

External Quality Assessment Scheme

TSH receptor antibodies Round 1, 2023

Specimens

Please find enclosed 2 human plasma or serum samples S001 and S002, each 0.4 mL.

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

TSH receptor, antibodies

Storage and use

After arrival, the samples should be stored at +2...8 °C, and used as soon as possible, preferably within a week. The samples are ready for use. 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



S002



2023-03-07

INSTRUCTIONS

Product no. 5913
LQ717723011-012/FI

Subcontracting: 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 30, 2023.**

The expected results of the round are published in LabScala in the View Reports section by April 4, 2023.

Inquiries

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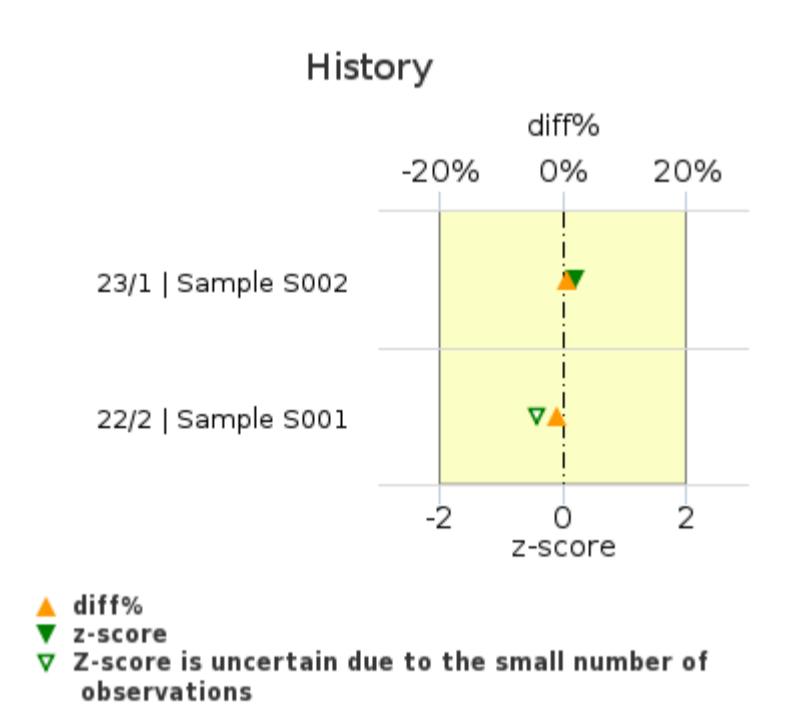
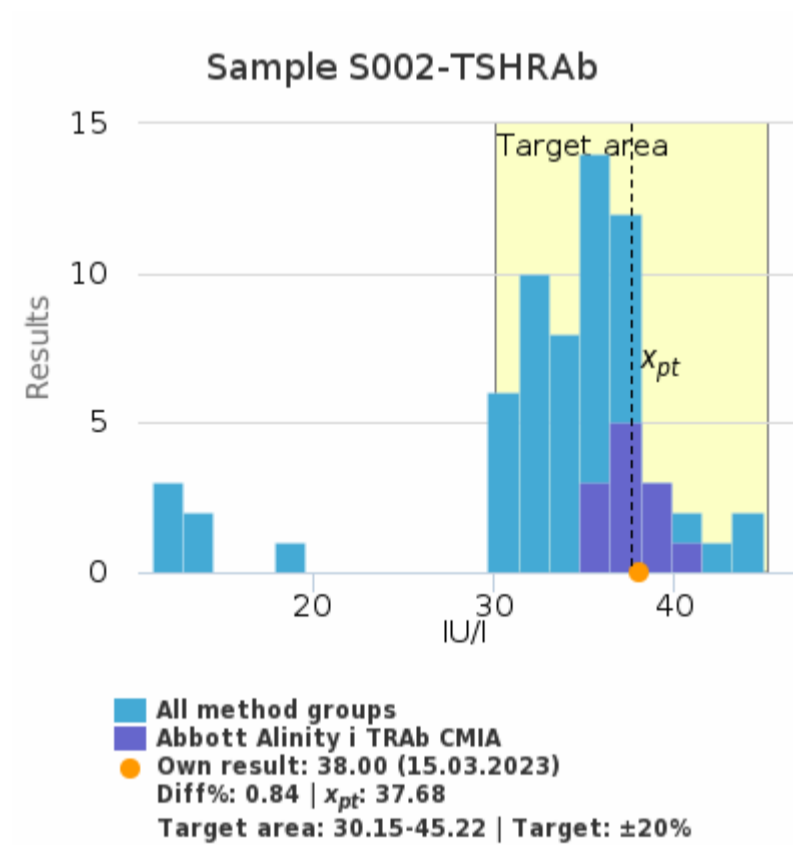
TSHRab | NR 4

Sample S001

Methodics	Negative	Total
Abbott Alinity i TRAb CMIA	12	12
Abbott Architect TRAb CMIA	2	2
Beckman Coulter/ImmunoTech RRA Anti-R TSH	1	1
Euroimmun TSH receptor ELISA	1	1
Roche cobas/ Elecsys Anti-TSHR	33	33
Siemens Immulite 2000/2000 XPI TSI	5	5
Snibe Maglumi TRAb (CLIA)	2	2
Thermo Sc. BRAHMS TRAK human RIA	1	1
Thermo Sc. BRAHMS TRAK LIA	1	1
Thermo Sc. Phadia EliA anti-TSH-R	7	7
Total	65	65

Sample S002

Methodics	Positive	Total
Abbott Alinity i TRAb CMIA	12	12
Abbott Architect TRAb CMIA	2	2
Beckman Coulter/ImmunoTech RRA Anti-R TSH	1	1
Euroimmun TSH receptor ELISA	1	1
Roche cobas/ Elecsys Anti-TSHR	33	33
Siemens Immulite 2000/2000 XPI TSI	5	5
Snibe Maglumi TRAb (CLIA)	2	2
Thermo Sc. BRAHMS TRAK human RIA	1	1
Thermo Sc. BRAHMS TRAK LIA	1	1
Thermo Sc. Phadia EliA anti-TSH-R	7	7
Total	65	65



	x_{pt}	sd	SEM	CV%	n
Abbott Alinity i TRAb CMIA	37.68 IU/l	1.48	0.43	3.9	12
All methods	35.15 IU/l	3.81	0.50	10.8	64

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	37.68	38.00	0.84%	0.21
22/2	Sample S001	32.40	32.05	-1.08%	-0.42

Report info**Participants**

63 participants from 13 countries.

Report info

Qualitative and quantitative results are presented in the same report. Always compare your results to those obtained with the same test kit.

The qualitative results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green colour and laboratory's own result with a black radio button .

The quantitative results from the positive specimens are presented as histograms. Quantitative results reported with < or > -signs are not processed. Results reported as ratios, titres, absorbances and without a unit are manually removed and not statistically processed.

Assigned values (target values) are mean 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 participant specific report your own result is shown with an orange dot. The target area is presented as a yellow area in the picture. In the history graphs you are able to see your performance graphically with both against the assigned value (xpt) and the z-score area of -2 ... +2.

If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EOA Coordinator.

Sample S001 | TSHRAb, IU/l

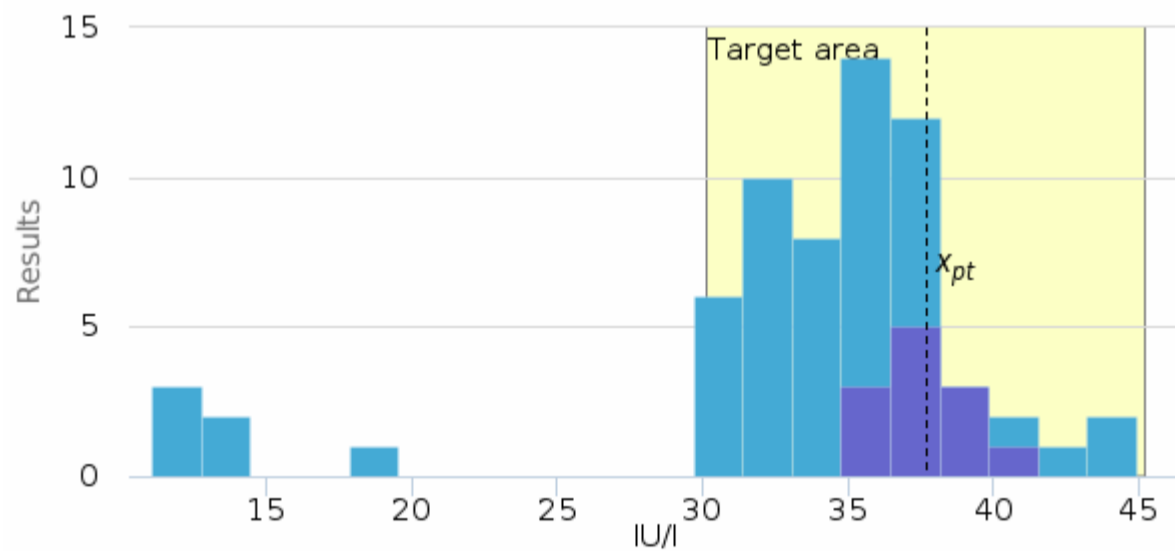
Methodics	Negative	Total
Abbott Alinity i TRAb CMIA	12	12
Abbott Architect TRAb CMIA	2	2
Beckman Coulter/Immunotech RRA Anti-R TSH	1	1
Euroimmun TSH receptor ELISA	1	1
Roche cobas/ Elecsys Anti-TSHR	33	33
Siemens Immulite 2000/2000 XPI TSI	5	5
Snibe Maglumi TRAb (CLIA)	2	2
Thermo Sc. BRAHMS TRAK human RIA	1	1
Thermo Sc. BRAHMS TRAK LIA	1	1
Thermo Sc. Phadia EliA anti-TSH-R	7	7
Total	65	65

Sample S002 | TSHRab, IU/l

Methodics	Positive	Total
Abbott Alinity i TRAb CMIA	12	12
Abbott Architect TRAb CMIA	2	2
Beckman Coulter/Immunotech RRA Anti-R TSH	1	1
Euroimmun TSH receptor ELISA	1	1
Roche cobas/ Elecsys Anti-TSHR	33	33
Siemens Immulite 2000/2000 XPI TSI	5	5
Snibe Maglumi TRAb (CLIA)	2	2
Thermo Sc. BRAHMS TRAK human RIA	1	1
Thermo Sc. BRAHMS TRAK LIA	1	1
Thermo Sc. Phadia EliA anti-TSH-R	7	7
Total	65	65

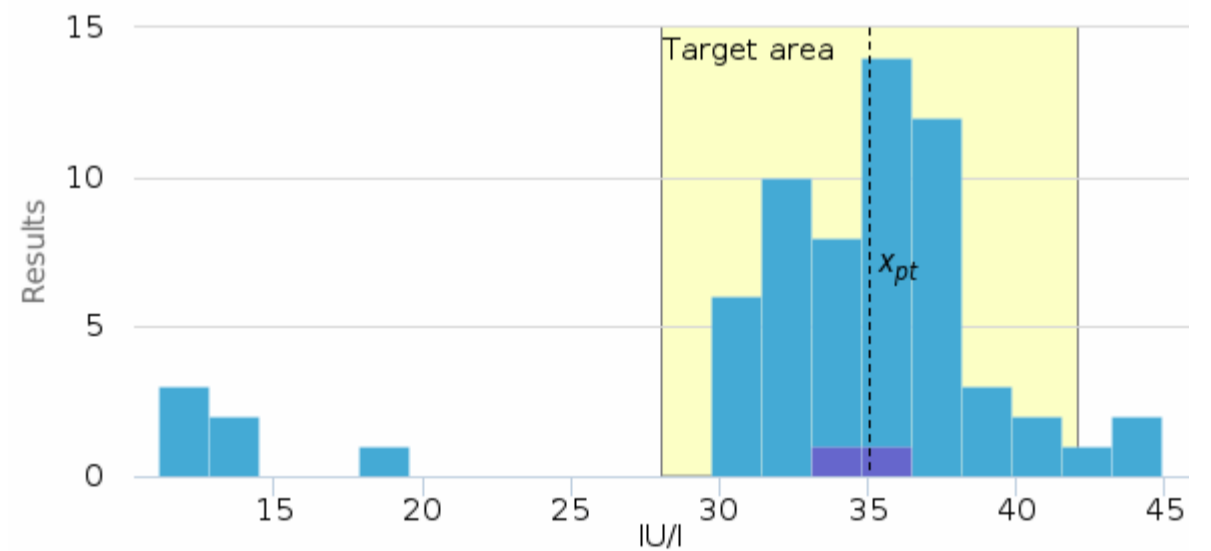
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Alinity i TRAb CMIA	37.68	38.02	1.48	3.9	0.43	35.94	40.77	-	12
Abbott Architect TRAb CMIA	35.08	35.08	0.60	1.7	0.43	34.65	35.50	-	2
Beckman Coulter/Immunotech RRA Anti-R TSH	-	-	-	-	-	19.26	19.26	-	1
Euroimmun TSH receptor ELISA	-	-	-	-	-	40.00	40.00	-	1
Roche cobas/ Elecsys Anti-TSHR	34.09	34.20	2.17	6.4	0.38	30.12	37.90	-	33
Siemens Immulite 2000/2000 XPI TSI	12.12	12.30	0.84	6.9	0.38	11.10	13.00	-	5
Snibe Maglumi TRAb (CLIA)	36.15	36.15	8.70	24.1	6.15	30.00	42.30	-	2
Thermo Sc. BRAHMS TRAK human RIA	-	-	-	-	-	32.20	32.20	-	1
Thermo Sc. BRAHMS TRAK LIA	-	-	-	-	-	44.93	44.93	-	1
Thermo Sc. Phadia EliA anti-TSH-R	36.33	34.50	4.13	11.4	1.69	33.00	44.00	-	6
All	35.15	35.40	3.81	10.8	0.50	19.26	44.93	5	64

Abbott Alinity i TRAb CMIA



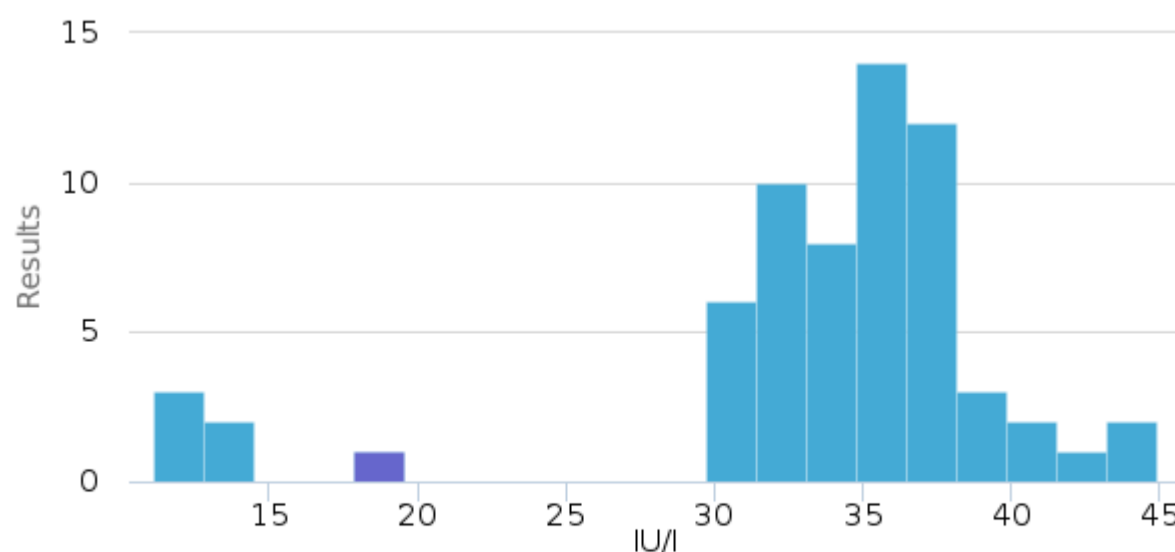
■ All method groups
 ■ Abbott Alinity i TRAb CMIA (x_{pt} : 37.68 | Target area: 30.15-45.22 | Target: $\pm 20\%$)

Abbott Architect TRAb CMIA



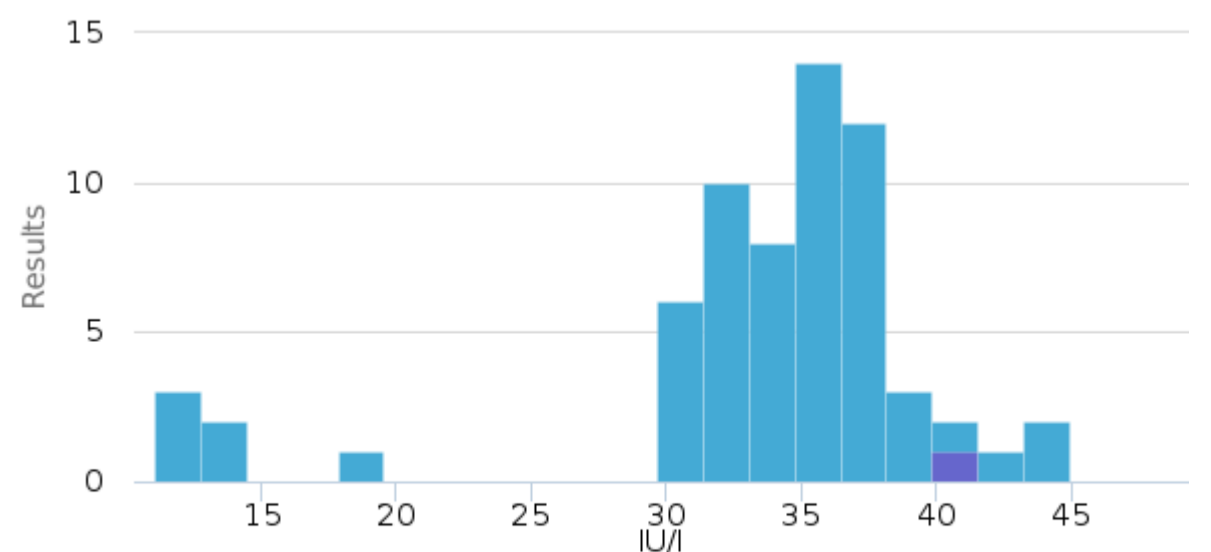
■ All method groups
 ■ Abbott Architect TRAb CMIA (x_{pt} : 35.08 | Target area: 28.06-42.09 | Target: $\pm 20\%$)

Beckman Coulter/Immunotech RRA Anti-R TSH

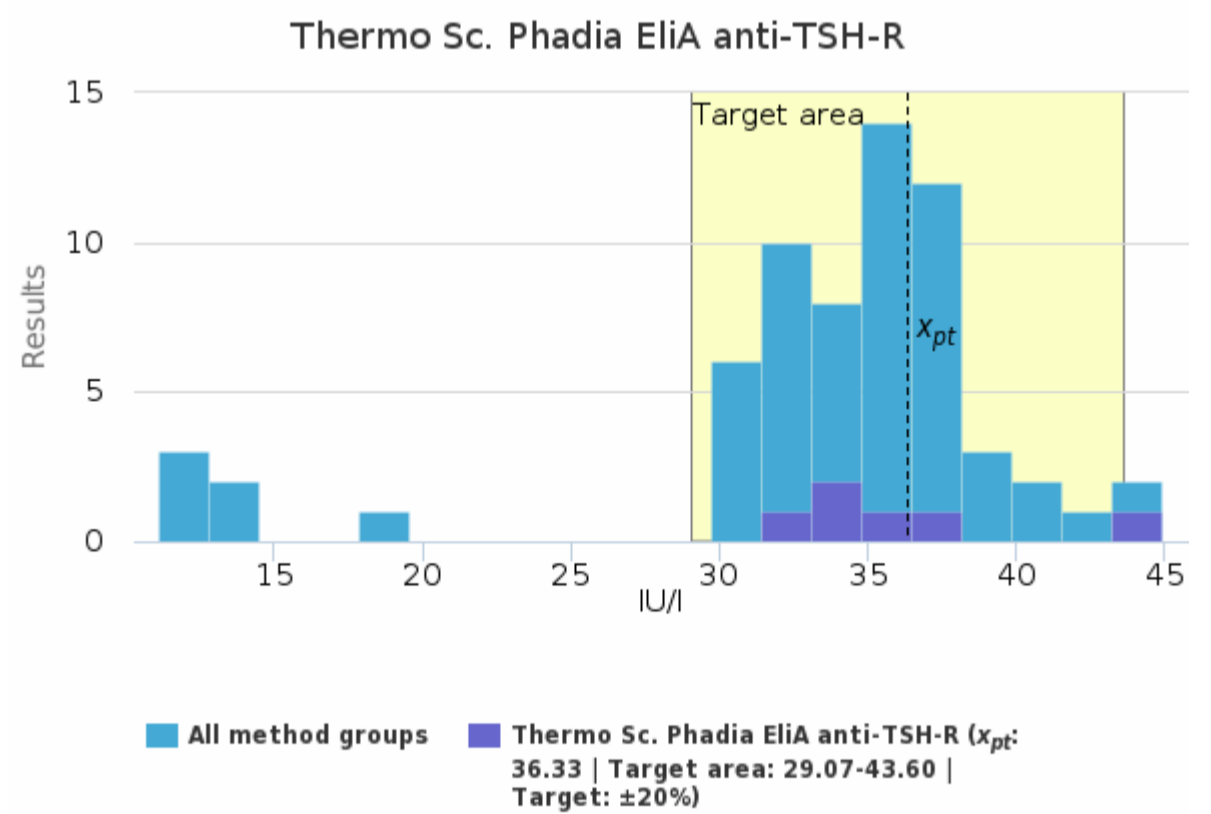
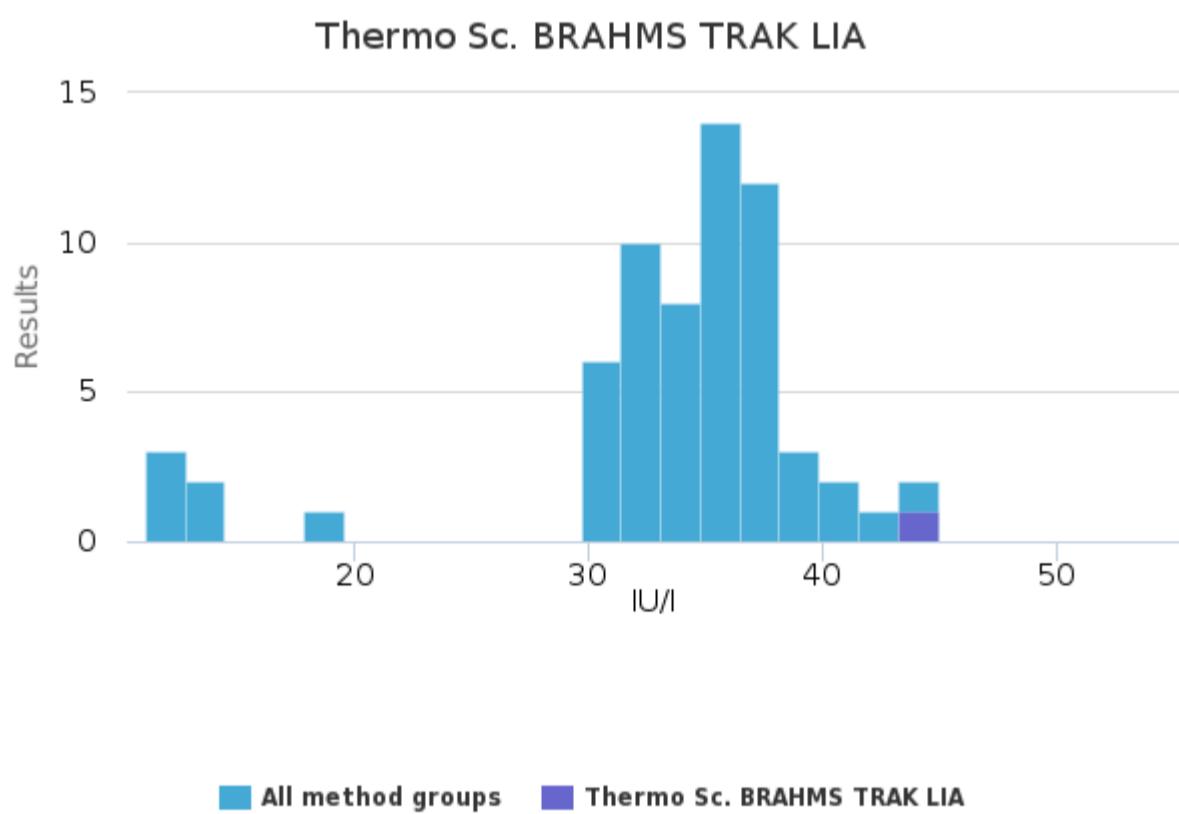
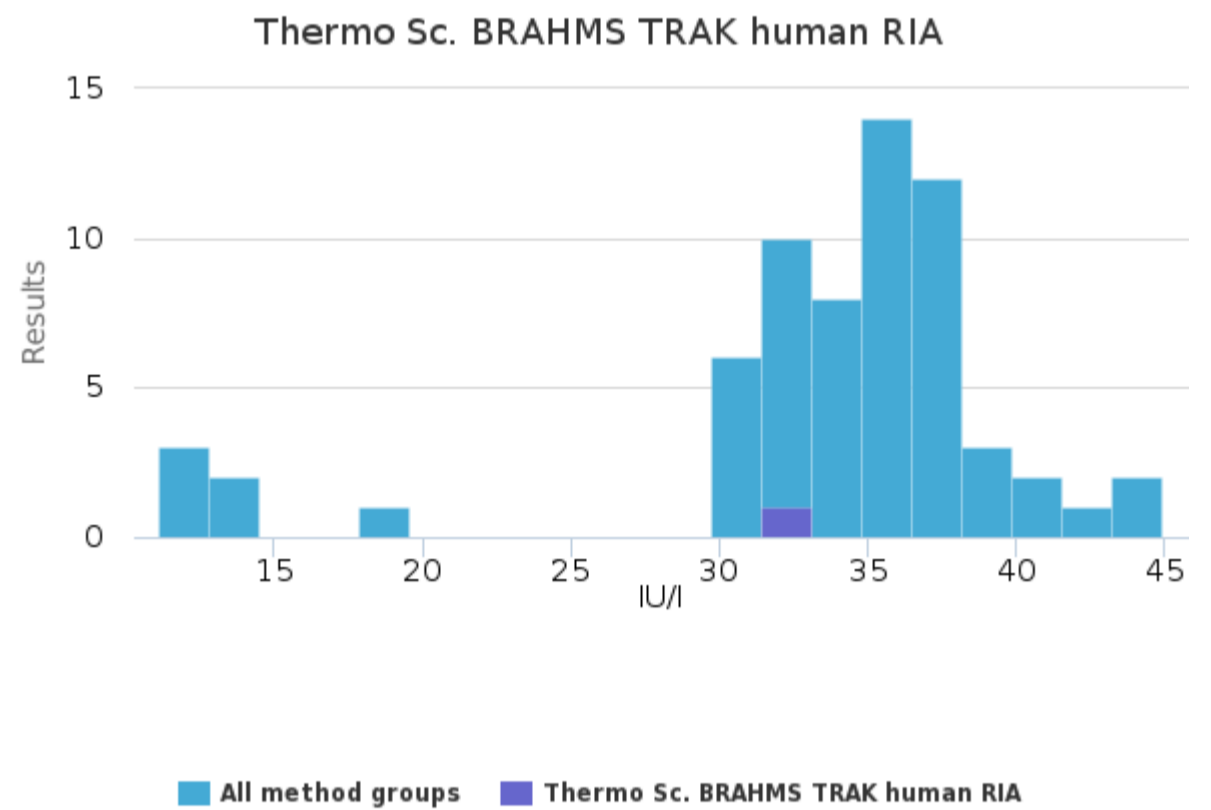
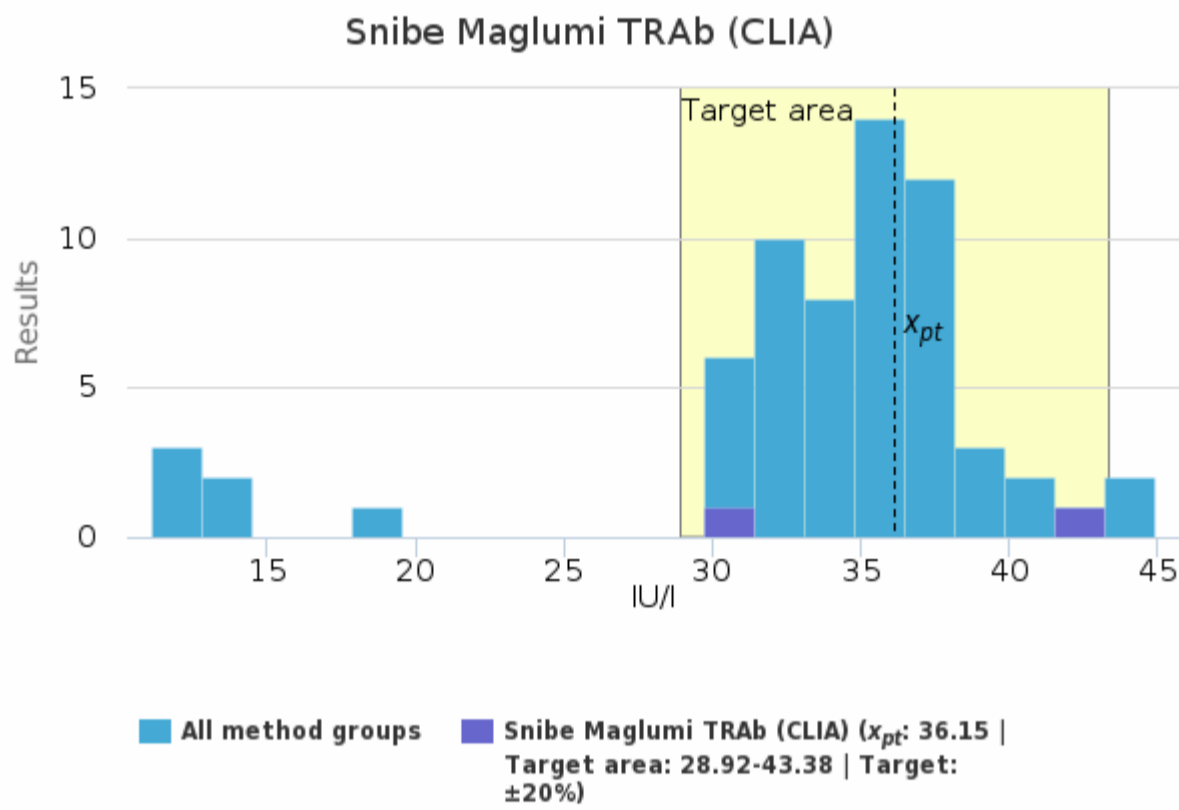
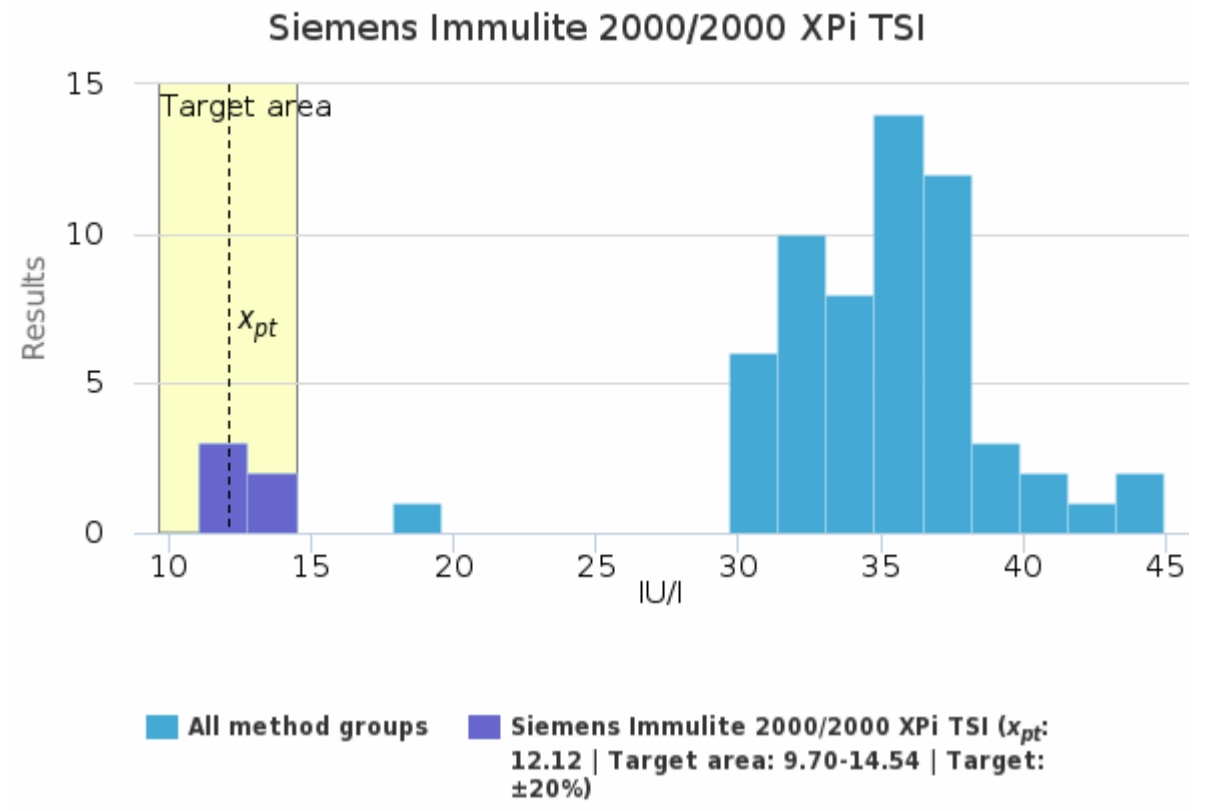
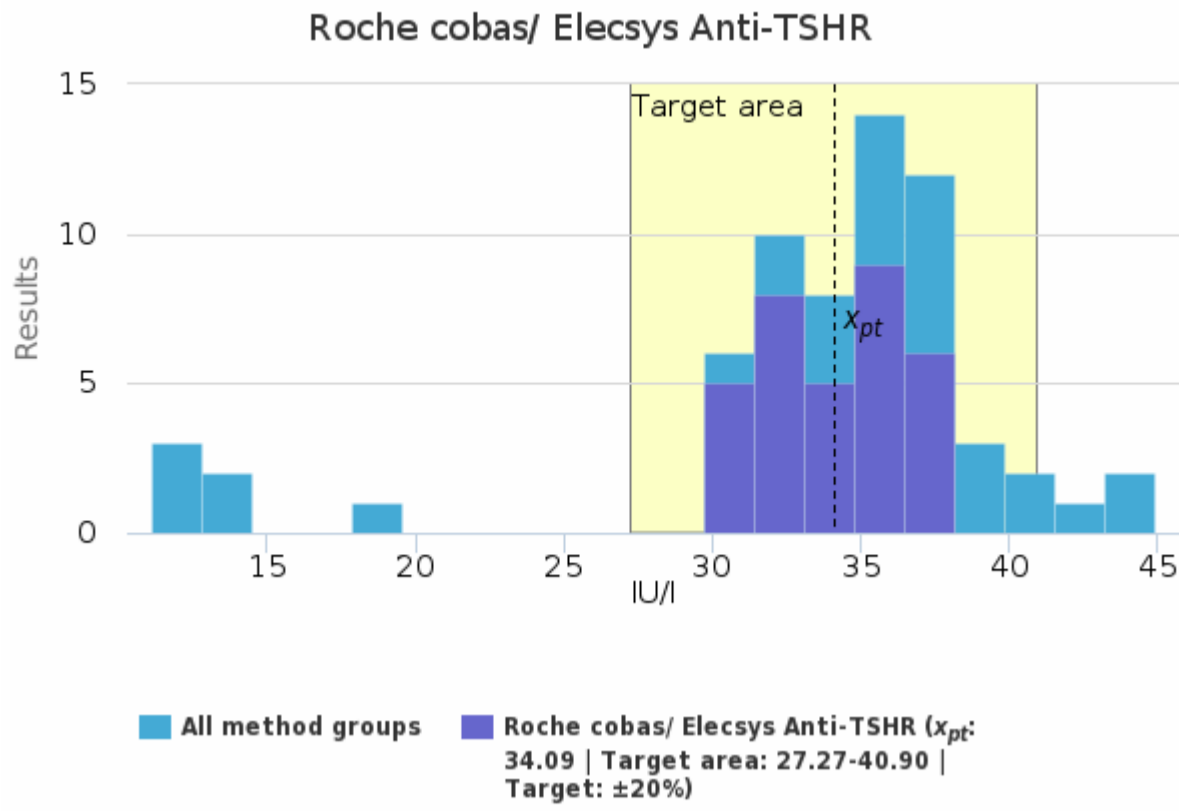


■ All method groups
 ■ Beckman Coulter/Immunotech RRA Anti-R TSH

Euroimmun TSH receptor ELISA



■ All method groups
 ■ Euroimmun TSH receptor ELISA



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External Quality Assessment Scheme

Thyroid stimulating hormone receptor antibodies Round 1, 2023

Specimens

Samples of this EQA round were human plasma or serum. Based on the pre-testing and the results obtained in the round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The accepted results were as follows:

Sample S001 (LQ717723011)
TSHRAb Negative

Sample S002 (LQ717723012)
TSHRAb Positive

Pre-test method: Thermo Scientific Phadia EliA anti-TSH-R.

Report info

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

Comments – Expert

The sample S001 was negative for TSH receptor antibodies, and all participants got a negative result. The sample S002 was positive and again, all participants got the correct result. Thus, the results of this round were perfect.

The antibody level in sample S002 was high by all methods used and there was little variation in the antibody level except for one method. Since there may be variation on the antibody level, it is of utmost important that the clinician knows in which laboratory a patient's follow-up samples are analyzed, and that the antibody level depends on the method used.

Exceptions

No exceptions.

End of report

2023-05-08

FINAL REPORT

Product no. 5913

Subcontracting: Sample pretesting

Samples sent	2023-03-07
Round closed	2023-03-30
Expected results	2023-04-04
Final report	2023-05-08

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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