Bio Farma X Nusantics Launches Limited Bio Saliva, Covid-19 PCR Detection Test With Gargle Method

Gargle-PCR has a sensitivity up to 95%, it can be used as an alternative to the gold standard Nasopharyngeal-Oropharyngeal Swab using a PCR Kit. Biosaliva has also received a distribution permit from the Ministry of Health on April 1, 2021 with the RI Ministry of Health Number AKD 10302120673.

(Bandung 3/7) Bio Farma and Nusantics launched the latest innovation, Bio Saliva, a test tool to detect Covid-19 using the gargling method. This method is much more convenient for detecting the Covid-19 virus in the body of patients with or without symptoms.

Bio Saliva is a complement to the previous product, namely mBioCov19 which was also developed by Nusantics. The product development process involved more than 400 samples of positive Covid-19 patients, both outpatients, as well as inpatients and validation research for 7 months. The validation test has been completed colaborate with the Faculty of Medicine, Diponegoro University, Diponegoro National Hospital (RSND) and Kariadi Doctor Hospital (RSDK). Biosaliva has received a distribution permit from the Ministry of Health on April 1, 2021 with the RI Ministry of Health Number AKD 10302120673

The Association of Clinical Pathology Specialists has held a national seminar discussing the function of this Bio Saliva PCR gargle product in early May 2021, which was attended online by thousands of doctors and health workers. Nusantics and Bio Farma have carried out various developments based

on input from various parties, especially from specialist doctors and health workers.

Compared to test equipment Bio Saliva has many advantages. The samples used in the product development process are all from Indonesian patients, which is compatible with the Indonesian population. Bio Saliva can detect up to a CT number of 40 and has excellent performance for CT <35 with a sensitivity of up to 93.57%. This of course makes Gargle-PCR an alternative to the gold standard Nasopharyngeal-Oropharyngeal Swab using a PCR Kit which has a sensitivity of up to 95%.

This product answers the challenges of clinical laboratories for testing needs suitable with conditions in Indonesia, which are generally far from health facilities. with a convenient and accurate sampling method, hoped that Gargle-PCR can contribute to increasing the national tracing capacity, especially for children and the elderly who need more convenience in sampling.

Besides of convenient collection method, in the future taking the sampling process can be carried out in non-medical areas, under the supervision of health workers, so that it can be reduced crowds, and avoiding contact and can the collection of very large sample carried out with no many additional medical personnel. Bio Saliva is suitable for routine screening of factory/industrial areas, office buildings, settlements and schools for monitoring and early detection needs.

Mutation Variant Detection

In the midst of the many variants of the Covid-19 mutation and the high number of spreads, Farma answered the need for comfortable and accurate test equipment. The use of Bio Saliva, together with m-BioCov-19 can detect mutations B 117 (Alpha), B 1,351 (Beta), P.1 (Gamma), B 1,617.2 (Delta), B 1,617.1 (Kappa), B 1,525 (Eta), B 1,526 (Iota), B 1,466.2 (Indonesian variant), B 1.427/29 (Epsilon), and C.37 (Lambda). Until now, there are no Covid-19 test equipment products in Indonesia that can detect 10 (ten) variants of the Covid-19 mutation.

“We have tested it with bioinformatics alignment on tens of thousands of Whole Genome Sequencing data of these variants. The ability of mBioCoV19 to detect all circulating variants is due to consideration of the target genes used in the PCR kit design since last year. Where the E, M, S, and N genes have high mutation rates, we chose the target gene helicase (nsp-13) and RdRp (nsp-12) which are highly conserved (or more resistant to mutations) and sensitive," said Revata. Utama, CTO Nusantics.

Limited launch for improvements

This is the first time Indonesia has built a diagnostic industry. Although we are 2-3 decades behind compared to developed countries, Bio Farma has managed to record important achievements during the pandemic.

Of course, it needed some additions to make the Bio Saliva test equipment will be more perfect,we must encourage the acceleration of product improvement. Input from various parties at this limited release stage is very helpful. We must not be left behind,” said Director of Bio Farma Honesti Basyir

Bio Farma is currently conducting post market testing of BioSaliva in 3 (three) laboratories, in line with the limited release, which was appointed by the Directorate of Supervision of Medical Devices

and Household Health Supplies, Ministry of Health, RI, among others; Microbiology Lab, Faculty of Medicine, University of Indonesia, Advanced Biomedical Lab, Faculty of Medicine, University of Padjadjaran and Clinical Microbiology Lab, Faculty of Medicine, Universitas Airlangga

Honesti emphasized support for the next month from various parties is very important for product improvement which is expected to be useful for increasing national tracing capacity.

To facilitate public access to this convenient test method, starting July 3, 2021, checking using Bio Saliva can be carried out at the GSI Kuningan and Cilandak laboratories (limited releases). Access to this test method will then be expanded to more clinical laboratories throughout Indonesia that are Bio Farma's partners.