श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेंद्रम, तिरुवनन्तपुरम - 695 011, केरल, भारत
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
THIRUVANANTHAPURAM - 695 011, KERALA, INDIA
(एक राष्ट्रीय महत्व का संस्थान, विज्ञान और प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)
टेलीफोन नं./Telephone No.: 0471-2443152 फैक्स/Fax: 0471-2446433, 2550728
ई-मेल/E-mail: sct@sctimst.ac.in वेबसाइट/Website: www.sctimst.ac.in

PROJECT COMPLETION REPORT

1. **Project Number** : 8235

2. **Title of the Project** : Rapid detection kit for IgG/IgM

3. **Funding Agency Name** : TRC

4. **Project Reference Number provided by the Funding Agency**: TRC/8235/PSN dated 11/05/2020

5. **Principal Investigator (Name & Address) :** Dr. Manoj G, Scientist D, Division of Artificial Internal Organs, Department of Medical Devices and Engineering, Biomedical Technology Wing

6. **Co-Investigators (Name & Address):**

i.	Dr. Anugya Bhatt, TRU, BMT wing
ii.	Dr. Renjith P Nair, TRU, BMT wing
iii.	Dr. Dinoop K.P, Department of Microbiology, SCTIMST
iv.	Dr. Jyothi EK, Department of Microbiology, SCTIMST
v.	Ms. Priyanka S, TRU, BMT Wing
vi.	Mr. Ranjith S Kartha, TRU, BMT wing
vii.	Mr. Anil Kumar V, TRU, BMT Wing

7. **Implementing Institution** : SCTIMST

8. **Collaborating Institutions** :
   a) SCTIMST
   b) Origin Diagnostics and Research PVT. LTD
   c) Dept. of Health and Family Welfare, GoK

9. **Date of Commencement** : 11th May, 2020

10. **Duration** : Six Months

11. **Date of Completion** : October, 2020

12. **Objectives as approved:**

Development of Rapid detection IgG/IgM kit for SARS CoV-2

13. Deviation made from original objectives if any, while implementing the project and reasons thereof :

No

14. Field/Experimental work giving full details of summary of methods adopted, data collected supported by necessary tables, charts, diagrams and photographs :

In Vitro Diagnostic Devices

Chitra Rapid Ab test kits

In response to the pandemic novel coronavirus disease 2019 (n-COV-19), SCTIMST had initiated a project for developing in-vitro diagnostic tests for detecting immunity to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). While medical diagnostic companies are racing to develop tests and governments are looking to purchase them in huge amounts for disease screening in outbreak areas, SCTIMST has developed a rapid test kit for COVID-specific IgG/IgM antibodies that is simple to use and can be performed even at the patient bed side. A small drop of whole blood or serum/plasma from the patient is sufficient to perform the tests. and visual results can be obtained within 15 to 20 min. This qualitative test provides information on whether a suspected person has developed antibodies. The kit, along with its novel diluent system that enhances the kit sensitivity, is very stable at room temperature. During the initial infection phase, IgM is the predominant antibody produced, whereas IgG is produced at the later infection stage. A positive IgM result indicates recent infection whereas a positive IgG indicates past COVID-19 infection. The technology for making this rapid kit was developed and clinically validated at COVID hospitals in Kerala for preliminary third-party testing. A Memorandum of Understanding (MoU) was signed between SCTIMST and M/s. Origin Diagnostic and Research Centre, Kerala, for commercialization. The technology is currently revising as suggested by ICMR.

(Team members include Dr Manoj G and Ms Vani Maya from the Division of Artificial Internal Organs, Dr Anugya Bhatt and Dr Renjith P Nair from the Thrombosis Research Unit, and Dr Dinoop KP and Dr Jyothi EK from the Department of Microbiology, SCTIMST Hospital Wing)

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15. Detailed anaylsis of results :

Maya, V., Kaviyil, J.E., Ponnambath, D.K. et al. Evaluation of diagnostic accuracy of developed rapid SARS-COV-2 IgG antibody test kit using novel diluent system. VirusDis. 32, 78–84 (2021). https://doi.org/10.1007/s13337-021-00669-4

16. Summary sheet of not more than 2 pages under following heads :
(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)

Please refer: https://doi.org/10.1007/s13337-021-00669-4

17. Contributions made towards increasing the state of knowledge in the subject :

Immunotechnology based product development introduced

18. Conclusions summarising the achievements and indication of scope for future work :

Maya, V., Kaviyil, J.E., Ponnambath, D.K. et al. Evaluation of diagnostic accuracy of developed rapid SARS-COV-2 IgG antibody test kit using novel diluent system. VirusDis. 32, 78–84 (2021). https://doi.org/10.1007/s13337-021-00669-4

19. Science and Technology benefits accrued :

a. List of research publications with complete details : 01

b. Manpower trained on the project : 01

i. **Research Scientists or Research Fellows** : **0**
ii. **No. of PhD's produced** : **0**
iii. **Other Technical Personnel trained** : **3**

c. **Patents taken, if any** :
d. **Products developed, if any** : **1**

20. **Abstract: (In 300 words for possible publication in ..... Bulletin)**

Immunochromatographic assay kits are used in primary diagnostics which is based on the principle of antigen and antibody interaction. These kits play pivotal role in rapid surveillance of infectious diseases at early stages as well as for the surveillance of the contagious diseases. The immunochromatographic test kits lacks sensitivity and specificity with certain diseases. In this study, our intention was to develop a rapid test kit for SARS-COV-2 with a novel diluent system to enhance the efficacy of antigen–antibody binding and thereby the improvement in the sensitivity outlined. Finally, IgG antibodies against SARS-COV-2 virus peptides were analyzed using 25 positive and 25 negative confirmed clinical samples. The sensitivity of the clinical studies showed 91% sensitivity and 100% specificity. Therefore, the authors propose that this assay will be a potential tool for efficient community or sentinel surveillance of SARS-COV-2 infection and additionally, for effective monitoring of convalescent sera therapy.

21. **Procurement/Usage of Equipment:**

a. **Details of Equipment:**

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown

b. **Suggestions for disposal of equipment(s):**

Dr. Manoj. G

(Name and Signature of PIs with date)

Routing: *Signed copy of "Project completion Report" by PI →* root@sctimst.ac.in, rpc@sctimst.ac.in