

Eureka Biotech in collaboration with ACEGID, NCDC, WHO validate a 30-minute visually detectable molecular diagnostic test for COVID-19 diagnosis

By Olumide Adenmosun

Eureka Biotechnologies – a biotech startup with minimal research and development (R&D) operations in Nigeria, has been able to assemble and technically optimize a simple nucleic acid amplification test (NAAT) with an average run time of 30minutes for severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) – which is the causative agent for coronavirus disease 2019 (COVID-19). The rapid molecular diagnostic kit utilizes low cost laboratory materials and consumables to conduct NAAT at an isothermal temperature with no need for expensive thermocyclers or real time polymerase chain reaction (rt-PCR) equipment. Results can there-after be read visually from an observable color change in the reaction tube right at the point of testing.

With a barrage of testing kits flooding the market, Eureka Biotech led by Olumide Adenmosun – a Nigerian microbiologist and bioengineer, has been able to adapt, optimize and validate in Nigeria – a colorimetric molecular diagnostic testing kit for COVID-19 which they have named CoVAMP (CoVID-19 colorimetric isothermal AMplification).

The preliminary validation exercise was conducted back in May, 2020 on SARS-CoV-2 positive samples in partnership with the African Centre of Excellence for Genomics of Infectious Diseases (ACEGID) at Redeemers University (RUN), Ede. ACEGID is also an independent World Bank funded, WHO reference center and a Nigeria Centre for Disease Control (NCDC) collaborating laboratory for COVID-19 diagnosis. ACEGID, which is currently being led by a seasoned molecular geneticist – Professor Christian Happi, will also be a collaborating partner with Eureka Biotech for continued technical support in the event of a national deployment for the kit in Nigeria. Additional validations of the CoVAMP kit were conducted at NCDC from July to November 2020.

Testing for COVID-19 has been particularly difficult in Sub-Saharan Africa because most clinical diagnostic labs in the region cannot afford the required equipment to conduct molecular diagnostic assays, which remain the gold standard for COVID-19 diagnosis. The machines required to run a quantitative RT-PCR assay – which is the gold standard currently in use for detecting SARS-CoV-2 – could have a cost range between \$10,000 and \$50,000. Furthermore, the consumables and other reagents required for the assays are not widely available as global supplies cannot meet up with demands across the world.

In contrast, CoVAMP colorimetric isothermal amplification kits by Eureka Biotechnologies can however run on cost-effective laboratory equipment such as heating block or a water bath. Following ribonucleic acid (RNA) purification from samples suspected of SARS-CoV-2 – which can be done with existing standard RNA purification kits, or by using a 5-minute dilution buffer included with CoVAMP; a simple NAAT can be performed at a single constant temperature within 30 minutes. Following isothermal amplification of SARS-COV-2 genes from suspected samples, results can be visually read off from a colour change in the tiny reaction tube – at the point of testing.

The validation tests conducted in Nigeria with live COVID-19 samples at ACEGID and NCDC, NRL showed that the 30-min test has comparable results to existing reference tests in use for COVID-19 diagnosis. This strongly suggests that the kit can be reliably used on clinical samples in resource-limited settings/laboratories within Nigeria and other countries in Africa for COVID-19 diagnosis.

With the stringent requirements for adoption of diagnostic kits by NCDC and other regulatory agencies within and beyond Nigeria, CoVAMP is also being validated as a CE-marked in vitro diagnostic (CE-IVD) medical device. A CE-mark may be regarded as the equivalence of a United States Food and Drug Administration (US-FDA) or Nigeria's National Agency for Food & Drug Administration & Control (NAFDAC's) approval for a medical kit but by European Union regulators. However, with a focus on national deployment within Nigeria, CoVAMP will also seek appropriate authorizations for decentralized diagnostics use within the country.

With the need for Nigeria to ramp up testing in Nigeria as the COVID-19 pandemic persists, Eurekan Biotechnologies will be able to quickly deploy 100,000 CoVAMP tests within a 4 to 8-week lead time, as a ready to use CE-IVD kit. In the event that CoVAMP also becomes approved for deployment as a decentralized point-of-care testing kit for COVID-19 diagnosis at secondary or tertiary health institutions, Eurekan Biotech may also collaborate with a potential commercial partner or big pharmaceutical company – to further deploy CoVAMP at all accredited medical laboratories in Nigeria including corporate, public and private institutions with the ability to set up testing sites to keep up with surveillance at the workplace, schools, airline industry and other potential hot spots. Conditions for such point of care testing deployment may however require appropriate clinical laboratory improvement and amendments to be in place at such sites – as guided by the WHO and the appropriate regulatory authorities in Nigeria.

While the deployment of CoVAMP is one of Eurekan Biotechnologies' top priorities to help Nigeria's pandemic response, our start-up company also recently won a \$150,000 AfDB-DTCA research grant. The grant was awarded to conduct an extensive study to mine and characterize therapeutic molecules – tagged “siRNA-Vaccines” against Ebola and Zika viruses, from bat samples. While this is ongoing, the team is also looking into the possibilities of mining for “Corona-Virus-siRNA” therapeutic molecules with the potentials for silencing the expression of genetic fragments from the human viral strain which can be cloned into surrogate bacterial cells for in vitro studies. All these and more are some of the little scientific innovations that the Eurekan Biotech team may be able to deploy as we join hands to help reduce the onslaught of the COVID-19 pandemic in Nigeria, on the African continent and the rest of the world.

Adenmosun is a pioneering alumnus of Bowen University, Nigeria, a Bioengineer and currently a Microbiology instructor and doctoral candidate at Florida Atlantic University, USA. He is also the Founder/CEO of Eurekan Biotechnologies and DNAEnsemble. He can be reached at olucyno@gmail.com