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Post-market monitoring of rapid tests for COVID-19 antibody detection: data analysis from the Microsoft® Power Bi platform

Monitoramento pós-mercado dos testes rápidos para detecção de anticorpos da COVID-19: análise de dados da plataforma Microsoft® Power Bi

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ABSTRACT

Introduction: The COVID-19 outbreak caused by a new type of coronavirus was confirmed by Chinese authorities on January 7, 2020, resulting in hundreds of deaths worldwide. Due to the rapid spread of the disease, the World Health Organization (WHO) declared a Public Health Emergency of International Concern on January 30, 2020, and later declared it a pandemic on March 11, 2020. In response to the public health emergency, the National Health Surveillance Agency (Anvisa) in Brazil published Collegiate Board Resolutions (RDCs) No. 379/2020 and RDC No. 445/2020. These regulations established the laboratory analysis of products for in vitro diagnosis by the National Institute for Quality Control in Health (INCQS). **Objective:** The purpose of this study was to evaluate the performance data of rapid tests for the detection (AcTR) of COVID-19 antibodies on the Microsoft® Power Bi platform on the Anvisa portal. Method: The evaluation period was from April 6, 2020, to December 28, 2021. **Results:** Out of 293 batches of AcTR products evaluated, 55.3% were found to be compliant, while 44.7% were non-compliant according to the established analysis criteria. **Conclusions:** The main reason for non-compliance was reduced sensitivity of the tests. Post-market monitoring was conducted to ensure the availability of quality, safe, and effective products in the Brazilian market and to support decision-making by Brazilian authorities.

KEYWORDS: Serological Tests; SARS-CoV-2; Quality Control; Rapid Test

RESUMO

Introdução: Desde a confirmação pelas autoridades chinesas de um novo tipo de coronavírus em 7 de janeiro de 2020, a *Coronaviris Disease* - 19 (COVID-19) já havia causado centenas de mortes. A rápida disseminação da doença levou a Organização Mundial da Saúde a declarar Emergência de Saúde Pública de Importância Internacional em 30 de janeiro de 2020 e uma pandemia em 11 de março do mesmo ano. A disponibilização mundial de testes para o diagnóstico e vigilância epidemiológica da COVID-19 tornou-se urgente e necessária. Em resposta à emergência de saúde pública, a Agência Nacional de Vigilância Sanitária (Anvisa) publicou as Resoluções da Diretoria Colegiada (RDC) nº 379, de 30 de abril de 2020 e nº 445, de 10 de dezembro de 2020 que estabelecem a análise laboratorial dos produtos para o diagnóstico *in vitro* pelo Instituto Nacional de Controle de Qualidade em Saúde. **Objetivo:** Avaliar os dados de desempenho dos testes rápidos para detecção de anticorpos (AcTR) contra COVID-19 publicados na plataforma Microsoft® Power Bi no portal Anvisa. **Método:** No período de 06/04/2020 a 28/12/2021, foi realizado o levantamento dos dados referentes à sensibilidade e à especificidade clínica ou diagnóstica dos AcTR. Resultados: Um total de 55,3% AcTR apresentou resultados conformes e 44,7%, não conformes, de acordo com os critérios de análise estabelecidos. A sensibilidade reduzida foi a principal causa de não conformidade dos 293 lotes de

produtos avaliados no período. **Conclusões:** O monitoramento pós-mercado garantiu a disponibilização de produtos de qualidade, seguros e eficazes no mercado nacional, além de subsidiar as tomadas de decisão por parte de autoridades brasileiras.

PALAVRAS-CHAVE: Testes Sorológicos; COVID-19; Controle de Qualidade; Pesquisa de Anticorpos

INTRODUCTION

At the end of December 2019, patients were admitted to hospitals in Wuhan, China, reporting symptoms suggestive of pneumonia. From analysis of the genetic material, it was determined that the agent responsible was a coronavirus, causing serious infections. Once the pathogen was identified, the World Health Organization (WHO) named it severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease was renamed Coronavirus Disease - 2019 (COVID-19)[1,2].

The initial diagnosis consisted of investigating and screening the symptoms, as well as carrying out complementary tests to assess the possibility of SARS-CoV-2 infection[3]. Given the clinical similarity to other respiratory syndromes caused by coronaviruses or other pathogens, such as the influenza virus, it was necessary to use specific diagnostic tests to detect SARS-CoV-2[4].

COVID-19 can be diagnosed using serological or molecular tests. Serology detects type A (IgA), type M (IgM), and type G (IgG) immunoglobulins using enzyme-linked immunosorbent assays (ELISA), rapid tests (immunochromatographic), and chemiluminescence assays (CLIA)[5]. Molecular diagnosis is based on the detection of SARS-CoV-2 genetic material by reverse transcriptase polymerase chain reaction (RT-qPCR), using the N, E, S, and RdRP genes as targets[6,7].

With the need to quickly identify the infected population, various products have become available on the national and international market, including rapid tests for IgA, IgM, and IgG antibodies[8]. IgA antibodies play a fundamental role in protecting against infections in mucosal areas and require two to five days after the onset of symptoms for detection. IgM antibodies are considered the first line of defense during viral infections and are detected within three to six days. In turn, IgG antibodies correspond to the high-affinity adaptive response and are responsible for long-term immunity and immunological memory, and can be positive on average between 10 and 18 days[8,9,10,11,12].

Rapid antibody detection tests are qualitative assays in which results can be obtained in between 5 and 30 minutes. They use antigens conjugated almost entirely with colloidal gold, which bind to immunoglobulins present in serum, plasma or blood samples from individuals infected with SARS-CoV-2. This process leads to the formation of an antigen-antibody complex that migrates through a nitrocellulose membrane by capillarity[13,14]. In the test area, anti-IgG antibodies are found attached to the membrane, which recognize and capture the immunoglobulins, thus forming a colored line, indicative of a reagent result. In the absence of these antibodies, the test line is not marked, indicating a non-reactive result. For the test to be validated, a control band must appear[11,15].

Therefore, diagnostic tests are extremely important for tracing and monitoring diseases and are one of the main strategies in health control policies[15].

Currently, the regulation and consequently the marketing of *in vitro* diagnostic products is based on Collegiate Board Resolution (RDC) No. 36, of August 26, 2015. This is responsible for establishing the risk classification, control regime, registration, and labeling requirements and instructions for use of *in vitro* diagnostic products, including their instruments[16].

Due to the Public Health Emergency of National Importance (PHEIC), the Brazilian National Health Surveillance Agency (Anvisa) published RDC No. 348 on March 17, 2020. This allowed emergency registration to be granted for up to one year for products that showed diagnostic effectiveness for COVID-19, provided there was technical justification for the lack of studies or to prove the restriction of data on the product. In addition, the rule established that, at the end of the one-year period, companies could amend the registration process, providing the missing information. In the event of approval, the registration would be valid for a regular period of ten years from the date it was initially granted[17].

In view of the growing demand for the regularization of COVID-19 diagnostic tests associated with the need to guarantee the availability of safe and effective products on the national market, RDC No. 356 was published on March 23, 2020. This resolution sets out the requirements for the manufacture, import, and acquisition of medical devices for use in health services, related to SARS-CoV-2. However, RDC No. 356 was amended by RDC No. 379 on April 30, 2020. According to the 7th paragraph of Art. 9, those responsible for importing the tests were required to send a minimum of 100 units of each batch of the imported product to the National Institute for Quality Control in Health (INCQS), within a maximum period of 5 days from receipt of the cargo[18]. At INCQS, the Blood and Blood Products Laboratory acts as a reference in the evaluation of the quality of *in vitro* diagnostic products, pre- and post-market, by means of prior (pre-market), control (post-market), and fiscal analysis (proving their conformity with their original formula) [11].

Considering the importance of diagnostic tests in the pandemic context, Anvisa published RDC No. 445 on December 10, 2020. The resolution allowed the retroactive application of shelf-life

extensions for in vitro diagnostic products already registered under products already registered under RDC No. 348/2020[19]. Currently, RDCs No. 379/2020 and No. 445/2020, created as a result of the SARS-CoV-2 related SPIN, have been revoked[9].

The aim of this study was to analyze the performance data (sensitivity and clinical specificity) of rapid tests for detecting IgA, IgM, and/or IgG antibodies to COVID-19. The data used was made available through the Anvisa website on the Microsoft® Power Bi (Business Intelligence) platform, related to the "Post-market monitoring of the quality of COVID-19 *in vitro* diagnostic devices: laboratory analyses" program. The study included products evaluated from April 6, 2020, to December 28, 2021.

METHOD

Data was collected from April 6, 2020, to December 28, 2021, using information published on the Microsoft® platform Power Bi, referring to the "Post-market monitoring of the quality of COVID-19 *in vitro* diagnostic devices: laboratory analyses", available for consultation on the Anvisa website (https://app.powerbi.com/view?r=eyJrIjoiZjQzMDE0NGUtN2M4Yi00NTZiLTliN2MtMzA2YTZkMjcyNDRhIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9).

The data related to serological markers and the sensitivity and specificity values of the batches of rapid tests for detecting antibodies (IgA, IgM, and/or IgG) evaluated were collected on the platform and organized in an Excel spreadsheet® according to the proposed objective.

The results relating to sensitivity and specificity were assessed by comparing the information provided by the manufacturer in the instructions for use with the results obtained after laboratory analysis at INCQS. Products whose sensitivity and/or specificity values were higher than or equal to those declared by the manufacturer were considered compliant, while those with lower values were considered non-compliant. Batches of products whose information available on the platform was incomplete, missing or discrepant were also excluded from the analysis.

RESULTS

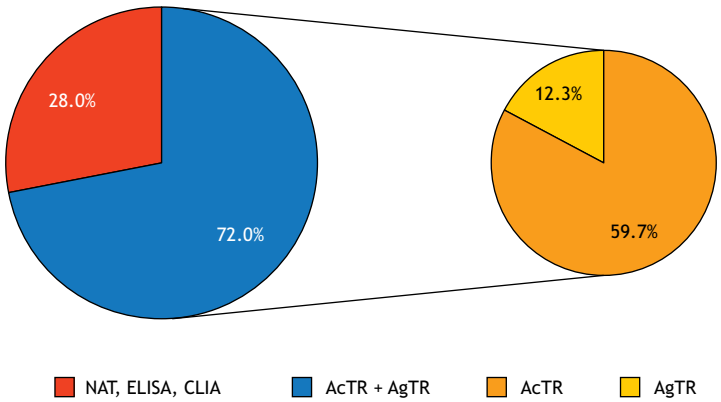
From April 6, 2020, to December 28, 2021, the data published on the Microsoft® platform Power Bi regarding the "Post-market monitoring of the quality of COVID-19 *in vitro* diagnostic devices: laboratory analyses", available for consultation on Anvisa's website, regarding the performance of 504 batches of COVID-19 diagnostic products, were analyzed. Of the total number of products evaluated, 59.7% (301/504) corresponded to tests for the detection of antibodies (AcTR) IgA/IgM/IgG, IgM, and IgG/IgM, and 12.3% (62/504) for the detection of antigens (AgTR). Methodologies such as ELISA, nucleic acid detection tests (NAT) and CLIA accounted for 28.0% (141/504) of the total evaluated (Figure 1).

Of the 301 AcTR batches, only 2.6% (8/301) were excluded from the analysis due to missing data or discrepancies in the platform, resulting in 293 batches for the study.

The AcTRs for the detection of combined IgA/IgM/IgG represented 0.34% (1/293) of the products evaluated and obtained results in line with the expected sensitivity and specificity parameters (Table 1).

Of the 293 batches of AcTR, only 4.5% (13/293) were intended for the detection of IgM antibodies. Of these, 76.9% (10/13) showed results in line with the sensitivity and specificity parameters declared by the manufacturer, while 23.1% (3/13) did not obtain compliant results (Table 1).

It was observed that, in relation to the percentage of non-compliant IgM AcTRs, 66.6% (2/3) showed discordant results in terms of both sensitivity and specificity. Meanwhile, 33.4% (1/3) of the tests showed disagreement only in sensitivity, maintaining the specificity as stated by the manufacturer (Table 2).



Source: Prepared by the authors, 2023.
NAT: Nucleic acid detection tests; ELISA: Enzyme-linked immunosorbent assays; CLIA: Chemiluminescence; AcTR: Rapid antibody test; AgTR: Rapid antigen test.

Figure 1. Distribution of COVID-19 diagnostic tests by the methodologies evaluated.

IgM/IgG AcTRs were the most frequent among the batches evaluated, accounting for 95.2% (279/293) of the total (Table 1). Of these, 54.1% (151/279) presented results that complied with the sensitivity and specificity parameters, while 45.9% (128/279) were non-compliant (Table 2).

Table 2 shows the data for the 128 non-compliant batches for AcTR IgM/IgG. Of the total evaluated, 46.0% (59/128) obtained sensitivity values lower than those declared, 19.6% (25/128) in specificity, and 32.0% (41/128) in both. Due to the lack of interpretable results, 2.4% (3/128) were considered invalid, according to the description.

The IgM and IgG AcTRs were also evaluated in terms of the class of immunoglobulin detected. Of the 59 batches that did not comply for sensitivity, 13.5% (8/59) showed false negative results for IgM antibodies, 6.8% (4/59) for IgG antibodies, and 79.7% (47/59) for both (Table 3).

Of the total of 25 non-compliant AcTRs in terms of specificity, 16.0% (4/25) showed false positive results for IgM, 4.0% (1/25) for IgG, and 80.0% (20/25) for IgM/IgG antibodies. Of the 41 batches that were non-compliant in terms of sensitivity and specificity, 7.3% (3/41) failed for IgM and 92.7% (38/41) for IgM/IgG antibodies (Table 3).

The sensitivity values reported by the manufacturers ranged from 77.4% to 100.0%, while the results obtained after laboratory analysis ranged from 54.0% to 100.0%. The declared specificity ranged from 91.8% to 100.0% and the obtained specificity ranged from 74.0% to 100.0%.

Table 1. Evaluation of rapid antibody detection tests for compliance with the established evaluation criteria.

AcTR	According to	Non-compliant	Total
IgA/IgM/IgG	1 (100.0%)	-	1 (0.3%)
IgM	10 (76.9%)	3 (23.1%)	13 (4.5%)
IgM/IgG	151 (54.1%)	128 (45.9%)	279 (95.2%)
Total	162 (55.3%)	131 (44.7%)	293 (100.0%)

Source: Prepared by the authors, 2023.
AcTR: Rapid antibody test; IgA: Immunoglobulin type A; IgM: Immunoglobulin type M; IgG: Immunoglobulin type G.

Table 2. Distribution of non-compliant IgM and IgM/IgG antibodies in terms of sensitivity and clinical or diagnostic specificity.

AcTR	Sens	Spe	Sens/Spe	Invalid	Total
IgM	1 (33.4%)	-	2 (66.6%)	-	3 (100.0%)
IgM/IgG	59 (46.0%)	25 (19.6%)	41 (32.0%)	3 (2.4%)	128 (100.0%)

Source: Prepared by the authors, 2023.
AcTR: Rapid antibody detection test; Sens: Sensitivity; Spe: Specificity; Sens/Spe: Sensitivity/Specificity;
IgM: Immunoglobulin type M; IgG: Immunoglobulin type G.

Table 3. Evaluation of the sensitivity and/or specificity parameters obtained in the tests for detecting non-compliant antibodies in terms of Immunoglobulin class (IgM, IgG, IgM/IgG).

Parameter	IgM	IgG	IgM/IgG	Total
Sensitivity	8 (13.5%)	4 (6.8%)	47 (79.7%)	59 (46.0%)
Specificity	4 (16.0%)	1 (4.0%)	20 (80.0%)	25 (19.6%)
Sensitivity/ Specificity	3 (7.3%)	-	38 (92.7%)	41 (32.0%)
Invalid	-	-	-	3 (2.4%)
Total				128 (100.0%)

Source: Prepared by the authors, 2023.
IgM: Immunoglobulin type M; IgG: Immunoglobulin type G.

DISCUSSION

Diagnostic tests are the main tools in disease control. Accurate diagnosis provides appropriate treatment, improving patients' quality of life, as well as preventing the spread of diseases and helping to plan public policies. In this regard, a wide variety of serological tests for detecting COVID-19 antibodies, mostly rapid tests, have become available on the international market. This was due to the urgent demand for products capable of correctly diagnosing the disease simply, quickly and at a reduced cost[20].

With the spread of COVID-19, several nations urgently needed to adopt large-scale population screening and understand the epidemiology of the disease. These actions were crucial to enable the implementation of measures to control the disease.

Over the course of 2020, the diagnostic tools used to conduct serological screenings were gradually made available. At the same time, a regulatory framework was drawn up to deal with the process of importing and evaluating the effectiveness of these tests.

Considering the importance of evaluating product performance, Anvisa set up the analytical monitoring program in partnership with INCQS in April 2020. The evaluation was carried out based on the product performance information (sensitivity and clinical or diagnostic specificity) provided by the manufacturers (in the instructions for use) and compared with that obtained by INCQS. According to RDC No. 379/2020 Art.13, sole paragraph, the importer should prove and ensure the sensitivity and specificity of the products. Only products that achieved the performance values stated in the instructions for use established by the manufacturer itself[18] were approved for sale and considered compliant.

The results of this evaluation showed that the declared sensitivity values of the AcTR ranged from 77.4% to 100.0%, while those obtained after laboratory analysis ranged from 54.0% to 100.0%. The declared specificity ranged from 91.8% to 100.0%, and the specificity obtained ranged from 74.0% to 100.0%.

According to data in the literature, COVID-19 AcTR showed reduced sensitivity ranging from 54.2% to 78.9% and specificity from 93.0% to 100.0%[21,22], when compared to other serological tests such as ELISA and CLIA[20].

In an analysis involving the evaluation of 25 different rapid tests, conducted by Lutalo et al.[23], there was a significant variation in the performance of the products. The authors stressed the importance of stepping up research and development efforts to achieve even more accurate and reliable tests[23].

In studies carried out in China and the United States, the sensitivity and specificity of serological tests for samples initially collected from hospitalized patients ranged from 38.3% to 85.4% and 100.0% for ELISA[24,25,26] and from 18.4% to 88.7% and 90.6% to 91.7% for rapid tests[8,27], respectively. In France, in a study that evaluated 17 rapid tests, the specificity values ranged from 77.4% to 100.0%, corroborating the data obtained in our study[28].

The highest percentage of non-compliant products observed corresponded to IgM/IgG AcTR. Data presented in a recent systematic review showed that in nine selected studies using rapid tests to detect IgM/IgG, sensitivity ranged from 44.1 to 97.0% and specificity from 87.4 to 99.5% for these antibodies[29].

Since the SARS-Cov-2 infection alert, the virus continues to evolve, and the variability of its strains can affect the ability of rapid tests to detect antibodies. It is important to note that, although rapid tests may have some limitations, they still play a relevant role in screening and detecting COVID-19 cases, especially when combined with other diagnostic strategies. There is still potential for improvement in testing in general, and emphasis should be placed on creating rapid and accurate assays for the prevention of future epidemics of SARS-CoV-2 and other infectious diseases that may arise.

CONCLUSIONS

During the pandemic period, 504 batches of products from different importers and manufacturers were analyzed: AcTR and AgTR, ELISA, CLIA, and NAT. All the results obtained from monitoring the quality of these products, as well as the sanitary measures adopted in response to the irregularities identified, were published on the Business Intelligence (BI) panel, available on Anvisa's website.

The laboratory evaluation and publication of the analytical results on Anvisa's website ensured that reliable and essential data was available to support decision-making by the authorities, health professionals, and the regulated sector itself in dealing with the pandemic. Effective monitoring has contributed to quality inspection actions, monitoring the performance of diagnostic tests, providing guidance on importing products, extending their shelf-life, assisting in public bidding processes, among other actions. Reduced sensitivity was the main cause of non-compliance in the 293 batches of products assessed during the period. It is worth noting that the batches of non-compliant products which accounted for 44.7% (131/293) of the total batches for detecting IgM/IgG and IgM antibodies evaluated were not made available on the domestic market.

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Authors' Contribution

Carvalho MG - Conception, acquisition, data interpretation, and writing of the paper. Adati MC, Borges HCBG - Planning (study design) and writing the paper. All the authors approved the final version of the paper.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.