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Rise of Molecular Diagnostic solutions

31 January 2022 | Features | By Dr (Prof) D M Vasudevan, Technical Director, Agappe Diagnostics

The COVID-19 testing scenario has brought significance of in-vitro diagnostic (IVD) solutions to the public at large and majority of people who travel or moving or having fever are invariably subjected to COVID-19 testing process, either rapid or RT-PCR or RT-LAMP. Never in history, diagnostic industry as well as diagnostic labs got such a massive acceptability and respect by the public, policy makers and other healthcare stakeholders.

As a rule, those IVD companies who took the leap into COVID-19 related diagnostic solutions could skyrocket their business and others suffered temporary dip during the pandemic. As most of the domestic and international flights were drastically reduced. As most of the lab reagents and kits are imported from world over, transportation of kits was a challenge. COVID-19 has generated a dual impact on the diagnostics industry. Thus, policy makers started convincing about the necessity of uplifting the indigenous healthcare industries.

Resultantly, many Atmanirbhar Yojanas have been initiated by the government to a large extent, due to worldwide stagnancy and disruption in the supply chain segment, where 60-65 per cent dependability of import needs to be addressed with greater emphasis. It was a fact that Agappe could support 70 per cent of COVID-19 prognostic markers like CRP, DDimer, Ferritin etc. when our national supply was very badly hit by irregular imports.

Corona pandemic lessons have established the very preponderance of diagnostic tools, where the molecular diagnostic (MDx) solutions as well as Point of Care solutions emerged as noticeable players in demand. Within the healthcare industry, there is now a growing slant towards genomics also in a big way. MDx sector has shown phenomenal growth from less than 2 per cent to above 35-40 per cent during the journey from pre-pandemic to post- pandemic scenario and the trend is still continuing to contribute a lot to the Molecular biology platform.

This was made possible by the inclusion of advanced technologies, such as genetic testing, molecular diagnostics, polymerase chain reaction (PCR), RT-LAMP technology and next-generation sequencing (NGS) in the IVD platform, which defines the future.

Need of the hour is to create quality and affordable, more accessible testing for SARS-CoV-2 as well as all other infectious diseases on faster and confirmatory platforms, which can be performed with ease and without the service of untrained technicians.

Neutralising antibody testing tools may evolve as the next priority for advocating new doses of vaccines depending on your immunity levels. There are unpublished reports that the efficacy of double vaccination may not be enough to provide a proper threshold of immunity, especially in a world of numerous mutants emerging within a short time. New variant Omicron has proved its super-fast infectivity and spread in many countries including the United Kingdom recently.

For emergency preparedness, point-of-care (POC) mobile diagnosis, right at the doorstep of the patient, will become a necessity in the coming days. The POC segment of diagnostics with handy, handheld, one step, cartridge-based multiple solutions will be the next generation tools in various platforms like Immunofluorescence, Chemiluminescence, dry chemistry, hematology will pick up.

Yet another change in diagnostics is the growing relevance of connected devices, IoT-based gadgets, where a new approach to self-monitoring has been ushered in. User-friendly and easy-to-operate medical devices for self-diagnosis like glucometers, BP monitors, oximeters and even self-testing of COVID-19 are in the market.

Large-scale testing, isolation and contact tracing are central points to control the pandemic effectively, especially in the light of new Omicron virus scare. Since December 2019, COVID-19 has resulted in over one million deaths and put extreme pressure on health systems and economies.

Clinical diagnostics laboratories currently rely on molecular tests based on the polymerase chain reaction (PCR) or Reverse-transcription Loop-mediated isothermal amplification (RT- LAMP) for detecting SARS-CoV-2 infection in samples, such as throat/nose swabs. PCR-based tests are probably the most widely used and are considered the gold standard in terms of sensitivity and specificity. But, of late, we have developed other equally good or more specific testing methods to have better specificity and sensitivity.

RT-LAMP technology is a very strong platform for diagnosing COVID-19 virus, with much shorter time as compared to RT PCR method. This test facilitates quicker analysis of genetic material than traditional PCR and has been successfully used in the detection of the COVID-19 virus. RT-LAMP achieves high specificity due to the target sequences.

Its isothermal reaction allows higher amplification efficiency, as there is no need to wait for thermal changes, thus no time is lost. Whereas a traditional PCR can take around 3 to 4 hours, RT-LAMP takes less than 40 minutes from sample collection.

Agappe has developed LAMP based technology named Mispa Lume with reagent LumeScreen n-Cov during 2020 for confirmatory COVID-19 testing in less than one hour.

Thereafter, a new reagent without RNA extraction step, AG InstaLume has been launched by Agappe which can perform the confirmatory test in just 40 minutes from collection of swabs. This has been approved by all regulatory bodies. This can be very highly useful for airport screening, social functions, hospitals etc, where the authorities get confirmatory results in less than 40 minutes. Many airports in India are presently using this technology for screening their international passengers.

AG InstaLume, the Rapid Molecular Diagnostic confirmatory test solution for COVID-19 strains, can detect all the 13 major variants of the globe such as, ? (Omicron) strains of South Africa, ? (Mu) strains of Colombia, ? (Lambda) strain of Peru, ? (Kappa) strain of India, ? (Iota) strain of America, ? (Theta) Strain of Philippines, ? (Eta) strain from multiple countries, ? (Zeta) Strain of Brazil, ? (Epsilon) Strain of USA, ? (Delta) strain of India, ? (Gamma) strain of Brazil, ? (Beta) Strain of South Africa, ? (Alpha) strain of UK (source WHO -Label detection About reactivity Mutant strain confirmed by Infectious Disease Research Institute).

Post-pandemic situation changes the structure of society. New geopolitical, socioeconomic dynamics will surface, values will change, and our lives and habits will also be subjected to modifications. Countries have to prioritise their expenditure. Weaker sections of society require all the possible assistance. Regardless of the devastation caused by the pandemic, the human population will prevail, and humanity will still find the strength to recover. Investing in public health, preparedness, and relying on science will bring a better future.

Agappe will also take up the gauntlet to tap the new market challenges and expectations of the ensuing markets with new introductions in the Point of Care segment in many divisions of IVD before long. We have to gain momentum to run faster than the market to get at the true meaning of our logo, ‘Agappe, your best partner in diagnostics.’

We are equipping our team to be at the forefront of this journey by developing cutting-edge products and investing more and more in R&D. Currently, MDx is the leading trend to reach the targeted corporate goal along with the Chemiluminescence platform. However, moving forward, we will be able to gain more and more ground in public health and wellness management, by providing quality, affordable and faster diagnostic solutions.

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