

Tests and Kits for CoV-2 Diagnosis

Dr Babita Goyal¹, Ms Pooja Sharma²

¹MD (Biochemistry, Consultant)

²Manager, Glostem Private Limited

Email: p.sharma@glostem.com

The testing kits available for SARS-CoV-2 can be categorized into 2 main classes viz. PCR based Molecular Assays, and Serological & Immunoassays. The principles of these tests were covered in Part 1 of this article. This part of the article will cover the test kits currently available and being tested/used worldwide. Several of these tests have been approved by the US FDA as Emergency Use Authorization¹.

Detection of Viral DNA: These tests are PCR based molecular assays or nucleic acid hybridization-related strategies and test the presence of viral RNA in the human body.

PathoDetect™ CVD-19 Qualitative PCR Kit (Mylab) is a PCR based kit designed as per CDC/WHO recommended protocol. It is claimed to be a highly sensitive real-time PCR test for novel coronavirus 2019 detection. The kit includes all reagents including positive controls. This provides a low contamination risk, high-throughput test, and gives results within 2 hours².

Smart Detect™ SARS-CoV-2 rRT-PCR Kit (InBios) is a real-time RT-PCR test intended for the qualitative detection of nucleic acid SARS-CoV-2 in human nasopharyngeal swab and offers results in about 4 hours³.

ID NOW™ COVID-19 (Abbott) is a rapid test that delivers high-quality molecular positive results in as little as 5 minutes, targeting the coronavirus (COVID-19) RdRp Gene⁴.

iAMP COVID-19 Detection Kit (Biotron Healthcare) is a real-time reverse transcription isothermal amplification test. The test is based on a proprietary isothermal amplification technology termed OMEGA amplification. This test is claimed to have the ability to detect SARS-CoV-2 RNA directly from samples without prior RNA extraction process and gives results in an hour⁵.

Sherlock™ CRISPR SARS-CoV-2 Kit (Sherlock Biosciences) is a kit for the detection of the coronavirus using gene-editing technology CRISPR. Based on the SHERLOCK method, which stands for Specific High-sensitivity Enzymatic Reporter unLOCKing, the kit works by programming a CRISPR molecule to detect the presence of a specific genetic signature of SARS-CoV-2 in samples. If the virus's genetic

material is found, a CRISPR enzyme generates a fluorescent glow⁶.

Truenat™ Beta CoV (Molbio Diagnostics) is a chip-based RT-PCR test for semi-quantitative detection of Beta Coronavirus (Sarbeco), RNA in human oro/nasopharyngeal swab specimen. This assay is based on Taqman chemistry and is claimed to have high primer sensitivity and specificity. It is a screening test that has to be confirmed by truenat SARS-Cov-2 testing⁷.

TaqPath COVID-19 Multiplex Diagnostic Solution (Thermo Fisher Scientific) is a new multiplex real-time RT-PCR diagnostic kit to quickly diagnose SARS-CoV-2 infection. This Applied Biosystems kit is a fast, highly sensitive multiplex diagnostic solution that contains both the assays and controls needed for the real-time PCR detection of RNA from the SARS-CoV-2 virus⁸.

Logix Smart™ Coronavirus 2019 (COVID-19) Test Kit (Co-Diagnostics, Inc.) The Logix Smart™ Coronavirus Disease 2019 (COVID-19) Test kit is an in vitro diagnostic test that uses our patented CoPrimer™ technology for the qualitative detection of the RNA from SARS-CoV-2 coronavirus (COVID-19). The test operates using a single-step RT-PCR process in the lower respiratory tract and upper respiratory tract fluids from patients⁹.

HYMON SARS CoV-2 Kit (SpectronRx) is a fast, high-capacity real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory and bronchoalveolar lavage specimens from individuals suspected of COVID-19. It gives results in 1.5 hours¹⁰.

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit CE-IVD (Solgent Co. Ltd.) is a screening kit to detect Novel Corona Virus as 2019-nCoV from isolated total RNA. The basic principle of this kit is the Real-time PCR method, which is able to detect specific target genes into total RNA. It is a one-step RT reaction and PCR amplification¹¹.

Detection of Antibodies: These are mainly rapid and/or ELISA based tests that detect the presence of IgG or IgM antibodies.

Standard Q COVID-19 IgM/IgG Duo (SD Biosensor) is a rapid test kit based on an immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to SARS-CoV-2 in the nasopharyngeal fluid. It is claimed to test SARS-CoV-2 antibodies within 10 minutes and required just 10microliter of the specimen¹².

Novel coronavirus antibody, COVID-19 IgM/IgG Test Kit (Ringbio) is based on lateral flow immunoassay to detect IgM/IgG antibodies of SARS-COV-2. It can be used as an aiding tool for RT-PCR testing. IgM is produced at the beginning of infection, indicates an early stage of the disease. IgG is produced after a period of infection, indicates the infection is ongoing or was infected. A combination of IgG/IgM indicates the infection is ongoing. It required 2-3 drops of a blood sample and take 10-15 minutes to give results¹³.

Coronavirus (COVID-19) IgM/IgG Rapid Test Kit (Biopanda Reagents) is a rapid test kit and works on qualitative lateral flow immunochromatographic assay for the detection of IgM and IgG antibodies to SARS-CoV-2 in human whole blood, serum or plasma samples. Results are available in only 10 minutes. This kit is easy to use, cost-effective, and needs no analyzer¹⁴.

Sofia 2 (Quidel) is SARS Antigen Fluorescent Immunoassay (FIA) which uses advanced immunofluorescence-based lateral flow technology in a sandwich design for the qualitative detection of nucleocapsid protein from SARS-CoV-2. The Sofia 2 SARS Antigen FIA, with the Sofia 2 analyzer, provides automated and objective results in 15 minutes, allowing for testing of patients suspected of COVID-19/2019-nCoV in near-patient testing environments.

Elecsys® Anti-SARS-CoV-2 (Roche) is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to SARS-CoV-2 in human serum and plasma. The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobase immunoassay analyzers. The assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2¹⁵.

COVID-19 IgG/IgM Rapid Test Cassette (Healgen) utilizes lateral flow technology that is used for the qualitative, differential detection of both anti-SARS-CoV-2 IgM and IgG antibodies¹⁶.

COVID-19 IgM/IgG Rapid Test Kit for Clinical Diagnosis (Ray Biotech) is 10 minutes rapid detection of SARS-CoV-2 (COVID-19) N-Protein Antibodies. Ray Biotech offers lateral

flow devices for the detection of IgG and IgM antibodies to the coronavirus N-protein in serum, plasma, and peripheral blood¹⁷.

COVID-19 IgG/IgM Rapid Testing Kit (Elabscience) is a rapid chromatographic immunoassay for the qualitative testing of IgG and IgM antibodies to COVID-19 in human serum, plasma or whole blood¹⁸.

SARS-CoV-2 Total Assay-COV2T Assay (Siemens) uses a proven antibody-bridging assay architecture, which involves the binding of a single SARS-CoV-2 antibody to two identical SARS-CoV-2 antigens, helping to avoid false-positive results. The COV2T assay detects both IgM and longer-lasting IgG antibodies with high sensitivity of recent and prior infection. This allows for the identification of patients who have developed an adaptive immune response, which indicates recent infection or prior exposure¹⁹.

Coronavirus COVID-19 IgG ELISA Assay (Eagle Biosciences) kit is used for the qualitative detection of novel coronavirus infected pneumonia cases, suspected clustering cases, and other new coronaviruses in serum samples (COVID-19) through measurement of the COVID-19 IgG antibody. It is a serological plate-based assay technique designed for detecting and quantifying substances such as peptides, proteins, antibodies, and hormones. This test is not the same as PCR or Rapid Test²⁰.

COVID-19 ELISA (Vircell) is an indirect immunoenzyme assay to test antibodies against SARS-COV-2 in human serum/plasma. It allows to perform IgG and IgM+IgA simultaneously in the same run. It is suitable for automated ELISA systems²¹.

This is not an exhaustive list and apart from the tests/kits mentioned above, there are many other tests available or still under development stage. Most of these tests have been temporarily approved by regulatory authorities looking into the urgency of their availability. These tests & kits will improve with time in their efficacy, sensitivity, reliability, and speed as more data of real-time patient testing becomes available.

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