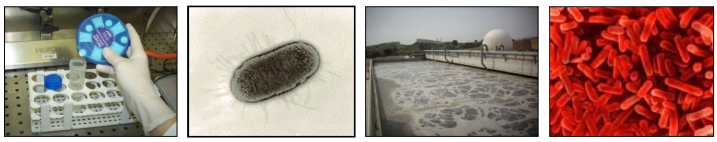


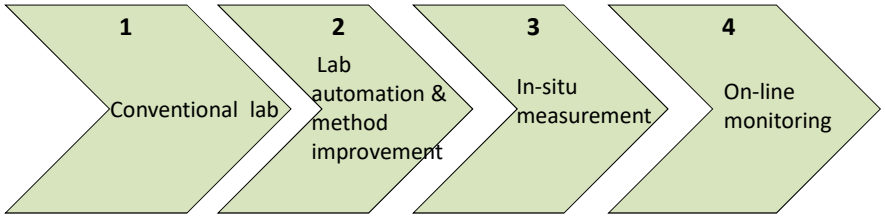

Importance of Interpretative Proficiency Testing Schemes

Eurachem Workshop October-2017

Mission of a laboratory

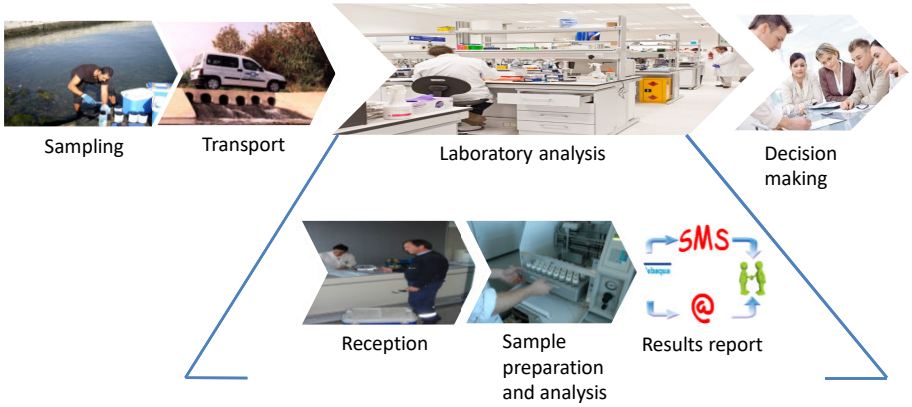
- To respond to industry needs for **analytical services** using creativity, flexibility, production depth and **technical expertise** in performing simple or complex analyses with total focus on **customer satisfaction** and **quality** workmanship.
- To provide the food and feed industry with independent laboratory **analytical services** that are the **highest quality** achievable, **accurate and timely** while also meeting or exceeding our **client's expectations**.
- Focusing every day, every project, every sample, and every analysis on earning our **customer's trust** and respect.
- To provide a high level of **analytical precision**, **quality**, and **accuracy**, with **timely results**, to every client, for every sample tested.
- To provide customers with **efficient**, **reliable** and **high quality analytical services**.

Evolution of laboratories

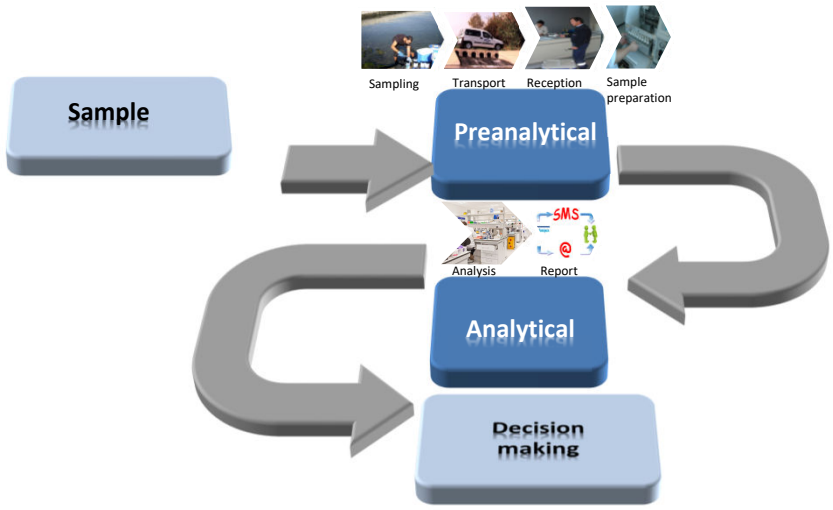


Analytical workflow

Current quality control workflow in a conventional lab…….



Analytical workflow



Sampling PTS

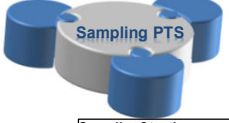
✓ **Internal quality control**
- ❑ Assessment between analysts
- ❑ Sampling guidelines
- ❑ Internal audits

✓ **External quality control:** proficiency testing schemes

Guidelines for the application of ISO/IEC 17043 for the organization of proficiency testing for sampling

Only sampling
Assessed by scoring or by an audit process

Sampling&testing
The test is performed in a single laboratory

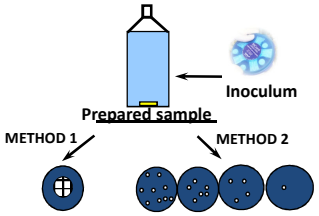


Sampling&testing
Sampling and testing performed by the participant

Requirements for the competence of testing laboratories

ISO 17025. Section 5.9
"The laboratory must have quality control procedures in order to asses the validity of the assays and the calibrations that are performed".

✓ **Internal quality control**
- ❑ Assessment between analysts
- ❑ Control process (Reference materials)
- ❑ Routine control charts



✓**External quality control:** proficiency testing schemes

Importance of PTS Management:

- Samples preparation
- Shipment to participants
- Exploitation and interpretation of results

Requirements for the competence of testing laboratories

LABAQUA

Analysis report

GENERAL DATA
REPORT Nº: 2011319
ANALYSIS Nº: 3802520
APPLICANT: [redacted]
ADDRESS: [redacted]
TOWN: [redacted]
SAMPLE DENOMINATION: Cobamamide. Ref 6104027. Lote A17180L
SAMPLE DESCRIPTION: Container(1), containing APIs
RECEIPT DATE: 30/03/2017
END AND SUBMIT DATE 5/04/2017

Analysis performed In LABAQUA; C/ Dracma,16-18- Pol. Ind. Las Atalayas 03114 ALICANTE - Tel. +34 965 10 60 70 - Fax +34 965 10 60 80:
Start analysis date 30/03/2017.

PARAMETERS	METHODS	RESULTS	UNITS
Metals			
Arsenic	MAD-E-PE-0119	<0.04	mg/Kg
Cadmium	A-D-PE-0026-1 Metals ICP-MS	< 0.05	mg/Kg
Lead	A-D-PE-0026-1 Metals ICP-MS	< 0.05	mg/Kg
Mercury	A-D-PE-0005 Atomic Fluorescence	< 0.01	mg/Kg

INFORMATION SUBMITED BY THE CLIENT
SAMPLING DATE: 29/03/2017

This report must not be partially reproduced, except with the prior written permission of the emitting laboratory

Validated in Labaqua Alicante by Technical Expert: Mercedes Berjano Guillán, Technical Director: Francisco García Andreu.

Electronically signed report in its digital format. Authenticity verifiable using the root certificate from the Fábrica Nacional de Moneda y Timbre

Issued in ALICANTE, 5 April of 2017

ENAC
ENSAYOS
Nº109/LE285

LABAQUA

Analysis report

* The marked activities in this report are not included in the accreditation scope of the laboratory.

GENERAL DATA
REPORT Nº: 2089732
ANALYSIS Nº: 3940448
APPLICANT: [redacted]
ADDRESS: [redacted]
TOWN: [redacted]
SAMPLE DENOMINATION: ANALISIS COMPLETO AGUA POTABLE 20/07/17
SAMPLE DESCRIPTION: 1L sterile container(3), containing potable water
RECEIPT DATE: 21/07/2017
END AND SUBMIT DATE 10/08/2017

Analysis performed in LABAQUA. Tests covered by ENAC accreditation nº 109/LE285; C/ Dracma,16-18- Pol. Ind. Las Atalayas 03114 ALICANTE - Tel. +34 965 10 60 70 - Fax +34 965 10 60 80:
Start analysis date 21/07/2017.

PARAMETERS	METHODS	RD 140/2003	RESULTS	UNITS
Organoleptics characters				
Colour	A-A-PE-0032 Multiparametric probe	15	< 1.0	mg/L Pt/Co
Odor	EN 1622:2007 Simplified method	3 a 25ºC	Non abnormal odour	Ind. de dil.
Taste	EN 1622:2007 Simplified method	3 a 25 ºC	Non abnormal taste	Ind. de dil.
Turbidity	A-A-PE-0032 Multiparametric probe	5	< 0.20	UNF
Physical and chemical constituents				
Ammonium	A-C-PE-0023 Espectrofotometría absorción	0.5	< 0.05	mg/L
Conductivity at 20ºC	A-A-PE-0032 Multiparametric probe	2500	848	µS/cm
* Dissolved solids	A-F-PE-0018 Gravimetry		594	mg/L
Free Residual Chlorine	A-C-PE-0018 Absortion spectrophotometry	1.0	< 0.05	mg/L

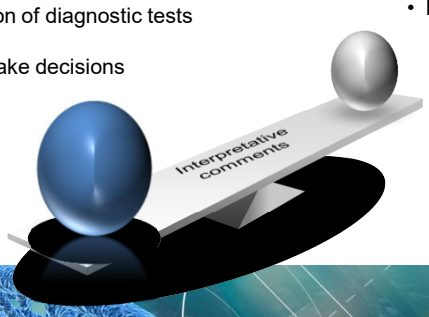
In many fields interpretative comments are:
(i) key,
(ii) can help customer making decisions based on results and
(ii) hence add value to laboratory reports

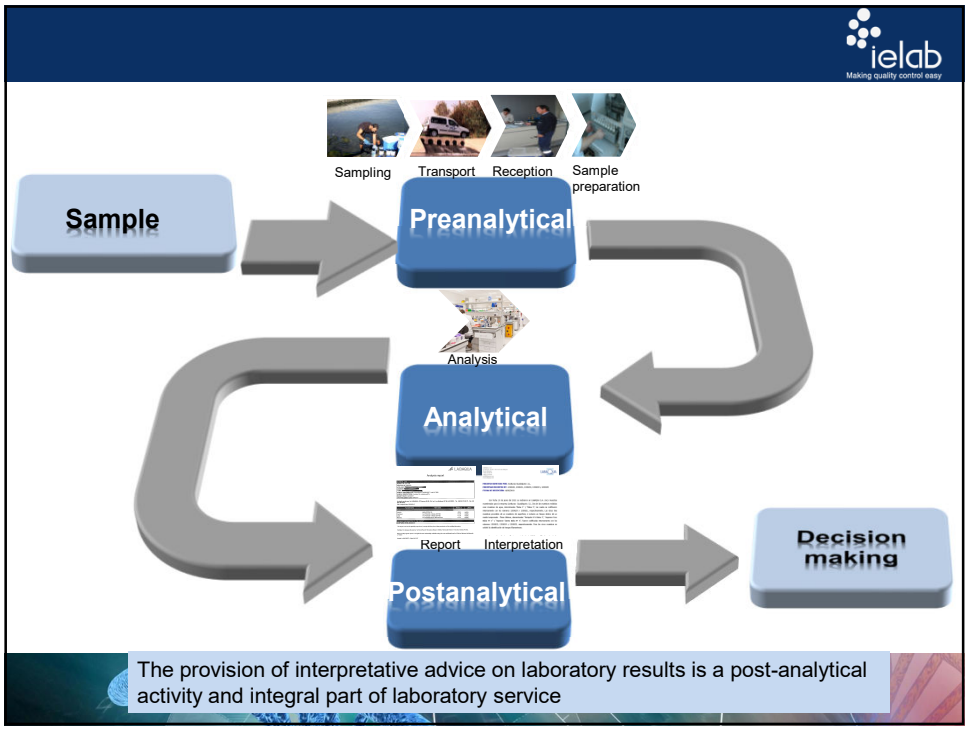
Benefits:

- Interpretation of complex data
- Avoid misinterpretation of diagnostic tests
- Uncommon tests
- Help customers to make decisions

Risks:

- Incorrect interpretation
- Delay the release of results





The provision of interpretative advice on laboratory results is a post-analytical activity and integral part of laboratory service

The laboratory is responsible of assuring the quality of all the phases of the analytical workflow:

Assuring the quality of interpretative comments:

A. Proven knowledge in, and experience of, providing accurate interpretative comments in respect of the tests being validated is required.

For junior staff, this should form part of their competency assessment while under supervision.
For senior staff, this could be by formal peer assessment and demonstration of continuous professional development.

B. Participation and satisfactory performance in an interpretative comments PT scheme.

A. Evidencing personal proficiency:

- Documentating scope of working
- Demonstrating proficiency in knowledge
- Demonstrating continuing learning and scientific and professional developmen
- Evidence of service quality improvement or innovation
- Evidence of effective leadership or teamwork
- Demonstrating of valued teaching or trainee supervision
- Feedback from colleagues, other staff and service users
- Complaints and compliments

Chartered status that recognizes the well-developed skills, knowledge and professionalism of those working in a specific scientific field

B. Interpretative Proficiency Testing Schemes

ISO 15189. *"External quality assessment programmes should , as far as posible, provide clinically relevant challenges….that check the entire examination process including pre- and postexamination procedures"*

ISO 17043. (Annex B.3.2.1 and B.3.2.2). There is not a clear reference to interpretative PTS, but some scoring is included for qualitative and semi-quantitative items

Interpretative PT schemes

Scope of assessment:

- No measurement is involved
- Simulated reports or clinical cases
- Samples with clinical information

Participants:

- Complementary to analytical PTS and would be aimed at individual assessement rather than laboratory asessement

Distribution:

- Web-based presentation or sample distribution .
- Deadline. Common a word or character limit.
- Questionnaries
- There is no agreement on no. cases per round or frequency of distribution (10 cases/year can be considered a mínimum and 24 cases/year a maximum

Assessment of comments:

- Performed by an assessor/peer-review panel.
- No. of assessors?
- Qualifications and experience should be specified
- If more than a panel is needed, measures should be put in place to minimize bias
- Panel members should be moniteored over time and compared with other members

Methods of asessment:

It is required a marking panel prepared and agreed upon in advance.

ISO 17043. (Annex B.3.2.1 and B.3.2.2)
Qualitative data evaluated by expert consensus
Ordinal scale divided into a five-point scale
5-very good; 4- good; 3-satisfactory, 2- unsatisfactory, 1- poor.

Proposed marking scale

Provider A

Score	Interpretation	Definition
5	Optimal	Identical interpretation as the panel leading to optimal diagnosis and/or follow-up
4	Good	A similar interpretation that would lead to the optimal or acceptable diagnosis and/or follow-up
3	Neutral	A different interpretation that may not contribute to diagnosis of follow-up, but no harm either
2	Unsatisfactory	A different interpretation that will lead to an inadequate diagnosis and/or follow-up
1	Poor	A different interpretation that will lead to a major diagnostic error and/or inapropriate follow-up

Proposed by Vasikaran et al. 2016

- The panel should provide an “ideal” or “suggested” comment (assigned value)
- Assessment done individually by each panel member and the mean score calculated
- Alternatively, marking by consensus by the panel as a whole require a meeting

- Report for the feedback to be educationally effective
- Performance of participants over time with individual reports
- Annual review
- Minimum standard of performance should be established including a mínimum rate
- and mean score

Provider B

They evaluate 3 criteria:

A	Analytical performance	Correct results	2
		Partially correct	1
		Unsatisfactory or misleading	0
I	Interpretative proficiency	Good	2
		Helpful but incomplete	1
		Misleading/wrong diagnosis	0
R	Recommendations for further investigations	Helpful	1
		Unsatisfactory or misleading	0

Scores assigned by the Scientific Advisor and agreed at the anual meeting reviewed by and independent advisor.

Provider C

A scenario and a clinical question are presented.

Marks are awarded for giving added value

Score	Interpretation
+3	Strong, well worded answer and expressed in a clear way
+2	Adding more value
+1	Adding more value
0	Adding nothing
-1	Deemed to be wrong or misleading

- Marks are awarded by a number of individual assessors and an average “Participang Case Mark” (PCM) is reported back
- An average “Participant Time-Window Score” (PTS) is calculated
- The report contains a summary of the background and outcome of the case together with some examples of high, average and low marks.

Provider D

The following aspects of EQA submissions are scored:

•**Analysis:** Scoring of the quality of submitted analysis and written description
•**Interpretation:** Scoring of submitted reports for interpretation of the results, including clinical advice and follow-up studies.
•**Clerical** Accuracy: Scoring the report contents and clerical accuracy of submitted reports. The Clerical Accuracy is not included when determining a laboratory's performance.

The overall marking criteria for the different EQAs have been agreed by the relevant Specialist Advisory Group (SAG) and are tailored to the specific EQAs by the Scheme Director and the assessors

Example:
- Total score for each category 2 points.
- Measurement of performance: penalty points, e.g. -0.5, -1.0, -2.0 scale of errors
- Performance categories. “satisfactory” and “poor”.

Provider E

- The organiser breaks down comments into key phrases
- Assessed by an expert panel that classify them as “preferred”, “of lesser value” or “inapropriate”
- Suggested comment by the expert panel

The participation in interpretative PTS allow participants to:

- Compare their comments with those from other laboratories
- Understand whether a misleading comment about an individual report has been made
- Widen their experience in this activity;
- Help educate junior analysts;
- Promote continuous quality improvement; and
- Helps staff to acquire new skills quickly and enable them to keep up to date with new research

Some pitfalls to avoid:

- Restating the obvious: e.g. “normal sodium”, although qualifying the degree os abnormality may be useful, for example “severe”
- Restating customer questions.
- Commenting on reports to a customer has indicated (s) he does not wish to receive them
- Commenting on speciality reports to a specialist in the field.
- Telling customer how to do his job.

Conclusions

- Importance of standardizing interpretative comments. Structure and wording.
- Interpretative PT schemes offer many advantages.
- Importance of demonstrating personal proficiency of the staff.
- Need of harmonizing scheme performance assessment.

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