IVD_18 - Assessment of Covid-19 self-tests for registration purposes with ANVISA as established in Resolution RDC 595/2022

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Introduction: During infectious disease outbreaks, health control policies aim to understand and minimize the spread of diseases, including within other activities the availability of accurate and accessible diagnostic tests. In response to this demand, the National Health Surveillance Agency (ANVISA) promulgated Resolution RDC No. 595 of January 28, 2022. This standard establishes the requirements and procedures for requesting registration and commercialization of self-tests for Covid-19. Self-tests consist of a cassette containing a membrane where an immunological reaction occurs, a buffer solution and a swab or nasal collector, accompanied by easy-to-read instruction manuals, allowing users to carry out tests in their homes. Furthermore, this resolution recommends, for registration purposes, that self-tests for detection of the SARS-CoV-2 antigen are subject to prior analysis carried out by the National Institute for Health Quality Control - INCQS, in order to verify the performance attributes of these tests. products, as well as establishing the acceptability criteria: sensitivity greater than or equal to 80% and specificity greater than or equal to 97%.

Objectives: The objective of the present study was to evaluate the performance of Covid-19 self-tests according to RDC no 595/2022, aiming to evaluate the product's performance attributes and consequently the distribution and commercialization record in Brazil.

Methodology: This study was carried out by INCQS from January 2022 to December 2023. The products were sent to the Blood Derivatives Laboratory/DI/INCQS/Fiocruz and sensitivity and specificity parameters were evaluated.

Results: During the study period, 57 batches of self-test kits were analyzed. Among them, a total of 50 (87.7%) self-tests met the minimum required sensitivity and specificity parameters and were approved. 07 (12.3%) batches were rejected as they failed to reach the sensitivity and specificity parameters established in current legislation.

Conclusion: From a public health perspective, self-tests offer advantages by improving accessibility to testing, allowing individuals to obtain a result very quickly, which could support early detection of infectious cases and reduce community transmission. The prior evaluation of self-tests before registration allowed the availability of safe and effective products for diagnosing Covid-19 in the Brazilian market, since unsatisfactory products were not registered with ANVISA and, consequently, not sold in the country.

Keywords: Self-tests; Covid-19; Quality control