LABQUALITY

External Quality Assessment Scheme

Allergy in vitro Diagnostics
Round 1, 2023

Specimens
Please find enclosed two liquid human serum samples 231-1 and 231-2 Dist: 2023/1 of UK NEQAS for specific IgEs, each 0.5 mL and one separate 0.5 mL serum sample S014 for total IgE. One lyophilized serum sample S015 0.3 mL is for ECP, which is sent only to those laboratories which have ordered it separately.

Caution
Quality control samples derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The samples 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 samples will not transmit these or other infectious diseases.

Examinations
Analyse from sample 231-1: f13 Peanut, f17 Hazelnut, t3 Birch and d1 D. pteronyssinus and from sample 231-2: f17 Hazelnut, g6 Timothy, t3 Birch and w6 Mugwort allergen specific IgEs and from sample S014 Total IgE and from sample S015 ECP.

Storage and use
After arrival the samples should be stored at +2…8 °C and the IgE samples be analyzed as soon as possible. If that is not possible, please store the IgE samples at -20 °C. The ECP sample should be stored at +2…8 °C until analysing. Dissolve the ECP sample into 300 µL of distilled or reagent grade water and mix well before analysis.

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

The specific IgE results should be entered direct to UK NEQAS website as grades and units (kU/L). Go to www.immqas.org.uk. Select from the right Enter Results/Print Scheme/ Reports and then Data Entry System. Enter your Lab Number/Identity and Password, the same as in the previous year (Only to new clients have been sent a password this year, Annex 2.) and Log in. Next Select programme/EUROEQAS for Specific IgE and Dist. Number 231. See the Annex 1 (UK NEQAS Web User Instructions).

Add/change your method if needed. Enter your < or > results only as numbers (e.g. < 0.10 kU/L as 0.1). Use point (.) as a decimal separator. ”SAVE” will send your results to UK NEQAS data base and you can change your results as long as the round in question is open. Please remember to SAVE after your correction as well.

UK NEQAS will inform you by email when the reports are available.

S014

LQ726323014

S015

LQ726323015

2023-02-28

INSTRUCTIONS

Product no. 2670, 2680
LQ726323014, LQ726323015,
231-1 and 231-2/UK, SE

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 21, 2023**.

Inquiries
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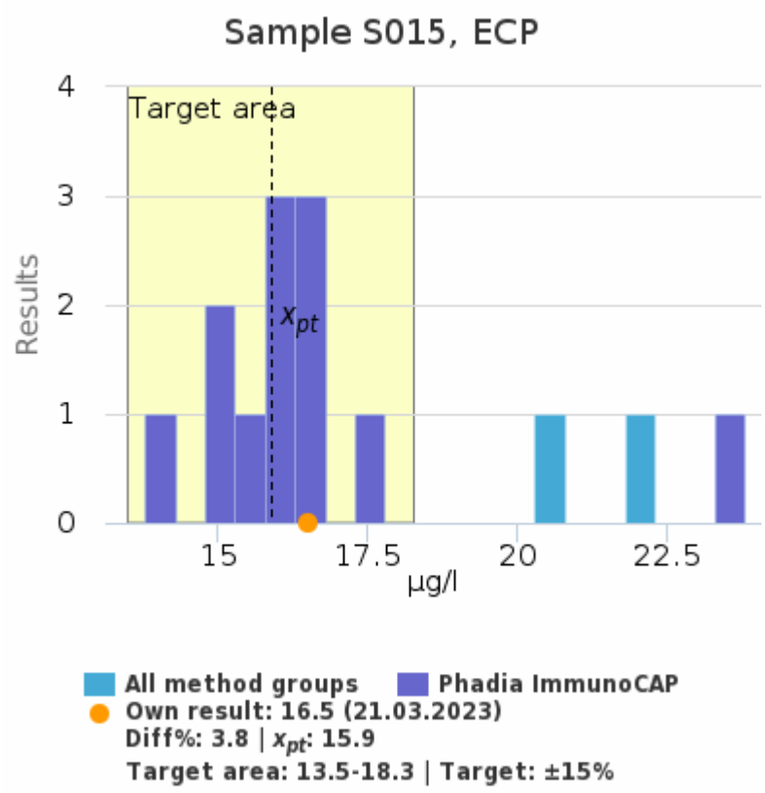
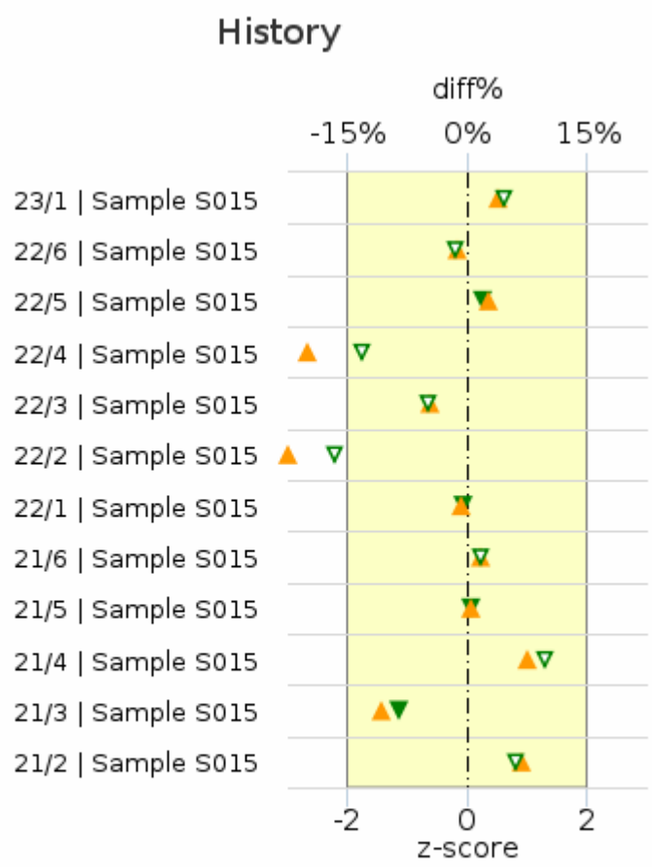
ECP |1

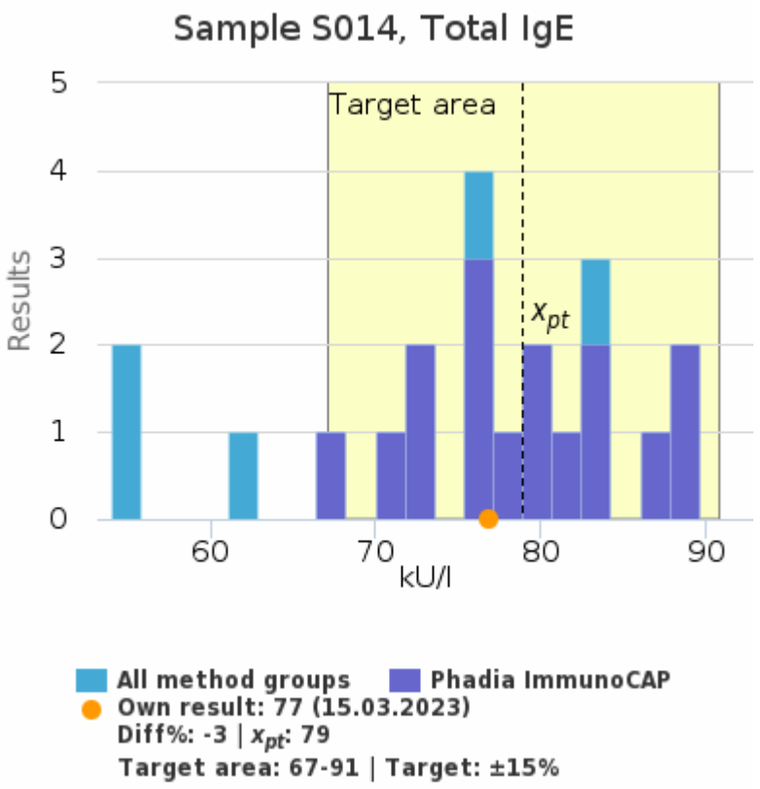


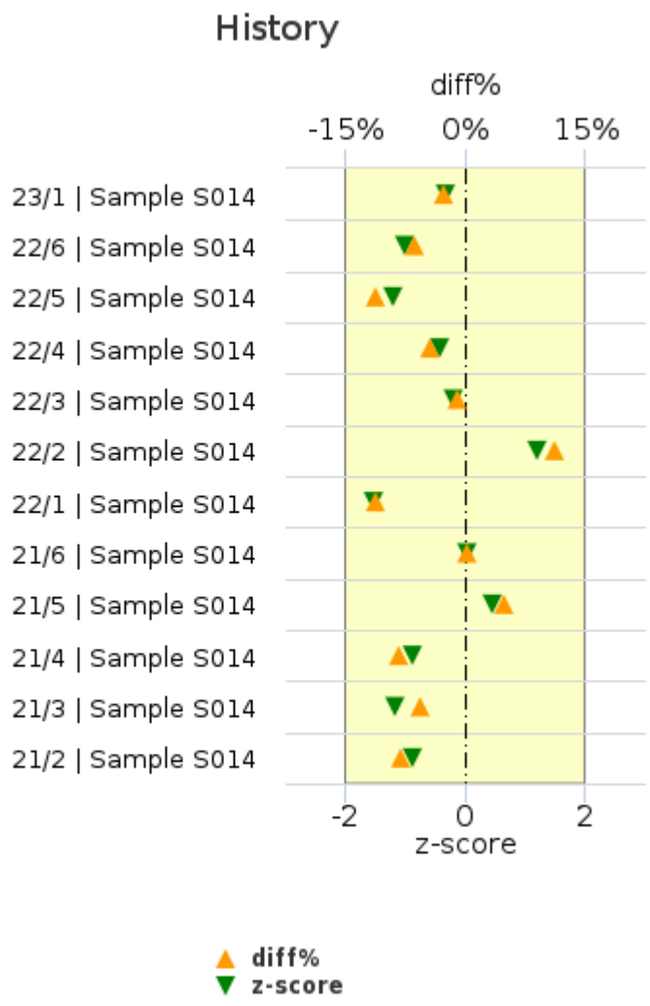


	x_{pt}	sd	SEM	CV%	n
Phadia ImmunoCAP	15.9 µg/l	1.0	0.3	6.2	12
All methods	17.2 µg/l	2.8	0.8	16.5	14

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S015	15.9	16.5	3.8%	0.62
22/6	Sample S015	59.0	58.2	-1.3%	-0.18
22/5	Sample S015	27.9	28.6	2.7%	0.25
22/4	Sample S015	70.6	56.5	-20.0%	-1.75
22/3	Sample S015	35.9	34.2	-4.7%	-0.66
22/2	Sample S015	62.0	42.1	-32.1%	-2.22
22/1	Sample S015	11.2	11.1	-0.7%	-0.07
21/6	Sample S015	41.9	42.6	1.6%	0.23
21/5	Sample S015	77.0	77.5	0.6%	0.05
21/4	Sample S015	22.2	23.9	7.5%	1.29
21/3	Sample S015	50.8	45.4	-10.6%	-1.14
21/2	Sample S015	35.2	37.6	6.8%	0.81

Total IgE |1





	x_{pt}	sd	SEM	CV%	n
Phadia ImmunoCAP	79 kU/l	6	2	8.1	16
All methods	76 kU/l	10	2	13.0	21

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S014	79	77	-3%	-0.32
22/6	Sample S014	154	144	-6%	-0.99
22/5	Sample S014	76	67	-11%	-1.21
22/4	Sample S014	130	124	-4%	-0.42
22/3	Sample S014	312	309	-1%	-0.18
22/2	Sample S014	87	97	11%	1.21
22/1	Sample S014	146	130	-11%	-1.51
21/6	Sample S014	127	127	0%	0.04
21/5	Sample S014	312	327	5%	0.46
21/4	Sample S014	86	78	-8%	-0.89
21/3	Sample S014	77	72	-6%	-1.16
21/2	Sample S014	302	278	-8%	-0.89

Report info

Participants

36 participants from 12 countries.

Report info

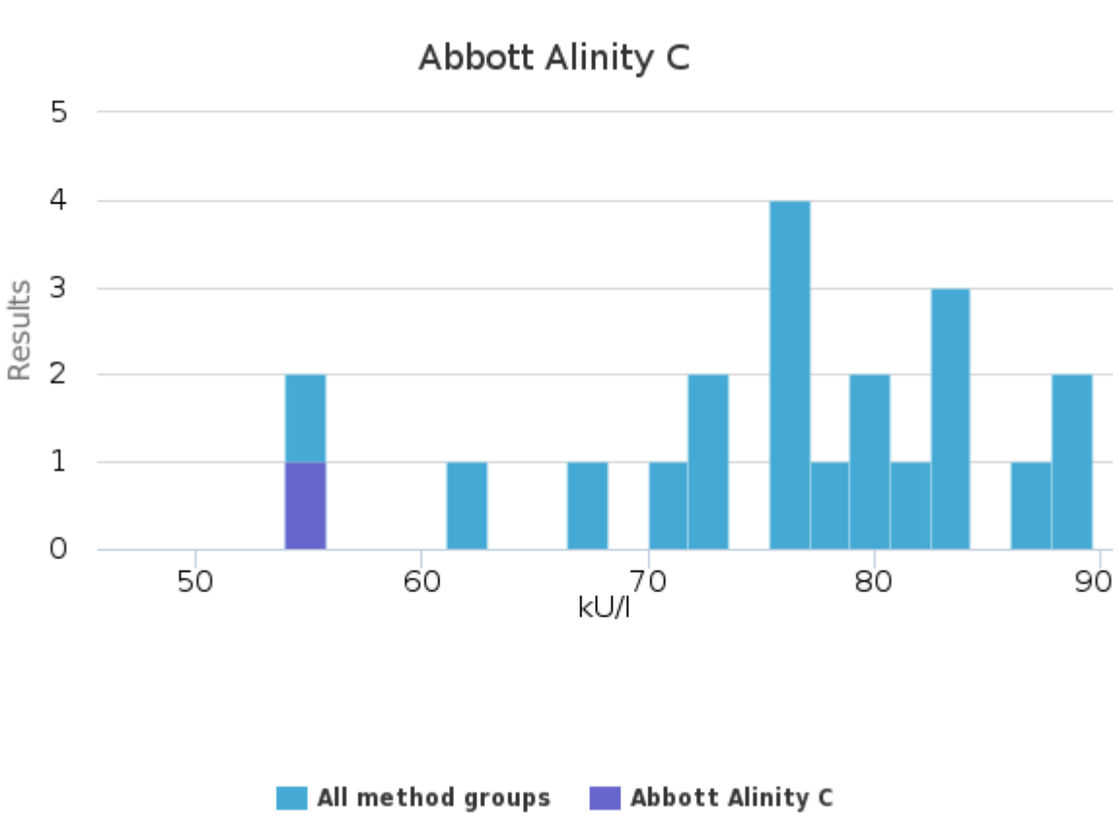
Your own result should be compared to others using the same method.
Assigned values (x_{pt}, target values) are means of the results where results deviating more than +/- 3*standard deviation from the median are removed. The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: “The uncertainty of the assigned value is not negligible, and evaluations could be affected.”
In case the client’s result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client’s own method group, the result can be compared to all method mean or to a group that is similar to the own method.
Results reported with < or > -signs cannot be included in the statistics.

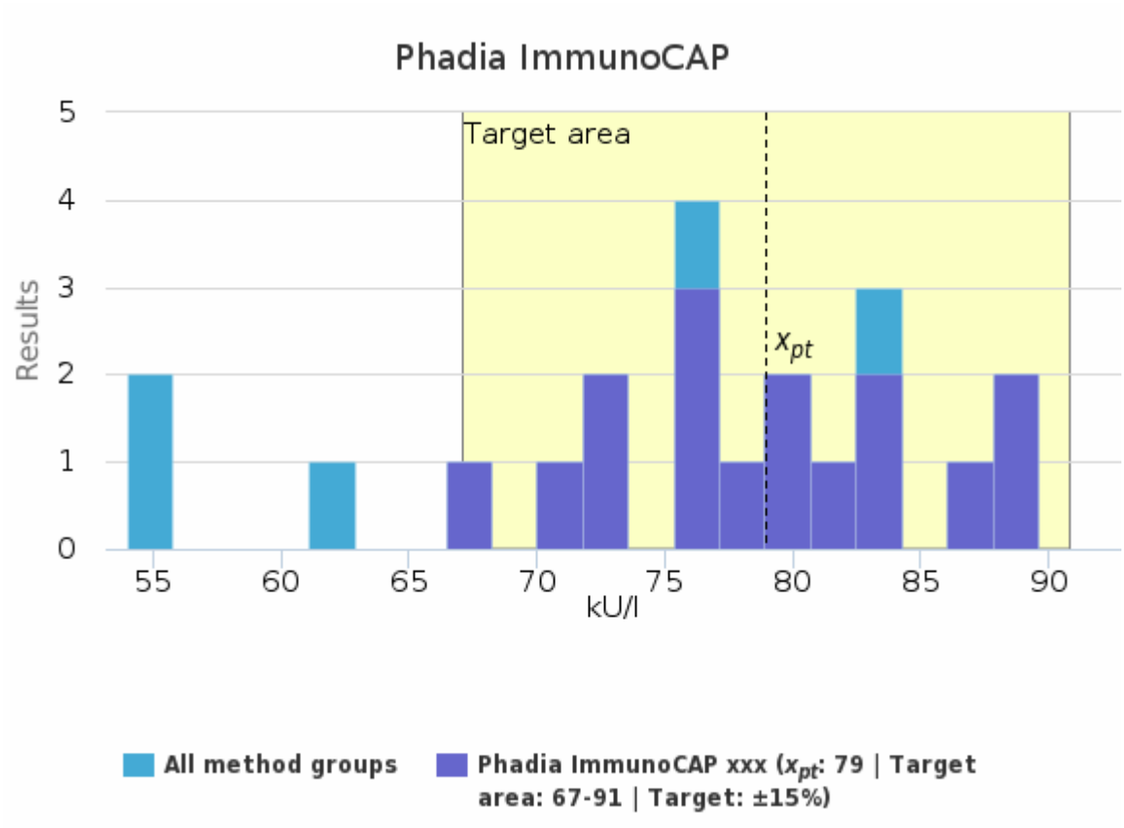
For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

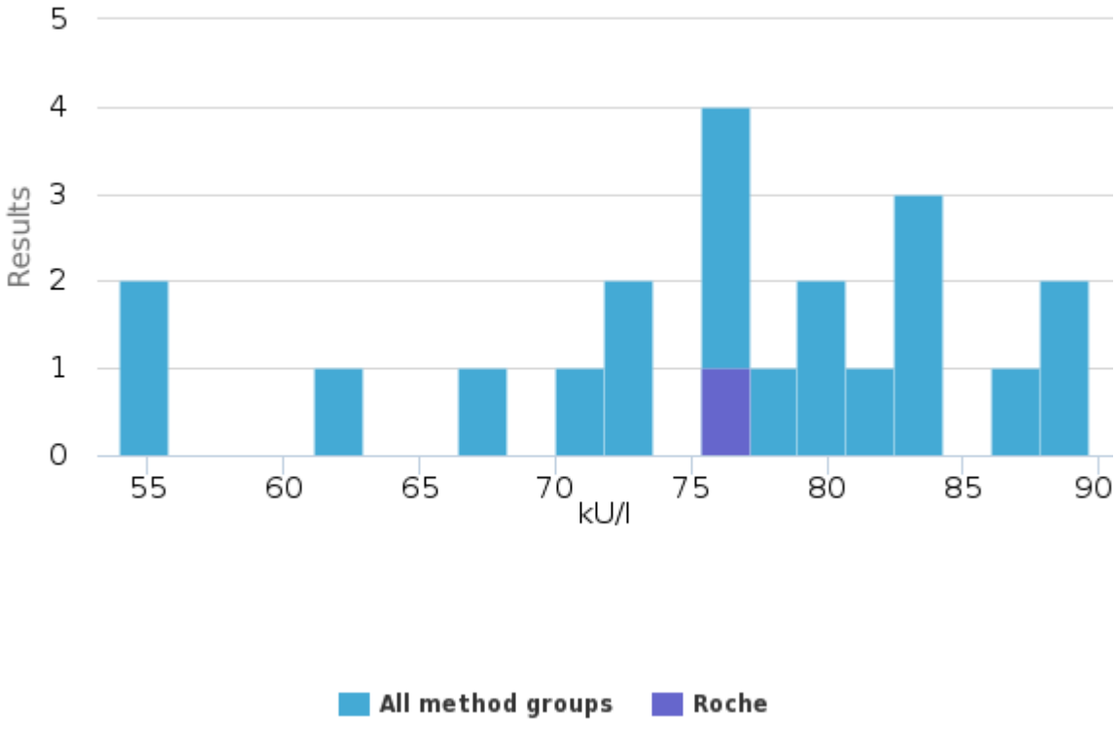
Sample S014 | Total IgE, kU/l

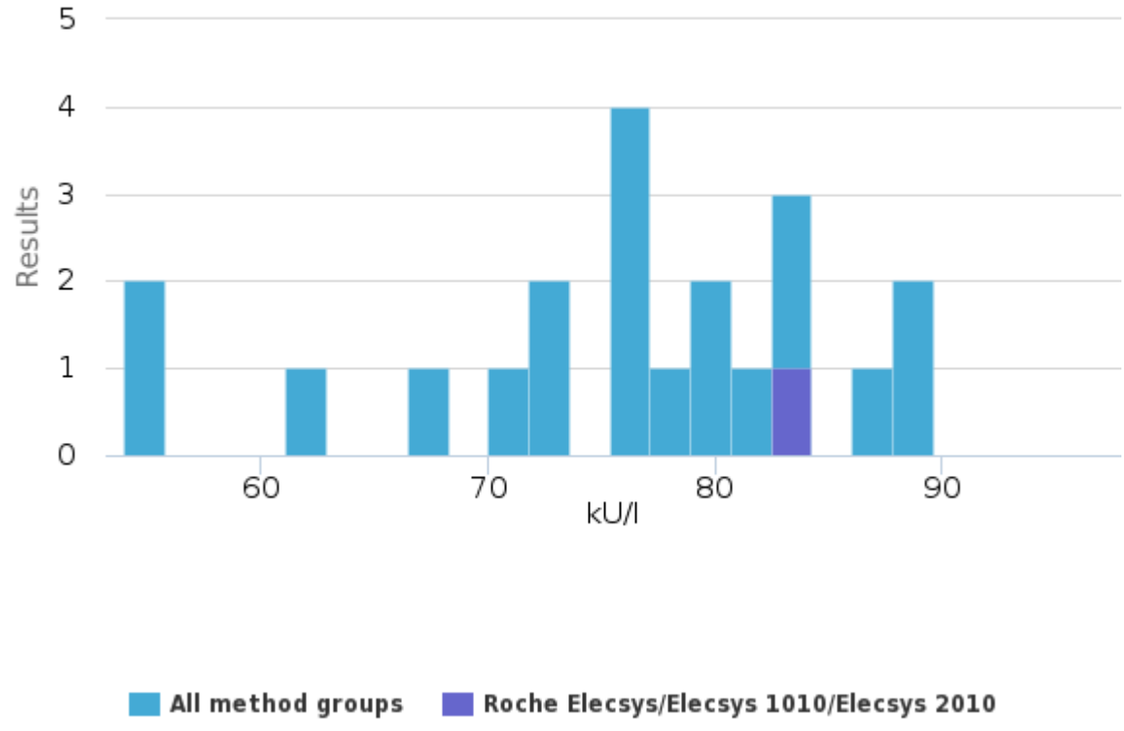
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Alinity C	-	-	-	-	-	55	55	-	1
Phadia ImmunoCAP	79	78	6	8.1	2	68	90	-	16
Roche	-	-	-	-	-	75	75	-	1
Roche Elecsys/Elecsys 1010/Elecsys 2010	-	-	-	-	-	84	84	-	1
Siemens Immulite 2000/2500	58	58	5	9.4	4	54	62	-	2
All	**76**	**77**	**10**	**13.0**	**2**	**54**	**90**	**-**	**21**

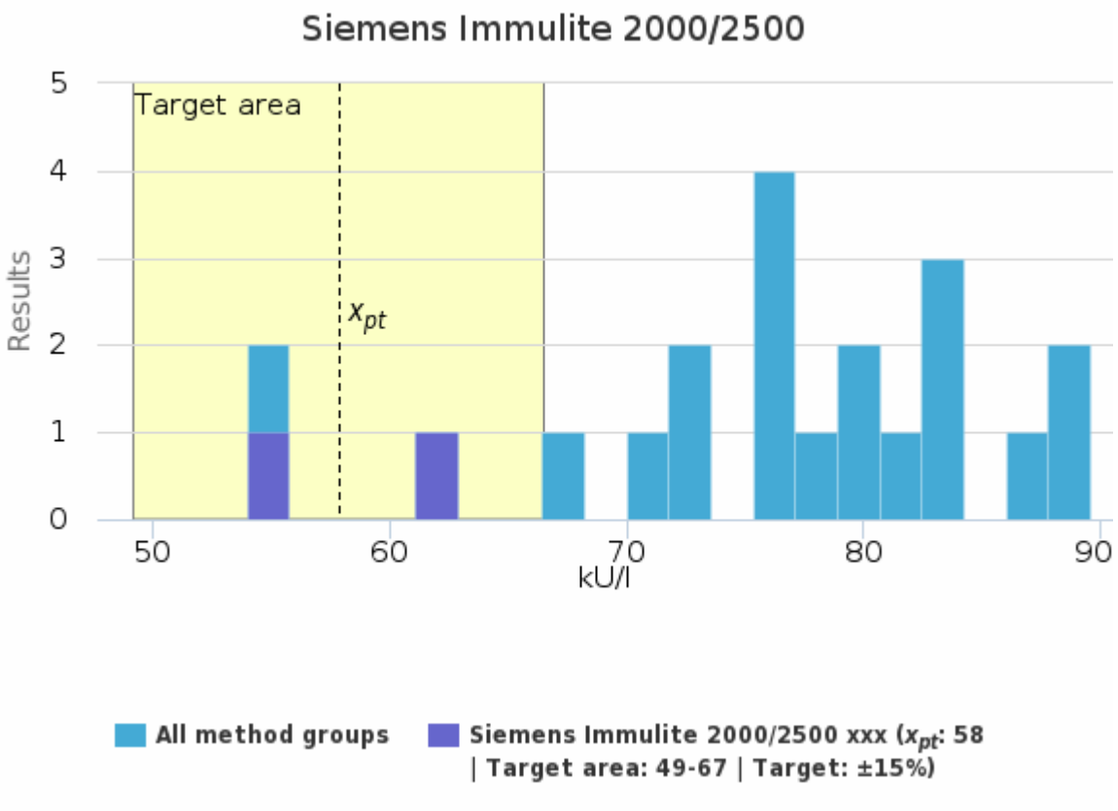
Sample S014 | Total IgE, kU/l| histogram summaries in LabScala







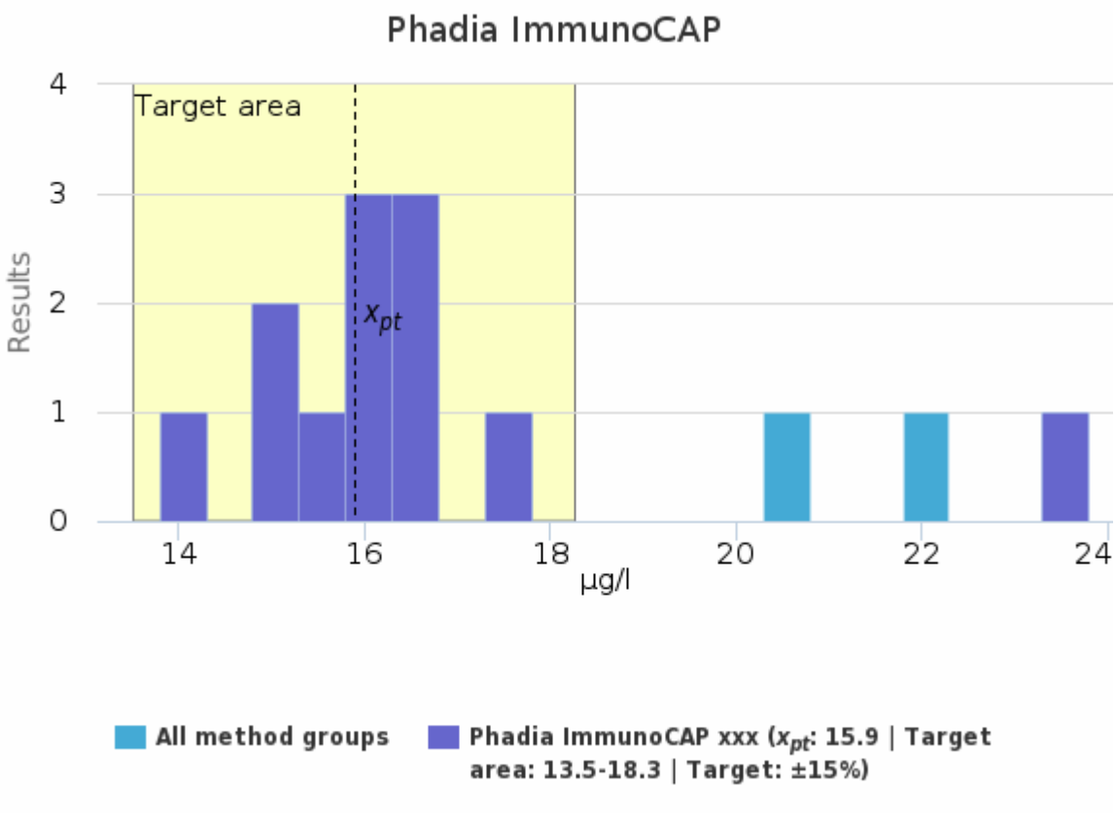


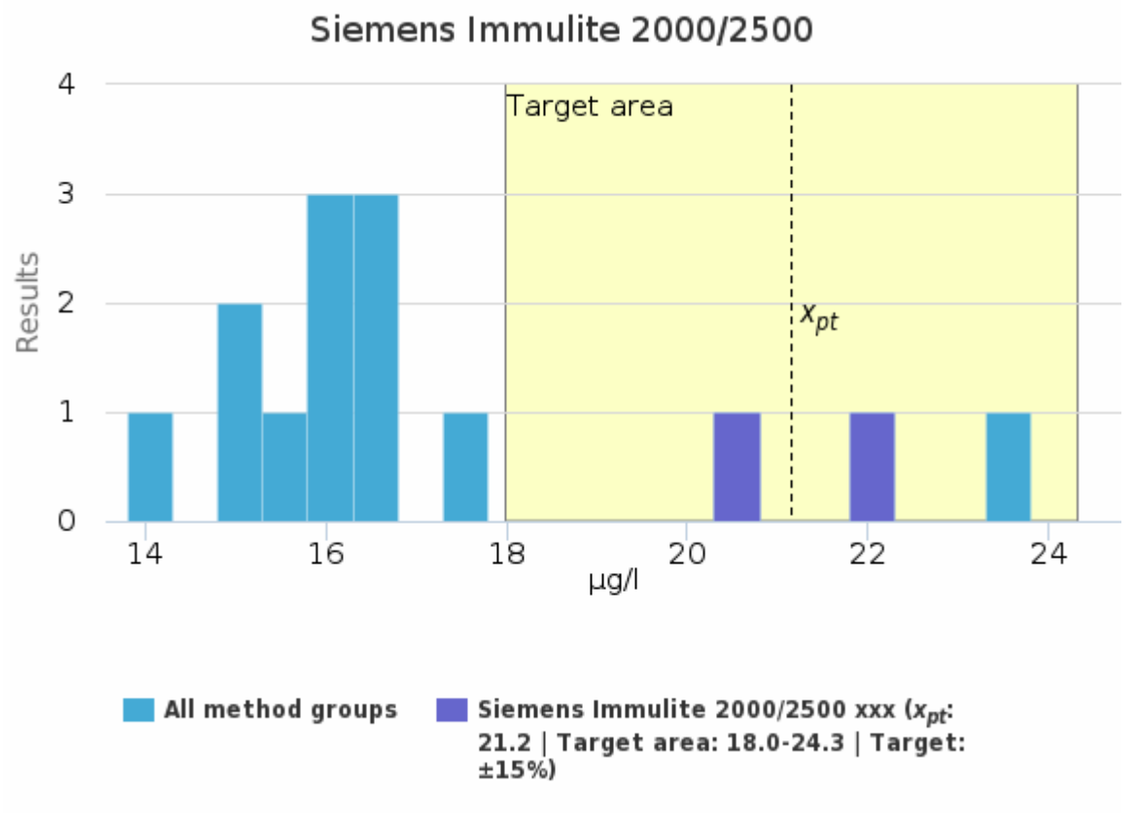


Sample S015 | ECP, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Phadia ImmunoCAP	15.9	16.0	1.0	6.2	0.3	13.8	17.3	1	12
Siemens Immulite 2000/2500	21.2	21.2	0.9	4.3	0.7	20.5	21.8	-	2
All	**17.2**	**16.4**	**2.8**	**16.5**	**0.8**	**13.8**	**23.8**	**-**	**14**

Sample S015 | ECP, µg/l| histogram summaries in LabScala





Report info

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External Quality Assessment Scheme

Allergy in Vitro Diagnostics
Round 1, 2023

Specimens
Sample S014 (LQ726323014) was liquid processed human serum for total IgE analysis. Sample S015 (LQ726323015) was lyophilized human serum for ECP analysis. Samples 231-1 and 231-2 were liquid processed human sera for UK NEQAS distribution 231.

Based on the previous tests and the results of this round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging. The total IgE sample has previously been used in round 5, 2022.

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

UK NEQAS sample 231-1 and sample 231-2 specific IgE reports will be available via www.immqas.org.uk after you have received a notification from UK NEQAS.

Comments – EQA Coordinator
Only in the Phadia ImmunoCAP and Siemens Immulite groups were reported more than one total IgE result. The results were in target areas. The mean of Phadia group was now 79 kU/L and CV 8.1% (n=16), the corresponding results in round 5, 2022 were 76 kU/L and CV 9.3% (n=18). Also, in this round the Abbott Alinity C group´s result 55 kU/L (in round 5, 2022 the result was 56 kU/L) was clearly lower than the other results.

All the reported ECP results were little above the reference limit. The mean of the Phadia ImmunoCAP group was 15.9 µg/L and CV 6.2% (n=12). All results except the highest were in target area. The mean of the Siemens Immulite results (21.2 µg/L, CV 4.3%, n=2) was clearly higher.

End of report

2023-04-12

FINAL REPORT

Product no. 2670-2680

Samples sent	2023-02-28
Round closed	2023-03-21
Final report	2023-04-12

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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