LABQUALITY

External Quality Assessment Scheme

Salivary cortisol
Round 1, 2023

Specimens
Please find enclosed 2 lyophilized artificial saliva samples S001 and S002, á 1 mL.

Caution
Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The artificial specimens have not been tested for HIV, HCV and HBV.

Examinations
Salivary cortisol

Storage and use
Lyophilized samples are stored at +2 …8 °C after arrival. The lyophilized samples are stable until the closing date of the round.

Please be ready to analyze the samples immediately after the reconstitution.

Add 1 mL of distilled or deionized water to the vial. Let the vial rest for 5 minutes at room temperature and vortex for about 30 seconds until complete homogenization has been achieved. Use immediately after reconstitution.

Analyze all three samples 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

LQ741423011

S002

LQ741423012

Salivary cortisol |Cobas 6000

S001-Salivary cortisol

The uncertainty of the assigned value is not negligible, and evaluations could be affected.
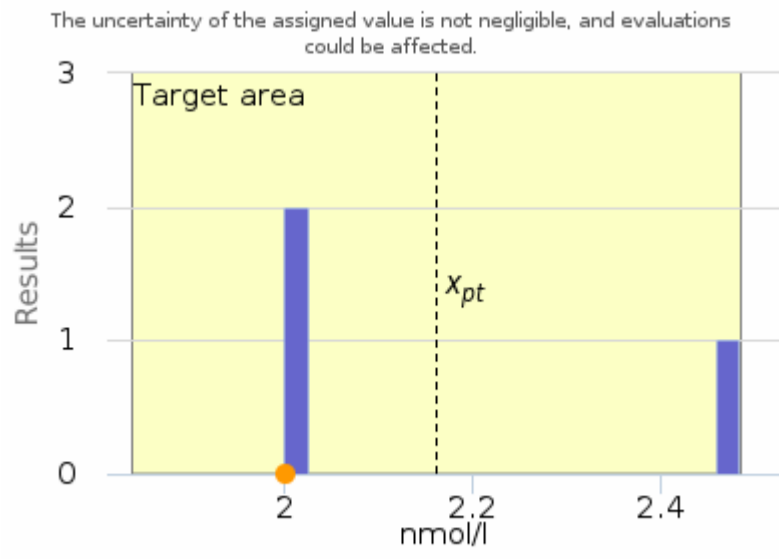
- All method groups
- Roche cobas/Elecsys Cortisol II
- Own result: 2.00 (05.05.2023)
- **Diff%: -7.45 | x_{pt}: 2.16**
- **Target area: 1.84-2.49 | Target: ±15%**

S002-Salivary cortisol

The uncertainty of the assigned value is not negligible, and evaluations could be affected.
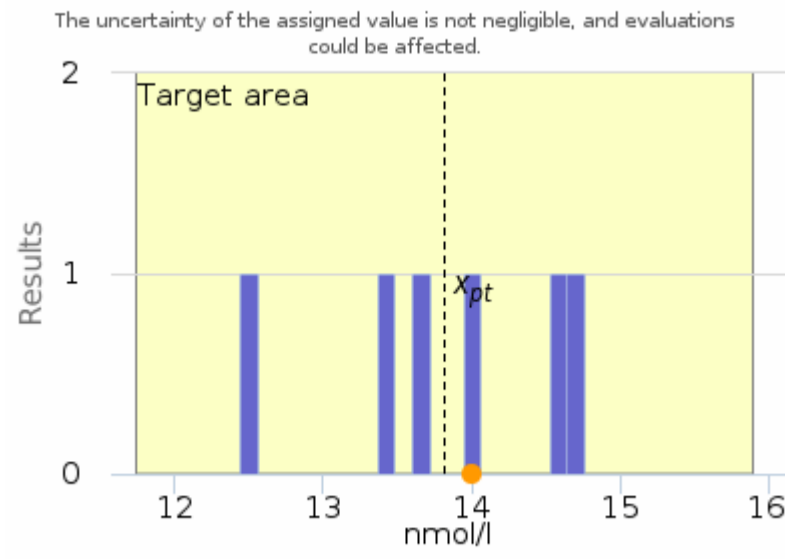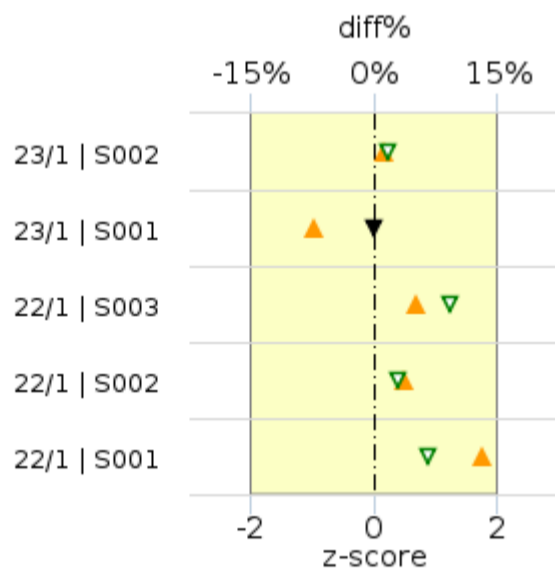

- All method groups
- Roche cobas/Elecsys Cortisol II
- Own result: 14.00 (05.05.2023)
- **Diff%: 1.34 | x_{pt}: 13.81**
- **Target area: 11.74-15.89 | Target: ±15%**

	x_{pt}	sd	SEM	CV%	n
Roche cobas/Elecsys Cortisol II	2.16 nmol/l	0.28	0.16	12.9	3
All methods	2.16 nmol/l	0.28	0.16	12.9	3

	x_{pt}	sd	SEM	CV%	n
Roche cobas/Elecsys Cortisol II	13.81 nmol/l	0.85	0.35	6.1	6
All methods	13.81 nmol/l	0.85	0.35	6.1	6

History

- ▲ 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	13.81	14.00	1.34%	0.22
23/1	S001	2.16	2.00	-7.45%	-
22/1	S003	14.14	14.88	5.23%	1.24
22/1	S002	4.49	4.65	3.61%	0.38
22/1	S001	2.01	2.28	13.20%	0.86

Report info

Participants

7 participants from 6 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).

LABQUALITY

S001 | Salivary cortisol, nmol/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Roche cobas/Elecsys Cortisol II	2.16	2.00	0.28	12.9	0.16	2.00	2.48	-	3
All	**2.16**	**2.00**	**0.28**	**12.9**	**0.16**	**2.00**	**2.48**	**-**	**3**

S001 | Salivary cortisol, nmol/l| histogram summaries in LabScala
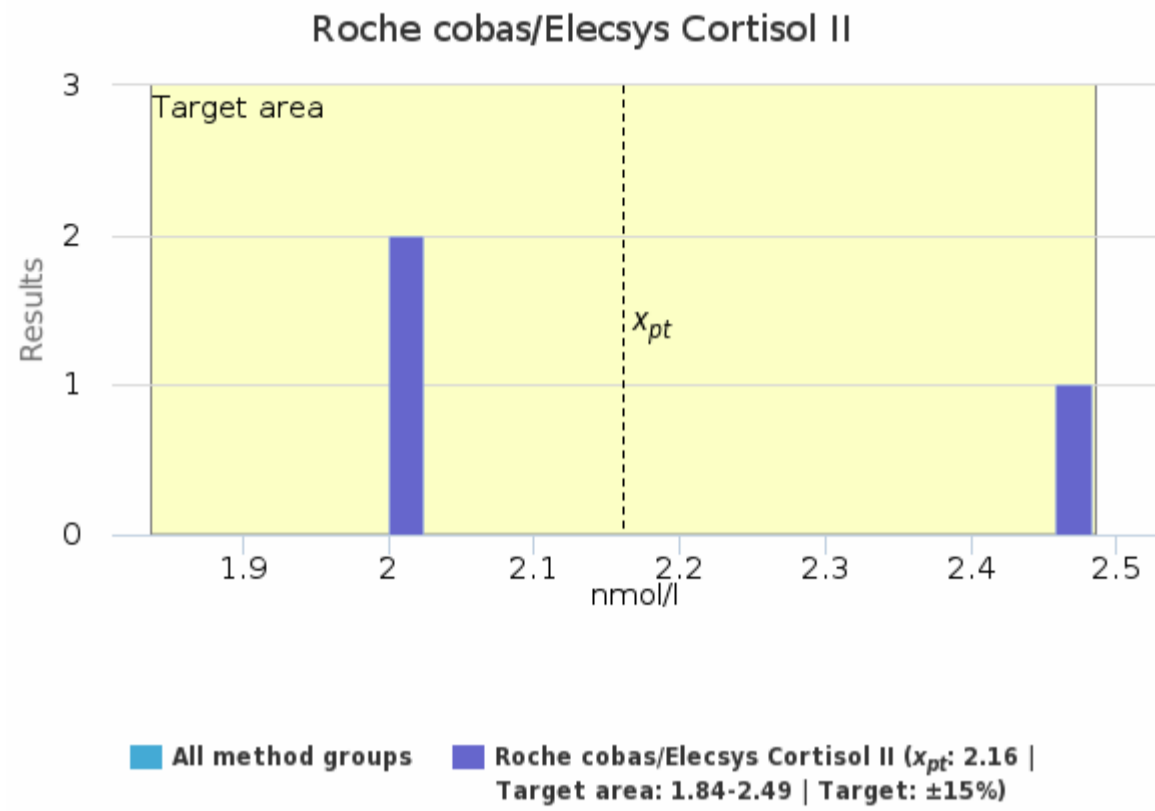
All method groups | Roche cobas/Elecsys Cortisol II (x_{pt}: 2.16 | Target area: 1.84-2.49 | Target: ±15%)

LABQUALITY

S002 | Salivary cortisol, nmol/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Roche cobas/Elecsys Cortisol II	13.81	13.83	0.85	6.1	0.35	12.44	14.76	-	6
All	**13.81**	**13.83**	**0.85**	**6.1**	**0.35**	**12.44**	**14.76**	**-**	**6**

S002 | Salivary cortisol, nmol/l| histogram summaries in LabScala

Roche cobas/Elecsys Cortisol II

■ All method groups ■ Roche cobas/Elecsys Cortisol II (x_{pt}: 13.81 | Target area: 11.74-15.89 | Target: ±15%)

Report info

Participants

7 participants from 6 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).

LABQUALITY

External Quality Assessment Scheme
Salivary cortisol
Round 1, 2023

Specimens
Sample S001 (LQ741423011) and sample S002 (LQ741423012) were lyophilized artificial saliva samples.

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 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 – EQA Coordinator
Measurement of salivary cortisol level may be the optimum test for the diagnosis of Cushing syndrome which is characterized by increased salivary cortisol levels. The sample for this diagnostic purpose shall be collected between 11 pm and midnight for the analysis. Normal level is below 2.8 nmol/L[1].

The level of sample S001 represents a normal level (Xpt = 2.16 nmol/L). Seven results were reported of which one result from Roche was <1.49 nmol/L (<0.54 ng/mL) and two results from Roche were reported to be 1.49 nmol/L. They were excluded from the statistics because they were much lower than the other Roche results and they may be <1.49 nmol/L without the < mark. Xpt of the Roche group was calculated using only three results. Also, one result (7.22 nmol/L = 2.62 ng/mL) was reported using Eiken method. The original value was reported as ng/mL which would have been close to Roche result level. The result was excluded from the calculation, and it was commented that the client shall check their original result if they have reported their result in correct unit in Labscala.

Sample S002 represents an elevated concentration (Xpt = 13.81 nmol/L). All six results in Roche method group agree well with each other. Also, one result (59.6 nmol/L = 21.598 ng/mL) using Eiken was reported and excluded from calculation with the same comment as the S001 result.

The round went very well, and the results of both samples are as expected.

References
[1] Mayo Clinic Laboratories, Salivary cortisol
https://www.mayocliniclabs.com/test-catalog/Overview/84225#Clinical-and-Interpretive

End of report