External Quality Assessment Scheme

Anti-Müllerian Hormone Round 1, 2023

Specimens

Please find enclosed 2 serum samples S003 and S004, each 1 mL. Samples are liquid human serum pools without preservatives.

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

Anti-Müllerian Hormone

Storage and use

Samples S003 and S004 are ready for use. Please analyse the samples as soon as possible. If you analyse the samples later than on the day of the sample arrival, please freeze immediately (-20 °C). Please, avoid several freeze-thaw cycles. A little before analysing, thaw and mix the samples well. 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 Coordinator.

S003



S004



2023-02-13

INSTRUCTIONS

Product no. 2703 LQ741223013-14 /FI

Subcontracting: Sample preparation

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 7, 2023**.

Inquiries

Coordinator
Ulla Tiikkainen
ulla.tiikkainen@labquality.fi

Labquality Oy

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

info@labquality.fi www.labquality.com



21/02

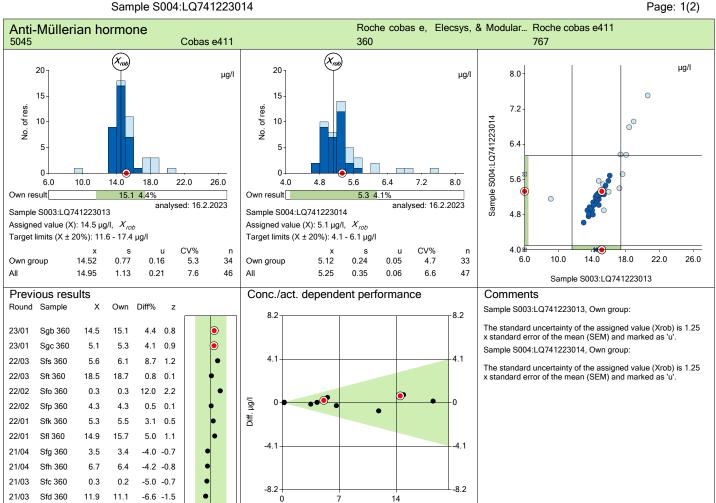
Sey 360

3.5

3.4

-2.0 -0.4

-20% x +20%



Conc./act. µg/l

Laboratory: XXXX

Powered by Innovatics 31.3.2023 © Labquality 2023

Sample S003:LQ741223013 Anti-Müllerian hormone 2023/1 Sample S004:LQ741223014

Laboratory: XXXX Page: 2(2)

Report info

Assigned value (target value) calculation and its uncertainty

Your own result should be compared to others using the same method.

The assigned values (Xrob) are calculated according to the robust procedure described in the standard ISO 13528 (Statistical methods for use in proficiency testing by interlaboratory

comparisons, Annex C, Algorithm A).

The standard uncertainty of the assigned value is expressed as 1.25 x the standard error of mean (SEM) and marked as "u" in numerical summary. Due to its iterative mode algorithm A adds the uncertainty of the assigned value and with this factor we want to adjust uncertainty accordingly.

In case there are 2-12 results in a method group, the robust calculation is not used but assigned values (Xpt) 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 too large (u > 0.1 * maximum allowable error) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

Please notice also that for groups that have only 1 result only the client's own result is shown. No target value (except for reference method values) is calculated, no target areas are

In case there are 2-5 results in a method group, no z-score is calculated, and a text is printed on the report: "Due to the small number of results, the z score is not calculated." In case there are 6-12 results, the report has a text: "Z score is uncertain due to the small number of observations.

Results reported with < tai > -signs cannot be included in the statistics.

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

31.3.2023 © Labquality 2023 Powered by Innovatics

NUMERICAL SUMMARY

Anti-Müllerian hormone 2023/01

Analyte Method group	х	med	S	CV%	u	Min	Max	Number
Sample S003:LQ741223013								
- Anti-Müllerian hormone, μg/l								
Beckman Coulter Access & Unicel	15.04	15.0	0.37	2.4	0.26	14.8	15.3	2
Beckman Coulter AMH Gen II ELISA	20.59	20.6	-	-	-	-	-	1
bioMerieux Vidas	16.55	16.6	1.05	6.3	0.52	15.4	17.6	4
Roche cobas e, Elecsys, & Modular E	14.52	14.5	0.77	5.3	0.16	13.0	16.1	34
Siemens Advia Centaur & Atellica	16.96	17.4	1.33	7.9	0.77	15.5	18.0	3
Snibe Diagnostic Maglumi	18.66	18.7	0.37	2.0	0.26	18.4	18.9	2
AII	14.95	14.8	1.13	7.6	0.17	13.0	20.6	46
Sample S004:LQ741223014								
Anti-Müllerian hormone, µg/l								
Beckman Coulter Access & Unicel	5.53	5.5	0.06	1.0	0.04	5.5	5.6	2
Beckman Coulter AMH Gen II ELISA	7.51	7.5	-	-	-	-	-	1
bioMerieux Vidas	5.37	5.4	0.32	6.0	0.13	4.9	5.7	6
Roche cobas e, Elecsys, & Modular E	5.12	5.2	0.24	4.7	0.05	4.6	5.7	33
Siemens Advia Centaur & Atellica	5.91	6.2	0.45	7.6	0.26	5.4	6.2	3
Snibe Diagnostic Maglumi	6.86	6.9	0.09	1.3	0.06	6.8	6.9	2
All	5.25	5.3	0.35	6.6	0.05	4.6	7.5	47

Participants

48 participants from 19 countries.

Report info

Assigned value (target value) calculation and its uncertainty

Your own result should be compared to others using the same method.

The assigned values (Xrob) are calculated according to the robust procedure described in the standard ISO 13528 (Statistical methods for use in proficiency testing by interlaboratory comparisons, Annex C, Algorithm A).

The standard uncertainty of the assigned value is expressed as 1.25 x the standard error of mean (SEM) and marked as "u" in numerical summary. Due to its iterative mode algorithm A adds the uncertainty of the assigned value and with this factor we want to adjust uncertainty accordingly.

In case there are 2-12 results in a method group, the robust calculation is not used but assigned values (Xpt) are means of the results where results deviating more than \pm -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 too large (u > 0.1 * maximum allowable error) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

Please notice also that for groups that have only 1 result only the client's own result is shown. No target value (except for reference method values) is calculated, no target areas are shown.

Z score

In case there are 2-5 results in a method group, no z-score is calculated, and a text is printed on the report: "Due to the small number of results, the z score is not calculated." In case there are 6-12 results, the report has a text: "Z score is uncertain due to the small number of observations."

Results reported with < tai > -signs cannot be included in the statistics.

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

External Quality Assessment Scheme

Anti-Müllerian Hormone Round 1, 2023

Specimens

Sample S003 (LQ741223013) and sample S004 (LQ741223014) were unprocessed human sera spiked with sera having elevated levels of AMH. No preservatives were added.

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.

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.

Comments - Expert

The mean concentrations of AMH whether produced by bioMerieux or Roche are close to each other (samples S003, S004) and the CV% satisfactory. In other analyzer groups, due to the small number of participants in the round, a statistical analysis is not meaningful (even one biased result may change the overall performance dramatically). You may want to compare the minimum and maximum values.

End of report

2023-04-20

FINAL REPORT

Product no. 2703

Subcontracting: Sample preparation

 Samples sent
 2023-02-13

 Round closed
 2023-03-07

 Final report
 2023-04-20

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

Coordinator
Ulla Tiikkainen
ulla.tiikkainen@labquality.fi

Expert

MD, Ph.D Specialist in Clinical Chemistry Anna Lempiäinen

Labquality Oy

Kumpulantie 15 FI-00520 HELSINKI Finland

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

info@labquality.fi www.labquality.com



Copyright © Labquality Oy.

Labquality does not permit any reproduction for commercial purposes of any portion of the material subject to this copyright. Labquality prohibits any use of its name, or reference to Labquality EQA program, or material in this report in any advertising, brochures or other commercial publications. Labquality EQA data do not necessarily indicate the superiority of instruments, reagents, testing equipment or materials used by participating laboratories. Use of Labquality EQA data to suggest superiority or inferiority of equipment or materials may be deceptive and misleading. Proficiency test results are handled confidentially. Labquality will not issue any statements to third parties of the performance of laboratories in external quality assessment schemes unless otherwise agreed.