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Editorial

Detection methods for the diagnosis of COVID-19

Métodos de detección para el diagnóstico de COVID-19

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COVID-19 is a disease caused by SARS-CoV2 that causes mild to severe infections in humans, transmitted by air with an incubation period of 2-14 days.[1] Despite efforts to contain the disease and advances in molecular techniques to identify the virus, it continues to prevail in the population worldwide. The COVID-19 pandemic leaves significant learning about the importance of developing early detection methods to stop the spread of the virus and take the corresponding health measures. Because the virus is constantly mutating, it is vital to know the different assays for its diagnosis and their advantages and sensitivity. Sensitivity refers to the lowest amount of analyte accurately measured in an assay.[2]

SARS-CoV2 belongs to the β-coronavirus family with an enveloped positive-sense single-stranded RNA genome.[3] Three main molecular methodologies have been developed to diagnose COVID-19: 1) detection of viral genes, 2) detection of viral antigens, and 3) detection of human antibodies. The first test corresponds to detecting viral genes with the real-time PCR assay with reverse transcriptase (RT-qPCR), considered the gold standard for detecting SARS-CoV2.[4] It offers a sensitivity of 91% but disadvantages such as infrastructure, specialized workforce, and time to carry it out.[5] Approximately sixty commercial kits have been developed to detect SARS-CoV2 based on RT-qPCR that include different SARS-CoV2 genes such as the RNA polymerase gene and the nucleocapsid gene, the spike gene, and the regions ORF1b and ORF8. Another molecular assay developed was loop-mediated isothermal amplification (RT-LAMP), with a more efficient and fast amplification capacity detected with a fluorescent dye. Classifying it as a fast test with greater sensitivity does not require specialized personnel or equipment. These assays represent the preferred assays for detecting early viral infection; however, it depends on the adequacy of viral content in the nasopharyngeal sample. Another molecular technique that combines RT-LAMP with clustered regularly interspaced short palindromic repeats (CRISPR) system detects the virus by hybridizing a probe with the envelope gene of SARS-CoV2. The results are assessed by fluorescence; this method is in the clinic validation process.[6] The second type of test, known as the nasopharyngeal swab sample antigen test, detects viral components (S-glycoprotein, M or N protein) released or virus without thermal PCR amplification.

Evidence test shows an active viral infection, not a recovery process, and is even more reliable than antibody tests. These tests were developed based on lateral flow immunoassays (fast-assay) and enzyme-linked immunosorbent assays (ELISA) with greater sensitivity.[7] Antigen tests have a sensitivity of 68% compared to RT-qPCR. Suggesting its use five days after the onset of symptoms and should be sampled with a high viral load.[6] Finally, the third type of test corresponds to the detection of antibodies generated in response to SARS-CoV2 infection; it represents an essential diagnostic method in the epidemiological surveillance of COVID-19 and evaluating the effectiveness of vaccines. It is widely used for detecting IgM and IgA in serum at six days and up to fourteen days for IgG from the onset of symptoms.[8] In this assay, ELISA plates pre-coated with specific anti-IgM antibodies or plates coated with recombinant SARS-CoV2 nucleocapsid proteins were developed to detect IgG presence. The complex (anti-IgM-IgM induced by SARS-CoV2) is detected by horseradish peroxidase (HRP)-labeled recombinant COVID antigen.[9,10] Currently, an effective and clinically validated treatment for COVID-19 is pending; therefore, the development of rapid assays without sacrificing sensitivity, added to the high mutation of the virus, requires an effort to develop cost-effective and suitable kits for timely diagnosis of COVID-19 and epidemiological surveillance.

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