Article

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Development of a Prototype Management Software for Testing Laboratories

Quality Control under ISO/IEC 17025:2017 Standard

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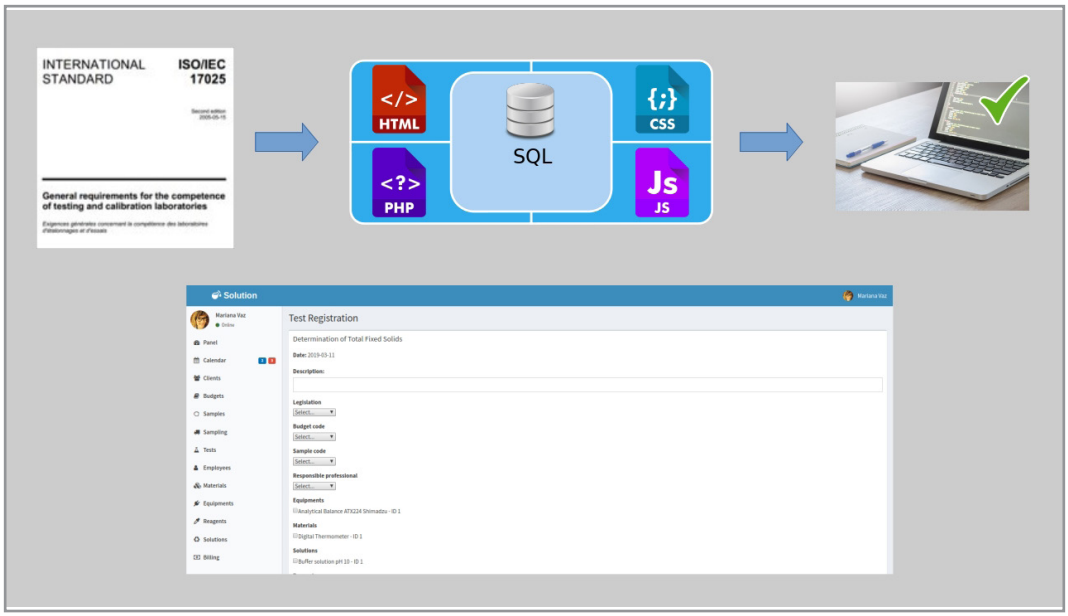
Graphical Abstract



Creation process of Software Solution, a quality management program for testing laboratories, focused on compliance with ISO/IEC 17025:2017 standard. The image also highlights the programming languages used for the development and a screenshot of the final result.

In the so-called Total Quality Era, it is necessary to implement standardized and recognized experimental procedures around the world. When testing laboratories are adapted to the requirements set forth in ISO/IEC 17025:2017 standard, the evaluation of results and the exchange of knowledge becomes easier and more dynamic. This adaptation can be simplified and accelerated through the use of a data management software. Thus, the objective of this work was to develop a platform for quality control of a chemical testing laboratory, focusing on compliance with managerial and technical requirements of ISO/IEC 17025:2017 standard. The developed software allows not only data recording, but also the comparison of the analysis results with limit values established by current legislation, guaranteeing greater reliability of the reports issued. The created prototype is useful in ensuring high efficiency of the activities of chemical testing laboratories, making the workflow faster and safer, aside from guaranteeing compliance with the requirements of ISO/IEC 17025:2017 standard.

Keywords: accreditation, quality management system, chemical testing laboratory

INTRODUCTION

Nowadays, in the so-called Total Quality Era, the control tools usually seek to solve problems and integrate processes, with the main goal of controlling the variability of results, maintaining the development of services and products in the company under stable control [1].

Global sharing of test and calibration results is facilitated when the companies meet the technical and managerial requirements established in ISO/IEC 17025:2017, an international standard that establishes "General requirements for the competence of testing and calibration laboratories". This adaptation facilitates collaboration, commercialization and communication between laboratories, making it easier to exchange information and harmonize experiences of their procedures [2].

According to information available on the website of the National Institute of Metrology, Quality and Technology of Brazil (Inmetro), there were, in 2018, 1039 accredited independent laboratories in the country that meet the requirements of ISO/IEC 17025. In relation to 2015, this number showed a growth of more than 100 percent, when there were only 438 accredited companies. This strong growth is a direct response to the demand of an increasingly globalized market, that seeks to improve the quality of its procedures and aims at the reliability of their services' results [3].

Procedures that follow internationally recognized standards are of uppermost importance in many areas within a testing laboratory. According to Batista and colleagues (2008), volumetric verification of pipettes is an example of standardized procedure that exists in many laboratories. However, these type of verification and validation routines are not satisfactorily standardized, because usually they are not performed regularly [4].

With the technology evolution witnessed today, it is fundamental to modernize even a small or medium-sized laboratory, evolving from a system managed with printed documents and forms to a digital and automated system, that assists in the process of quality management and control [5]. The use of a digital management system is generally also linked to minimization of waste production, and, according to the principles of Green Chemistry, minimizing the waste is preferable than treating them after their generation [6].

Therefore, this work aimed at developing a software to facilitate the planning and accomplishment of a chemical testing laboratory activities, in order to avoid losses during the whole process. The Brazilian national market in the field of quality management software for testing laboratories is heated due to the need to provide services that meet the requirements of ISO/IEC 17025:2017. What differentiates the software created in the present work from the already existing in corporate market is the possibility of integration between managerial and technical activities, in accordance with the guidelines set forth by the standard.

MATERIALS AND METHODS

For the development of the management software, it became necessary the detailed knowledge of the company routine and operational flow. Over two months, the routine of small laboratory that works with physical-chemical and microbiological tests of waters, effluents, foods and oils was monitored. All activities developed within the company were identified, step by step, from the contact of a client requesting a budget until the invoice issued after the completion of the services.

This audit and control allowed for the identification of the procedures that were most susceptible to generating errors and, therefore, could make it difficult to implement and maintain an efficient quality management system.

With this previous work it was possible to gather and systematize the main information of the step by step of the different analysis. It was, then, set up the planning and layout of a computer program that met the needs of the company and could assist in the adaptation of its procedures to ISO/IEC 17025:2017 standard.

RESULTS AND DISCUSSION

The implementation of the prototype hereby presented made easier to ensure quality control in different stages within the laboratory. Gaining organizational performance, security and reliability in routine activities at various levels and functions within the company allows for the issuance of reports with greater reliability [7].

Analysis of the Laboratory

The analysis of the laboratory's documents and records led to the identification of the most performed physicochemical tests in 2016, involving classical analytical techniques, such as gravimetric and titrimetric methods, and three instrumental techniques, as listed below:

1. Determination of chloride by Mohr Method
2. Determination of total hardness by titration with EDTA
3. Determination of pH by potentiometric method
4. Determination of total solids by gravimetric method
5. Determination of dissolved solids by gravimetric method
6. Determination of suspended solids by gravimetric method
7. Determination of aluminum by UV-Vis spectrophotometric method
8. Determination of ammonia by UV-Vis spectrophotometric method
9. Determination of iron by UV-Vis spectrophotometric method

Based on the findings above, three tests were selected as pilot, which means that they were the first procedures managed by the prototype software developed in this work, called Software Solution. These procedures were selected based on the number of tests performed in one month, so that they can put the maximum of significance on the Software Solution, and based on their nature, so that the pilot tests are diverse and cover the main types of analytical methods (gravimetric, titrimetric and instrumental methods). The pilot tests used for the development of the prototype are shown below:

- Determination of chloride by Mohr Method (Titrimetric)
- Determination of total solids by gravimetric method (Gravimetric)
- Determination of nitrate by UV-Vis spectrophotometric method (Instrumental)

The studied laboratory presents a daily routine without major changes, being the stages of budgeting, traceability of measurements and issuance of reports the three crucial stages the makes it hard to maintain a management system focused on quality control and governed by ISO/IEC 17025:2017 standard.

Planning Software Solution

In order to objectively plan the development of the Software, it was determined the topics of ISO/IEC 17025:2017 that would be initially addressed and controlled by its pilot version. Figure 1 below shows the essential features present in Software Solution, which covers the main categories of activities performed in the laboratory, all according to ISO/IEC 17025:2017 standard.

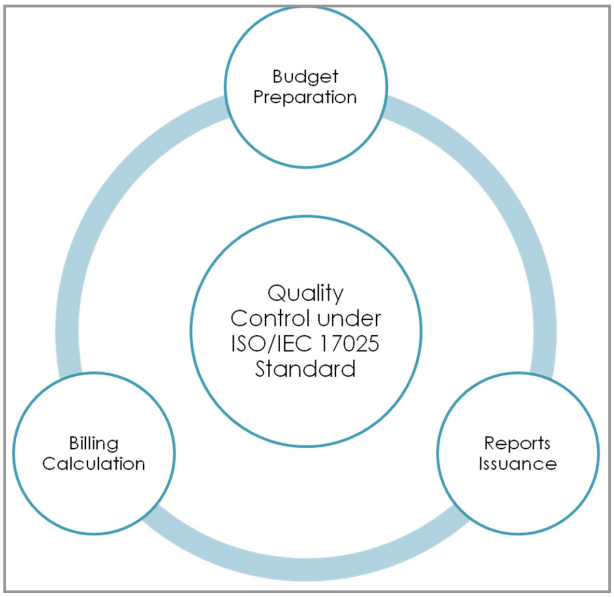


Figure 1. Essential categories developed in Software Solution.

After the survey and a detailed analysis of the requirements for the Software, a description of *'minimundo'* was created, which can be defined as the instructions in words of what will be represented in the database, and makes it possible to create an entity–relationship diagram (ERD).

The ERD model was developed using an online program called "ERDPlus", and contains the connection between the Software entities and their relationships of dependency. Figure 2 presents an example of a diagram created for Software Solution.

Technical Aspects and Languages

The main language used on the development of Software Solution was HTML5, a markup language that allows for online use of the platform. This means that anywhere with an Internet connection is the perfect place to view and manage the laboratory activities, controlling the most important tasks at any time, and bringing efficiency to the routine of all employees.

The security of data accessed from outside of the laboratory is ensured by mainly three processes:

1. Daily backups of all the files from the server to a local computer stored on a safe place;
2. Authenticity confirmation, requesting usernames and passwords to access the pages; and
3. Encryption procedures at the beginning and at the end of the files' path from the server.

According to Shacham and colleagues (2012), HTML5 offers a set of specifications that provide for structured data storage, as well as benefits such as the possibility of using geolocation services and the ability to manipulate browser history and cache [8].

The software has two main building blocks: a back-end and a front-end. The back-end was developed with PHP language and MySQL server, as the front-end was mainly written in HTML, CSS and JavaScript, using Admin LTE as a base code for programming.

As the development was done under a widely used framework, Admin LTE, it can be said that the software works in the main browsers of the market — Google Chrome®, Mozilla Firefox® and Internet Explorer®, and provides a unique environment with useful resources to manage a testing laboratory.

The Software's database was developed using SQL language, and its management was done with MySQL, a free and open source program widely used in professional applications.

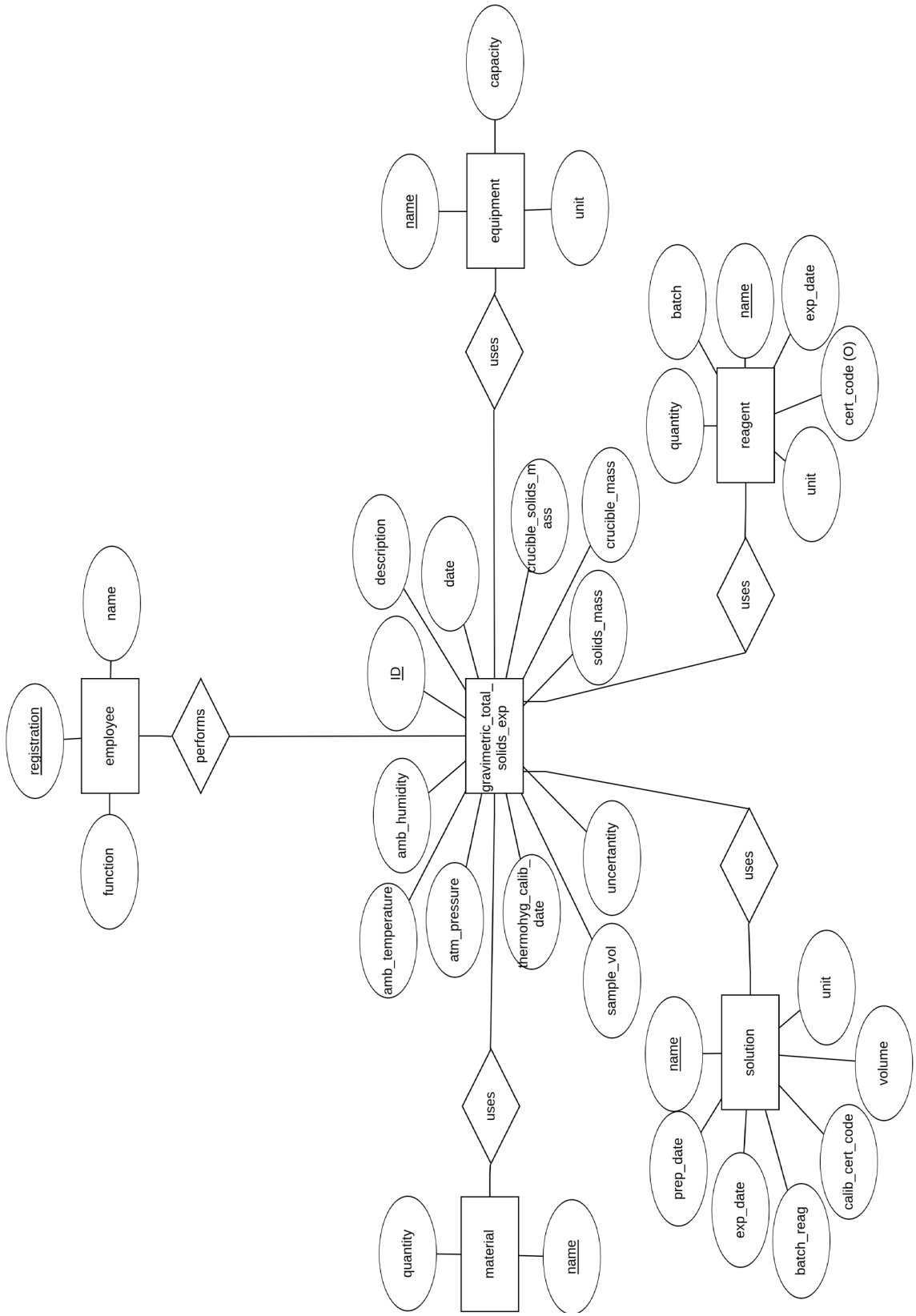


Figure 2. Entity-relationship diagram (ERD) of gravimetric method.

Software Solution has a user-friendly and responsive interface for a smoother user experience, which makes the platform adaptable to all devices (desktops, tablets and phones), using CSS3 and HTML5 technologies to create well-designed pages that give a clean look to the software.

Functionalities

The final version of the prototype Software Solution is able to control customer records, budgets and internal tests. It can also compare a result with the limit value established in specific legislation, as well as aid in the creation of budgets, presentation of up-front technical analysis of results and generation of reports.

In order to detail the functionalities of the software and its approach to ISO/IEC 17025:2017, the following pages present the items from the Standard, their characteristics and how they will be treated in the platform.

Item “Test Method”, as shown below in Figure 3.

- The Standard Operating Procedure is presented and instructed to the technician responsible for the analysis.
- Data processing security is ensured with backup, authenticity confirmation, and encryption procedures.

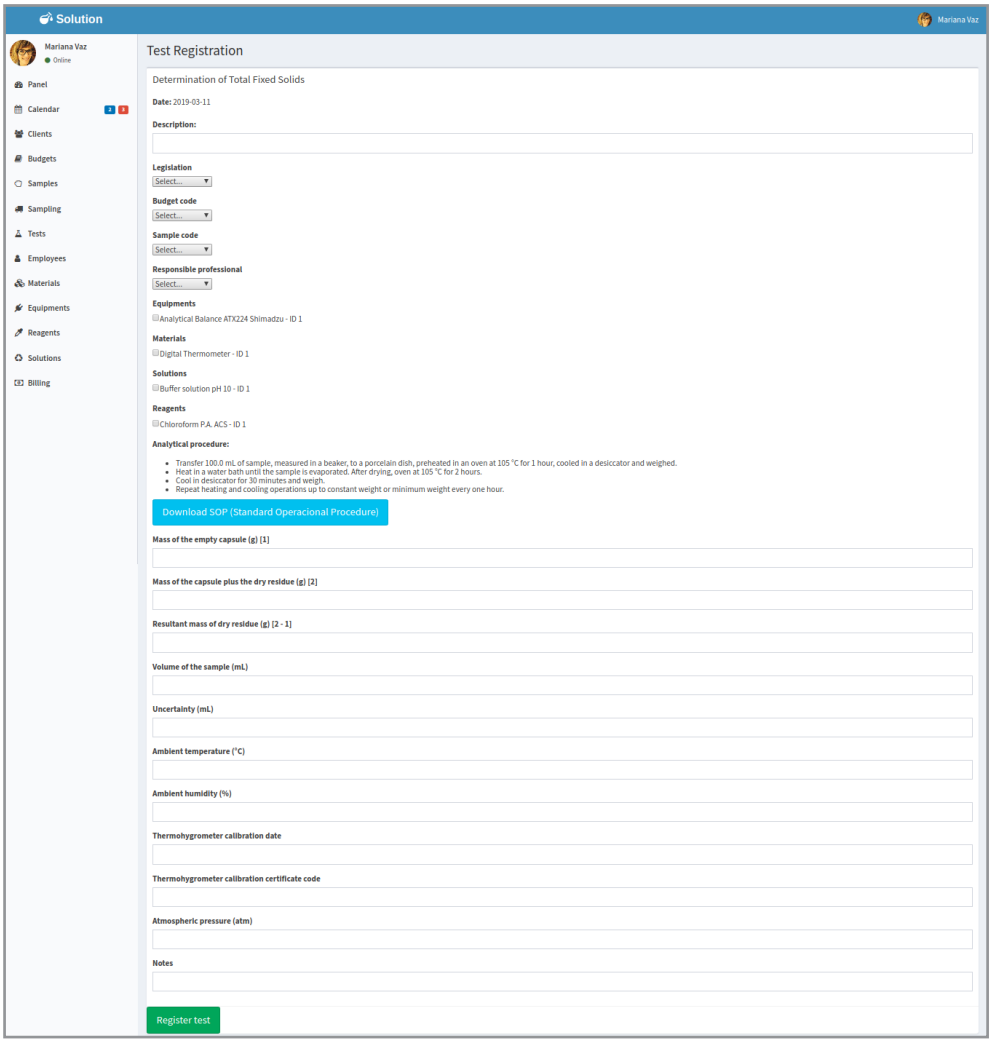


Figure 3. Test registration screen — determination of total fixed solids by gravimetric method.

Item “Quality Assurance of Results”, as shown below in Figure 4.

- A comparison is made between the value found in the test and the reference value established by the legislation.

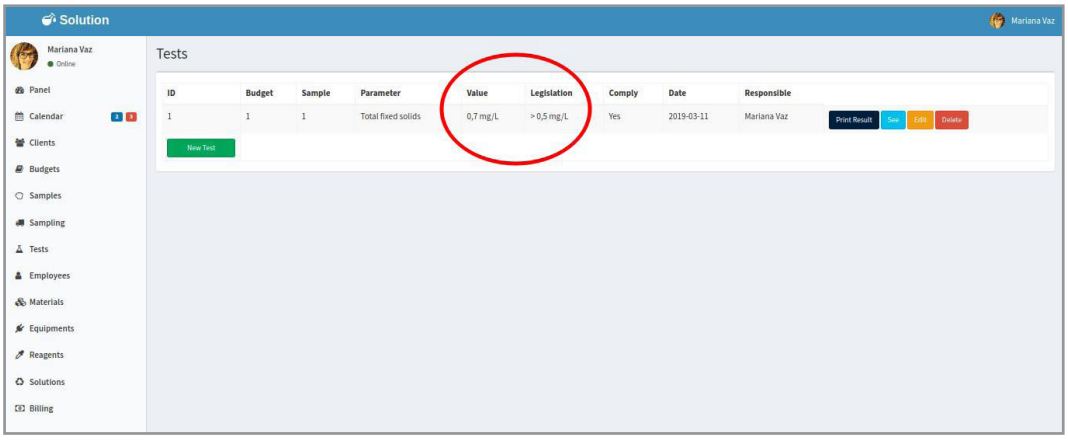


Figure 4. Tests page, highlighting the comparison between the value found as result and the reference value established by current legislation.

Item “Results presentation”, as shown below in Figure 5.

- Test results are recorded on electronic forms.

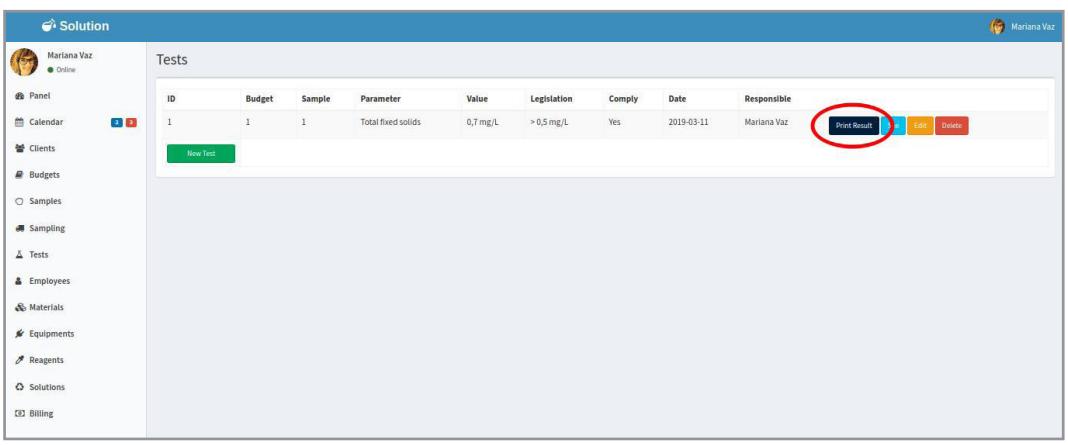


Figure 5. Tests page, highlighting the button to print the electronic form registered with the information of the test and its results and conclusions.

Its responsive layout and online nature, with cloud operation, allows access to the software through different platforms, like desktops and smartphones. This brings several benefits to the laboratory, such as registration of analysis *in loco*.

All procedures managed by the Software are in accordance with ISO/IEC 17025:2017, focusing primarily on items that relate to measurement traceability and reporting, which have been found to be the main sources of errors in the studied laboratory.

The Software provides a concise way for implementing and simplifying quality systems using automated and interactive processes, making it possible to manage, track and report quality indicators. The Figures S1, S2, S3 and S4 are shown in the Supplementary Material section in order to illustrate the Software’s functionalities and screens. The implementation of the digital system also ensures

compliance with ISO/IEC 17025:2017 and helps to conduct continuous improvement processes throughout the organization.

CONCLUSION

The implementation of Software Solution resulted in an improvement of the laboratory's routine and consequent fulfillment of international standard requirements. Daily monitoring of the routine was essential for the identification of procedures' different stages, as well as for the recognition of the main laboratory needs.

Evaluation at the laboratory as well as integration between technical knowledge of Chemistry and Information Technology areas were essential factors for proper planning and development of Software Solution.

Prospects for future research include expanding Software's functionalities, as well as performing comparative tests of laboratory dynamics before and after the digital implementation.

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SUPPLEMENTARY MATERIAL

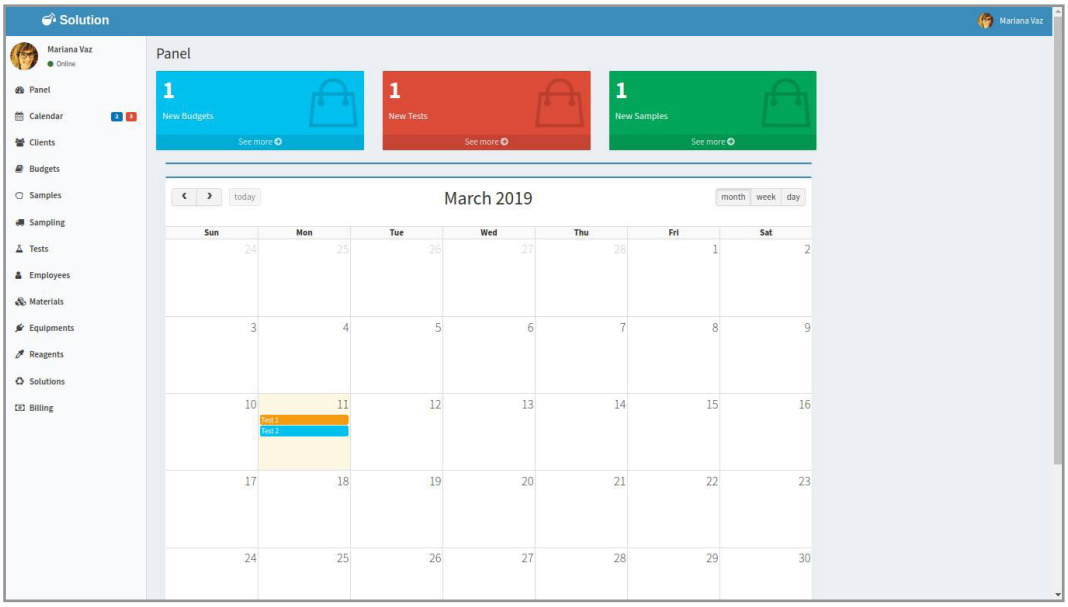

Figure S1. Home page of Software Solution.

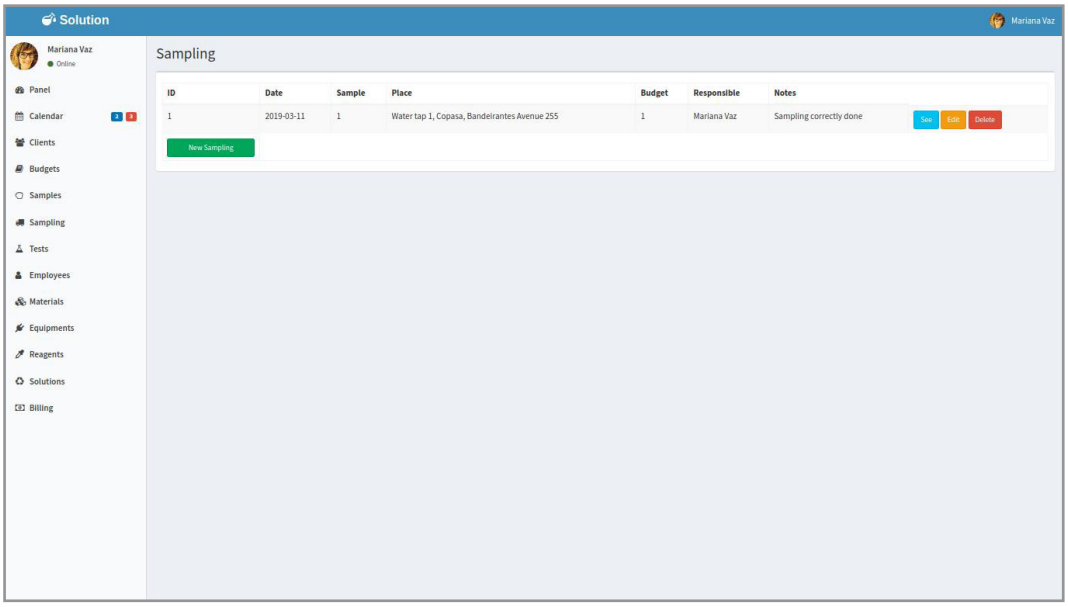

Figure S2. Sampling page of Software Solution.

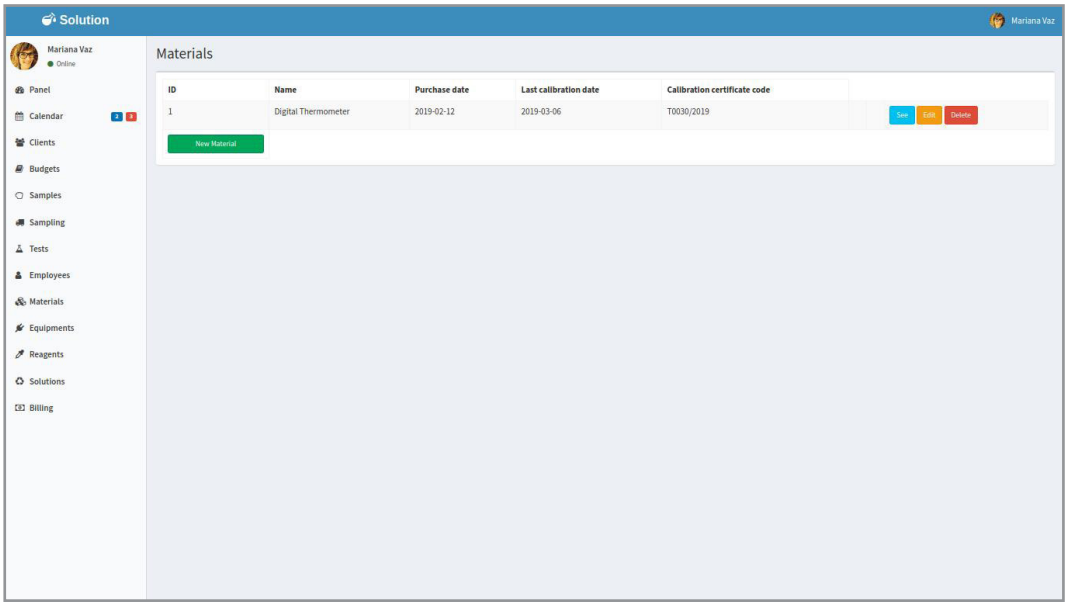

Figure S3. Materials page of Software Solution.

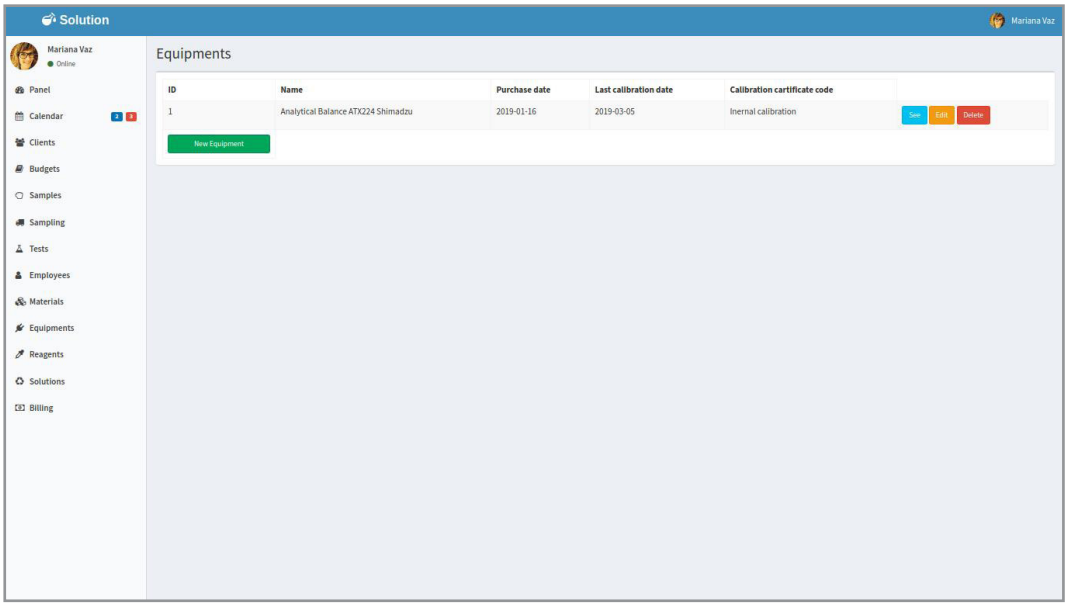

Figure S4. Equipment page of Software Solution.