LABQUALITY

External Quality Assessment Scheme

Chemokine CXCL13 Round 1, 2023

Specimens

Please find enclosed 2 liquid samples S001 and S002, each 0.5 mL.

Caution

Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases.

Examinations

Chemokine CXCL13 detection

Storage and use

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



2023-01-31

INSTRUCTIONS

Product no. 5965 LQ758123011-012/FI

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 21, 2023**.

Inquiries

EQA Coordinator Mira Saarinen mira.h.saarinen@labquality.fi

Labquality Oy

Kumpulantie 15 FI-00520 HELSINKI Finland

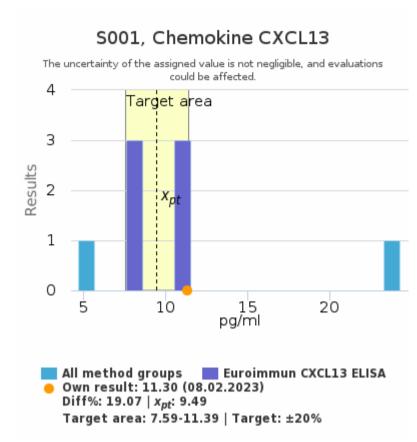
Tel. + 358 9 8566 8200 Fax + 358 9 8566 8280

info@labquality.fi www.labquality.com



LABQUALITY

Chemokine CXCL13 |1



^Xpt

9.49

pg/ml

10.74

pg/ml

Euroimmun CXCL13

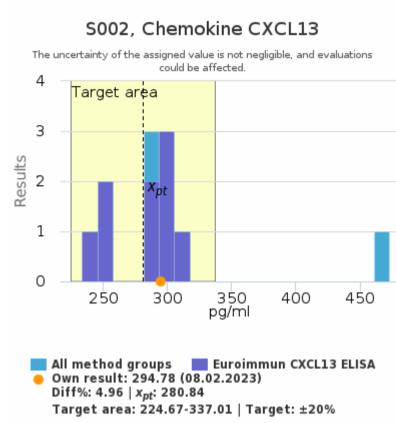
ELISA

All methods

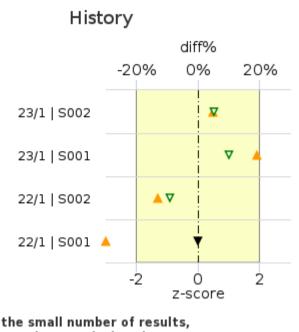
SEM CV% n

1.77 0.72 18.6 6

5.92 2.09 55.1 8



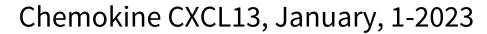
	^X pt	sd	SEM	CV%	n
Euroimmun CXCL13 ELISA	280.84 pg/ml	27.23	9.08	9.7	9
All methods	299.40 pg/ml	62.68	18.90	20.9	11



- diff% Due to the small number of results, the z score is not calculated
- ▼ Z-score is uncertain due to the small number of observations

Round	Sample	^X pt	Result	diff%	z-score
23/1	S002	280.84	294.78	4.96%	0.51
23/1	S001	9.49	11.30	19.07%	1.02
22/1	S002	472.46	411.00	-13.01%	-0.91
22/1	S001	847.17	517.00	-38.97%	-

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Report info

Participants

16 participants from 10 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).

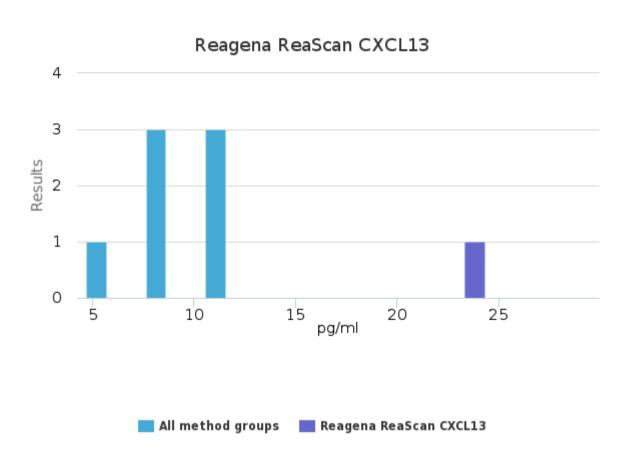
23.02.2023 2/2

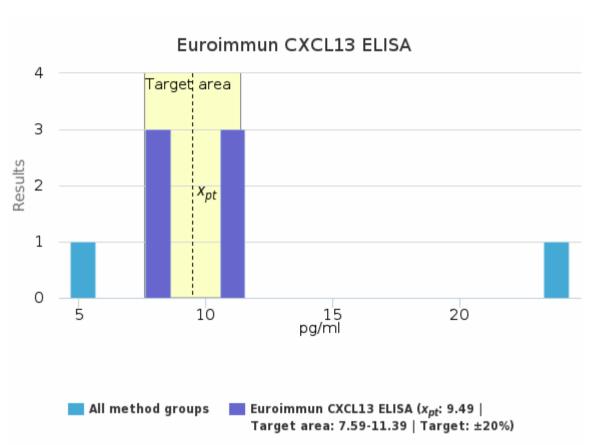


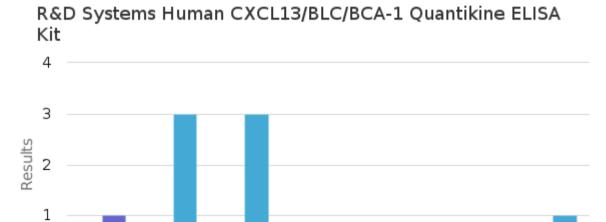
S001 | Chemokine CXCL13, pg/ml

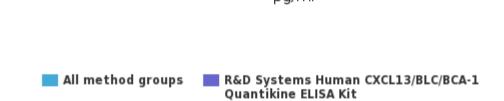
Methodics	x _{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Reagena ReaScan CXCL13	-	-	-	-	-	24.30	24.30	-	1
Euroimmun CXCL13 ELISA	9.49	9.34	1.77	18.6	0.72	7.81	11.30	-	6
R&D Systems Human CXCL13/BLC/BCA-1 Quantikine ELISA Kit	-	-	-	-	-	4.70	4.70	-	1
All	10.74	9.34	5.92	55.1	2.09	4.70	24.30	-	8

S001 | Chemokine CXCL13, pg/ml| histogram summaries in LabScala









20

10

0

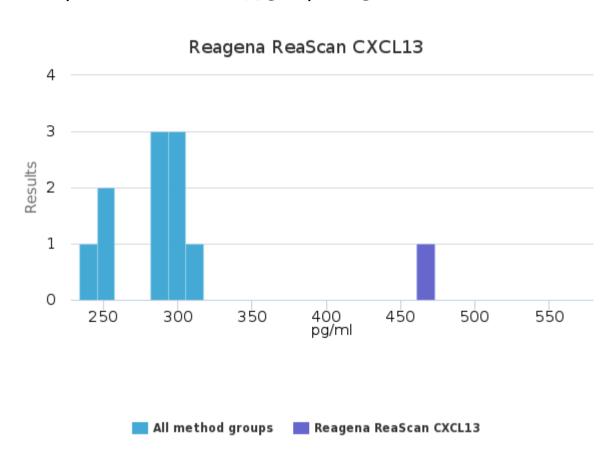
22.02.2023

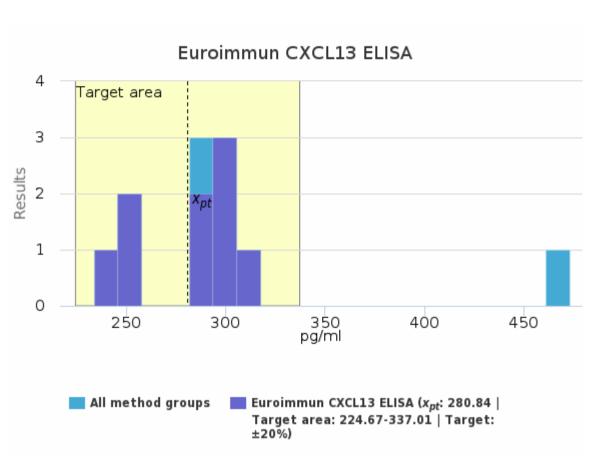


S002 | Chemokine CXCL13, pg/ml

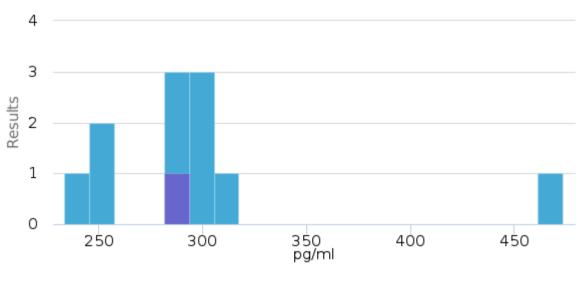
Methodics	^X pt	Median	sd	CV%	SEM	min	max	Outliers	n
Reagena ReaScan CXCL13	-	-	-	-	-	473.22	473.22	-	1
Euroimmun CXCL13 ELISA	280.84	292.00	27.23	9.7	9.08	233.81	316.27	-	9
R&D Systems Human CXCL13/BLC/BCA-1 Quantikine ELISA Kit	-	-	-	-	-	292.60	292.60	-	1
All	299.40	292.60	62.68	20.9	18.90	233.81	473.22	-	11

S002 | Chemokine CXCL13, pg/ml| histogram summaries in LabScala











22.02.2023



Chemokine CXCL13, January, 1-2023

Report info

Participants

16 participants from 10 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."
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LABQUALITY

External Quality Assessment Scheme

Chemokine CXCL13 Round 1, 2023

Specimens

Samples S001 (LQ758123011) and sample S002 (LQ758123012) were liquid simulated samples. Based on the quality controls conducted by the sample material manufacturer and the results obtained in the round, the sample lots are to be considered as homogeneous, stable and suitable for external quality assessment. 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 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

CXCL13 in the cerebrospinal fluid is a useful diagnostic biomarker for Lyme neuroborreliosis (LNB), especially in the early phase of the disease, and for the discrimination between acute LNB and a previously treated LNB.

The major unresolved issue concerning the use of CXCL13 concentration determination in the laboratory diagnostics of LNB is the optimal CXCL13 cutoff value for the discrimination of LNB patients and patients with CNS symptoms and pleocytosis due to other infections or inflammatory conditions. The meta-analysis by Rupprecht et al (Clinical Microbiology and Infection, 2018) resulted in two different cut-off values (91 pg/mL and 162 pg/mL) depending on which studies were included in the analysis.

In this round, we had two simulated CXCL13 samples with target CXCL13 concentrations 5 pg/mL (S001) and 250 pg/mL (S002). There were 15 participants in the round using three different CXCL13 assays.

The reported results of sample S001 with low CXCL13 concentration were all correct. This means that the results of Elisa assays (Euroimmun and Quantikine) were in the expected range (ca. 10 pg/mL). Results of Reascan assay are reported in three categories, namely <250 pg/mL, 250-500 pg/mL, and >500 pg/mL. All results of sample S001 were in the correct category.

Elisa results of sample S002 were also nicely in line with the target concentration with the results ranging from 233 pg/mL to 316 pg/mL. Reascan results were, from some reason, higher than expected in the category of >500 pg/mL.

In summary, all reported results were correct in that regard that they categorized sample S001 as a non-LNB sample, and sample S002 as one representing potential LNB patient.

Exceptions

No exceptions.

Annex

The results of the round (Annex 1)

End of report

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2023-03-01

FINAL REPORT

Product no. 5965

Subcontracting: Sample pretesting

 Samples sent
 2023-01-31

 Round closed
 2023-02-21

 Final report
 2023-03-01

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 Mira Saarinen mira.h.saarinen@labquality.fi

Expert

Dr. Jukka Hytönen, MD, PhD University of Turku and Turku University Hospital Turku, Finland

Labquality Oy

Kumpulantie 15 FI-00520 HELSINKI Finland

Tel. + 358 9 8566 8200 Fax + 358 9 8566 8280

info@labquality.fi www.labquality.com



Annex 1. The results of the round.

SAMPLE	RESULT pg/mL	METHOD
S001	<7.8	Euroimmun CXCL13 ELISA
S001	7.8	Euroimmun CXCL13 ELISA
S001	7.9	Euroimmun CXCL13 ELISA
S001	8.0	Euroimmun CXCL13 ELISA
S001	10.7	Euroimmun CXCL13 ELISA
S001	<10.8	Euroimmun CXCL13 ELISA
S001	11.3	Euroimmun CXCL13 ELISA
S001	11.3	Euroimmun CXCL13 ELISA
S001	<20	Euroimmun CXCL13 ELISA
S001	4.7	R&D Systems Human CXCL13/BLC/BCA-1 Quantikine ELISA Kit
S001	24.3	Reagena ReaScan CXCL13
S001	<250	Reagena ReaScan CXCL13
S001	<250	Reagena ReaScan CXCL13
S001	<250	Reagena ReaScan CXCL13
S001	<250	Reagena ReaScan CXCL13
S001	<250	Reagena ReaScan CXCL13
S002	233.8	Euroimmun CXCL13 ELISA
S002	254.0	Euroimmun CXCL13 ELISA
S002	254.3	Euroimmun CXCL13 ELISA
S002	283.0	Euroimmun CXCL13 ELISA
S002	292.0	Euroimmun CXCL13 ELISA
S002	294.8	Euroimmun CXCL13 ELISA
S002	299.4	Euroimmun CXCL13 ELISA
S002	300.0	Euroimmun CXCL13 ELISA
S002	316.3	Euroimmun CXCL13 ELISA
S002	292.6	R&D Systems Human CXCL13/BLC/BCA-1 Quantikine ELISA Kit
S002	473.2	Reagena ReaScan CXCL13
S002	500.0	Reagena ReaScan CXCL13
S002	>500	Reagena ReaScan CXCL13
S002	>500	Reagena ReaScan CXCL13
S002	>500	Reagena ReaScan CXCL13
S002	>500	Reagena ReaScan CXCL13