International Conference on Emerging Technologies to Combat the COVID-19

Enabling policy ecosystem and strategies to promote use of emerging technologies for addressing COVID-19 challenges

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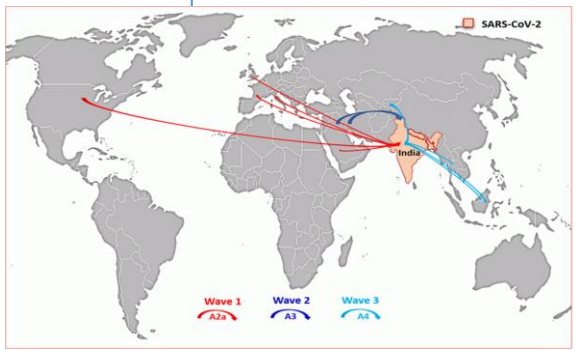
Director- National Aerospace Laboratories (India)

Technology Verticals to Mitigate COVID-19 challenges

Council of Scientific & Industrial Research (CSIR)-India

Digital & Molecular surveillance



Rapid & Economical Diagnosis

FELUDA

IGIB
INSTITUTE OF GENOMICS & INTEGRATIVE BIOLOGY
Genomics Knowledge Partner

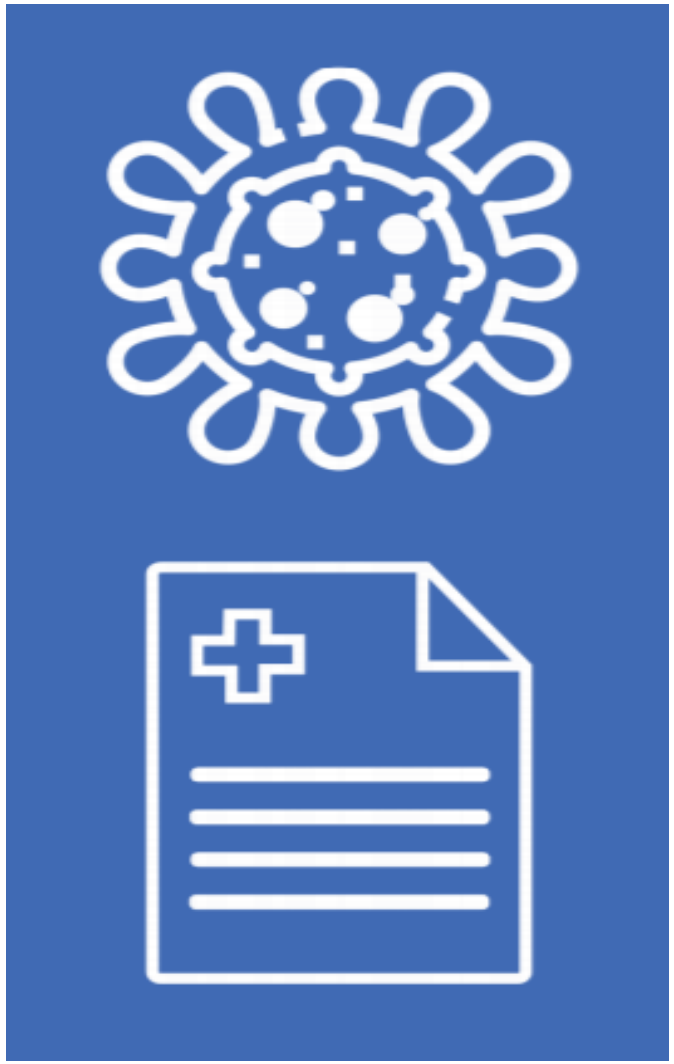
TATA SONS

New and repurposed drugs & Vacancies

Hospital assisted devices & PPE

Supply Chain and logistics

#CSIRFightsCOVID19



Rapid and Economical Diagnostics

Innovations in Diagnostics for SARS-CoV-2

Desirable Parameters

- Point of Care
- High Throughput
- Reliable
- Affordable
- Speed
- Ease

CSIR Possesses Spectrum of Expertise to Address any National Emergency

- **Established sequencing and bioinformatics pipelines**
- **Expertise in diagnostics**
- **Design and engineering expertise for medical devices**
- **Capacity and capability for R&D**

CRISPR Based Diagnostics

- In 2019, CSIR-IGIB developed a new highly specific FnCas9. A sickle cell disease test was developed with a patented platform technology (**FELUDA, F**ncas9 **E**ditor **L**inked **U**niform **D**etection **A**ssay)
- In 2020, once the threat of COVID-19 pandemic came, it was decided to also create a SARS-CoV2 diagnostic

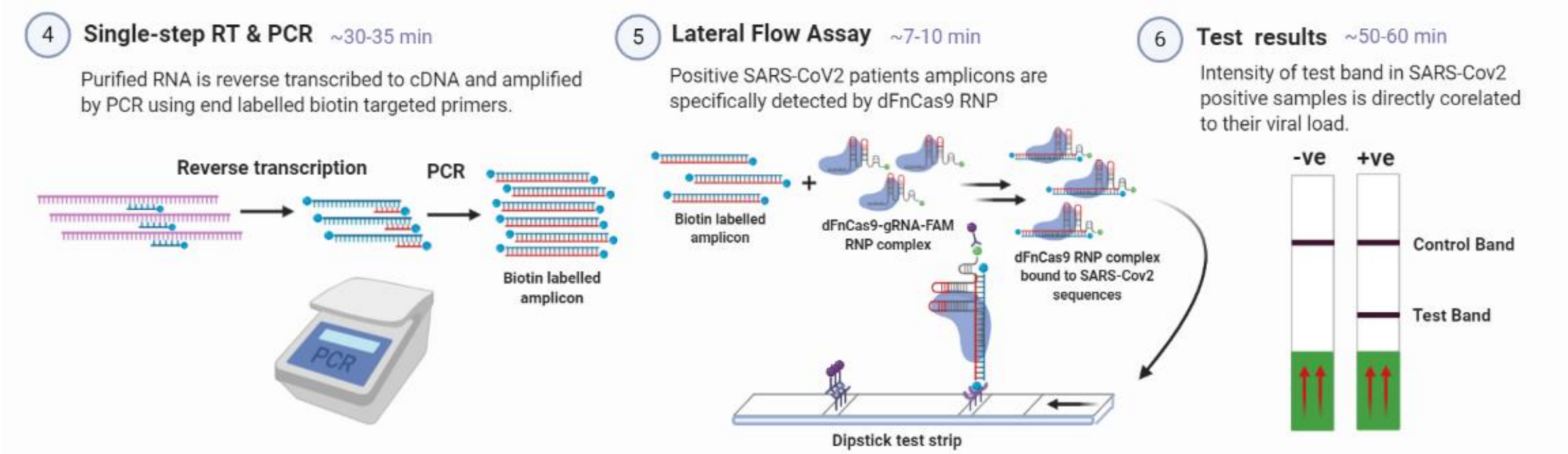
Date	Event
27.03.2020	Patent filed for FELUDA platform technology
07.05.2020	FELUDA SARS-CoV2 test demonstrated and licensing agreement signed with TATA Sons
20.09.2020	DCGI approval to TATA kit powered by FELUDA
22.10.2020	ICMR notification that CRISPR test equivalent to qRT-PCR
09.11.2020	TATA MD CHECK powered by FELUDA technology launched by TATA MD

Prov. patent nos. 201911049432 (02.12.2019) and 202011013418 (27.03.2020)

FELUDA: How and Why?

- After one step reverse transcription PCR, a CRISPR (FnCas9) recognizes specific nucleic acid sequence and produces paper strip band. Because of inbuilt simple PCR and CRISPR – **high sensitivity and specificity comparable to qRT-PCR**

- After sample collection, transport, and RNA extraction (1-3), the steps are:



Variants of FELUDA to Harness Advantages and Overcome Limitations

	qRT-PCR	RAT	FELUDA
Sample	Swab/Saliva*	Swab	Swab/Saliva*
Substrate / Extraction	RNA / Yes**	Protein / No	RNA / Yes**
Pooling	Yes	No	Yes
Infrastructure	qPCR machine (20-30 lakhs)	None	Thermocycler; (Rs 25-50,000). Instrument free prototype exists
Sample to result	180 min	30 min	75 min
Sensitivity/Specificity	Benchmark	60% / 99%, cannot detect low viral load	96%/98%, can detect viral load as low as Ct 35-37

* Saliva not yet approved but multiple publications, NEJM Sept 24, 2020

** Extraction free processing exists but not approved, See next slide

Dry Swab-Direct RT-PCR Diagnostic Method

- **RNA Extraction Free and Direct RT-PCR; should be used with ICMR approved kit for RTqPCR.**
- No new equipment or reagents needed
- With the current manpower and funds up to **3 times more testing can be done with this method immediately**

Advisory Permit obtained by Indian council of Medical Research (ICMR)

Globally Accepted Method

- *Easing diagnosis & pushing the detection limits of SARS-CoV-2; **Biol Methods Protoc**. 2020 Aug 20;5(1):bpaa017*
- *Massive and rapid COVID-19 testing is feasible by extraction-free SARS-CoV-2 RT-PCR; **Nat Commun**. 2020 Sep 23;11(1):4812.*
- *Direct RT-qPCR detection of SARS-CoV-2 RNA from patient naso-pharyngeal swabs without an RNA extraction step; **PLoS Biol**; 2020, Oct 2: 18(10): e3000896*
- *Detection of SARS-CoV-2 with SHERLOCK One-Pot Testing: **N Engl J Med**. 2020 Oct 8;383(15):1492-1494.*

Saliva based diagnostics without RNA isolation step have received FDA approval

New & Repurposed Drugs and Vaccines

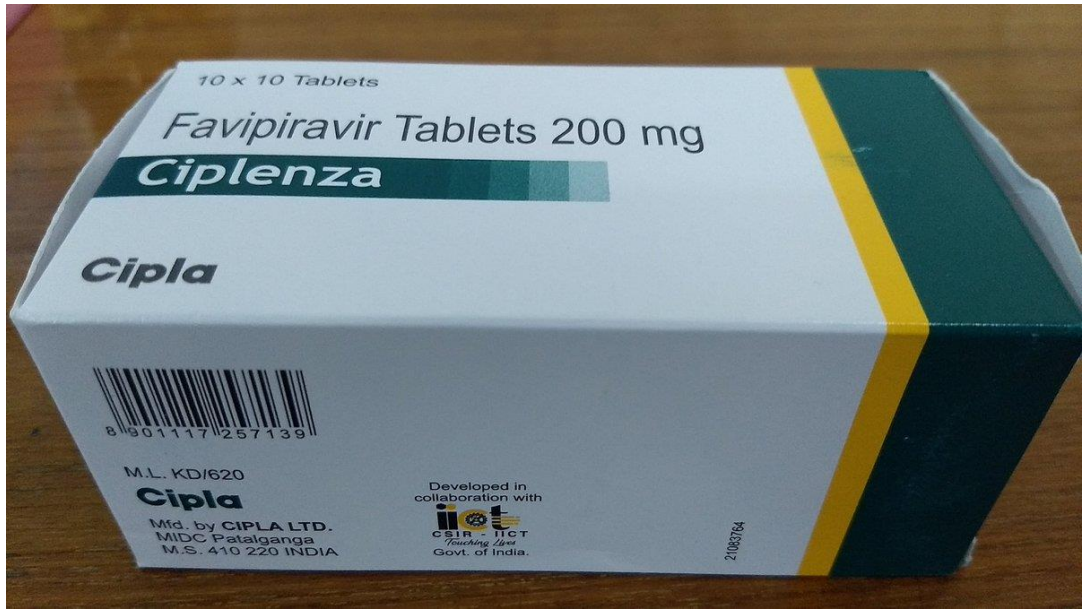
Cost Effective Process Technology of Favipiravir

- Repurposed generic drug
- Cost effective process of API with locally available chemicals developed by CSIR
- Provided API and Key starting materials to Cipla

Cipla

CSIR - IICT
Touching Lives

CSIR has played a pivotal role in launch of Ciplenza by Cipla which has triggered market competition leading to lower pricing of drug



CSIR-Mylan Partnership for Clinical Trials

- CSIR and Mylan Laboratories Limited are in partnership to address unmet patient needs amidst the evolving COVID-19 pandemic.
- Under the partnership, CSIR-IICT and Mylan will collaborate to identify potential therapies for COVID-19.
- A series of clinical trials will be conducted towards new and innovative solutions to manage COVID-19 pandemic in India as part of this collaboration.
- Application for phase III of Combination clinical trials examined by DCGI and asked to do Phase II Clinical trial; application of Sofosbuvir+Daclatasvir (SOF/DCV) submitted

CSIR - IICT
Touching Lives

Mylan

Clinical Trials of Repurposed Drugs for COVID-19

Drug	Mode of Action	Industry Partner	Current Status
Umifenovir	**Prevents entry of virus into human cells and also boosts immune system.**	MEDIZEST Agrawal GROUP	• **Phase III trial initiated** • RMLIMS, Era's Lucknow Medical College & Hospital & KGMU
(1) Favipiravir + Colchicine; **(2) Umifenovir + Colchicine** **(3) Nafamostat + 5-ALA**	**Antivirals (viral-entry and replication inhibitors)** **Host-directed therapies (HDTs)**	LAXAI Enriching life through innovation	• Application submitted to DCGI for regulatory clinical phase III trials at Medanta Medicity • Total of 300 patients in 4 different groups • 75 patients in each arm • Treatment for 17 -21 days including screening and treatment.
(1) Favipiravir + Bromohexine **(2) Niclosamide**	**Prevents viral entry Mucolytic drug** **Anti-viral and host directed response modifier**	Cipla Caring for life; LAXAI Enriching life through innovation	• PI driven Clinical Trial • Ethics Approval Received • Cipla shall provide Favipiravir for clinical trial
(1) Sofosbuvir+Daclatasvir (SOF/DCV) **(2) Sofosbuvir+Daclatasvir (SOF/DCV)+Nitazoxanide** **(3) Favipiravir+Bromohexine**	**Used to treat HCV** **SOF Inhibits the NS5B & DCV inhibits the NS5A of HCV** **Nitazoxanide is a broad spectrum anti parasitic and anti viral**	Mylan	• Application submitted to DCGI • The trials will be conducted in adult patients with mild to moderate Covid-19 at risk of complications.

Ongoing Clinical Trials for COVID-19

Sepsivac

- Trials at PGI Chandigarh; AIIMS Delhi, and AIIMS, Bhopal.
- Approval for Phase-III trials in place: one on 600 patients, another on 500 patients.
- **Phase II trial on critically ill Covid-19 patients completed sucessfully**
- **DCGI has given approval for Phase III trials**

CADILA PHARMACEUTICALS LIMITED
The Care Continues...

ACQH

- DCGI approval for clinical trials.
- First-ever approval in India in phytopharmaceutical route
- Clinical trials being done by Sun Pharma in collaboration with ICGEB & CSIR-IIIM Jammu.
- Clinical trials on at 12 centers; in 210 patients
- **Trial to be completed soon**

SUN PHARMA

CSIR-IIIM

ICGEB

Plasma Therapy

- The trial involves CSIR-IICB, Calcutta Medical College and Iinfectious Disease Hospital, Belegata, Kolkata
- Dedicated 'Epidemic Immune Monitoring Lab' has been prepared for this program.
- Clinical trial has been approved by DCGI
- **To be completed soon**

IICB Translational Research Unit of Excellence — CSIR-Indian Institute of Chemical Biology

Medical College and Hospital, Kolkata

Infectious Diseases & Beliaghata General Hospital (I.D. & B.G. Hospital)

Drug Discovery Initiatives

Drug Discovery HACKATHON (DDH2020)

MHRD, AICTE and CSIR with Guidance of Principal Scientific Advisor

CSIR may take forward the drug hits/drug targets of DDH2020 for experimental validation and further Drug Discovery

1st Round Open

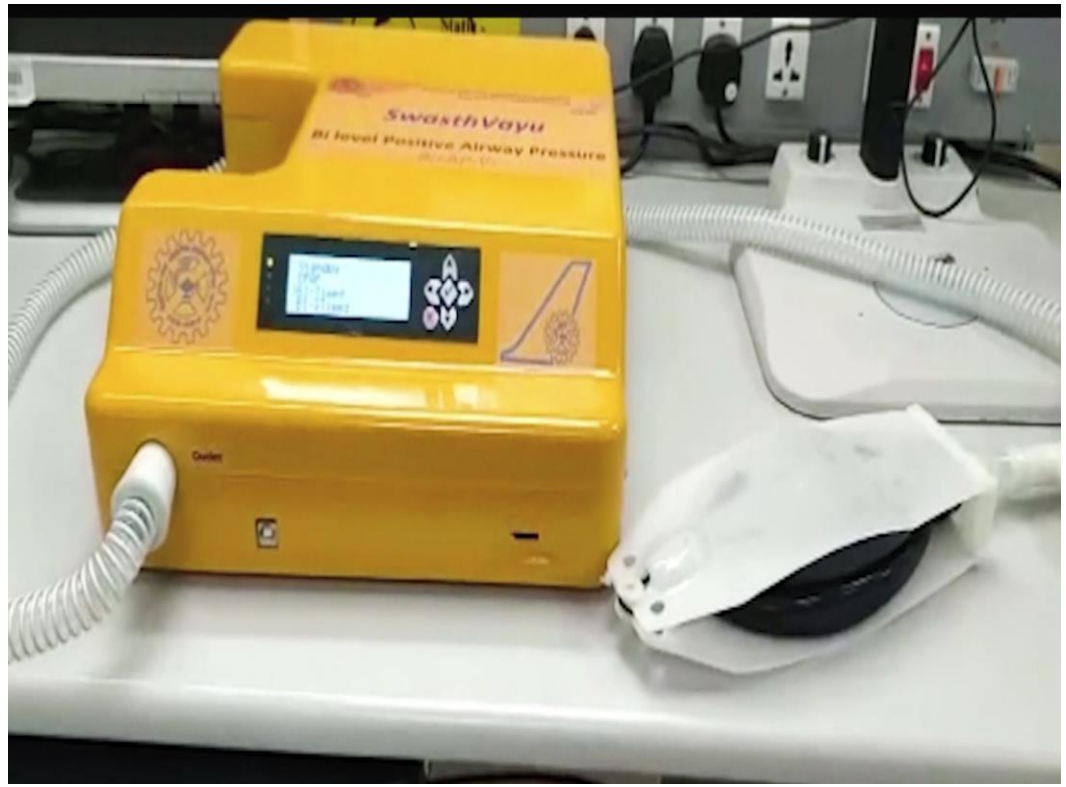
In Silico	Target Based Assays	Testing on Viral Cultures
• CSIR-CLRI • Screening underway	• CSIR-CDRI • CSIR-IICB • Spike-ACE 2 Interaction • PLPro • MPro	• CSIR-CCMB • CSIR-IMTECH • Screening ongoing

Hospital Assistive Devices and Personal Protective Equipment (PPE)

SwasthVAYU Ventilator

- Developed by CSIR-NAL in 36 days
- Non-invasive Ventilator with **HEPA 'T' filter**
- Cost effective, easy to use in Makeshift hospitals, wards, dispensary
- Certified by NABL accredited labs (Safety, Calibration & Performance)
- **Transferred to 7 Industries** including Bharat Forge and Paras Industries
- Clinical trials completed on 30 Covid-19 patients
- Production capacity 350/week

- **DGHS approval Expected soon**



Government of Delhi has given order of 1200

Electrostatic Disinfection Unit

- No. of nozzles = Single headed
- Tank capacity = 10/15 litres
- Battery usage hours[3] = 10-12 hour
- 360 degree area and uniform coverage, small droplet size, applicable for all fluid types
- Technology Transferred to BHEL,
- Rite water
- M/s. Jhosna Corporation,
- M/s. Dashmesh Industries
- ~200 units produced
- **ENCEESPRAY selected for Top COVID-19 Innovation Award with RITE Water Solution Pvt. Ltf, Nagpur, CSIR-CSIO and Univ. of Florida as partners by USISTEF**

CSIR-CSIO

Make Shift Hospitals

Make Shift Hospital and Isolation Center, Chennai with NDRF

CSIR-SERC
ENGINEERING SUSTAINABLE STRUCTURES

License agreement with L & T Limited, for technology transfer of Portable lightweight foldable module for makeshift hospitals

Prototype at Ghaziabad made by CBRI with NDRF

CBRI

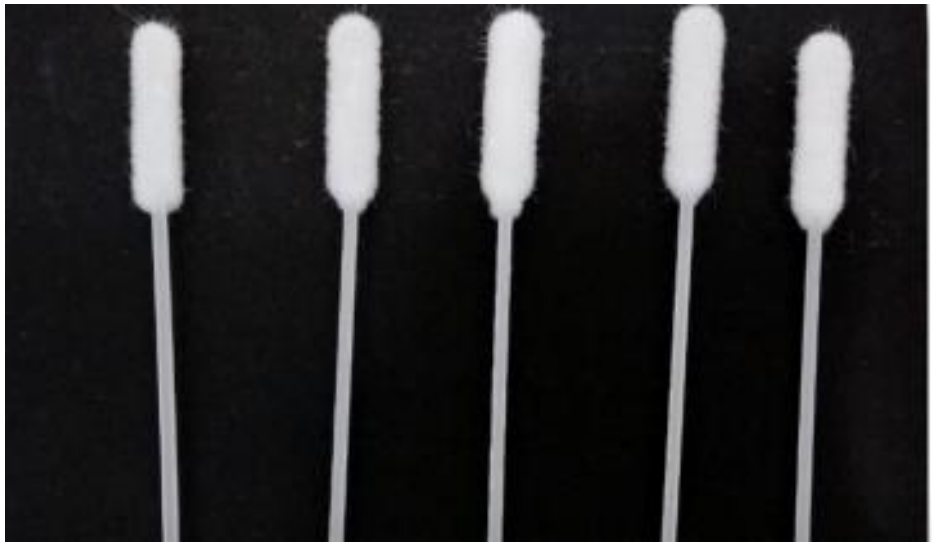
Working with State Governments in HP

Coverall with Protective Shoe Cover

- Designed, developed & certified in 7 days with Indigenous materials
- SITRA certified
- **>1,50,000 pieces supplied**
- Industry Partner-MAFL
- Current capacity: 7000/day & can go to 30,000/day
- Supplied to HLL, Jaslok, St John Medical Hospital , AIIMS – Bhubaneshwar, Govt. Hospital – Mysore, Govt. of Karnataka Health Department

Swabs

- Sterile Flocks material
- Nylon micro-fiber tip
- Flexible ABS shaft
- Breakpoint at which swab can be broken after sampling and put in a sample tube
- Easy collection and release of cells into transport media-nylon microfibers attached vertically to shaft
- Appropriate small size for pediatric, nasopharyngeal or urethral genital sample collection
- Have been **approved by ICMR**, and CPML has now started commercial manufacturing of these nasal swabs under the name, **"KEMYLON SWABS"**
- The company has established a facility to produce 1 lakh swabs/day and plans to expand this to 3 lakh swabs/day



Licensed to Ms. Chembond Polymers and Materials Pvt. Ltd. (CPML), Mumbai

Aarogyapath: National HealthCare Supply Chain Management System

An integrated public platform provides single-point availability of key healthcare goods can be helpful to customers, manufacturers and suppliers

CSIR CRRI

How CSIR Can Contribute to Vaccine Supply Chain

- Integrate with current Surveillance and Diagnostics initiatives
  - Screen out those who are infected or seropositive
  - Track post-vaccination performance, individually as well as existing cohorts
- Integrate with existing Supply Chain platform
  - PIN Code based delivery available at www.Aarogypath.in
- Build drone-based last-mile delivery network
  - Combine with Drone, AI and Analytics capabilities at CSIR-NAL, CSIR-4PI and other institutions of repute
- Direct therapeutic and assistive device stocks to non-vaccinated areas
  - Use Aarogyapath and geospatial data to build gap models

Major Industry Partners

and more.....