

Proposal Title: Development and Manufacturing of 'InstaCOVID nAb' : A Rapid Diagnostic Test Kit for determination of Post-Vaccination Effectiveness for COVID-19.

Name of Institute : QAWaCh Bio Pvt Ltd. (a start up at SINE IIT Bombay, Mumbai)

Incubator: Society for Innovation and Entrepreneurship (SINE) IIT Bombay

Faculty: n/a

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Objectives: 1. Development and standardization of the protocol for InstaCOVID nAb, for determination of presence of neutralizing antibodies in COVID-19 vaccinated population.

2.Third party (ICMR) validation of InstaCOVID nAb test kit protocol.

3. To manufacture the highly sensitive InstaCOVID nAb test kit and plan its reach to the masses.

Type of intervention: 4) Post Vaccination studies

Details of Intervention:

(Should cover details about the product/technology, methodology, milestones, timeline, Line---item

Wise financials along with tentative cost of transportation, annual maintenance etc.)

Please refer to pages 2 and 3 for all the details.

Do you have State Government connection, or will you require support from CSR? NO, we do not have connections and would require support from CSR.

State to which you can provide technology to: Maharashtra and later all over India.

Please answer following questions depending on the intervention you choose and if applicable to you:

Can you do the Community engagement yourselves or will need help by CSR---

We will need help by CSR.

If you have a Market ready technology available,: Currently the technology is not market ready.

Do you wish to partner with an NGO?

If yes, name the NGO and provide details on how you will partner?

(item wise costing should include cost to NGO for their scope of work)

We do not have any connections with any NGO.

**** For this type intervention, please send a separate 1---2 pager proposal that will include abstract of the planned/proposed work, methodology, tentative budget, and estimated timeline.**

Kindly refer to pages 2 & 3 of this proposal for all the details about abstract, timeline, methodology tentative budget.

Abstract

India has started the COVID vaccination drive in mid-January 2021, giving priority to 30 million healthcare and frontline workers.^[1] One of the major bio-pharmaceutical company based in Pune, Maharashtra, has 50 million doses of vaccines packed at its Pune plant and another 50 million doses are ready to be packed. It can make available around 60-70 million doses per month. Due to the need of the hour, COVID vaccine was fast-tracked and was launched under emergency regulations. Though the data for release of vaccine is available for the volunteers and trial participants, however, a very limited data is available for post-market surveillance to understand the efficacy of the vaccines. The data for neutralizing antibody for COVID is near to insignificant. The post-vaccination efficacy study is difficult to obtain, however, the study on the effectiveness of the vaccine can be performed comparatively with ease using the neutralizing antibody. These neutralizing antibodies against SARS CoV-2 have been proven protective against infection in animal models^[2,3,4] and have been evaluated as therapeutic agents in humans^[5]. These antibodies target SARS CoV-2 spike (S) trimer^[3,6], a viral glycoprotein that mediates binding to the angiotensin converting enzyme-2 (ACE-2) receptor. The S trimer comprises of three copies of S1 subunit that contains RBD and three copies of S2 subunit which includes the fusion peptide and transmembrane region.^[7] Many studies have shown that inhibition of RBD of SARS CoV-2 inhibits viral infection.^[8]

Here, we propose to develop and manufacture rapid point-of-care test, called InstaCOVID nAb test kit, for determining the presence of neutralizing antibodies against SARS CoV-2 spike protein (RBD), as one of the most important government objectives as a part of post-vaccination drive.

Methodology

1. Screening of recombinant COVID-19 Spike Protein Antigen and Angiotensin-converting enzyme 2 (ACE2) antigen along with RBD humanized COVID 19 IgG positive control.
2. Preparation of COVID-19 Neutralizing Antibody Rapid assay or test kit
 - a. Preparation of gold nanoshells/gold nanochains like particles for higher sensitivity.
 - b. Conjugation of ACE 2 with gold nanoshells/gold nanochains like particles.
 - c. Immobilization of Spike protein antigen on test line on assay.
 - d. Cassette assembly.
3. In-house validation of the test kit using humanized RBD antibody.
4. Obtaining test license for the test kit.
5. Submission of InstaCOVID nAb test batches to ICMR (Novel claim) for validation.
6. Obtaining manufacturing license for the test kit from CDSCO.
7. Bulk manufacturing of test kit for introduction of the product in Indian market.

Work Plan/Activities, Timeline and Tentative Budget

Activities/Work Plan	Milestone	Estimated Timeline (months)
Screening of Antigens	Validated protocol preparation and characterization of gold nanochains	0-2
Standardization of conjugate and capture antigens by preparation of different conc.	A working pair of conjugates and capture antigens	2-3

(ug/mL) of conjugate and various conc. (mg/mL) of capture antigen and vice versa. The assay would be prepared from above mentioned antigen concentrations and would be checked for positive signals.		
Submission of documents to CDSCO in the form of MD 12	Approval in the form of MD 13	3-5
Submission of test batches to ICMR for Novel claim	Approval from ICMR	5-8
Manufacturing of bulk batch of the test kit	Launch of the product	8-10

Estimated Timeline: 10 months

Total Budget: INR 47.0 Lakhs

References

1. India to start Covid vaccination drive from January 16: Check details. Bussiness standards.
2. Baum, A. et al. REGN-COV2 antibody cocktail prevents and treats SARS-CoV-2 infection in rhesus macaques and hamsters. *Scienc.* (2020)
3. Rogers, T. F. et al. Isolation of potent SARS-CoV-2 neutralizing antibodies and protection from disease in a small animal model. *Science* **369**, 956–963 (2020).
4. Zost, S. J. et al. Potently neutralizing and protective human antibodies against SARS-CoV-2. *Nature* **584**, 443–449 (2020).
5. Robbiani, D. F. et al. Convergent antibody responses to SARS-CoV-2 in convalescent individuals. *Nature* **584**, 437–442 (2020).
6. Liu, L. et al. Potent neutralizing antibodies against multiple epitopes on SARS-CoV-2 spike. *Nature* **584**, 450–456 (2020).
7. Walls, A.C. et al. Structure, function, and antigenicity of the SARS-CoV-2 spike glycoprotein. *Cell* **181**, 281–292 (2020).
8. Christopher O. B. et al. SARS-CoV-2 neutralizing antibody structures inform therapeutic strategies. *Nature* volume 588, pages682–687(2020).