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Current status of COVID-19 diagnostic methods

Estado actual de los métodos diagnósticos de COVID-19

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Abstract

The diagnosis of SARS-CoV-2 infection was an essential component for controlling the COVID-19 pandemic. Diagnostic methods are primarily grouped into molecular tests, antigen detection tests, and serological tests, each with specific applications and limitations depending on the phase of the infection. Molecular tests, such as real-time reverse transcription-polymerase chain reaction (rRT-PCR), continue to be considered the gold standard for etiological diagnosis due to their high sensitivity and specificity. However, this assay requires numerous manual steps that are time-consuming and error-prone, a situation that led to the development of alternative methods. These alternatives have been utilized and have even demonstrated higher diagnostic performance than the test adopted as the preferred standard throughout the pandemic. The objective is to describe the known diagnostic methods and the alternative tests developed during the COVID-19 pandemic.

Keywords: *Coronavirus. SARS-CoV-2. COVID-19. Antigen test. RT PCR.*

Resumen

El diagnóstico de la infección por SARS-CoV-2 fue un componente esencial para el control de la pandemia de COVID-19. Los métodos diagnósticos se agrupan, principalmente, en pruebas moleculares, pruebas de detección de antígenos y pruebas serológicas, cada una con aplicaciones y limitaciones específicas según la fase de la infección. Las pruebas moleculares, como la reacción en cadena de la polimerasa con transcriptasa inversa en tiempo real (rRT-PCR), se siguen considerando el referente en el diagnóstico etiológico por su alta sensibilidad y especificidad. Sin embargo, para este ensayo se requieren numerosos pasos manuales que son largos y propensos a errores, situación que llevó al desarrollo de métodos alternativos. Estos últimos han sido utilizados e incluso han demostrado un mayor rendimiento diagnóstico que la prueba adoptada como preferente a lo largo de la pandemia. El objetivo es describir los métodos diagnósticos conocidos y las pruebas alternativas que se desarrollaron durante la pandemia de COVID-19.

Palabras clave: *Coronavirus. SARS-CoV-2. COVID-19. Prueba de antígenos. RT PCR.*

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Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel coronavirus that emerged in December 2019 in Wuhan, China. Despite the prompt identification of the virus and the public health measures implemented in China, these actions did not prevent its spread, ultimately resulting in a pandemic.[1,2] The World Health Organization (WHO) declared the outbreak a pandemic on March 11, 2020. From its emergence through December 7, 2025, coronavirus disease 2019 (COVID-19) had caused 778,994,897 cases, including more than 7 million reported deaths.[3] Since then, COVID-19 has posed a major public health challenge because of its rapid spread, heterogeneous clinical presentation, and high prevalence of asymptomatic infections, which facilitates transmission to vulnerable groups.[4]

Although the virus was identified and diagnostic methods were subsequently implemented extremely rapidly, the pandemic could not be contained, unlike the 2002-2003 SARS-CoV-1 outbreak. One reason is the highly efficient transmission of SARS-CoV-2, partly driven by asymptomatic individuals who can transmit the virus without being detected. Given the magnitude of the pandemic, the WHO recommended widespread testing for SARS-CoV-2.[5-7] However, the global response to the pandemic varied considerably, with some governments imposing stay-at-home orders, closing schools, workplaces, and public transportation, and/or restricting domestic and international travel in an attempt to mitigate transmission.[8,9] Currently, nonpharmacological interventions, together with booster vaccine doses and individual use of personal protective equipment, continue to be recommended to reduce transmission and disease severity.[10,11] Testing remains a crucial measure for controlling SARS-CoV-2 transmission because identifying a positive case enables individuals to take appropriate measures to prevent further transmission, such as isolation, mask use, and seeking medical care.[12] In addition, evidence indicates that patients who test positive and are at risk of severe disease benefit from early antiviral treatment. Therefore, timely identification of these high-risk patients helps reduce the risk of progression to severe disease. At the population level, testing plays a key role in identifying infected individuals who, despite being asymptomatic or presymptomatic, can spread the disease. This enables health authorities to track the spread of infection, implement targeted interventions, and allocate resources effectively.[13,14]

The importance of early diagnosis of COVID-19 was recognized from the earliest stages of the pandemic, prompting numerous manufacturers to actively pursue the design, development, validation, verification, and implementation of diagnostic tests. Hundreds of molecular tests and immunoassays were rapidly developed. Currently, more than a dozen commercial SARS-CoV-2 detection kits have received authorization for use from the US Food and Drug Administration (FDA) and Mexico's *Instituto de Diagnóstico y Referencia Epidemiológica (InDRE)*. The main types of available tests are: 1) tests that identify specific viral genetic regions using molecular techniques, such as nucleic acid amplification by real-time reverse transcription polymerase chain reaction (RT-qPCR), currently considered the gold standard; 2) tests that detect antibodies produced by the immune system in response to viral infection, including immunoglobulin M and immunoglobulin G (IgM/IgG) serological tests; and 3) antigen tests based on lateral-flow immunochromatographic assays.

The specificity and sensitivity of the different diagnostic techniques vary according to the timing of testing (figure 1). During the incubation period, currently available tests are ineffective because of the low amount of RNA, undetectable viral proteins, or absence of antibodies. Therefore, more sensitive methods are required for early virus detection. Techniques such as clustered regularly interspaced short palindromic repeats/Cas (CRISPR/Cas)-based approaches, digital PCR, and chemiluminescence, which have been developed in research settings, have shown improved performance (figure 2).[15] This review describes several available methods for sensitive and specific detection of SARS-CoV-2.

Molecular methods

Molecular methods are techniques used to detect DNA, RNA, and proteins. Among the available tools, molecular methods are notable for their high sensitivity and specificity because they allow direct detection of viral genetic material. Real-time reverse transcription polymerase chain reaction (rRT-PCR) is considered the gold standard for the etiological diagnosis of SARS-CoV-2 infection and enables specific detection of viral genetic material in multiple types of clinical samples, including nasopharyngeal and oropharyngeal swabs, saliva, sputum, and stool. RT-qPCR combines reverse transcription with PCR and real-time fluorescence detection. The increase in fluorescence is proportional to the amount of amplified genetic material, allowing detection and quantification of viral RNA.[16] RT-qPCR assays designed for SARS-CoV-2 generally target

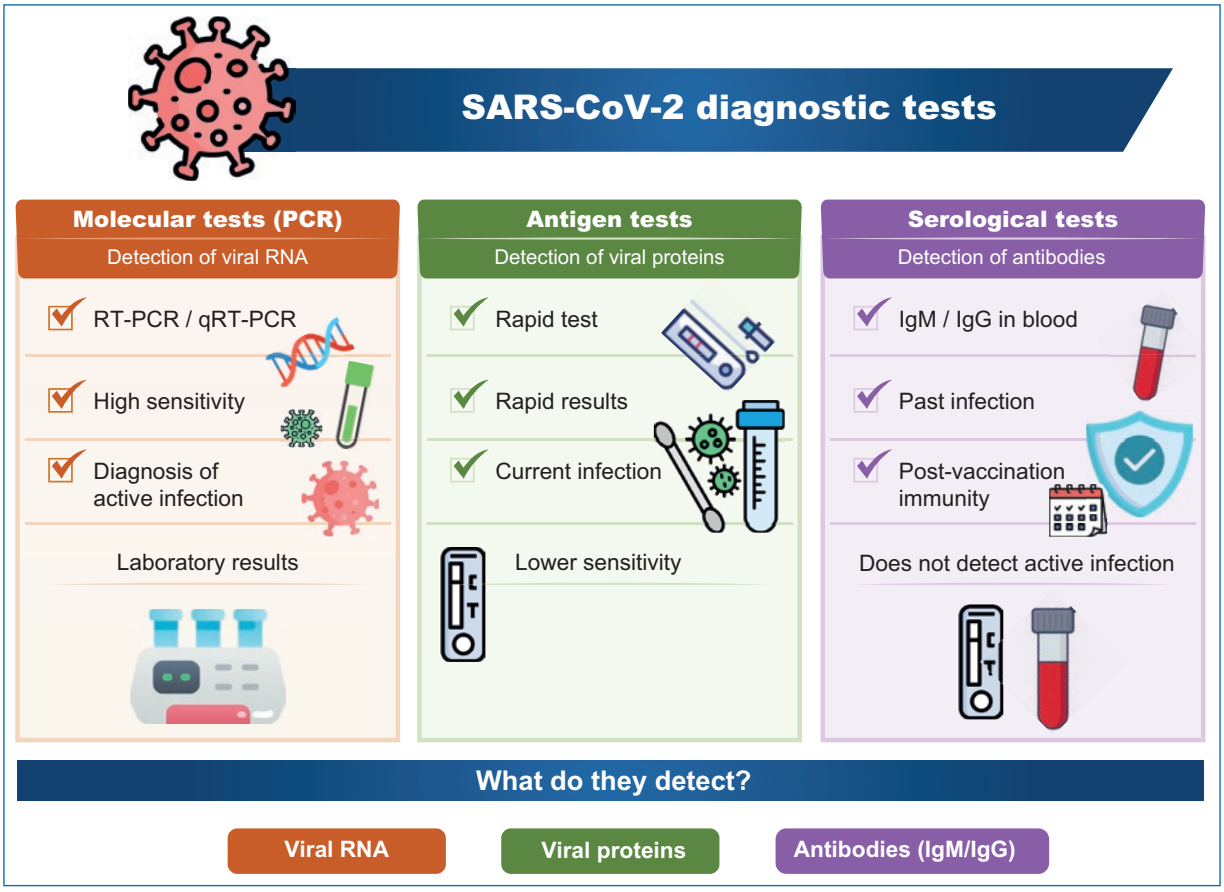

Figure 1. Laboratory methods for SARS-CoV-2 detection.

highly conserved genes within the viral genome, such as *ORF1ab*, including RdRp, as well as the N, E, and S genes. Throughout the pandemic, numerous kits using different primer designs and target genes have been commercialized.[17] More than 350 conventional RT-PCR kits are commercially available, of which at least 29 have been authorized by the FDA for clinical use in the United States.[18]

The diagnostic performance of different commercial kits varies in terms of limit of detection and sensitivity and is influenced by sample type, sample quality, and the interval between symptom onset and sample collection. A systematic meta-analysis evaluating multiple studies of commercial PCR assays found an overall mean sensitivity of 80.5%, with substantial variation among kits. Kits such as GeneFinder, InBios, NxTAG, and Simplexa showed better performance, while overall specificity was high at 97.9%.[19] In another comparative clinical detection study, several commercial kits (Altona, Thermo, Multiplex, Meril, SD Biosensor, and LabGun) achieved sensitivity close to or equal to 100% for certain target genes, although slight differences were observed among genetic targets. Although all RT-PCR kits provide high specificity, clinical sensitivity varies depending on kit design, the number and selection of target genes, and sample quality.[20]

RT-PCR requires numerous manual steps that are time-consuming and prone to error. These include preparation of solutions, nucleic acid extraction and purification, and preparation of the master mix for the amplification device. All these steps require specialized equipment and delay the availability of results. These technical limitations can be overcome by using automated PCR platforms. Such platforms integrate nucleic acid extraction, amplification, and result interpretation, thereby reducing the risk of human error and increasing laboratory capacity in settings with high testing demand. Systems such as Cepheid Xpert Xpress, BD MAX, Roche cobas, and Hologic Aptima have demonstrated high diagnostic accuracy, with sensitivity and specificity generally > 90%.[21]

During the COVID-19 pandemic, amplification of RNA from nasopharyngeal swab samples by RT-PCR became the most widely used method for diagnosing the disease and is considered the reference molecular

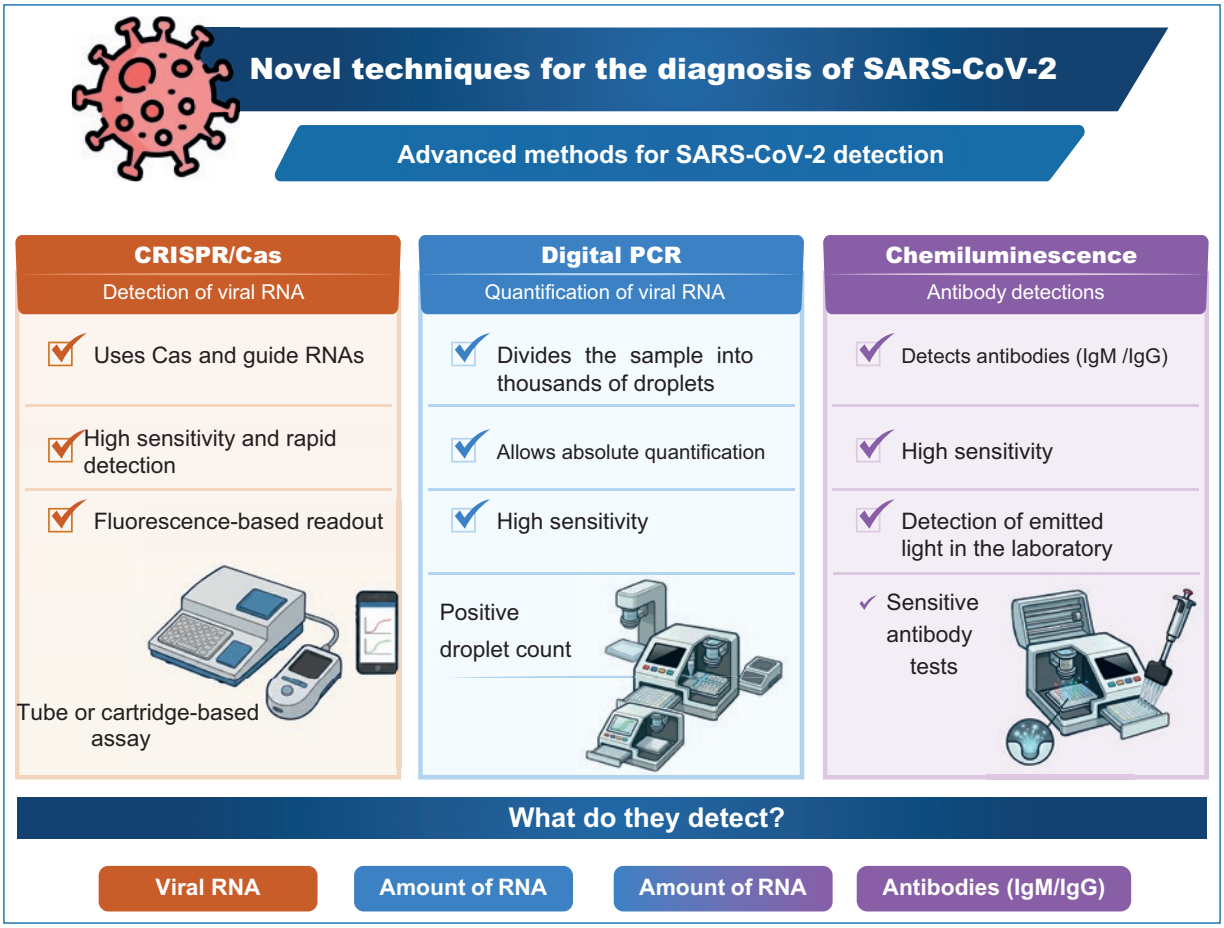

Figure 2. Novel techniques for the diagnosis of SARS-CoV-2.

test for COVID-19 and other infectious diseases. However, the need for specialized equipment and prolonged turnaround times has driven the development and validation of alternative methods that can expand diagnostic capacity, shorten reporting times, and facilitate implementation in resource-limited settings. The main alternative techniques are RT-LAMP (isothermal amplification), digital PCR (dPCR), and CRISPR/Cas methods integrated with isothermal amplification or used independently. These methods overcome some of the limitations of PCR by providing faster, more cost-effective, and portable solutions.

RT-LAMP (reverse transcription loop-mediated isothermal amplification) is a rapid and sensitive molecular diagnostic technique that amplifies nucleic acids at a constant temperature of 60-65 °C without requiring a thermocycler. This method combines reverse transcription of viral RNA into complementary DNA (cDNA) and subsequent amplification in a single reaction. It uses a set of 4-6 specific primers (F3, B3, FIP, BIP, and optionally LoopF and LoopB) targeting conserved regions of the viral genome, such as N, E, RdRp, or ORF1ab. Finally, the use of a strand-displacing DNA polymerase (Bst) enables formation of loop structures, resulting in rapid and highly specific exponential amplification (figure 3).[22]

Compared with PCR, LAMP offers several advantages. It is technically simpler and can operate under isothermal conditions, making it suitable for rapid diagnosis without the need for complex laboratory equipment. One notable limitation of LAMP is its susceptibility to nonspecific amplification, which may reduce diagnostic accuracy, particularly in complex clinical samples. A systematic review focused on COVID-19 diagnosis found pooled sensitivity and specificity of 92% and 99%, respectively, for LAMP,[23] whereas PCR achieved slightly higher sensitivity of 96% and specificity of 100%. Because of its advantages and diagnostic accuracy during the COVID-19 pandemic, LAMP was used as an alternative to PCR for detection of SARS-CoV-2. Its low cost and rapid turnaround make LAMP particularly valuable in resource-limited regions.[23]

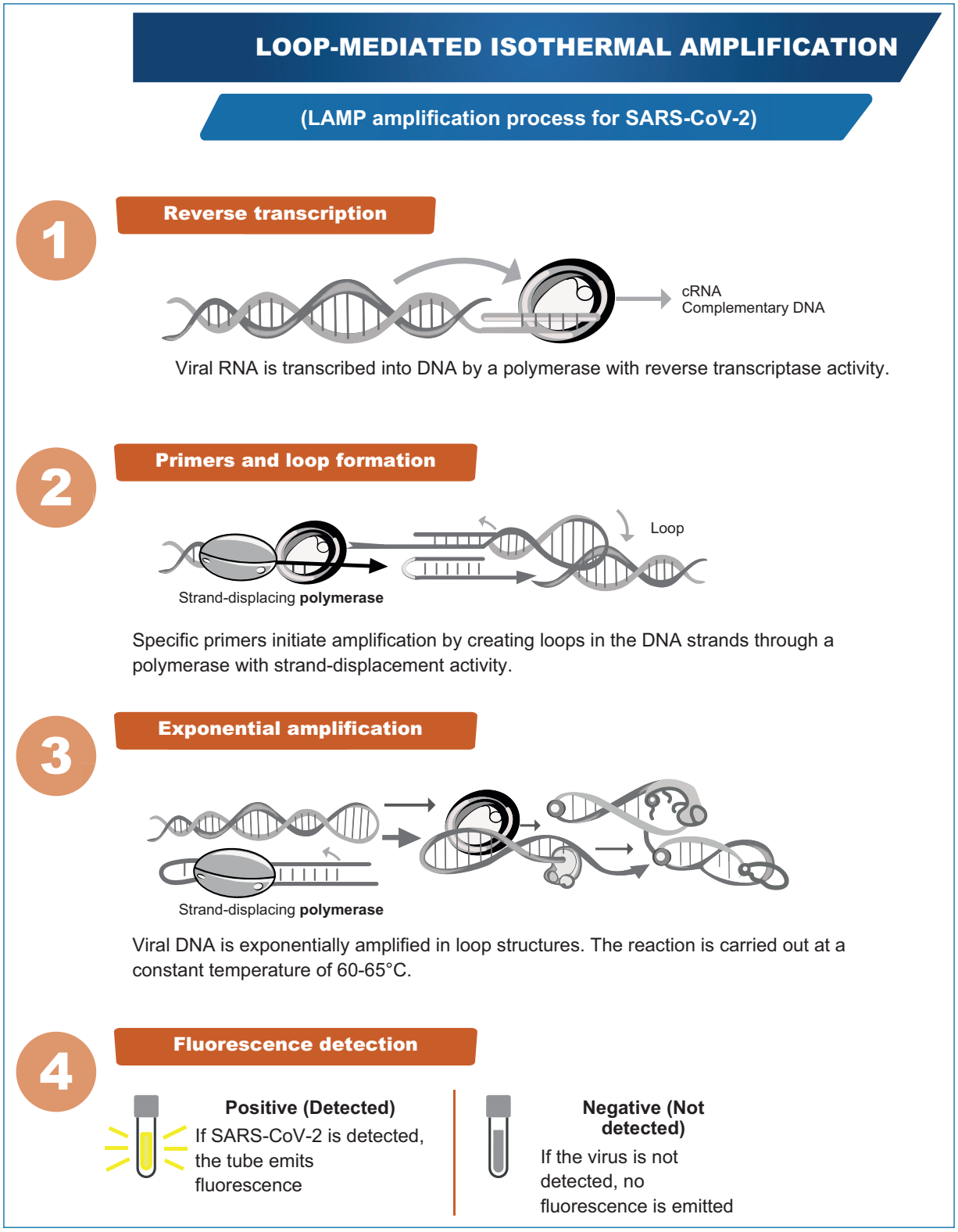

Figure 3. Principle of LAMP for SARS-CoV-2 detection.

Throughout the SARS-CoV-2 pandemic, dPCR demonstrated greater sensitivity than the diagnostic standard, particularly for low viral loads or difficult samples. As a basic principle, dPCR divides a reaction mixture containing the RNA/DNA sample, primers, probes, and PCR mixture into thousands of individual

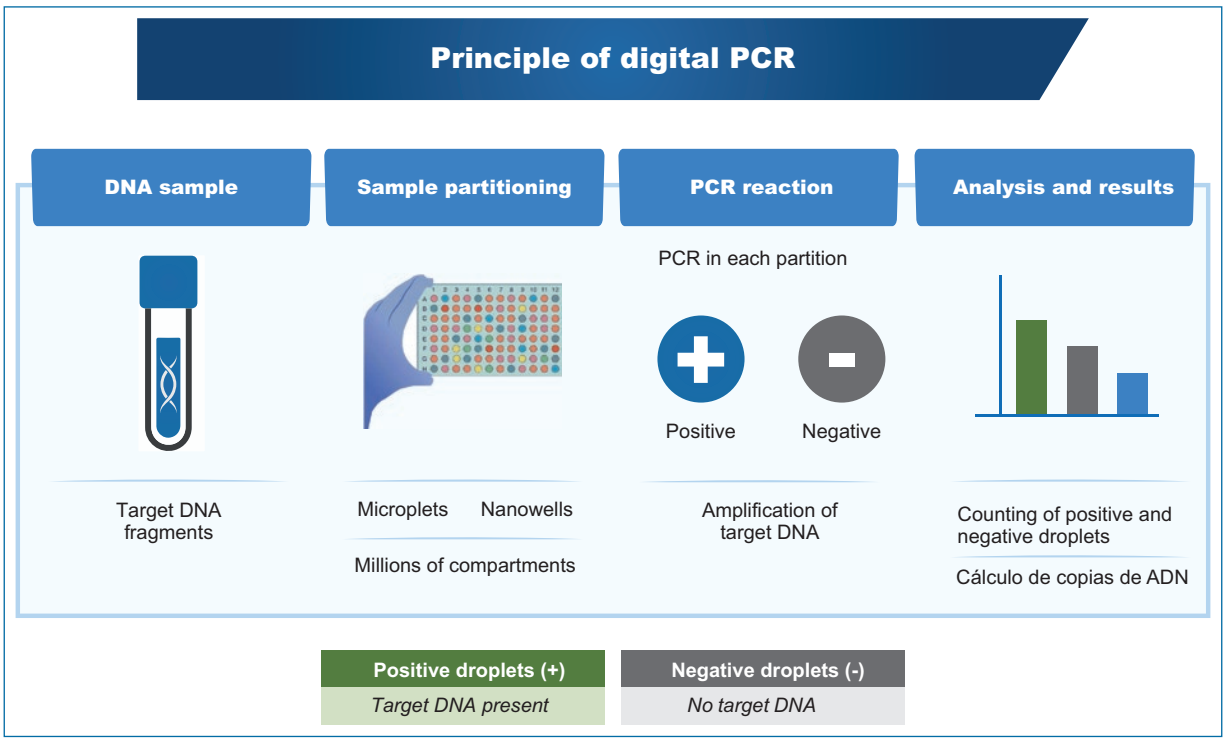

Figure 4. Principle of digital PCR for the diagnosis of SARS-CoV-2.

microreactions, such as partitions, droplets, or microchambers. Each partition may contain zero or only a few target nucleotide molecules. After PCR amplification, the presence or absence of a fluorescent signal is detected in each partition (figure 4). This enables direct calculation of the number of copies in the sample without the need for a standard curve. Numerous studies have demonstrated that RT-dPCR improves SARS-CoV-2 detection compared with RT-qPCR.[24-26]

Antigen detection tests

Antigen detection tests, together with nucleic acid amplification tests (NAATs, such as RT-PCR) and serological tests, constitute 1 of the 3 fundamental methodologies for diagnosing SARS-CoV-2 infection. Their clinical utility lies in their rapid turnaround time and operational feasibility at the point of care, enabling decentralization of diagnosis.[27-29]

These assays directly detect viral proteins in respiratory samples. The main target is the nucleocapsid (N) protein because of its relative abundance and structural conservation. Detection is performed using lateral-flow immunoassay (LFA) or immunofluorescence (IF) platforms.[30-32] These devices provide qualitative results within 15-30 minutes, facilitating triage in emergency and primary care settings.[32]

The specificity of antigen tests is consistently high. The most recent Cochrane systematic review (2025), which analyzed 146 studies including more than 144,000 samples, reported a mean specificity of 99.5% (95% CI, 99.5%-99.6%) in asymptomatic populations, minimizing false-positive results and providing a high positive predictive value.[1] Former studies had already reported specificity ranging from 99.5% to 100%.[32,33] However, sensitivity is heterogeneous and critically dependent on the clinical context:

- Asymptomatic vs symptomatic individuals: according to the 2025 Cochrane meta-analysis, mean sensitivity among asymptomatic individuals was 55.0% (95% CI, 50.9%-59.0%), increasing slightly to 58.6% when there was epidemiological suspicion based on contact exposure or among symptomatic individuals, compared with 53.0% in general screening populations.[28]
- Viral load (Ct values): there is an inverse correlation between the RT-PCR cycle threshold (Ct) value and antigen test sensitivity. Sensitivity is high in samples with a high viral load (Ct < 25), reaching values of up to 100%.[4] However, performance decreases in samples with a low viral load

(Ct > 30-35), with sensitivity falling below 20% in some subgroups.[30,31]

– Impact of vaccination and variants: longitudinal studies conducted between 2020 and 2023 observed a decline in the clinical sensitivity of rapid tests throughout the pandemic, with an overall sensitivity of 34.5% reported in clinical screening settings during the Omicron variant era.[33] This phenomenon has been associated with changes in clinical presentation: vaccination and previous immunity reduce the frequency of classic symptoms, which correlates with viral loads or viral shedding patterns that may limit antigen detection.[34]

Because of viral kinetics, the WHO and accumulated evidence recommend using these tests within the first 5-7 days after symptom onset, when viral load is highest and the correlation with infectivity is greatest.[30,34]

Taking advantage of this diagnostic window, technological innovation has simplified lateral-flow platforms to enable their use outside healthcare settings, empowering users to manage their own diagnosis independently through the implementation of self-tests.

To determine whether this technical independence maintained the necessary clinical rigor, a prospective study was conducted at the *Instituto Nacional de Enfermedades Respiratorias Ismael Cosío Villegas (INER)* to evaluate the Abbott™ PANBIO™ COVID-19 TEST. The results confirmed that the self-test maintained a specificity of 100% (95% CI, 96.4%-100%), indicating an absence of false-positive results when performed by patients without medical training.[35]

In terms of sensitivity, the study reported an overall value of 71.2% (95% CI, 62.5%-79.9%). However, performance was confirmed to be time-dependent:

– Early phase (≤ 48 hours): sensitivity reached 93% when the test was performed within the first 2 days after symptom onset.[35]
– Late phase (≥ 4 days): sensitivity decreased to 58% among patients with symptoms lasting 4 days or longer.[5]

In conclusion, antigen tests are highly valuable tools for rapid confirmation of cases, particularly in the presence of symptoms and a high viral load. A positive self-test result, particularly within the first 72 hours, confirms the diagnosis with a high degree of certainty. However, given the variable sensitivity of these tests (34.5%-55% in asymptomatic or vaccinated individuals), a negative result does not rule out infection and should be confirmed by RT-PCR when clinical suspicion persists.

Serological tests

These assays detect antibodies, proteins produced by the immune system in response to exposure to an antigen. Antibodies are also known as immunoglobulins (Ig). There are 5 classes of antibodies: IgM, IgD, IgG, IgA, and IgE, which differ in their C-terminal regions. IgM is the first antibody produced during infection, whereas IgG is the most abundant antibody in serum and appears later. Antibodies are secreted into mucosal surfaces and blood and neutralize pathogens by binding to antigens and inactivating them. Antibody-mediated neutralization therefore prevents the virus from infecting cells.[22]

These tests are not used to diagnose acute SARS-CoV-2 infection because of their low sensitivity during the first week after symptom onset. Sensitivity as high as 90% has been reported during the second week after symptom onset.[36] They are useful for: 1) retrospective diagnosis in individuals with symptoms compatible with acute COVID-19 who did not undergo RT-PCR testing or who had negative or inconclusive results; 2) estimating the timing of infection to help define the infectious period; and 3) conducting serological surveys to assess exposure and infection rates within a given population.[37]

Confirmation of infection requires demonstration of seroconversion or at least a 4-fold increase in antibody titers between acute-phase and convalescent-phase serum samples. Both in-house and commercial serological assays are available for detection of antibodies against SARS-CoV-2, based on different methods such as lateral-flow immunochromatography, enzyme-linked immunosorbent assays (ELISA), indirect immunofluorescence assays (IFA), and viral neutralization tests.[38]

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Conflicts of interest

The authors declared no conflicts of interest whatsoever.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. The study does not involve patients' personal

data and does not require ethical approval. The SAGER guidelines do not apply.

Declaration on the use of artificial intelligence. The authors declare that they did not use any type of generative artificial intelligence in the writing of this manuscript.

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