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Reserch paper

Development of protocol for Validation and Technical Qualification of Hemaglutination Display

Desenvolvimento de protocolo para Validação e Qualificação Técnica de Visor de Hemaglutinação

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ABSTRACT: Clinical analysis laboratories and blood banks throughout Brazil carry out blood typing tests in their routine, which are observed through hemagglutination reactions. The laboratory routine uses equipment and instruments as an aid to the completion of blood typing, increasing immunohematological reactions, but this equipment has had its production discontinued, so it is necessary to develop validation and qualification protocols, so that they are properly manufactured. This article aims to develop a protocol for the validation and one for the technical qualification of hemagglutination displays. Through a research on the Google Scholar and PubMed, we found 1429 articles, of which 155 were used for the construction of the protocol published between 1/1/1990 and 10/1/2018. After reading the articles, one checklist was built for validation and one for technical qualification, containing items to be evaluated. These items received different weights for the final score (weight 1 and weight 2), according to the level of interference on the observation of the result, as well as the minimum average that the equipment must reach when going through this analysis. Final scores range from 24 to 12 for validation and 22 to 11 for qualification. If the equipment does not reach this average, then it is disqualified. The validation and technical qualification protocols, written in the form of a checklist in this work, were not tested on hemagglutination displays, only developed based on their observation in loco, so future studies with the application of the protocols are necessary. However, this protocol will provide greater security in the issue of blood typing results in the future, for laboratories that use the hemagglutination display.
Keywords: Equipment Design, Hemagglutination, Innovation, Validation Studies

RESUMO: *Os laboratórios de análises clínicas e bancos de sangue em todo o Brasil, realizam em sua rotina exames de tipagem sanguínea, que são observadas através de reações de hemaglutinação. Equipamentos e instrumentos são utilizados na rotina laboratorial como auxílio da conclusão da tipagem sanguínea ampliando as reações imunohematológicas, porém estes equipamentos tiveram sua produção descontinuada, dessa forma, faz-se necessária a elaboração de protocolos de validação e de qualificação, para que os mesmos possam ser fabricados corretamente. Este trabalho tem como objetivo desenvolver um protocolo para a validação e um para qualificação técnica de visores de hemaglutinação. Foram pesquisados nas plataformas de busca Google Acadêmico e PubMed 1429 artigos, sendo utilizados 155 artigos para construção do protocolo publicados entre 1/01/1990 até 01/10/2018. Após a realização da leitura dos artigos foi construído um check-list para a validação, e um para a qualificação técnica, contendo itens a serem avaliados. Estes itens receberam pesos diferentes para a pontuação final (peso 1 e peso 2), de acordo com o nível de interferência para a análise do resultado, bem como média mínima que o equipamento deve atingir ao passar pela análise. Os escores finais variam de 24 a 12 para a validação e de 22 a 11 para a qualificação. Caso esta média não seja atingida, o equipamento é desclassificado. Os protocolos de validação e qualificação técnica, redigidos na forma de check-list neste trabalho, não foram testados em visores de hemaglutinação, somente desenvolvidos com base na observação in loco destes, por isso são necessários estudos futuros com a aplicação dos protocolos. Contudo, este protocolo irá proporcionar maior segurança na emissão de resultados de tipagem sanguínea no futuro, para laboratórios que utilizam o visor de hemaglutinação.*
Palavras-chave: *Desenho de Equipamento, Estudos de Validação, Hemaglutinação, Inovação.*

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INTRODUCTION

Clinical analysis laboratories and blood banks throughout Brazil routinely perform blood typing tests. These tests, which are observed through hemagglutination reactions, are mainly performed using the tube technique. To increase the sensitivity of hemagglutination reactions, equipment and instruments are used in the laboratory routine as an aid to the completion of blood typing, expanding immunohematological reactions (BRASIL, 2013; BRASIL, 2014a).

Hemagglutination reactions are extremely important for clinical analysis laboratories and blood centers, as they are the reactions that allow the analysis of the blood group of a patient or blood donor (BRASIL, 2017) When using the tube technique for blood group classification an equipment called “haemagglutination display” is used. The hemagglutination display is an important piece of equipment that is currently lacking in the Brazilian market, but it is ideal for this type of analysis (BRASIL, 2014a). This product was traded by the company Phoenix Luferco®, but it abandoned its production, and clinical analysis laboratories and blood centers began to develop alternative techniques for visualizing this type of reaction (PHOENIX, 2018; VIEIRA, 2016). The hemagglutination visor consists of a concave mirror. The hemagglutination reaction is amplified by the reflection of the mirror, with the aid of an incident light to facilitate visualization. Magnification is necessary to increase the visual sensitivity of the test, and reduce the chance of false negative results in immunohematological tests (VIEIRA, 2016).

New technologies are of paramount importance to improve the visualization of immunohematological reactions in tube techniques, since the production of hemagglutination displays was discontinued, and this equipment were the “Gold Standard” for immunohematological analyzes (BRASIL, 2014a; VIEIRA, 2016). These new technologies need technical qualification and validation before being duly registered with the National Health Surveillance Agency (ANVISA), Ministry of Health and National Institute of Metrology, Quality and Technology (INMETRO) (BRASIL, 2011; BRASIL, 2014b; INMETRO, 2016).

Validation and technical qualification are essential procedures for the consolidation of any product, as it is through this process that it can be classified as suitable or not for commercialization (BRASIL, 2001). Qualification can be defined as a series of documented operations in accordance with a predetermined test plan and defined acceptance criteria, ensuring that suppliers, inputs, equipment and instruments meet specified requirements, i.e., the set of tests that allows evaluating the functionality of the evaluated item, if it works as it should (refers to installation). Validation, on the other hand, is documented evidence that a procedure, process, system or method actually leads to the expected results, that is, if the item analyzed provides the expected result (refers to the process and the result). That said, it is clear that the validation process depends on the qualification and vice-versa (WHO, 2002). These processes aim at the quality of the object offered, which is guaranteed through the Good Operating Practices (GMP), which are the components of Quality Assurance that ensure that services are offered with adequate quality standards, in accordance with current legislation (BRASIL, 2011).

It is extremely important that the quality and reliability of a product are ensured through the validation and technical qualification processes. Therefore, this work aimed to

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develop a protocol for the validation and technical qualification of hemagglutination displays, enabling their use for routine laboratory purposes.

MATERIAL AND METHODS

Scientific search for elaboration of protocols

From August 2017 to November 2018, the process of bibliographic consultation of scientific articles was started for the preparation of the protocols. The search was conducted in national and international journals in databases with the terms "validation studies immunohematology", called T1, "validation protocol immunohematology" (T2), "validation methods immunohematology" (T3), "qualification methods immunohematology" (T4), “methods immunohematology” (T5), which were used in the US National Library of Medicine database and National Institutes of Health (PubMed®) (PUBMED, 2018). The terms “protocol for validation of immunohematology techniques” (T6) and “equipment validation” (T7) were used in search engine sites or search engines (GOOGLE, 2018). The criteria for inclusion of manuscripts were the date, being selected those published between 1990 and 2018 and that, in the presentation of the title, showed specific studies with the theme of laboratory immunohematology. The criteria for the exclusion of articles were repeated or that escaped from the study topic. Books related to Hemotherapy and Immunohematology and documentation from the National Health Surveillance Agency (ANVISA) that determine how to carry out the validation and technical qualification processes of equipment were also used.

After the initial investigation of the terms on the search platforms, we made a new research, but using specific filters. It was used in the PubMed® date filter platform, which selected articles published from 01/01/1990 to 10/01/2018, and in Google Scholar, the term T6 was searched with results only in Portuguese and the term T7 was searched using quotes. The checklist items to be evaluated were developed based on the prototypes of hemagglutination displays that were produced by students from the Production Engineering course at UNIVALI (VIEIRA, 2016).

Qualification and validation score development

The checklist was elaborated by determining a score for each item, in which the score was assigned from 0 to 2, with 0: Non-Compliant, 1: Partially Complies and 2: Fully Complies. To classify an item as validated or qualified, the average between the maximum score to be achieved in the score and the minimum score was calculated, so that the equipment that achieves this average, or exceeds it, is classified as validated and/or qualified (AYSOLA et al, 2017). Hemagglutination displays that obtained an average lower than the stipulated for validation or qualification cannot be used in laboratory routine. Concomitantly, with the development of the score, a score was developed that took into account the minimum technical criteria that any hemagglutination screen should meet in order to guarantee reliable immunohematological results.

In order to calculate the score for the display to be classified as validated or qualified, two formulas were developed, one for validation and one for qualification, as shown in Figure 1 and Figure 2, respectively. The formulas were elaborated using the sum

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symbol, since the final result of both is the sum of the scores of the items weighing 2 with the sum of the scores of the items weighing 1.

Figure 1: Formula for calculating the result of the evaluation of the Validation checklist.

$$\sum_{i'=(X\times 2)}^{5} i' + \sum_{i''=(X\times 1)}^{2} i'' = Y$$

Caption: X = grade given to the respective item; Y = final score achieved by the analyzed hemagglutination display; 5 = number of items weighing 2 on the checklist; 2 = number of items weighing 1 in the checklist; i' = "X" multiplied by the weight 2; i'' = "X" multiplied by weight 1.
Source: Made by author (2019).

Figure 2: Formula for calculating the result of the evaluation of the Qualification checklist.

$$\sum_{i'=(X\times 2)}^{2} i' + \sum_{i''=(X\times 1)}^{7} i'' = Y$$

Caption: X = grade given to the respective item; Y = final score achieved by the analyzed hemagglutination display; 2 = number of items weighing 2 on the checklist; 7 = number of items weighing 1 in the checklist; i' = "X" multiplied by the weight 2; i'' = "X" multiplied by weight 1.
Source: Made by author (2019).

INPI patents

After the development of the scores and the checklist, a survey was carried out on patent registration, as the hemagglutination displays were no longer being manufactured and marketed in Brazil. The research was carried out on the website of the National Institute of Industrial Property (INPI, 2019), in order to verify the possible existence of a patent on hemagglutination displays in Brazil.

RESULTS

The documents researched for the construction of the protocols, published between 1990 and 2018, are presented in Table 1. We found a total of 1429 scientific articles without the use of a filter. After using the advanced filter, we obtained a total of 155 articles, which were used to develop the score and checklist model of the validation and qualification parameters for the hemagglutination display.

Table 1: Codes of search terms used in search engines, as well as the number of articles presented by platforms with and without filters.

Term code	Search plataform	Absolute nº of articles without using a filter	Absolute nº of articles using a filter
T1	PubMed	20	0
T2	PubMed	3	0
T3	PubMed	41	2
T4	PubMed	3	2
T5	PubMed	1256	47
T6	Google scholar	6	5*

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T7	Google scholar	100	99
Total	-	1429	155

Note: * - An article was removed due to duplicate publication on the platform.

The items considered for the checklist received different weights for the final score (weight 1 and weight 2), taking into account the potential interfering in the evaluation of the test result. That is, the items to be evaluated that directly interfere in the evaluation of the result of the hemagglutination reaction received a higher weight (weight 2), whereas the items that do not directly interfere in the result evaluation received a lower weight (weight 1), these are presented in Table 2 and Table 3. It is worth mentioning that if the equipment obtains a score of zero in any item with a weight of 2, it will automatically fail, not being classified as validated or qualified.

Table 2: Checklist of items to be evaluated for validation of the agglutination display and expected results.

Validation item	Expected result	Weight	Grade
Reading of agglutination intensities	Equipment must provide the visualization of positive readings greater than or equal to 1+	2	
Quality of the magnification instrument	Magnification instrument should provide a clear amplification of the reaction	2	
Light angle	Light should not interfere with the visualization of the agglutination	2	
Cleaning execution	Sanitation must in no way affect the results observed on the device.	2	
Stability	Equipment must be stable, with its base leveled, so as not to oscillate	1	
Durability	Lamp and magnifying instrument must have good durability	1	
Light intensity	Light intensity should not interfere with reaction visualization	2	

The laboratory specialist must analyze the aspects mentioned in the checklists and classify the items with a score from 0 to 2 (0 = not complying; 1 = partially complying; 2 = fully complying) in the “score” column of the respective table. After assigning the scores, the result of the validation checklist must be applied to the formula in **Figure 1**, and the result of the qualification checklist, to the formula in **Figure 2**. The results of the equations must comply with the criteria of **Table 4**, presented below.

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Table 3: Checklist of items to be evaluated for qualification of the agglutination display and expected results.

Qualification Item	Expected result	Weight	Grade
Light switch	Light switch must have good durability	1	
Amplification instrument mobility	Instrument to be used for magnifying must be easily movable	1	
Flexibility/mobility of the lamp rod (if present)	Lamp support rod must have good flexibility/mobility	1	
Material	Equipment sanitation should be easy and not compromise its functionality	2	
Ergonomics	The equipment must be light, easy to handle and transport	1	
Maintenance	Lamp and magnifying instrument must be easily replaceable	2	
Voltage	Device must be bivolt (110V/220V)	1	
Outlet	Outlet must meet NBR 14136/07 specifications	1	
Wire	Wire should not be too long or too short, so as not to make handling the equipment difficult	1	

Table 4: Table of averages for classification of validation and qualification.

Validation	*Maximum grade*	*Minimum grade*
	24	12
Average to be reached	18 – Not zeroing on any items with weight 2	
Qualification	*Maximum grade*	*Minimum grade*
	22	11
Average to be reached	16 – Not zeroing on any items with weight 2	

The average to be achieved in the validation and qualification when evaluating the hemagglutination display was calculated by adding the maximum and minimum score possible for each checklist and dividing them by 2. The scores for each criterion in the Tables were then applied 2 and 3 in the formulas, as shown in Figures 1 and 2.

To better elucidate the activities and summarize the application of the protocols, a flowchart was developed (Figure 3) that will assist the laboratory technician in carrying out validation and qualification.

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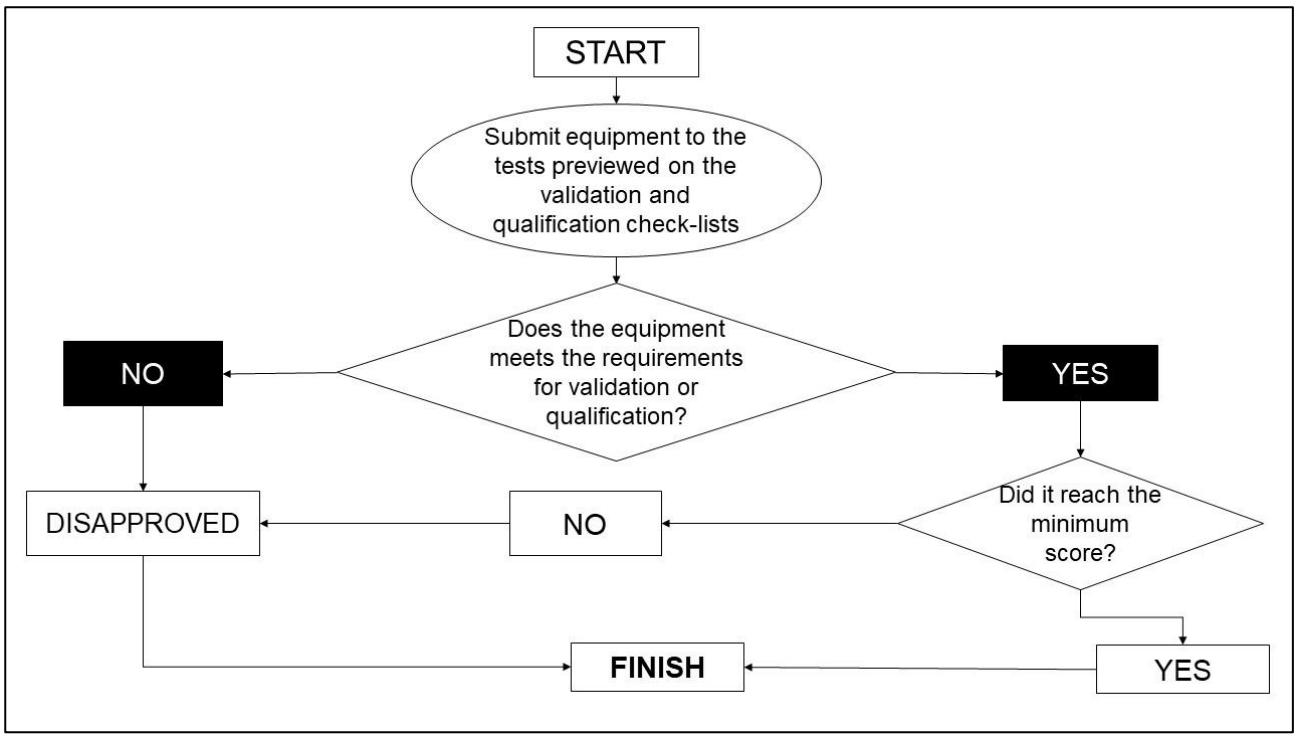
Figure 3: Flowchart of procedures regarding the application of the Validation checklist.



The search for the existence of patents, carried out on the INPI website, demonstrated the inexistence of patents, which contain the terms “hemagglutination display” or “agglutinoscope” in their title, or abstract. As for patents that contain any of the words, 380 processes were found for “hemagglutination display” in the title, and 1723 in the abstract, and none for “agglutinoscope” in both the title and the abstract. In addition, for patents that contain words similar to “hemagglutination display” in the title, 618 patents were found, since they contain approximate words in the abstract, 2633 processes. For patents that contain words similar to “agglutinoscope” in the title, 38 processes were found, whereas approximate words in the abstract, 51 processes were found.

DISCUSSION

Validation and qualification processes are of paramount importance to ensure the quality of a product, process, equipment or service before it can be used correctly and be considered reliable, as stated in the BPF (BRASIL, 2011). In a study carried out in 2009, the importance of carrying out these processes is evident, since this research aimed to validate the Sysmex XS-1000i hematology analyzer, by comparing the leukocyte count of the equipment and the manual count by extension blade blood. The validation classified the product as reliable, and this corroborates the importance of carrying out these processes, which ensure that an item meets the expectations placed on it, thus reducing possible errors due to wrongly calibrated materials (BORGES; SIQUEIRA, 2009).

Unfortunately, there was a shortage of bibliography that talks about the development of validation protocols and technical qualification of equipment for the health

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area, and most of the ideas for the elaboration of the results were taken from works and articles related to other areas, however which also deal with validation and qualification.

The development of prototypes was carried out in parallel with the Biomedicine Course, with the purpose of providing the re-implantation of this product on the market, for use in the laboratory routine (VIEIRA, 2016). The choice of preparing a protocol as a guide for carrying out these processes becomes important when observing the benefits of using it, such as the standardization of the information collected and the periodic analysis of the data obtained (LOPES; FERREIRA; SANTOS, 2010). Evidence of the importance of standardizing and applying these protocols was observed in a study carried out in a hospital in the state of São Paulo, evaluating the treatment approach used for patients with acute myocardial infarction, and implementing a protocol for its standardization. At the end of the study, a significant increase in the use of drugs proven to be effective for the treatment of this disease was observed, and consequently a significant reduction in mortality, within a period of 30 days after the application of the protocol (BORDON et al., 2004).

In another study, a protocol was implemented to improve individual nutritional care in primary health care, in the city of Belo Horizonte, Minas Gerais. The study proposed an anthropometric assessment form and a protocol for attending return visits for the patients studied. These items were then implemented in nine basic health units and were followed for six months to assess inconsistencies and adaptation needs to the population served. After six months, the protocols were readjusted to local needs, resulting in the final version of the document, which best served the population, according to the protocol (LOPES; FERREIRA; SANTOS, 2010).

Considering the present evidence, the importance of a protocol to be followed to obtain the validation and qualification of the hemagglutination screens becomes clear. This equipment is highly necessary in the laboratory routine of immunohematology tests, and its lack has a direct impact on the quality of work of employees in blood centers and clinical laboratories (BRASIL, 2014a). A study carried out on the organizational climate of the blood center coordinating the state of Amapá showed that 50.3% of employees were motivated by having the necessary equipment to carry out daily tasks at the institution (BRITO, 2010). These results are in line with other Brazilian states such as the blood center in Sergipe, in which 48% of employees report that adequate equipment and materials are available to carry out the work, 49% in the Blood Center in Acre and 55% in the Blood Center in Roraima (PASSOS, 2010; ROSA, 2010; MOREIRA, 2010).

The development and use of protocols that can assess the validation and qualification of the hemagglutination display, developed in this study, may also provide future institutions with a better organizational climate, since employees will have confidence in their daily use equipment. This evidence demonstrates that the availability of efficient and reliable equipment in the work field directly reflects on the efficiency of employees. The availability of these equipments can only be made after they have been submitted to the validation and qualification processes (Brasil, 2017). Quality assurance, regardless of the field in which it operates, must be considered a mechanism to avoid non-compliances, and, ultimately, if they occur, they must be resolved, especially in terms of inserting new products in the Brazilian market (DE PAULA; ALVES; NANTES, 2017).

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CONCLUSION

The present work shows that the validation and technical qualification processes are extremely important to classify equipment as reliable, and thus, classifying them as suitable or not for commercialization. When performing the literature search, a shortage of scientific articles was detected in the researched platforms that aim to solve the proposed problem.

In this way, the validation and qualification protocols presented as results of the present work, in theory, are ready for application, given the fact that they were developed only based on the mere observation of the hemagglutination displays. Therefore, it is necessary a future study in which their application is carried out, and their applicability in the laboratory routine is evaluated. It is also noteworthy that the data obtained and the form of preparation of the protocols, both the checklist format and the assignment of grades, can serve as a guide for future works, with similar objectives, or with a similar structure for other equipment in the healthcare area.

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