

External Quality Assessment Scheme

Autoimmune liver disease and gastric parietal cell 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 HIVAb 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

LKM-1 antibodies	Liver kidney microsomal antibodies
SMA	Smooth muscle antibodies
AMA	Mitochondrial antibodies
PCA (GPCA)	Gastric parietal cell 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. Report only the results of examinations that are in use in your laboratory.

S001



S002



2023-05-09

INSTRUCTIONS

Product no. 5930
LQ717923011-012/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 **June 2, 2023**.

The expected results of the round are published in LabScala in the View Reports section by June 7, 2023.

Inquiries

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LKM |EI

Sample S001

Methodics	Negative	Total
ALEGRIA, Orgentec	2	2
ELISA, Diesse Chorus	1	1
ELISA, DRG Diagnostics	1	1
ELISA, Euroimmun	2	2
ELISA, Inova	2	2
Euroline, Euroimmun	7	7
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	8	8
IFA, Inova	3	3
IFA Kallestadt, Bio-Rad	2	2
Microblot-Array Liver-Profile,TestLine	1	1
Total	30	30

Sample S002

Methodics	Negative	Borderline	Positive	AMA interferes interpretation	Total
ALEGRIA, Orgentec	2	-	-	-	2
ELISA, Diesse Chorus	1	-	-	-	1
ELISA, DRG Diagnostics	-	-	1	-	1
ELISA, Euroimmun	2	-	-	-	2
ELISA, Inova	2	-	-	-	2
Euroline, Euroimmun	6	1	-	-	7
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	-	-	-	1
IFA, Euroimmun	8	-	-	-	8
IFA, Inova	1	-	-	2	3
IFA Kallestadt, Bio-Rad	2	-	-	-	2
Microblot-Array Liver-Profile,TestLine	1	-	-	-	1
Total	26	1	1	2	30

SMA |EI

Sample S001

Methodics	Negative	Borderline	Weak positive	Positive	Total
ELISA, Inova	1	-	-	-	1
Euroline, Euroimmun	2	-	-	-	2
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	-	-	-	1	1
IFA, Euroimmun	6	-	-	9	15
IFA, Inova	-	1	1	3	5
IFA Kallestadt, Bio-Rad	1	-	-	1	2
Total	10	1	1	14	26

Sample S002

Methodics	Negative	Total
ELISA, Inova	1	1
Euroline, Euroimmun	2	2
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	14	14
IFA, Inova	5	5
IFA Kallestadt, Bio-Rad	2	2
Total	25	25

AMA | EI

Sample S001

Methodics	Negative	Total
ALEGRIA, Orgentec	3	3
EliA Phadia, Thermo Fisher	2	2
ELISA, Diesse Chorus	1	1
ELISA, Euroimmun	2	2
ELISA, Inova	1	1
ELISA, Orgentec	1	1
Euroline, Euroimmun	5	5
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	9	9
IFA, Inova	5	5
IFA Kallestadt, Bio-Rad	2	2
Microblot-Array Liver-Profile,TestLine	1	1
Total	33	33

Sample S002

Methodics	Positive	Total
ALEGRIA, Orgentec	3	3
EliA Phadia, Thermo Fisher	2	2
ELISA, Diesse Chorus	1	1
ELISA, Euroimmun	2	2
ELISA, Inova	1	1
ELISA, Orgentec	1	1
Euroline, Euroimmun	5	5
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	9	9
IFA, Inova	5	5
IFA Kallestadt, Bio-Rad	2	2
Microblot-Array Liver-Profile,TestLine	1	1
Total	33	33

PCA |Immunocap2500

Sample S001

Methodics	Negative	Total
ALEGRIA, Orgentec	2	2
EliA Phadia, Thermo Fisher	5	5
ELISA, Euroimmun	2	2
ELISA, Inova	2	2
ELISA, Parietalcell-Ab, IBL	1	1
Euroline, Euroimmun	1	1
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	6	6
IFA, Inova	2	2
IFA Kallestadt, Bio-Rad	2	2
Total	24	24

Sample S002

Methodics	Negative	Positive	AMA interferes interpretation	Total
ALEGRIA, Orgentec	2	-	-	2
EliA Phadia, Thermo Fisher	5	-	-	5
ELISA, Euroimmun	2	-	-	2
ELISA, Inova	2	-	-	2
ELISA, Parietalcell-Ab, IBL	1	-	-	1
Euroline, Euroimmun	1	-	-	1
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	-	-	1
IFA, Euroimmun	3	1	1	5
IFA, Inova	1	-	1	2
IFA Kallestadt, Bio-Rad	2	-	-	2
Total	20	1	2	23

Report info

Participants

29 participants from 12 countries.

Report info

The 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 . If you have not reported any results you will get a note: "You have not responded in time, only global report is available." Always compare your results to those obtained with the same test method.

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 | LKM, --

Methodics	Negative	Total
ALEGRIA, Orgentec	2	2
ELISA, Diesse Chorus	1	1
ELISA, DRG Diagnostics	1	1
ELISA, Euroimmun	2	2
ELISA, Inova	2	2
Euroline, Euroimmun	7	7
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	8	8
IFA, Inova	3	3
IFA Kallestadt, Bio-Rad	2	2
Microblot-Array Liver-Profile,TestLine	1	1
Total	30	30

Sample S001 | SMA, --

Methodics	Negative	Borderline	Weak positive	Positive	Total
ELISA, Inova	1	-	-	-	1
Euroline, Euroimmun	2	-	-	-	2
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	-	-	-	1	1
IFA, Euroimmun	6	-	-	9	15
IFA, Inova	-	1	1	3	5
IFA Kallestadt, Bio-Rad	1	-	-	1	2
Total	10	1	1	14	26

Sample S001 | AMA, --

Methodics	Negative	Total
ALEGRIA, Orgentec	3	3
EliA Phadia, Thermo Fisher	2	2
ELISA, DIESSE Chorus	1	1
ELISA, Euroimmun	2	2
ELISA, Inova	1	1
ELISA, Orgentec	1	1
Euroline, Euroimmun	5	5
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	9	9
IFA, Inova	5	5
IFA Kallestadt, Bio-Rad	2	2
Microblot-Array Liver-Profile, TestLine	1	1
Total	33	33

Sample S001 | PCA, --

Methodics	Negative	Total
ALEGRIA, Orgentec	2	2
EliA Phadia, Thermo Fisher	5	5
ELISA, Euroimmun	2	2
ELISA, Inova	2	2
ELISA, Parietalcell-Ab, IBL	1	1
Euroline, Euroimmun	1	1
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	6	6
IFA, Inova	2	2
IFA Kallestadt, Bio-Rad	2	2
Total	24	24

Sample S002 | LKM, --

Methodics	Negative	Borderline	Positive	AMA interferes interpretation	Total
ALEGRIA, Orgentec	2	-	-	-	2
ELISA, Diesse Chorus	1	-	-	-	1
ELISA, DRG Diagnostics	-	-	1	-	1
ELISA, Euroimmun	2	-	-	-	2
ELISA, Inova	2	-	-	-	2
Euroline, Euroimmun	6	1	-	-	7
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	-	-	-	1
IFA, Euroimmun	8	-	-	-	8
IFA, Inova	1	-	-	2	3
IFA Kallestadt, Bio-Rad	2	-	-	-	2
Microblot-Array Liver-Profile,TestLine	1	-	-	-	1
Total	26	1	1	2	30

Sample S002 | SMA, --

Methodics	Negative	Total
ELISA, Inova	1	1
Euroline, Euroimmun	2	2
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	14	14
IFA, Inova	5	5
IFA Kallestadt, Bio-Rad	2	2
Total	25	25

Sample S002 | AMA, --

Methodics	Positive	Total
ALEGRIA, Orgentec	3	3
EliA Phadia, Thermo Fisher	2	2
ELISA, Diesse Chorus	1	1
ELISA, Euroimmun	2	2
ELISA, Inova	1	1
ELISA, Orgentec	1	1
Euroline, Euroimmun	5	5
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	1
IFA, Euroimmun	9	9
IFA, Inova	5	5
IFA Kallestadt, Bio-Rad	2	2
Microblot-Array Liver-Profile, TestLine	1	1
Total	33	33

Sample S002 | PCA, --

Methodics	Negative	Positive	AMA interferes interpretation	Total
ALEGRIA, Orgentec	2	-	-	2
EliA Phadia, Thermo Fisher	5	-	-	5
ELISA, Euroimmun	2	-	-	2
ELISA, Inova	2	-	-	2
ELISA, Parietalcell-Ab, IBL	1	-	-	1
Euroline, Euroimmun	1	-	-	1
IFA, AESKU DIAGNOSTICS AESKUSLIDES rLKS	1	-	-	1
IFA, Euroimmun	3	1	1	5
IFA, Inova	1	-	1	2
IFA Kallestadt, Bio-Rad	2	-	-	2
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Report info

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External Quality Assessment Scheme

Autoimmune liver disease and gastric parietal cell 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 expected results were as follows:

Sample S001 (LQ717923011)

LKM-1-Ab	Negative
SMA	Weak positive
AMA	Negative
PCA (GPCA)	Negative

Sample S002 (LQ717923012)

LKM-1-Ab	Negative
SMA	Negative
AMA	Positive
PCA (GPCA)	Negative

Pre-test methods: Line blot: EUROLINE Liver Profile (IgG), Euroimmun (LKM-1 antibodies and AMA), IFA: Nova Lite Rat Kidney/Stomach, Inova (LKM-1 antibodies, SMA and AMA) and FEIA: Phadia EliA Parietal Cell antibodies (GPCA).

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 LKM, mitochondrial and parietal cell antibodies. The sample contained a low amount of smooth muscle antibodies and depending on the method and reference range the sample was interpreted as negative, borderline or positive and no consensus was reached. Since the clinical significance of low level SMA is doubtful. Thus, negative, borderline, weakly positive or positive at the lower end of the reference range are acceptable results.

The sample S002 was positive for mitochondrial antibodies and all participants correctly found these. In addition, a few laboratories reported LKM and parietal cell antibodies, which were not present. In immunofluorescence assays AMA can disturb the interpretation of LKM and parietal cell antibodies and cause false positive findings. However, on this round the incorrect LKM antibodies were reported using ELISA and line blot methods.

Exceptions

No consensus was reached for smooth muscle antibodies in sample S001, but negative, borderline, weakly positive or positive at the lower end of the reference range are acceptable SMA results.

End of report

2023-06-30

FINAL REPORT

Product no. 5930

Subcontracting: Sample pretesting

Samples sent	2023-05-09
Round closed	2023-06-02
Expected results	2023-06-07
Final report	2023-06-30

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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