UNDERSTANDING WHAT IS NEEDED TO PRODUCE QUALITY DATA

Mariana Santos

National Institute of Health (INSA)

Food and Nutrition Department

16 July 2015

GOVERNO DE PORTUGAL
MINISTÉRIO DA SAÚDE

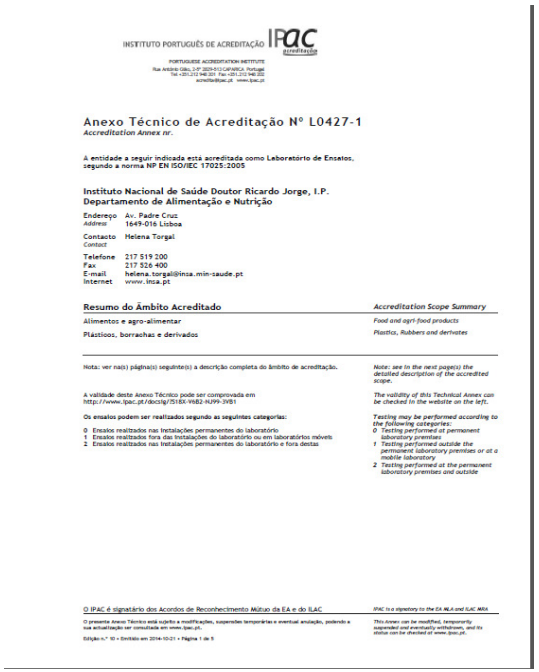
Instituto_Nacional de Saúde
Doutor Ricardo Jorge

Overview of the presentation

1. Quality Control: Why?
2. Basic accreditation: ISO/IEC 17025
3. Understanding what is needed to produce quality data
   - 3.1 Method validation: a quick intro
4. QA in practice
5. About Food Chemistry Lab.

Quality Control: Why?

1. You want to deliver correct results
2. Your customer demands it Accreditation
3. Marketing purposes



INSTITUTO PORTUGUÊS DE ACREDITAÇÃO IPAC

Anexo Técnico de Acreditação Nº L0427-1
Accreditation Annex nr.

A entidade a seguir indicada está acreditada como Laboratório de Ensaios, segundo a norma NP EN ISO/IEC 17025:2005

Instituto Nacional de Saúde Doutor Ricardo Jorge, I.P.
Departamento de Alimentação e Nutrição

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Resumo do Âmbito Acreditado	*Accreditation Scope Summary*
Alimentos e agro-alimentar	*Food and agri-food products*
Plásticos, borrachas e derivados	*Plastics, Rubbers and derivates*

Nota: ver na(s) página(s) seguinte(s) a descrição completa do âmbito de acreditação.

Note: see in the next page(s) the detailed description of the accredited scope.

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0 Ensaios realizados nas instalações permanentes do laboratório.
1 Ensaios realizados fora das instalações do laboratório ou em laboratórios móveis
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Testing may be performed according to the following categories:
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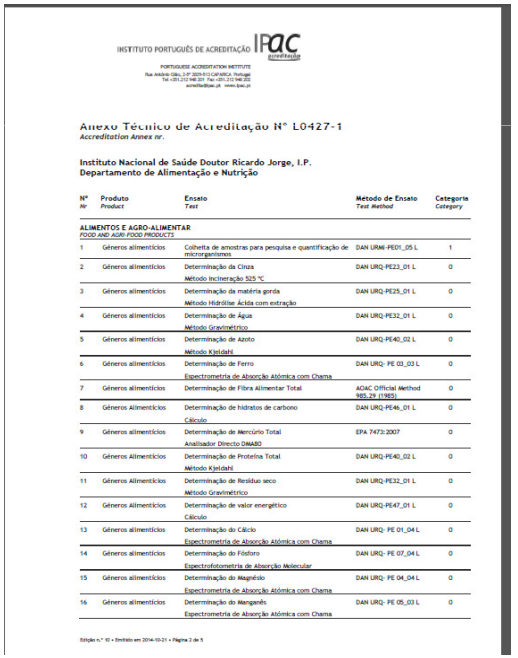

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Nº *Nr*	Produto *Product*	Ensaio *Test*	Método de Ensaio *Test Method*	Categoria *Category*
ALIMENTOS E AGRO-ALIMENTAR *FOOD AND AGRI-FOOD PRODUCTS*				
1	Géneros alimentícios	Colheita de amostras para pesquisa e quantificação de microrganismos	DAN URM-PE01_05 L	1
2	Géneros alimentícios	Determinação da Cinza Método incineração 525 ºC	DAN URQ-PE23_01 L	0
3	Géneros alimentícios	Determinação da matéria gorda Método Hidrólise Ácida com extração	DAN URQ-PE25_01 L	0
4	Géneros alimentícios	Determinação de Água Método Gravimétrico	DAN URQ-PE32_01 L	0
5	Géneros alimentícios	Determinação de Azoto Método Kjeldahl	DAN URQ-PE40_02 L	0
6	Géneros alimentícios	Determinação de Ferro Espectrometria de Absorção Atómica com Chama	DAN URQ- PE 03_03 L	0
7	Géneros alimentícios	Determinação de Fibra Alimentar Total	AOAC Official Method 985.29 (1985)	0
8	Géneros alimentícios	Determinação de hidratos de carbono Cálculo	DAN URQ-PE46_01 L	0
9	Géneros alimentícios	Determinação de Mercúrio Total Analisador Directo DMA80	EPA 7473:2007	0
10	Géneros alimentícios	Determinação de Proteína Total Método Kjeldahl	DAN URQ-PE40_02 L	0
11	Géneros alimentícios	Determinação de Resíduo seco Método Gravimétrico	DAN URQ-PE32_01 L	0
12	Géneros alimentícios	Determinação de valor energético Cálculo	DAN URQ-PE47_01 L	0
13	Géneros alimentícios	Determinação do Cálcio Espectrometria de Absorção Atómica com Chama	DAN URQ- PE 01_04 L	0
14	Géneros alimentícios	Determinação do Fósforo Espectrofotometria de Absorção Molecular	DAN URQ- PE 07_04 L	0
15	Géneros alimentícios	Determinação do Magnésio Espectrometria de Absorção Atómica com Chama	DAN URQ- PE 04_04 L	0
16	Géneros alimentícios	Determinação do Manganês Espectrometria de Absorção Atómica com Chama	DAN URQ- PE 05_03 L	0

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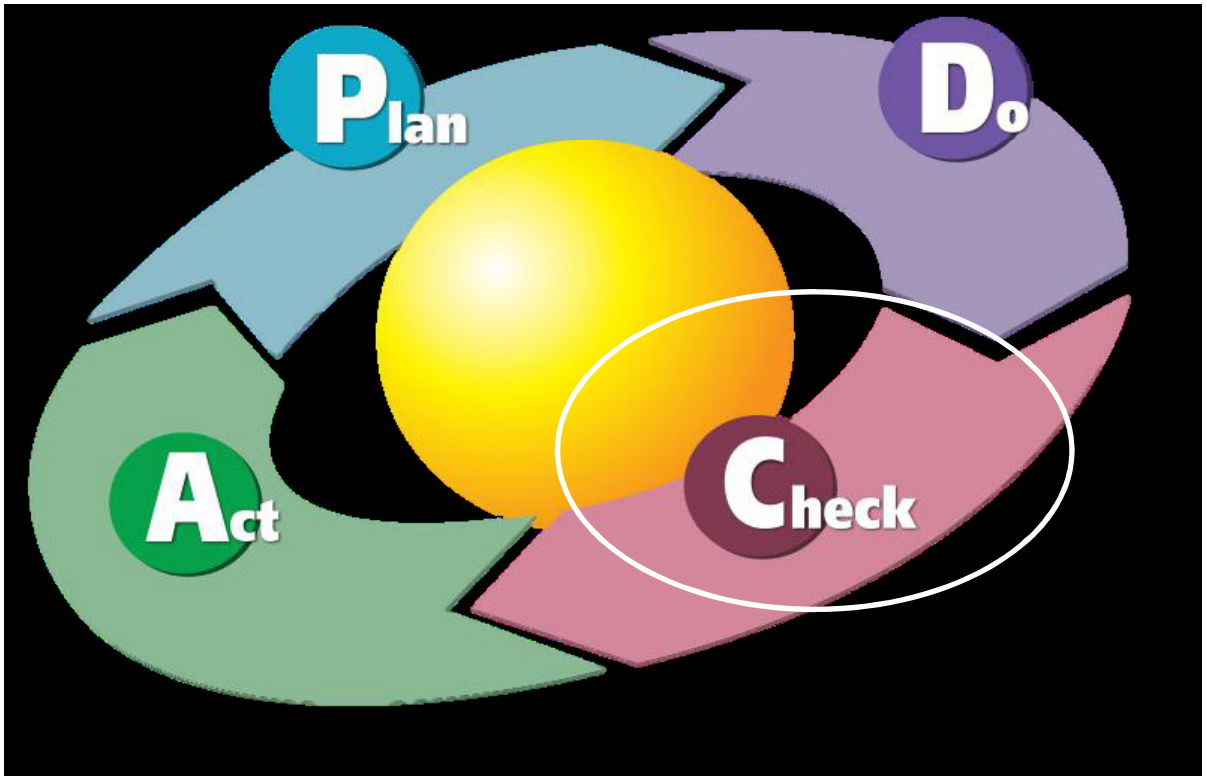
Quality Control: Why?

International Organization for Standardization

ISO 9001	ISO 17025	ISO 15189
CERTIFICAÇÃO	ACREDITAÇÃO	ACREDITAÇÃO
Quality management systems -- Requirements	General requirements for the competence of testing and calibration laboratories	Medical laboratories -- Requirements for quality and competence

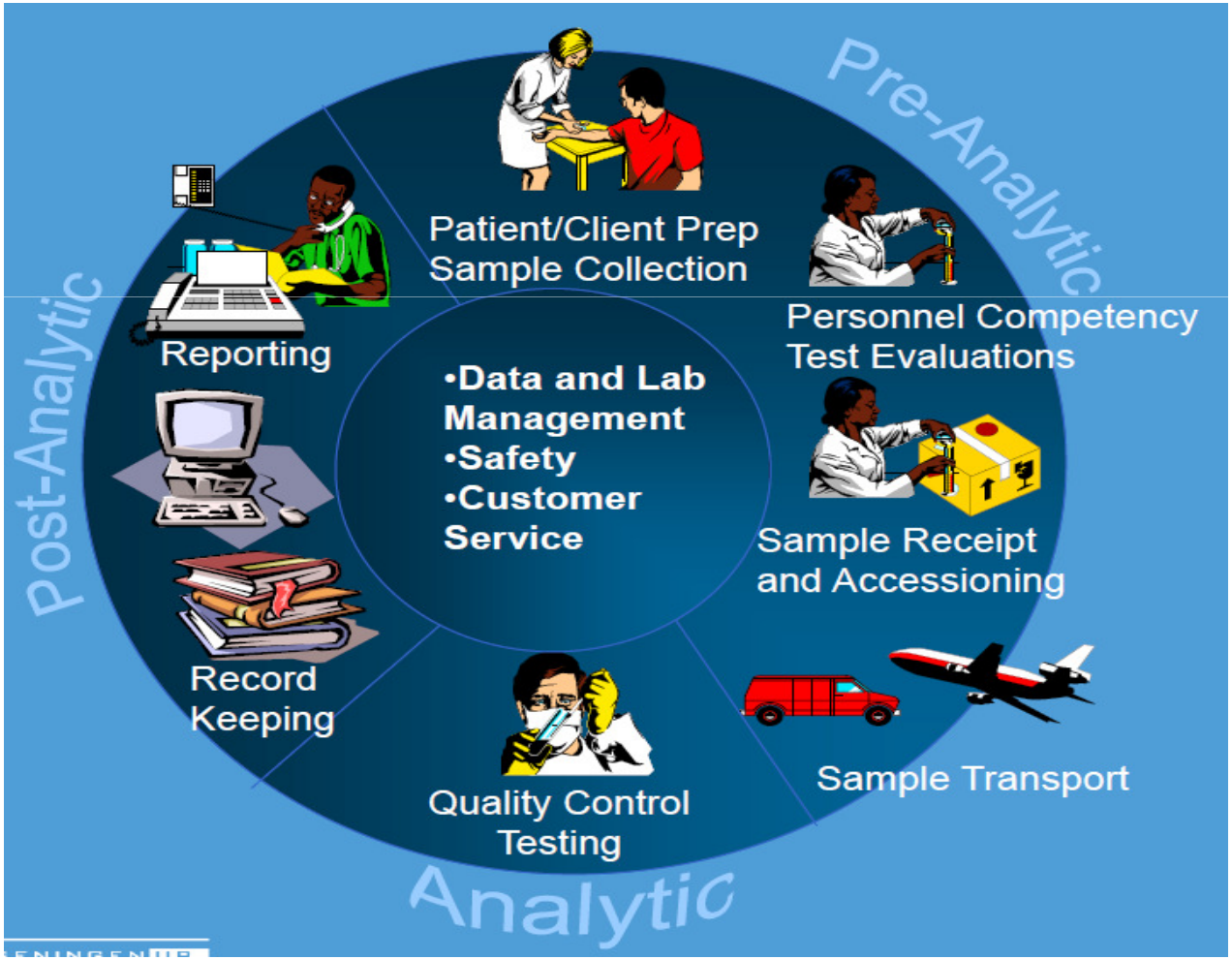
Quality Control: Why?

QS: based on the Deming cycle (continuous improvement / living system)



Quality Control: Why?

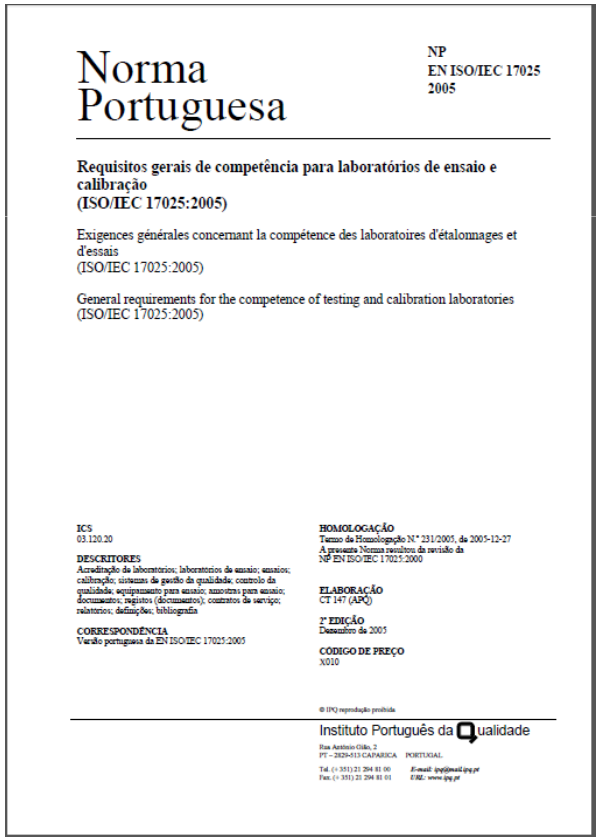
The quality assurance cycle



ISO/IEC 17025

General requirements for the competence of testing and calibration laboratories

- Second edition 2005-05-15
- Scope
- Normative References
- Terms and Definitions
- Management requirements
- Technical requirements



Norma Portuguesa

NP EN ISO/IEC 17025 2005

Requisitos gerais de competência para laboratórios de ensaio e calibração (ISO/IEC 17025:2005)

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais (ISO/IEC 17025:2005)

General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)

ICS 03.120.20

DESCRITORES Acreditação de laboratórios; laboratórios de ensaio; ensaios; calibração; sistemas de gestão da qualidade; controlo da qualidade; equipamento para ensaio; amostras para ensaio; documentos; registos (documentos); contratos de serviço; relatórios; definições; bibliografia

CORRESPONDÊNCIA Versão portuguesa da EN ISO/IEC 17025:2005

HOMOLOGAÇÃO Termo de Homologação N.º 231/2005, de 2005-12-27. A presente Norma resultou da revisão da NP EN ISO/IEC 17025:2000

ELABORAÇÃO CT 147 (APQ)

1ª EDIÇÃO Dezembro de 2005

CÓDIGO DE PREÇO X010

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ISO/IEC 17025

ISO/IEC 17025 Management requirements

- Policy
- Organisation
- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests
- Purchasing services and supplies
- Service to the customer
- Complaints and non conformities
- Corrective and preventive actions
- Control of records
- Internal audits and management review

ISO/IEC 17025

ISO/IEC 17025 Management requirements

Complaints and non conformities

- Registration of the deviation
- Causal analysis
- Corrective and preventive actions
- Evaluation
- Continuous improvement

ISO/IEC 17025

ISO/IEC 17025 Technical requirements

- Personnel
- Accommodation and environmental conditions
- Equipment
- Selection of methods
- Measurement traceability
- Handling of samples
- Assuring quality of test results
- Reporting of results

ISO 17025

ISO/IEC 17025

ISO/IEC 17025 Technical requirements

Personnel

- Competence – relevant knowledge and experience
- Training and development
- Job descriptions

Accommodation and environmental conditions

- Suitable for the correct performance of the tests
- Monitor environmental - storage conditions
- Controlled access

ISO/IEC 17025

ISO/IEC 17025 Technical requirements

Equipment

- Comply with specifications, relevant to the tests
- Operating instructions
- Identification
- Preventive maintenance
- Calibration

ISO/IEC 17025

ISO/IEC 17025 Technical requirements

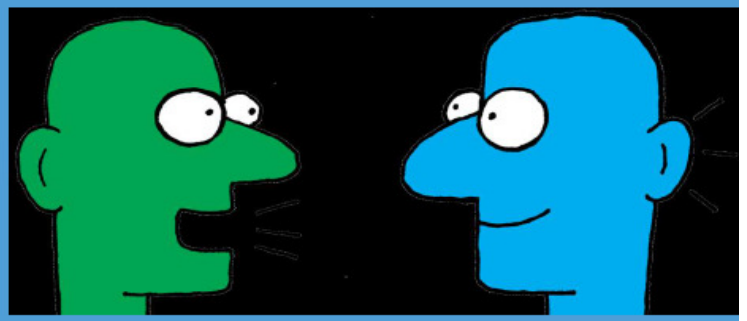
Test methods and method validation

- Appropriate methods (fit for purpose)
- Preferably international or national standards
- Validation of in-house methods
- Estimation of uncertainty of measurement
- Control of data (calculations and data transfers)

ISO/IEC 17025

ISO/IEC 17025 STAC principle

- See (look – observe)
- Think (start brain flow)
- Act (notes – SOP's)
- Communicate (share the knowledge)

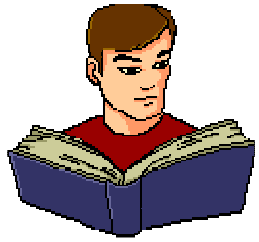


UNDERSTANDING WHAT IS NEEDED TO PRODUCE QUALITY DATA

- With so many fictional crime solving dramas on television it's easy to believe that analytical results can be determined instantaneously.

- Without adequate quality control data, results can be misleading or incorrect.

Use the Correct Method



- Choosing the appropriate method is the first critical step in ensuring accurate and reliable results.
- Methods published by industry-recognized organizations is a good start.
- Most widely used methods come from the AOAC, ISO or CEN and are often called “Standard Methods.”

Use the Correct Method

The following factors must be considered when choosing a method:

- **objective of the test,**
- **type of matrix,**
- **detection limit,**
- **turnaround time needs.**

Verify or Validate the Method

- Method verification **is a process in which a lab proves they are able to perform a Standard Method correctly.**
- Method validation **is the process in which a lab proves a non-standard method, such as a method developed in-house, actually works as intended and meets the requirements of a client.**

In short: know what it can do and what to expect

Verify or Validate the Method

Table 1. Analytical performance parameters

Analytical Performance Parameter	Assays	Quant.	Limit test	Specific tests	I.D.
Accuracy	Yes	Yes	*	*	No
Precision	Yes	Yes	No	Yes	No
Specificity	Yes	Yes	Yes	*	Yes
LOD	No	No	Yes	*	No
LOQ	No	Yes	No	*	No
Linearity	Yes	Yes	No	*	No
Range	Yes	Yes	No	*	No
Robustness	Yes	Yes	No	Yes	No

+ measurement uncertainty

» * May be required, depending on the nature of the specific test.

Table 1 below, summarizes the parameters required to validate a method.

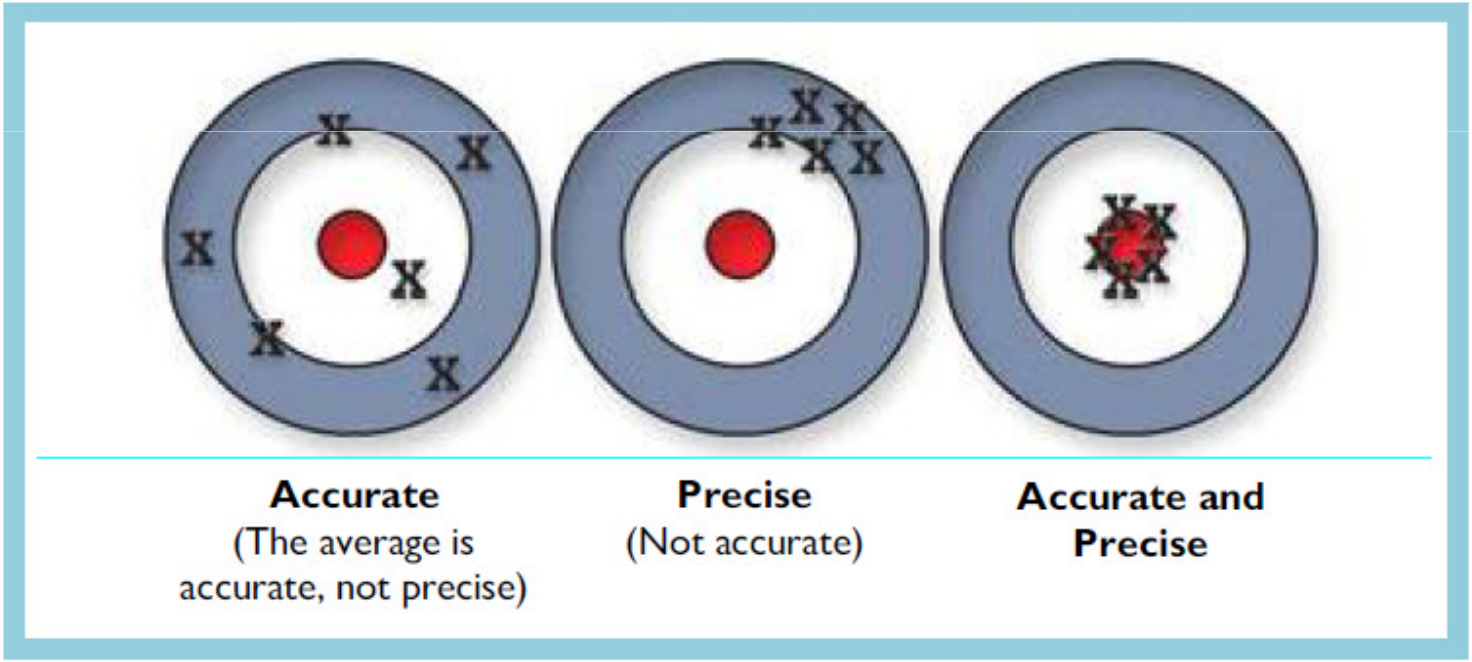
Elements of Method Verification or Validation

Accuracy and Precision

- **Accuracy** is the closeness of the test results obtained by the method to the actual or true value.
- **Precision** is the degree of agreement among individual test results when the procedure is applied repeatedly to multiple samplings of a homogeneous sample.

Elements of Method Verification or Validation

Figure 1: The Relationship Between Accuracy and Precision



Elements of Method Verification or Validation

Accuracy

Accuracy can be determined by comparing the results of a series of samples to the true value.

The true value can be:

- **published results of a certified reference material,**
- **calculated by consensus of multiple laboratories, or comparison of the results of fortified samples, also referred to as spiked samples, against the published method.**

Elements of Method Verification or Validation

Precision

Precision can be determined by calculating the standard deviation of a series of like samples.

Selectivity/ Specificity

Selectivity refers to the extent to which a method can determine particular analytes in mixtures or matrices without interferences from other components.

Elements of Method Verification or Validation

IUPAC: "Specificity is the ultimate selectivity" and "Sometimes the term specificity is used (100% selectivity (or 0% interferences).

If you have a sample, with matrix and ingredients (e.g. more than one ingredient), and you can only detect one ingredient. That method is specific for that ingredient.

If you can separate and detect more ingredients without interferences, than that method is selective.

Elements of Method Verification or Validation

Detection Limit (LOD)

Lowest concentration of analyte in a sample that can be detected (not necessarily quantitated)

Not useful in practice

Quantification Limit (LOQ)

Lowest concentration of analyte in a sample that can be determined with acceptable precision and accuracy

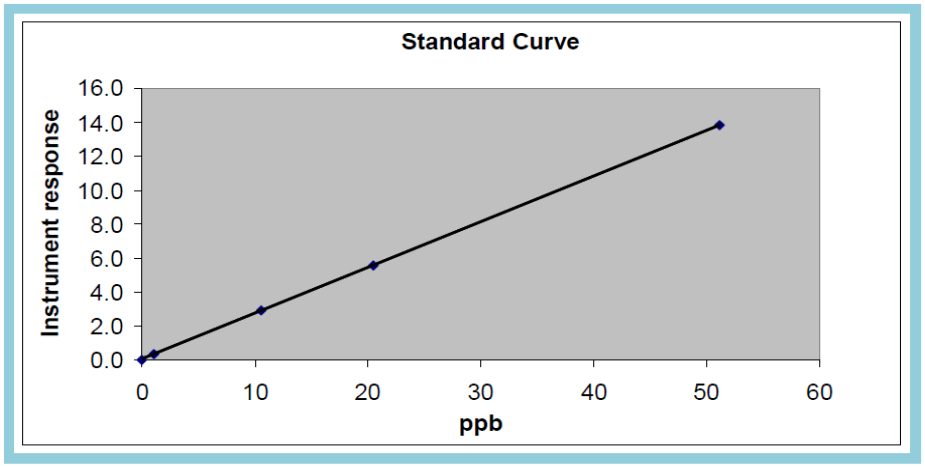
The rule is:

- **LOD is 3 times the noise (standard deviation) above the blank response, and the LOQ is 10 times the noise.**
- **LOD and LOQ are determined by calculating the standard deviation of a series of samples at the suspected LOD.**

Elements of Method Verification or Validation

Linearity: compares the relationship between an instrument response and concentration of an analyte. The ideal situation is when there is a one to one linear response.

Figure 2: Example Standard Curve to Demonstrate Linearity



To determine the linearity, a series of analytical standards at different concentrations is analyzed.

Elements of Method Verification or Validation

Range

Range is the upper and lower concentration limits of the analyte that can be determined with precision, accuracy, and linearity.

Range is determined by fortifying a blank matrix with a representative analyte at the highest expected value of your samples.

Robustness

Measure of the capacity to remain unaffected by small (deliberate) variations in method parameters.

Use Appropriate Standards

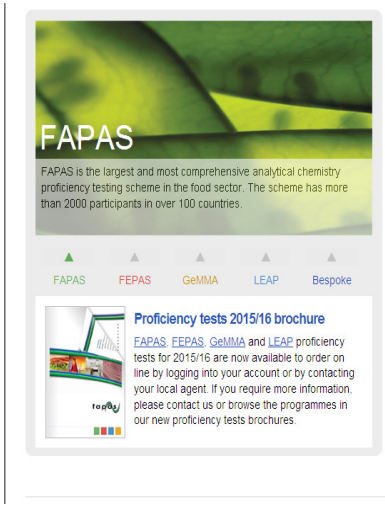
Many methods require analytical standards to properly identify the analyte and/or determine the concentration.

No matter the source, all standards should have a certificate of analyses to prove authenticity.

- » Selection of reference materials (“standards”)
- » Internal standard(s)
- » External standard(s)
- » Calibration standards

Participate in Proficiency Programs

- **ISO 17025 accredited labs must participate in proficiency testing (PT) programs on a yearly basis.**
- **PT programs enable laboratories to assess their performance by comparing their data with other laboratories.**



Perform Internal Quality Control

Once the right method and standards have been chosen and validated and the lab has proven its proficiency, the next step is having systems in place to ensure that everything goes right on any given day.

This can be done through the use of Laboratory Control Samples (LCS), also referred to as Quality Control (QC) samples.

Perform Internal Quality Control

- LCS are samples with known true values.
- Running LCS with every batch of samples will demonstrate accuracy every time the test is run.
- The type of LCS is chosen to reflect the qualities of common client samples.
- Spiking of client samples may also be performed for difficult or uncommon matrices to check for sample matrix effects.

Perform Internal Quality Control

There are several types of LCS that can be used in a food testing laboratory to prove accuracy:

- **Food samples with a known true value of the component of interest (Standard Reference Materials (SRM) / Reference Materials)**
- **Fortified samples: Fortifying a sample is to add known amounts of test components to the clean sample at the beginning of the test, and then prepare the fortified sample for analysis like all other samples**

Perform Internal Quality Control

LCS results are plotted on control charts to demonstrate that results are within the acceptable range and prove the method's accuracy.

Figure 3: Example Chart Demonstrating Accuracy

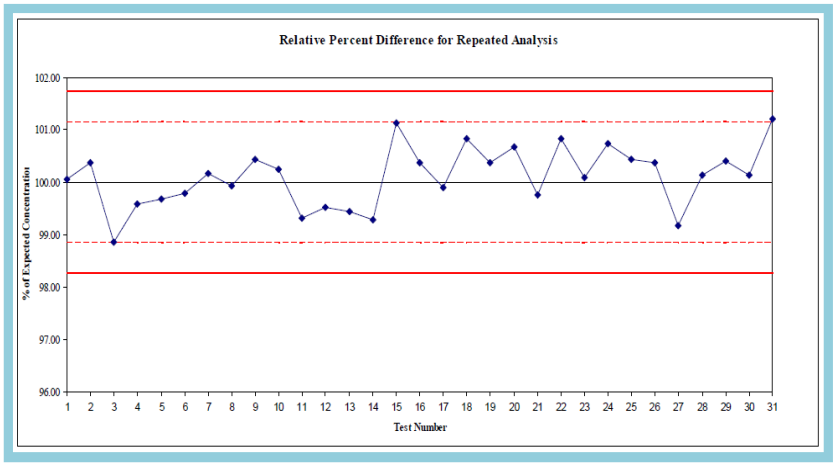
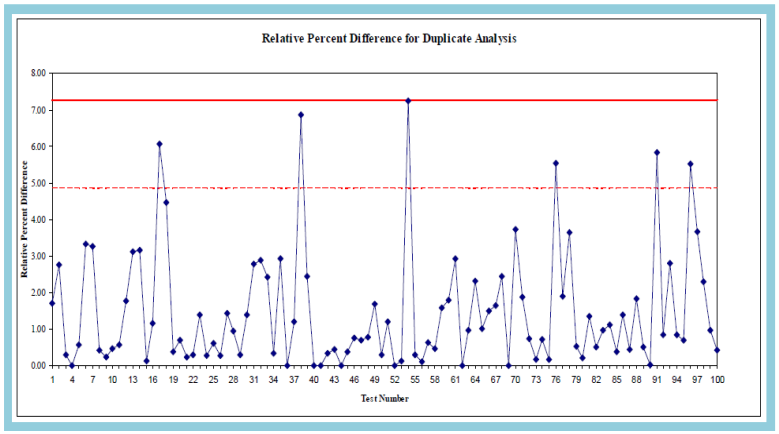


Figure 4: Example Chart Demonstrating Precision



Confirm Results

The last quality check is to confirm results. This is accomplished by performing a second review of all data by a qualified analyst.

Looking Forward and being Prepared

Quality data does not come easily or instantaneously. It takes time and dedication to get the "correct" answer

Looking Forward and being Prepared

ISO 17025 provides the road map for laboratories to develop a comprehensive and robust quality management system.

Having quality management systems in place throughout the lab can ensure that the lab has taken the time and is dedicated to getting the "correct" answer for all tests.

Food and Nutrition Department

About the Food Chemistry Lab

Coordenador
Maria Antónia Calhau

Estruturas de suporte Gestão da Qualidade

Unidade de I&D
Helena Soares Costa

- Identificar as necessidades de I&D em alimentação e nutrição
- Desenvolver Programas e Projectos em alimentação e nutrição
- Produzir e Divulgar conhecimento
- Formação em I&D

Unidade de Observação e Vigilância
Luísa Oliveira

- Riscos Biológicos
- Riscos Químicos
- Riscos Alimentares e Nutricionais

Unidade de Referência
Margarida Saraiva

- **Química**
  Mariana Santos
- **Microbiologia**
  Margarida Saraiva
  Cristina Belo Correia
- **Materiais de Referência**
  Isabel Castanheira

Food and Nutrition Department

About the Food Chemistry Lab

The Food Chemistry Lab. develops activities in the areas

- **Food and nutrition analysis,**
- **Food composition ,**
- **Food chemical contaminants (mycotoxins, mercury, nitrates)**
- **Food Aditives,**
- **Packaging and Food Contact Material**
- **Food allergens (Determination of total allergen gluten/gliadin)**

Our lab received the accreditation according to EN ISO/IEC 17025 on January 21 in 2008, by the Portuguese Accreditation Institute (IPAC).

IPAC acreditação INSTITUTO PORTUGUÊS DE ACREDITAÇÃO

Food and Nutrition Department
About the Food Chemistry Lab

IPAC acreditação INSTITUTO PORTUGUÊS DE ACREDITAÇÃO

Informação geral	
Acreditação	L0427
Referencial	NP EN ISO/IEC 17025:2005
Entidade	Instituto Nacional de Saúde Doutor Ricardo Jorge, I.P. - Departamento de Alimentação e Nutrição
Sigla	INSA - DAN
Data de Concessão	2008-01-21
Certificado em vigor	2008-01-21
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Distrito	Porto
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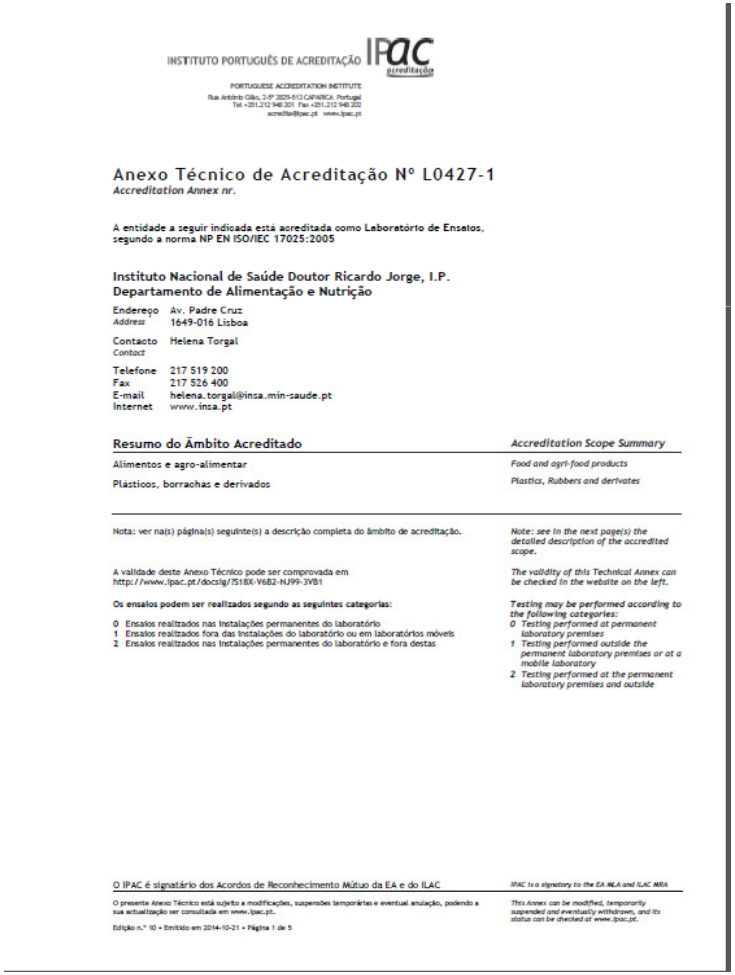
Âmbito de acreditação - Local: 1649-016 Lisboa
Anexo técnico em vigor: 2014-10-21

Produto	Ensaio	Método	Categoria



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Resumo do Âmbito Acreditado / *Accreditation Scope Summary*

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Plásticos, borrachas e derivados / *Plastics, Rubbers and derivates*

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Food and Nutrition Department
About the Food Chemistry Lab

Nutritional Analysis - Why?

- All food products that are offered on a market have to comply with the respective regulation.
- Consumers are increasingly concerned about the quality and nutritional content of food.
- Nutritional information must be confirmed and validated by analytical techniques in order to be accurately included on labels and packaging.

Food and Nutrition Department

About the Food Chemistry Lab

New Food Information Regulation (FIR) –

- This was published by the European Union in 2011 and was designed to make food labelling easier to understand for consumers.
- The regulation combines rules on general food and nutrition labelling into a single EU regulation.
- Most requirements will not apply until 2014, with nutrition labelling becoming compulsory in 2016.

Food and Nutrition Department
About the Food Chemistry Lab

New Food Information Regulation (FIR) – EU Regulation 1169-2011

The current rules specify the nutrients that can be included. The information has to be presented per 100g/ml, but could also be provided per portion.

Further information can be added to labels such as the amounts of polyunsaturates, monounsaturates, starch, cholesterol, vitamins or minerals.

Format 1: 'Big 4'	
Energy	(kJ and kcal)
Protein	(g)
Carbohydrate	(g)
Fat	(g)

Format 2: 'Big 4 and Little 4'	
Energy	(kJ and kcal)
Protein	(g)
Carbohydrate	(g)
of which sugars	(g)
Fat	(g)
of which saturates	(g)
Fibre	(g)
Sodium	(g)

Food and Nutrition Department

About the Food Chemistry Lab

New Food Information Regulation (FIR) – EU Regulation 1169-2011

Current back of pack nutrition panel

	Per 100g
Energy	1500kJ/356kcal
Protein	9.9g
Carbohydrates	58.1g
of which sugars	16.8g
Fat	7.4g
of which saturates	1.1g
Fibre	8.9g
Sodium	Below 0.1g

New back of pack nutrition panel

	Per 100g
Energy	1500kJ/356kcal
Fat	7.4g
of which saturates	1.1g
Carbohydrates	58.1g
of which sugars	16.8g
Protein	9.9g
Salt	Below 0.1g

Food and Nutrition Department
About the Food Chemistry Lab

Our nutritional analysis include:

- **Lipids, Fats & Oils: Fatty Acid Profiles**
- **Proteins: Amino Acid Profile, Proteins**
- **Carbohydrates: Total Dietary Fiber; Starch, Sugar and Sugar Profiles,**
- **Vitamins: Water-soluble and fat-soluble**
- **Minerals: Commonly labeled minerals; Individual Element Analyses**
- **Basic Composition / Proximates: Ash, Fat, Dietary Fiber, Moisture, Protein and Salt**

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Parameter	Method
Moisture	Air Oven (AOAC 925.10)
Ash	Ash furnace (AOAC 923.03)
Total N-proteins	Kjeldahl (AOAC 920.87)
Total fat	Acid hydrolysis (AOAC 954.02)
Total dietary fibre	Enzymatic-Gravimetric (AOAC 985.29)

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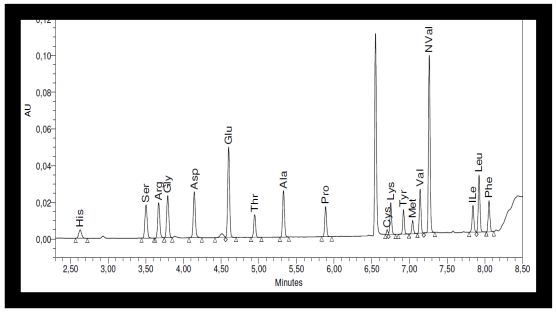
Amino Acid Profile

Waters Acquity UPLC

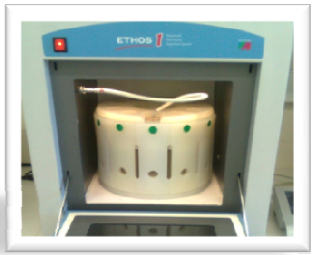


Vitamins Analyses

Waters HPLC

Individual Element Analyses

Inductively coupled plasma optical emission spectrometry (ICP-OES)



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Food Composition

Information about food composition is necessary for:

- **the assessment of diet quality,**
- **providing a useful tool for the field of public health nutrition.**
- **Food composition data (FCD) are important to food manufacturers, food retailers, governmental agencies, health professionals and consumers**

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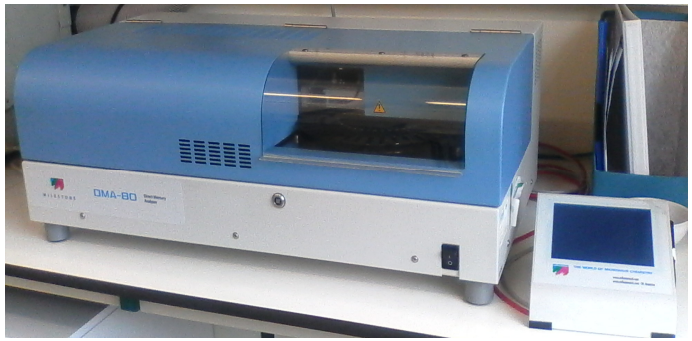
➢ Food chemical contaminants
(mycotoxins, mercury)

Total mercury (Hg) in a Direct Mercury Analyser DMA 80 (Milestone Inc.; CT, USA),



20.12.2006 EN Official Journal of the European Union L 364/5

COMMISSION REGULATION (EC) No 1881/2006

of 19 December 2006

setting maximum levels for certain contaminants in foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [1], and in particular Article 2(3) thereof,

food. In the case of contaminants which are considered to be genotoxic carcinogens or in cases where current exposure of the population or of vulnerable groups in the population is close to or exceeds the tolerable intake, maximum levels should be set at a level which is as low as reasonably achievable (ALARA). Such approaches ensure that food business operators apply measures to prevent and reduce the contamination as far as possible in order to protect public health. It is furthermore appropriate for the health protection of infants and young children, a vulnerable group, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children. This strict

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Food additives must comply with specifications which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity.

22.3.2012 EN Official Journal of the European Union L 83/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 231/2012

of 9 March 2012

laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

(4) The European Food Safety Authority (hereinafter 'the Authority') expressed its opinion on the safety of basic methacrylate copolymer (6) as a glazing agent. That food

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Testing of Packaging and Food Contact Material

Food packaging and food packaging materials should be safe and should not transfer their components into food in unacceptable quantities

(In European Union, the COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)

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➢ Food allergens (Determination of total allergen gluten/gliadin)

- **Nowadays, as the number of people with gluten intolerance increases, the food industry shows a greater concern to produce food that can be consumed safely by this group of people.**
- **In accordance with the European Regulation No. 1169/2011, which came into force on 13 December 2014, it is required to indicate on the label substances or products causing allergies or food intolerances.**

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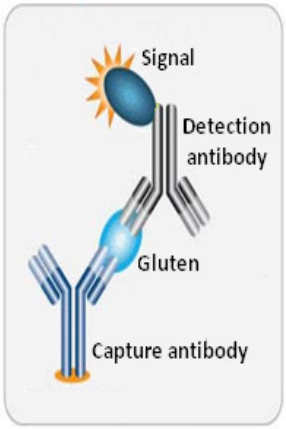
Analysis for detection and quantification of gluten in food and raw materials:

Enzyme-linked Immunoassay (ELISA) R5 (RIDASCREEN® Gliadin)



Foodstuffs intended for particular nutritional uses have their own Regulation No. 41/2009, applicable since January 2012

Thanks for your attention

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