Public-Private-Partnership to make India self-reliant in RT-PCR and Serological Testing for Coronavirus

CSIR Invites Applications

The ongoing pandemic of coronavirus disease 2019 (COVID-19) is caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The World Health Organization declared the outbreak to be a Public Health Emergency of International Concern on 30 January 2020 and recognized it as a pandemic on 11 March 2020. As of May 3, 2020, more than 3,42 million cases of COVID-19 have been reported in 187 countries, resulting in more than 2,43,000 deaths.

Real-time reverse transcription-polymerase chain reaction (RT-PCR) assay is used to rapidly detect the severe acute respiratory syndrome-associated coronavirus (SARS-CoV). The assay, based on multiple primers and probe sets located in different regions of the SARS-CoV genome, can discriminate SARS-CoV from other human and animal coronaviruses with a potential detection limit of less than 10 genomic copies per reaction. The real-time RT-PCR assay is more sensitive than a conventional RT-PCR assay or culture isolation and is suitable to detect SARS-CoV in clinical specimens.

RT-PCR assay requires several reagents to do the tests. These are: Kit components of RNA isolation, reverse transcription and Real Time PCR with detection system (a list of chemicals relevant to these steps is available). Most of these reagents are imported and in a critical situation like this when all countries need them, they are available in limited quantity in India. CSIR endeavors to support the Indian industry to make these reagents in India.

There is also need for substitutes of RT-PCR based detection of nucleic acids as diagnostics approach, for example, LAMP-PCR, paper based lateral flow devices, microfluidics based devices, etc. In addition to the nucleic acids based detection, there is great need for serological testing. Such tests will not only be useful for late and post infection status at population/area scale for surveillance and monitoring which will help in key decision making by the government. Such tests will also be useful the therapeutic area like antibody based therapy, passive immunization/plasma therapy, etc.

The offer of CSIR to Industries

- *Hand* holding till the last step;
- Infrastructure facility of CSIR;
- Human Resource Training; and
- Support in the validation of kits made from these reagents

The expectation from Industry

- Have requisite infrastructure and human resources to take up the manufacture of these reagents or join in an Incubation Centre set up by CSIR labs;
- Deploy financial resources for manufacture;
- Validation of kits made out of these reagents;
- Commercialization and marketing of reagents.

Some relevant reagents that may require indigenization

♦Guanidinium isothiocyanate; ♦MMLV Reverse Transcriptase; ♦RNase inhibitor, RNASE H, RNASE OUT; ♦Taq DNA polymerase recombinant; ♦Power SYBR mix (polymerase); ♦Taqman probes or substitutes; ♦dNTPs monomer units for chemical synthesis of DNA/RNA; ♦Various fluorescent probes used in labeling DNA/RNA fragments; ♦FITC,Rhodamine-Flurophore tags; ♦T7DNA dependent RNA polymerase; ♦Streptavidin, Biotin; ♦Interacalating Dyes; LAMP Polymerse; etc.

Screening Criteria

The criteria for screening of the projects will include fast timeline of delivery, cost of the test per sample, one time initial investment for production, scalability, point of care potential, throughput of the test, etc.

The interested industry or start-up may apply to CSIR as per given proforma to
In-charge, Mission Directorate, Council of Scientific & Industrial Research, New Delhi at
rpsingh@csir.res.in

Last Date of receiving applications: May 18, 2020

Proforma for Collaboration with CSIR in PPP mode to make India self-reliant in RT-PCR and Serological Testing for Coronavirus

Part I – Company Profile

1. Name, address and contact details
    i. Name of the Company
    ii. Address (Registered Address and Plant Address)
    iii. Contact Person (Name, Designation, E-mail & Mobile no.)

2. Details of The Company
    i. Incorporation / Registration details (Attach registration Certificate as Annexure)
    ii. Type of Company (Public, Private, Propriety etc.)
    iii. Ownerships and shareholding pattern

3. Company Profile
    i. HR Strengh
    ii. Product Portfolio (being manufactured and supplied)
    iii. Technology portfolio(technology developed/licensed/in-licensed)
    iv. Whether have R&D Centre, if so:
        a. Whether DSIR recognized (Attach Certificate)
        b. R&D HR Profile
        c. R&D Areas
        d. R&D Strengths
        e. R&D Facilities / infrastructure available

4. Present Manufacturing Facility:
    i. Manufacturing Plant type,
    ii. Manufacturing Infrastructure / facilities available
    iii. Size and installed vs utilized capacity,
    iv. Strengths and Gaps

5. Financials: Latest Annual/Financial Reports (Balance Sheet / Profit Loss Account) for last 3 Financial Years (Attach as Annexure)

6. Other details, if any

P.T.O

Part II – Proposal

1. Executive Summary of work proposed (not more than half Page)
2. Title of the Proposal
3. Describe the Proposal with Objectives
4. PI state whether interested in manufacturing of Complete kit of reagents for RT-PCR and Serological Testing (it may warrant manufacturing of multiple reagents)
5. List of Reagents identified for manufacturing (please refer indicative list of reagents given in advt.)
6. Reasons for selecting these Reagents for manufacturing
7. Collaboration / Support (except financial support) sought from CSIR (please elaborate in detail)
8. Any other support required from CSIR
9. CSIR Lab with whom the collaboration / Networking is sought, if any
10. Technical Plan for Manufacturing of identified reagents
11. Availability of Raw Materials and details of Supply Chain established and to be established (describe the status and plan)
12. Possibility of adding / initiating new product lines in existing plant as proposed in the proposal
13. Time period required for manufacturing (immediately/within 3 months/ within 6 months)
14. The proposed work plan - give details of project components, work plan of each component along with time frame
15. Infrastructure and Analytical Facilities Available / to be made available for manufacturing and quality control of reagents (describe the status and plan)
16. HR Resource to be deployed for specially for this activity (training, plant operation & manufacturing / marketing & commercialization), segment wise
17. Financial liquidity/capacity available for manufacturing of reagents or arrangement of financing from other sources (describe the status and plan)
18. Business / Marketing and Commercialization Plan
19. Viability Analysis
20. Output/Outcome/Deliverables