

SOP Code COVID # 002	Standard Operating Protocol for Specimen Registration and Report Management of Clinical Specimens
Version-I – (10/2021)	

1. PURPOSE

The purpose of this document is to enable compliance with government guidelines for registration of COVID-19 specimens received and updating of the reports on the portal.

1. Introduction

At the onset of COVID-19 pandemic, the challenge was to standardize the format of sample data from various Tests conducted across the country. ICMR designed the Specimen Referral Form (SRF) for use with every COVID-19 sample; NIC developed the RT-PCR and RATI mobile apps on Android, iOS and Windows mobiles for ICMR along with the web-portal to whitelist phlebotomists (sample collectors) for using the mobile apps and web-portal. It is mandatory to fill this form for each and every sample being collected.

2.1 RTPCR APP

RT-PCR App is a handheld tool for the Medical Staff at Sample Collection Centres spread across the country. The Sample Collection Facility will be sending the sample for various type of specimen to ICMR labs conducting the RT-PCR test for confirmation of COVID-19. Advance intimation is being shared through the App with ICMR. On successful saving any sample, the Collection Centre and the User can view the collection details.

2.2 Data Reporting

The data management system covers RT-PCR, Rapid Antigen and Rapid Antibody tests.

Salient features of the COVID-19 Data Management System developed by NIC

- Robust, reliable Cloud infra, with redundancy, zero down-time and region-wise Databases with responsive portal and apps, tested for 50,000 concurrent users
- Single sign-on using Government official email IDs and Mobile number-based access for Labs (including Private), Collection Centres and Sample Collectors
- Extensive training material, videos, FAQs AVAILABLE
- SRF data accessible on real-time basis by ICMR Labs. Data Analytics, Auto Alert SMS/ Emails and GIS integrated
- Option to enter offline data after generation of SRF-ID
- Configurable- Skip Patient OTP for verification and warning on multiple use of same patient mobile
- RT-PCR, Rapid Antigen and Rapid Antibody tests covered

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- Patient mobile and location details to help in tracking of patients and tracing of contacts

2. RESPONSIBILITY

Authorized specimen collection personnel, Data entry team and In-charge

3. PROCEDURE

STEP WISE (WITH IMAGES) SOP FOR USING RTPCR APP

While using the app, please ensure your internet connection is active



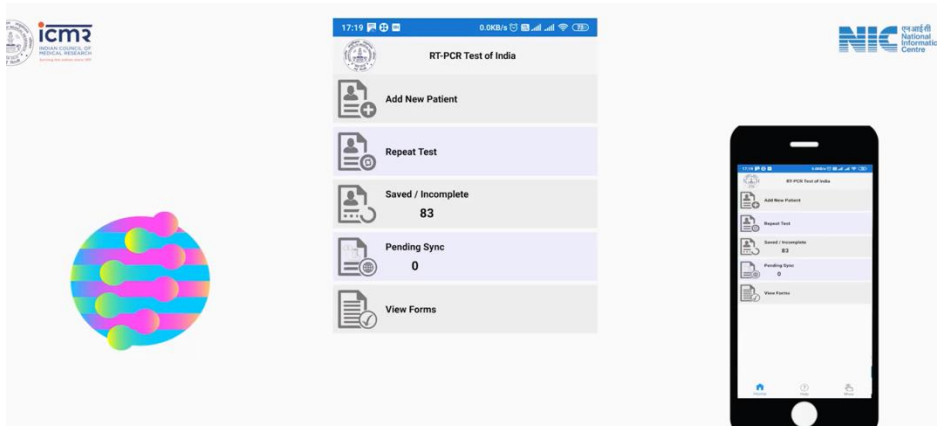
A. REGISTERING A PATIENT FOR THE FIRST TIME

1. **STEP 1:** Download and install the app from the portal/playstore. Before accepting terms and conditions, check your mobile no. authorization by visiting over the portal

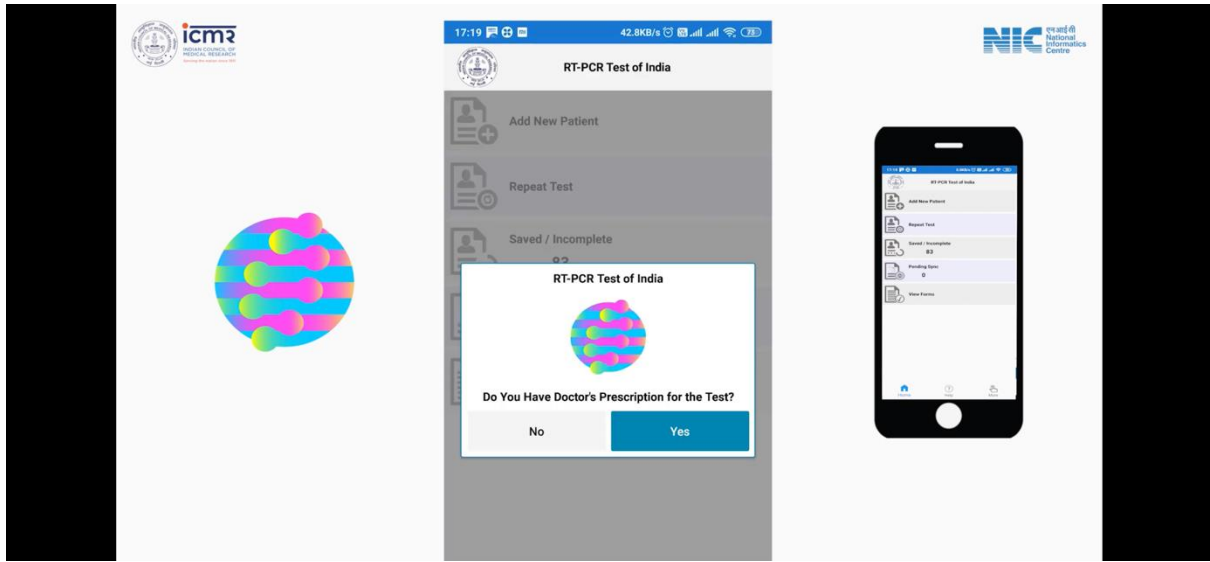


2. **STEP 2:** This app will now ask you to enter your mobile no. against which an OTP will be generated The very 1st menu at the top will ask you to add New Patient.

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3. **STEP 3:** After adding a new patient the app will ask for Doctor’s prescription (not a mandatory field anymore).

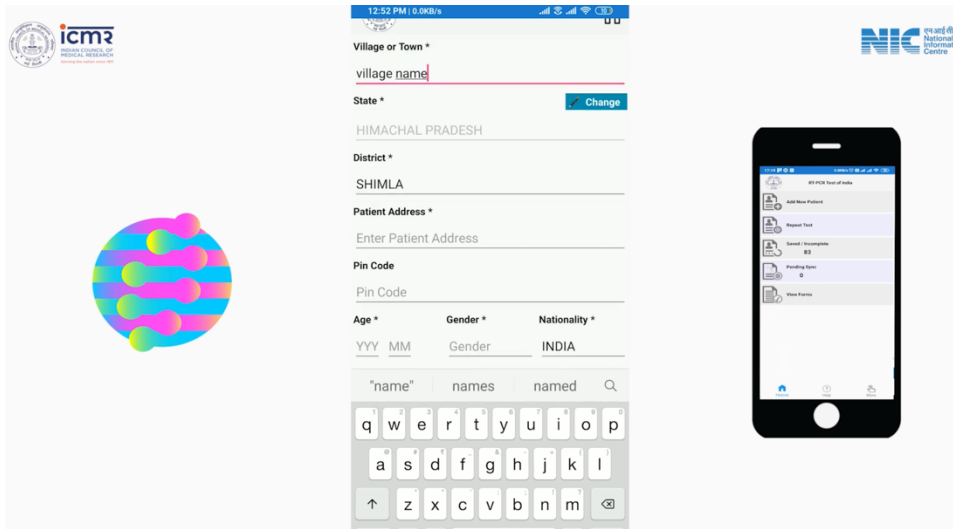


The app will then ask the name and mobile no. of the patient and OTP will be sent to patient’s registered phone no. provided

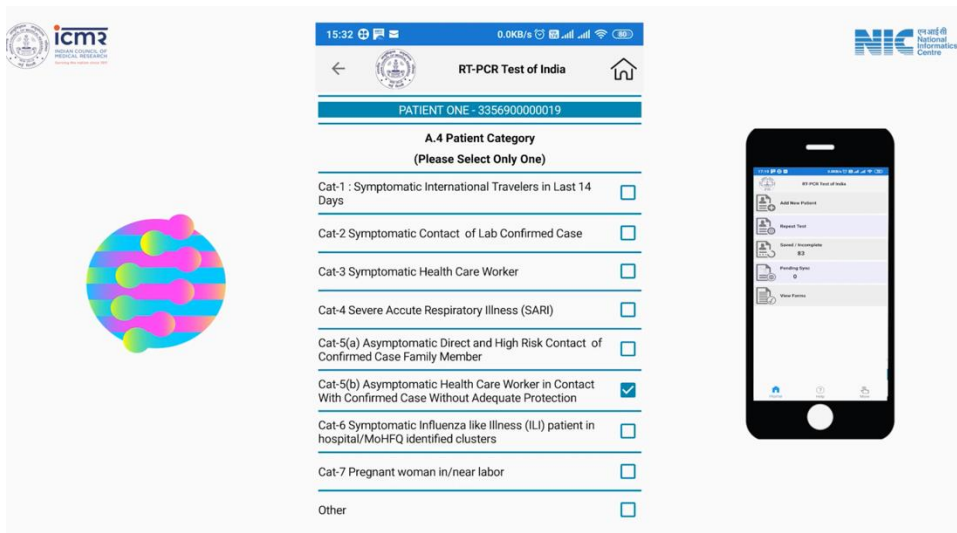
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The screenshot shows a mobile application interface for patient registration. On the left is the ICMR logo and a colorful virus-like graphic. The main form fields are: Village or Town * (with a text input containing 'village name'), State * (HIMACHAL PRADESH), District * (SHIMLA), Patient Address * (with a text input 'Enter Patient Address'), Pin Code (with a text input), Age * (YY MM), Gender * (Gender), and Nationality * (INDIA). A keyboard is visible at the bottom. On the right is a smartphone displaying the application's main menu with options: Add New Patient, Report Test, Search / Resumption, Pending Tests, and View Forms.

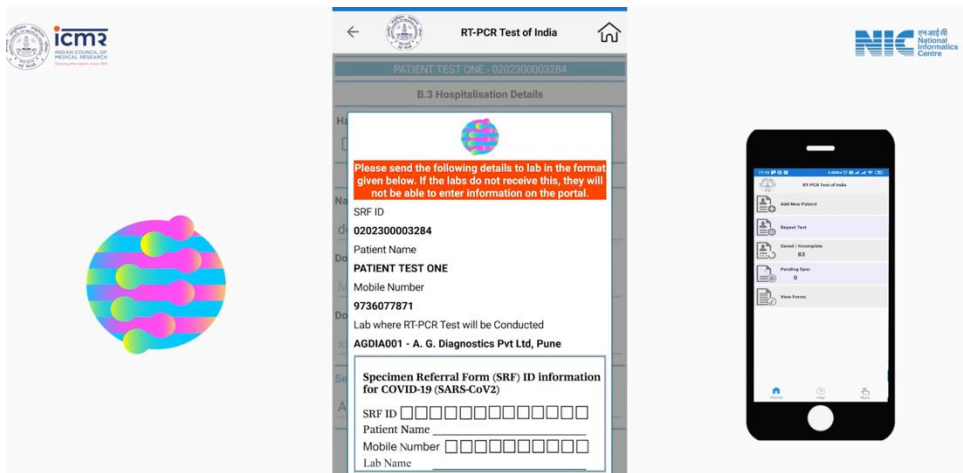


The screenshot shows the 'RT-PCR Test of India' screen. At the top, it says 'PATIENT ONE - 3356900000019' and 'A.4 Patient Category (Please Select Only One)'. Below this is a list of categories with checkboxes:

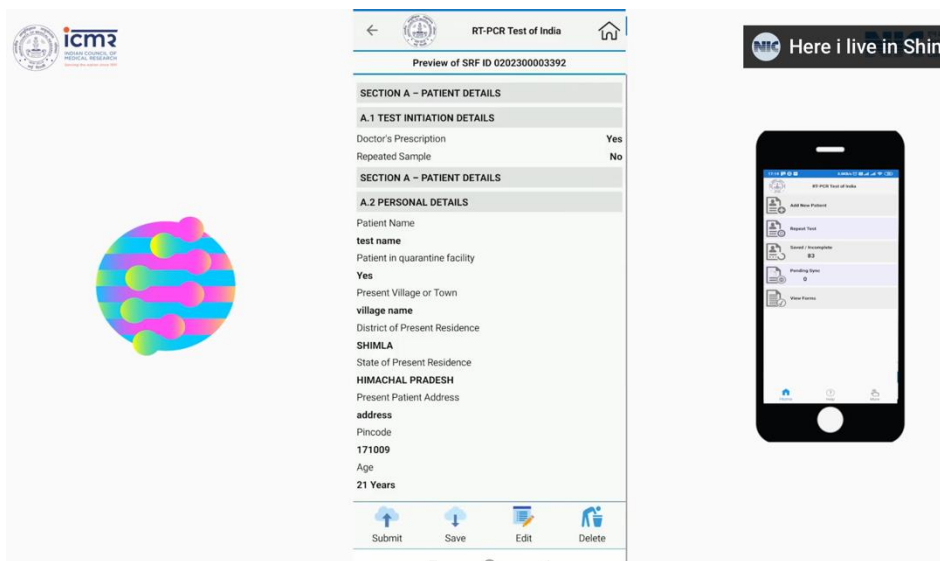
- Cat-1 : Symptomatic International Travelers in Last 14 Days
- Cat-2 Symptomatic Contact of Lab Confirmed Case
- Cat-3 Symptomatic Health Care Worker
- Cat-4 Severe Accute Respiratory Illness (SARI)
- Cat-5(a) Asymptomatic Direct and High Risk Contact of Confirmed Case Family Member
- Cat-5(b) Asymptomatic Health Care Worker in Contact With Confirmed Case Without Adequate Protection
- Cat-6 Symptomatic Influenza like Illness (ILI) patient in hospital/MoHFQ identified clusters
- Cat-7 Pregnant woman in/near labor
- Other

On the right is a smartphone displaying the application's main menu.

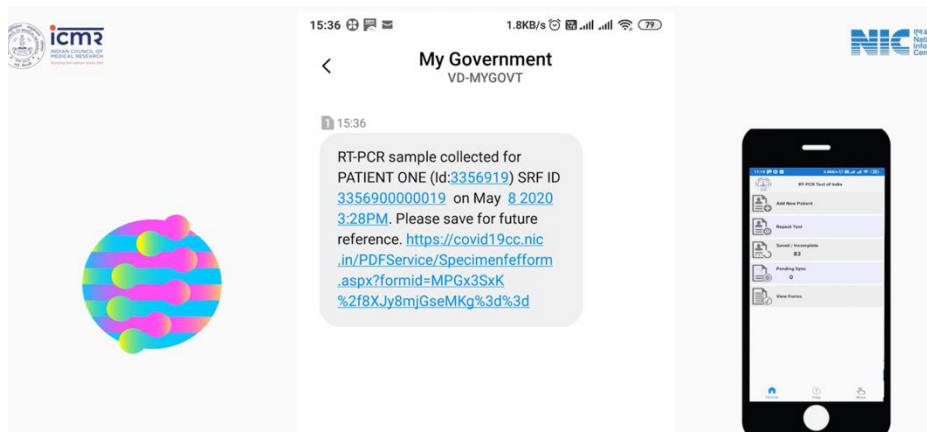
5. **STEP 5:** After saving the information, before making final submission, screen the pop up displaying your SRF ID.



6. **STEP 6:** You can edit/continue. You can now also preview your form and proceed with submit/save/edit/delete options.

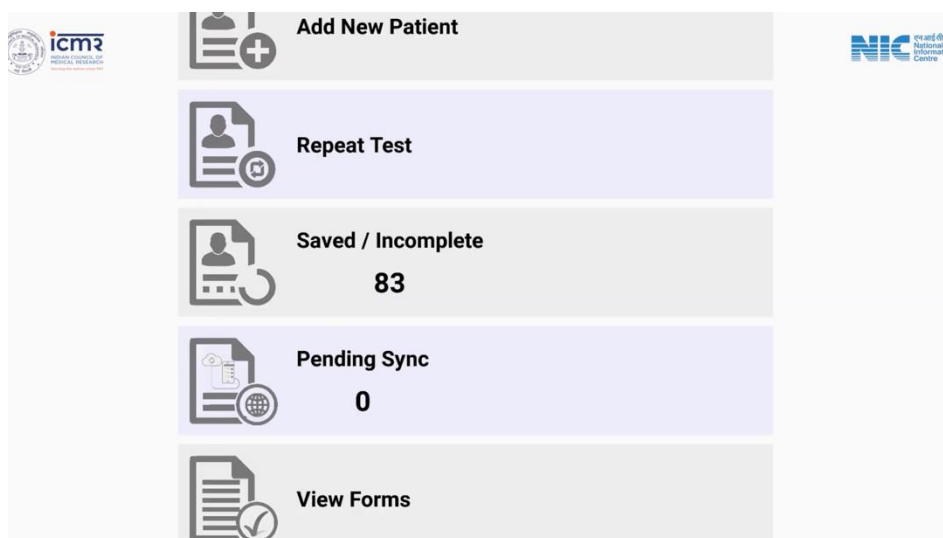


7. **STEP 7:** Once submitted, patient will receive an SMS to view report



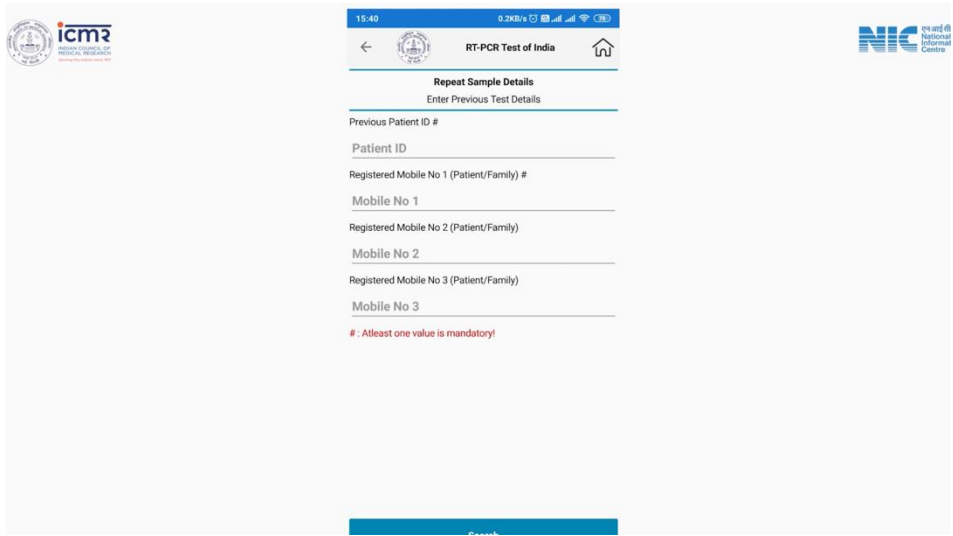
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B. PROTOCOL FOR REPEAT TEST

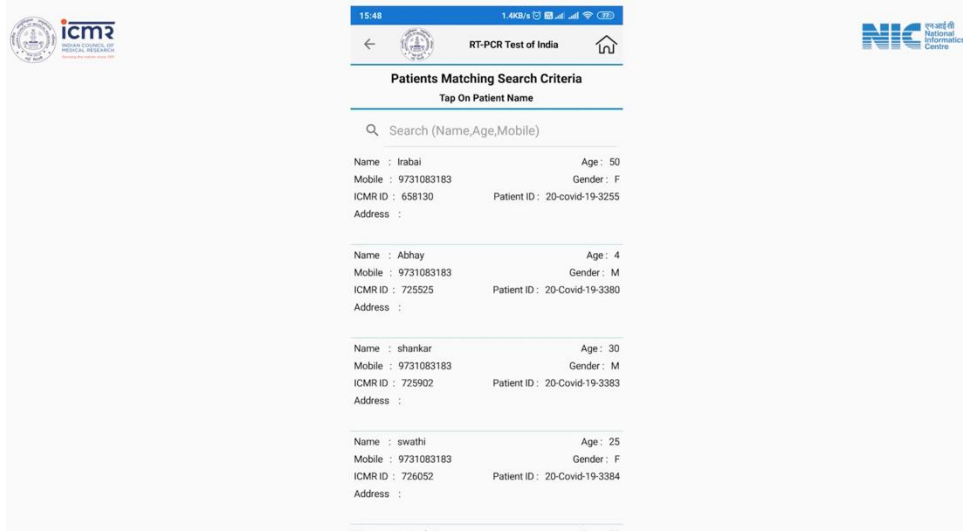


STEP 1: After clicking on Repeat test menu- the screen will ask for the parameters as shown in the image below and at least 1 value is mandatory.

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Right after entering mandatory field/, you will be able to view patient matching search criteria



STEP 2: Tapping the desired patient record, the app will populate A2 and A4 section with limited editing privileges.

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RT-PCR Test of India

AFTER STATE CHANGE

A.2 Personal Details

Repeat Test - Preview / Selective edit!

Name *

AFTER STATE CHANGE

Mobile Belongs To? *

Self Family

Mobile Number *

7807905622

Patient in quarantine facility *

Yes No

Person's present address

Village or Town *

TOWN

State *

LAKSHADWEEP

District *

Lat : 31.0882945 Long : 77.1804108

Cancel Next >

RT-PCR Test of India

AFTER STATE CHANGE - 020230003444

A.4 Patient Category

(Please Select Only One)

Repeat Test - Preview / Selective edit!

Cat 1: Symptomatic international traveller in last 14 days

Cat 2: Symptomatic contact of lab confirmed case

Cat 3: Symptomatic Healthcare worker / Frontline workers

Cat 4: Hospitalized SARI (Severe Acute Respiratory Illness) patient

Cat 5a: Asymptomatic direct and high risk contact of lab confirmed case - family member

Cat 5b: Asymptomatic healthcare worker in contact with confirmed case without adequate protection

Cat-6 Symptomatic Influenza like illness (ILI) in hospital

Cat-7 Pregnant woman in / near labour

Cat-8 Symptomatic (ILI) among returnees and migrants (within 7 days of illness)

Cat-9 Symptomatic Influenza like illness(ILI) patient in Hotspot / Containment zones

Lat : 31.0882945 Long : 77.1804108

Cancel Next >

Sections A3 and B1 to B4 may be entered.

RT-PCR Test of India

AFTER STATE CHANGE - 020230003444

A.3 Specimen Information From Referring Agency

Throat Swab Collection Date & Sample ID (Label)

Nasal Swab Collection Date & Sample ID (Label)

BAL Collection Date & Sample ID (Label)

ETA Collection Date & Sample ID (Label)

Nasopharyngeal Swab Collection Date & Sample ID (Label)

Lat : 31.0882945 Long : 77.1804108

RT-PCR Test of India

PATIENT ONE - 335690000019

B.1 Clinical Symptoms and Signs

Symptom Present *

Yes No

Select Symptom(s)

Cough? Chest Pain?

Breathlessness? Abdominal Pain?

Sore Throat? Vomiting?

Sputum? Haemoptysis?

Diarrhoea? Nasal Discharge?

Nausea? Fever at Evaluation?

Body-ache?

Date of Onset of First Symptom

01/01/2020

Which of above mentioned was First Symptom *

Haemoptysis

Lat : 31.0882945 Long : 77.1804108

RT-PCR Test of India

B.4 Referring Doctor Details

Hospital State

Select Hospital State

Hospital District

Select Hospital District

Hospital Name

Name of Hospital

Name of Doctor *

Doctor Name

Doctor's Mobile Number

Mobile No.

Doctor's Email ID

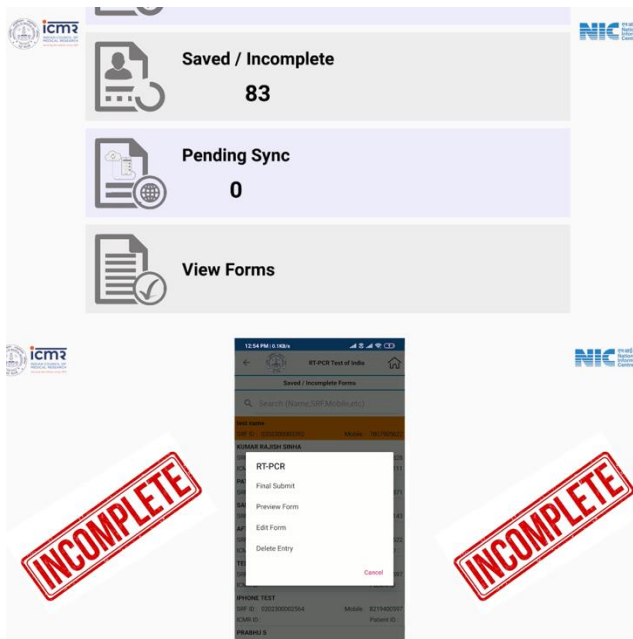
Select Lab where RT-PCR Test will be Conducted*

Search Lab

Lat : 31.0882945 Long : 77.1804108

C. Protocol for saved/incomplete registration forms and pending sync

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Complete registration of all pending forms and submit information.

D.VIEW FORMS-There is also an option of VIEW FORMS menu. You can select a date to view SRF forms submitted by you. Tap on SRF to view PDF.

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The dashboard displays three key metrics:

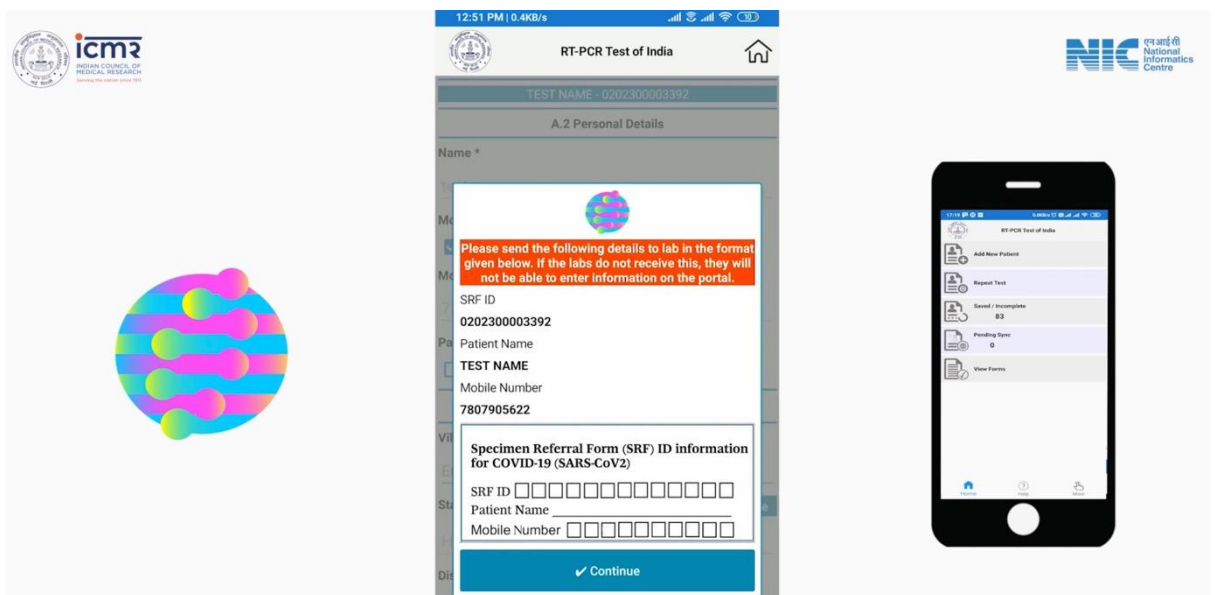
- Saved / Incomplete:** 83 (represented by a person icon with a checkmark)
- Pending Sync:** 0 (represented by a document icon with a globe)
- View Forms:** (represented by a document icon with a checkmark)

The mobile app interface shows a calendar for May 2020. The date 'Fri 8 May' is highlighted in a pink box. The calendar grid shows the following dates:

M	T	W	T	F	S	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Buttons for 'Cancel' and 'OK' are visible at the bottom of the calendar pop-up.

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Descriptive Video available on: <https://youtu.be/CXTmT6JIXII>

4. SPECIMEN ACCESSIONING IN LAB INFORMATION MANAGEMENT SYSTEM (automated/manual)

1. Accessioning of samples in Laboratory Information Management System (Automated/Manual) shall be done for ALL samples.
2. Samples shall be accessioned ONLY after collection is done through RTPCR app by authorized users (refer the manual issued from time to time).
3. The SRF ID generated through RTPCR app shall be included in LIMS registration, along with other details as mandated by in-house SOP on sample accessioning. Note: Wherever required, such as for international travelers, passport number is mentioned during accessioning as per travel requirements.
4. All records shall be maintained for the sample collected including necessary Govt recognized ID such as Aadhar card, PAN card etc for positive identification of patients.
5. The compliance to all mandated requirements is ensured from collection till reporting and record keeping. The lab reference number is the sample ID that is

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uniquely generated through LIMS and is used to ICMR data entry. The testing batches are maintained in google excel/manual registers (whichever is applicable) to allow information exchange for samples tested in a batch, their kits/methodology/time trail etc.

6. The records such as patient's IDs are maintained in soft format along with other information in LIMS. The data is regularly backed up as per lab's established procedures.
7. All sample collected shall be accessioned in LIMS and all shall be updated on ICMR in a real time manner to ensure compliance to government guidelines.

For authenticity of Reports and traceability

As per a mandate issued by NABL on 19.5.2021 on provision of QR Code on the Medical Test Reports is as follows: _

- Medical laboratories may note that, in a memorandum issued on 13.05.2021 by the Ministry of Civil Aviation, Government of India, it is mandatory for travellers flying abroad to carry their negative RT-PCR test report having QR codes linking to the original report.
- Medical Laboratories should provide QR code on all test reports issued which can be scanned using any QR scanning application available on mobile / any devices to authenticate and reproduce the test report online. This will prevent the manipulation of test results & the usage of fake test reports.
- Laboratories to ensure that all the requirements of ISO 15189, NABL, regulators are met. Authorized test results in a tamper-proof and non-editable test report will build trust in laboratory results.

5. OBSERVATION COMPLIANCE

The laboratory must ensure periodic audits of accessioning data and record any mismatch/incomplete information in the occurrence log book with corrective and preventive action.