

PROFICIENCY TEST

QUALINOVA FOOD

REPORT OF RESULTS

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REPORT OF RESULTS



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ROUND: XX-XXXXX



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REPORT OF RESULTS

Dear Participant:

We are pleased to introduce you the report of results, Round XX XXXXX of Proficiency Test where you have participated.

A total of XX laboratories have participated in this exercise.

Analyses of the results and the statistical treatment have been carried out on the supplied data by the participants in computerized form, which have not been manipulated in any way.

1. INTRODUCTIÓN

Proficiency Tests of QUALINOVA's programme are responsibility of Labnova Distribuciones SL. Each Proficiency Test is independently of each other so, it is not necessary to sign up a minimum number of rounds. The general structure of each of the Proficiency Test included in the program is as follows:

- The organization of Qualinova takes responsibility for preparing and distributing the samples in a homogeneous way. Each sample shall be identified by a label with the code of Proficiency Test and if necessary, an instruction sheet to make the corresponding analysis. You have to treat the sample according to the instructions on the sheet.
- Qualinova sends to the participants an email notice with the shipping date of the sample and with the instructions given in the previous section upon the material is sent.
- You can make all proposed analysis or only a part of them in each Proficiency Test.
- Participating laboratories will register the results obtained through the website <u>www.labnovasl.com</u> Proficiency Test tab, registering with the username and password provided by the organization.
- It is important that in value entered there must be not thousands separators and, decimals are separated by a dot (.) Microbiology results should be expressed in units requested, but without expressions like 7XEO3 or the tenth power. Results should be whole number without decimals: 7000, 1000000 etc.
- Each laboratory must indicate method of analysis used in the box of the registration form results.
- Upon all results are receives, the organization of Qualinova makes the statistical data treatment and prepare a final report of each Proficiency Test.
- Participating laboratories receive the report of results where the quality of their results is evaluated. Every participant will be identified by a code, which is only known by the laboratory, so the confidentiality of results is guaranteed. This code is indicated in the custom report which accompanies the general report to each laboratory.

2. DEFINITIONS

Assigned value (X_{PT}). Reference value expected in each parameter analyzed. It is obtained by consensus, through the robust mean of the results obtained by the participants in each parameter analyzed.

Robust mean (X^{*}). Average on all the values by applying robust techniques that minimize the effect of extreme values. In general this value is obtained by applying winsorisation by Huber H15 method.

Robust standard deviation (S[°]). Value of the dispersion of results for the year calculated using robust techniques to minimize the effect of extreme values. It is obtained by Huber H15 system. These values are obtained by Robust Statistics Toolkit software application, of the Royal Society of Chemistry.

Target standard deviation (σ_{PT}). Value of the appropriate dispersion for the proficiency in each parameter. This value is estimated as follows:

- If there is a legal tolerance for the parameter, the value is used.



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- If there is not that tolerance, the estimated deviation by the Horwitz equation modified by Thomson is used. This value is obtained starting from dimensionless units and is independent of the deviation of the exercise. This equation is based on the following values:

1. If the assigned value $(X_{PT}) < 120 \text{ ppb}$:

 $\sigma_{PT} = 0,22 * X_{PT} / m$

2. Si 120 ppb < assigned value (**X**) < 13,8%:

 $\sigma_{PT} = 0.02 * X_{PT}^{0.8495} / m$

3. If the assigned value (**X**) > 13,8 %:

 $\sigma_{\rm PT} = 0.01 * X_{\rm PT}^{0.5} / {\rm m}$

Where **m** is the dimensionless parameter value in question (1 ppm = 10^{-6} , % = 10^{-2} , etc.).

- In microbiological tests is estimated like σ_{PT} the value of 0,25 in logarithmic scale, except in Legionella determinations where 0,35 will be used.

- In some specifics determinations are used target deviation fit-for-purpose, that is, appropriate to the range and variability of each parameter.

Uncertainty of the assigned value (\mu_x). Uncertainty associated to the calculation method of assigned value. If it is obtained by consensus and through the robust statistical, the calculation formula is as follow:

$$J_x = 1,25 * S^* / \sqrt{n}$$
 (Ref.: Standard ISO 13528:2015, point 7.7.3)

Where n is the number of participants of the round.

If $\mu_x > 0.3 \ x \ \sigma_{PT}$, then the value calculated to assess the outcome of each laboratory is not Z, but Z', as explained below.

3. HOMOGENEITY AND STABILITY

Samples have been subjected to a preliminary test of homogeneity and stability that has been successful for use in proficiency test.

4. STATISTICAL ANALYSIS

The main measure of laboratories participating in a proficiency test is the veracity of each outcome, as measured by the difference between the value obtained by the laboratory and the value set as the assigned value or reference.

In order to minimize the effects on robust statistics for atypical values, are not taken into account the values outside the range of the median value \pm 50%, though they are then apply the calculation to obtain its value z corresponding -score. These securities will be highlighted in blue boxes.

To verify possible multimodality test, a kernel estimate is calculated using as value $h = \sigma p * 0.75$. In case of appears a multimodal distribution. not assigned values or robust deviation of proficiency test.

5. QUANTITATIVE TESTS

The assigned or reference value (X) for determinations analyzed in the QUALINOVA Program is established from the robust mean of all results submitted by participating laboratories (X_a).

In order to evaluate the results obtained by each participating laboratory, it is used the statistical parameter **Z-score**, which is ael cual es una medida de las desviaciones de los resultados frente al valor asignado (X). This Z-score is calculated as:

Z-score =
$$\frac{(Xi - Xa)}{\sigma_p}$$
 (Ref.: Standard ISO 13528:2015, point 9.4.1)



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If $\mu_x > 0.3 * \sigma_p$

Z'-score =
$$Xi - Xa / \sqrt{\sigma_p^2 + \mu_x^2}$$

(Ref.: Standard ISO 13528:2015, point 9.5.1)

Being σ_p the target standard deviation, this considers adequate dispersion of results in each parameter, and μx uncertainty of the assigned value.

Finally, the quotient is calculated I = μ_x^2 / σ_{PT}^2 :

- If I < 0.1, the z-score is suitable
 - If 0.1 < I < 0.5, el z-score is considered informative
- If I > 0.5, z-score is not calculated in this test.

(Ref: IUPAC 2006, International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories)

The acceptance criteria of **Z-score** and **Z'-score** are the next:

Satisfactory	z <2
Questionable	$2 \leq z \leq 3$
Unsatisfactory	z ≥ 3

6. REFERENCES.

1. Eurachem guide on selection, use and interpretation of PT schemes. Ed. 1.0 (2000).

2. ILAC-G13:2000. Guidelines for the requirements for the competence of providers of proficiency testing schemes.

3. **IUPAC 2006:** International harmonized protocol for the proficiency testing

4. ISO 13528:2015 "Statistical methods for use in proficiency testing by interlaboratory comparisons".

5. UNE-EN ISO/IEC 17043:2010 "General requirements for proficiency testing"

6. Thomson, Michael: Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. The Analyst communication. January 2000

7. Huber, P. J. (1981). Robust Statistics, Wiley, N. Y.



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7. EXPLANATION OF THE REPORT OF RESULTS.

For each suggested result in the proficiency test, results are given following the next scheme:

Parameter toUnits	determinate		
Code assigned to each laboratory	Parameter value for each laboratory	Z of each laboratory	Method applied
Value out of Value with Z Robust mean of all mea Robust standard deviat Target deviation of the Uncertainty of the assig	$ \\ median \pm 50\%. \\ score > 2 \\ asures of laboratories.(× tion (S°) \\ parameter (\sigma_{PT})gned value (\mu_x)COMMENTARY of re$	(⁽) sults of each parameter	
G	GRAPHIC OF Z – SCORI	E OF ALL LABORATORI	ES

8. DATA AND RESULTS.

Sample data	
Description	
Homogenization	
Package	
Distribution	
Date	