LABQUALITY

External Quality Assessment Scheme

Proteins, electrophoresis
Round 1, 2023

Specimens
Please find enclosed 1 liquid human serum sample S001 and one lyophilized sample S002, each 1mL.

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
Protein, total
Albumin
Alfa-1-globulin
Alfa-2-globulin
Beta-1-globulin
Beta-2-globulin
Beta-globulins (total)
Gammaglobulin
M-component

Storage and use
Liquid sample S001 is stable for 30 days at +2 to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should not be returned to the original vial.

The lyophilized sample S002 is stored at + 2 … 8°C before use. Add 1 mL distilled or deionized water into sample and let stand for 30 minutes. Handle the sample in the same way as patient specimens and analyse it as soon as possible after reconstitution. Let the sample warm to room temperature before use. Sample is stable for 48 hours after reconstitution in + 2 … 8°C.

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 the protein fractions as % (please check that the sum is 100%), and as g/L units. Fill in total beta-globulins only if beta-1- and beta-2-globulins are not reported separately.

Please report also if there is a monoclonal fraction. Select “YES” or “NO”. If you perform the immunofixation please give the answers on the result form. The type of heavy chain can be selected the found immunoglobulin type (IgA, IgE, IgD, IgG, IgM) and for each of these the light chain type (kappa/lambda or kappa, free/lambda, free).

S001
LQ735423011

S002
LQ735423012

2023-02-20

INSTRUCTIONS

Product no. 2240
LQ735423011-012/DE, US

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 13, 2023**.

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

Only the analysis phase is accredited

Quality Management
ISO 9001:2015

LQ2240001|Sample S001

Immunofixation

Methodics	Findings	IgG
Helena Biosciences	Heavy chain	2
Sebia Hyrys/Hydrasys	Heavy chain	3
Sebia Capillarys	Heavy chain	◉ 10
All		**15**

Methodics	Findings	Kappa
Helena Biosciences	Light chain	2
Sebia Hyrys/Hydrasys	Light chain	3
Sebia Capillarys	Light chain	◉ 10
All		**15**

M-component

Methodics	M-component	Yes	No
Helena Biosciences	M-component	2	4
Sebia Hyrys/Hydrasys	M-component	4	9
Sebia Capillarys	M-component	◉ 14	25
Interlab Microtech	M-component		4
Seleo Miniphor	M-component		1
All		**20**	**43**

LQ2240002|Sample S002

M-component

Methodics	M-component	Yes	No
Helena Biosciences	M-component		6
Sebia Hyrys/Hydrasys	M-component		13
Sebia Capillarys	M-component	2	◉ 34
Interlab Microtech	M-component		4
Seleo Miniphor	M-component		1
All		**2**	**58**

Report info

Participants

80 participants from 16 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).

LQ2240001|Sample S001

Immunofixation

Methodics	Findings	IgG
Helena Biosciences	Heavy chain	2
Sebia Hyrys/Hydrasys	Heavy chain	3
Sebia Capillarys	Heavy chain	10
All		**15**

Methodics	Findings	Kappa
Helena Biosciences	Light chain	2
Sebia Hyrys/Hydrasys	Light chain	3
Sebia Capillarys	Light chain	10
All		**15**

M-component

Methodics	M-component	Yes	No
Helena Biosciences	M-component	2	4
Sebia Hyrys/Hydrasys	M-component	4	9
Sebia Capillarys	M-component	14	25
Interlab Microtech	M-component		4
Seleo Miniphor	M-component		1
All		**20**	**43**

LQ2240002|Sample S002

M-component

Methodics	M-component	Yes	No
Helena Biosciences	M-component		6
Sebia Hyrys/Hydrasys	M-component		13
Sebia Capillarys	M-component	2	34
Interlab Microtech	M-component		4
Seleo Miniphor	M-component		1
All		**2**	**58**

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LABQUALITY

External Quality Assessment Scheme

Proteins, electrophoresis
Round 1, 2023

Specimens
Sample S001 (LQ735423011) was a liquid human serum sample and sample S002 (LQ735423012) was lyophilized human serum sample.

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.

If you have not answered the question about finding the M-component, heavy/ light chains, then a summary report will appear as your laboratory's report. If you have replied, your own results are marked in the report with a radio button.

Comments – EQA Coordinator
Sample S002 has previously been in round 3–2022 as sample S002. The result level of this round corresponds very well to the result level of the previous round. Customers can check their laboratory-specific reports to see if their results match the results of that previous round. Most of the results were reported with the Sebia Capillarys method. The second most common method was Sebia Hyrys/Hydrasys. In these groups, the number of results was more than 12, while in other groups the number of results was less than 12. Statistical conclusions can be drawn from large groups.

In sample S002 beta-1 –, beta-2- globulins in Sebia Capillarys result levels, there are two or three main groups.

From sample S001, a total of 20 respondents reported that they found the M component and 43 reported that they did not. The type of finding was reported as heavy IgG chain (N=15) and light kappa chain (N=15). Sixteen customers reported the quantitative M-component result for sample S001. The average of all results is 1.3 g/L. A few respondents have commented that the amount of paraprotein in the sample was so small that it is detectable but quantitative result could not be reported.

In sample S002, a total of two respondents reported finding the M component and 58 respondents did not. The type of the finding was not reported at all. The quantitative M-component result for sample S002 was reported by two customers. One of the respondents commented on his result as a suspected M protein in the beta-2 fraction, but there is no reaction to any antibody in the fraction.

End of report

2023-03-16

FINAL REPORT

Product no. 2240

Samples sent	2023-02-20
Round closed	2023-03-13
Final report	2023-03-16

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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Only the analysis phase is accredited.

Quality Management
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