4.1	0.08	3.2	3.4	3
Autobio AutoLumo	3.46	3.4	0.33	9.6	0.15	3.1	3.8	5
bioMerieux Vidas	4.21	4.2	-	-	-	-	-	1
Brahms Kryptor	4.50	4.5	0.06	1.3	0.04	4.5	4.5	2
maccura	3.27	3.4	0.44	13.3	0.16	2.4	3.8	7
Roche cobas e, Elecsys, & Modular E	3.49	3.5	0.18	5.2	0.05	3.1	3.8	20
Siemens Advia Centaur & Atellica	3.38	3.3	0.24	7.1	0.09	3.2	3.9	7
All	**3.46**	**3.4**	**0.27**	**7.7**	**0.04**	**2.4**	**4.5**	**45**
PSA free, µg/L								
Abbott Architect	0.300	0.30	-	-	-	-	-	1
Brahms Kryptor	0.335	0.34	0.007	2.1	0.005	0.33	0.34	2
Roche cobas e, Elecsys, & Modular E	0.314	0.32	0.015	4.9	0.005	0.29	0.34	8
Siemens Advia Centaur & Atellica	0.345	0.35	0.007	2.0	0.005	0.34	0.35	2
Siemens Dimension & Vista	0.240	0.24	-	-	-	-	-	1
All	**0.318**	**0.32**	**0.023**	**7.3**	**0.006**	**0.24**	**0.35**	**14**
PSA free/total, %								
Abbott Architect	9.00	9.0	-	-	-	-	-	1
Brahms Kryptor	7.45	7.5	0.07	0.9	0.05	7.4	7.5	2
Calculated	9.00	9.0	-	-	-	-	-	1

NUMERICAL SUMMARY **Prostate specific antigen 2023/01, Sample 002**

Analyte Method group	x	med	s	CV%	u	Min	Max	Number
PSA free/total, %								
Roche cobas e, Elecsys, & Modular E	8.69	8.8	0.28	3.2	0.13	8.4	9.0	5
Siemens Advia Centaur & Atellica	10.00	10.0	0.00	0.0	0.00	10.0	10.0	2
All	**8.76**	**8.9**	**0.95**	**10.8**	**0.29**	**7.4**	**10.0**	**11**
PSA, complexed, µg/L								
Roche cobas e, Elecsys, & Modular E	3.14	3.2	0.20	6.4	0.12	2.9	3.3	3
Siemens Dimension & Vista	5.14	5.1	-	-	-	-	-	1
All	**3.64**	**3.3**	**1.15**	**31.5**	**0.57**	**2.9**	**5.1**	**4**

Participants

34 participants from 9 countries.

Report info

Assigned value (target value) calculation and its uncertainty

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LABQUALITY

External Quality Assessment Scheme

Prostate specific antigen
Round 1, 2023

Specimens
Sample S001 (LQ741123011) and sample S002 (LQ741123012) were prepared by dilution of plasma pools with elevated PSA level into a serum matrix.

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.

Comments - Expert
In sample S001 the total PSA level was elevated in all method groups (mean total PSA of all method groups 18 µg/L) which in early diagnosis setting would likely lead to further evaluations of the patient. For complexed PSA all results in two method groups were also elevated (range 14 – 27 µg/L).

In sample S002 the mean of all total PSA method groups was 3.5 µg/L (range of the mean levels 3.3 – 4.5 µg/L). Thus, total PSA level was close to the commonly used prostate cancer early diagnosis cut-off 4 µg/L. The proportion of free PSA was fairly low (the mean of all total PSA method groups 8.8 %), which can indicate elevated risk of prostate cancer. Thus, these results may lead to further evaluations of the patient. For complexed PSA there were results in two method groups (range 2.6 – 5.1 µg/L).

End of report

2023-03-10

FINAL REPORT

Product no. 2226
Subcontracting: Sample preparation, sample pretesting

Samples sent	2023-02-06
Round closed	2023-03-02
Final report	2023-03-10

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
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PT02 (EN ISO/IEC 17043)

Quality Management
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ISO 9001:2015