/25378/2020

NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part(3) - 6513

National Health Mission
SDA Complex, Kasumpti, Shimla-9
Himachal Pradesh
Dated: Shimla-171009, the

MISSION DIRECTOR (NHM)
28 AUG 2020
New Shimla-9 (H.P.)

CIRCULAR

There are multiple strategies for undertaking testing for SARS CoV2 (COVID-19). Amongst these, there are molecular based diagnostics viz RT-PCR, CBNAAT and TrueNAT. The State of Himachal Pradesh is already undertaking these molecular based tests at various locations in the State. Guidelines/ Advisories/ Circulars bearing no. NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (3)-2728 dated 21st March 2020, NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (3)-2968 dated 11th April 2020, NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (2)-3236 dated 15th May 2020, NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (2)-3338 dated 20th May 2020 and NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (1)-3598 dated 1st June 2020 have been issued from time to time for the testing protocols for RT-PCR. The guidelines for using CBNAAT and TrueNat tests for COVID -19 have been issued vide Guidelines/Advisories/Circulars bearing nos. NHMHP-RNTC0TRN./1/2019-RNTCP-Section-NATIONAL HEALTH MISSION-HP dated 23rd April 2020, NHMHP-RNTC0NAAT(1516)/1/2019-RNTCP-Section-NATIONAL HEALTH MISSION-HP-3282 dated 18th May 2020, NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (1)-3620-27 dated 3rd June 2020, NHMHP-RNTC0NAAT(1516)/1/2019-RNTCP-Section-NATIONAL HEALTH MISSION-HP-4910 dated 8th July 2020 and Even no.-6118 dated 13th August 2020.

The testing strategy for molecular based tests shall remain the same as notified vide the guidelines mentioned above. However, it has been observed that some Districts/hospitals are not sampling the ILI patients presenting to their health facilities. It is reiterated that the ILI patients presenting to Health Institutions should be sampled and tested for COVID-19 through these molecular based diagnostics,

without fail. Further the need for testing the symptomatic Health Care Workers and SARI patients admitted in private and public hospitals of the State is reiterated.

Further, to augment the testing for SARS-CoV-2 in the State of Himachal Pradesh, the State has also issued advisories for Antigen based assays as per the recommendations of ICMR vide circular no. NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (3)-5824 dated 27th July 2020 and notification of even no. 5899 dated 31st July 2020 for the Industrial establishments and Private Hospitals/Laboratories respectively. ICMR has recommended the use of Rapid Antigen Test for detection of COVID-19 and IgG ELISA test for sero-surveillance in various settings (copies enclosed). The State of Himachal Pradesh is soon providing the Antigen based Assay kits and IgG ELISA kits for use across the State in various Public health facilities and for the purpose of containment of COVID-19.

The indications/guidelines for the use of Antigen Based tests for the detection of COVID-19 shall be as under:

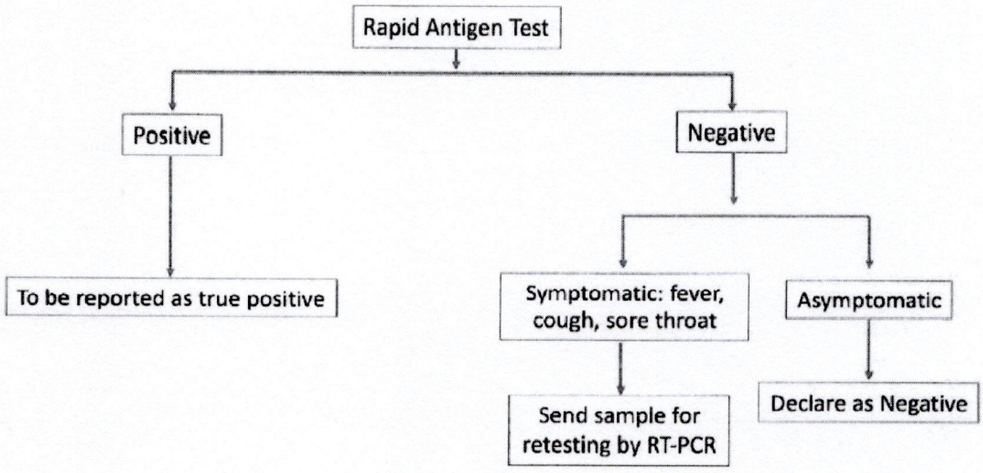
1. The Antigen tests should be used in the following settings:
    a) Asymptomatic cases in Containment zones or hotspots.
    b) Institutional Quarantine facilities where the interstate travelers from high load cities have completed 6-7 days of quarantine.
    c) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high- risk groups:
        - Patients undergoing chemotherapy
        - Immunosuppressed patients including those who are HIV+
        - Patients diagnosed with malignant disease
        - Transplant patients
        - Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)
    d) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:
        - Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures.

- Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis.

e) Non Vulnerable ILI patients/individuals with mild symptoms reporting to any Health Institution – PHC/above*

**The Elderly patients (>65 yrs of age) & patients with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders) presenting with ILI symptoms and the ILI patients/individuals with moderate to severe symptoms presenting to Health Institution – PHC/Above shall invariably be referred to higher centres for molecular based diagnosis and further management.*

2. The results of the Rapid Antigen Kits shall be interpreted as per the following algorithm:



3. The login credential and password will be shared with the respective districts for performing and entering rapid antigen test results by the State Surveillance Officer.
4. For all symptomatic patients who are negative by rapid antigen test, another Naspharyngeal and Oropharyngeal swab collected in VTM should be sent to the nearest RT-PCR laboratory for COVID-19 testing as soon as possible.
5. The patient ID, Patient name and Contact number used for rapid antigen testing should be communicated to the attached RT-PCR COVID-19 testing lab along with the SRF ID so that PCR results can be uploaded into ICMR

portal as a follow-up entry for the antigen test. Please ensure a new patient is not registered for the follow up RT PCR test.

6. The methodology to be adopted while undertaking the test is attached at **Annexure A** to this circular.

Further, there is a need to establish systematic surveillance for SARS-CoV-2 infection in all districts of the State. This surveillance through IgG ELISA will be in addition to the routine testing as per testing guidelines. Furthermore, the deployment of IgG ELISA can also give an insight into the presence of antibodies in front line workers including Health Care Workers and the results can be used as a guide for deployment of these personnel in various health care institutions of the State. The indications/guidelines for the use of IgG ELISA tests shall be as under:

1. Low risk population: Outpatient attendees (non-ILI patients) and pregnant women
2. High risk population: Health care workers, Immuno-compromised patients, Individuals in containment zones, Security personnel, Police and paramilitary personnel, civil defense, Press corps, Rural, tribal population (after reverse migration), Industrial workers or labour force, Farmers, vendors, Staff in municipal bodies, Drivers, Banks, postal & couriers personals, telecom offices, Shops, Congregate settings, Prisons etc.
3. The minimum sample size per District should be as under:

Sentinel Group	Samples per District per Week	Samples per District per Month
High risk	100	400
Low risk		
Outpatient attendees (Non-ILI patients)	50	200
Pregnant women	50	200
Total	200	800

4. Nothwithstanding, the normative sample size indicated above, all the Health Care Workers of the State shall be tested by Antibody tests before 10th of September 2020. The Block Medical Officers under supervision of Chief Medical Officers shall be responsible for such testing in respect of peripheral Health institutions and such testing shall be undertaken at such institutions in the Block where facility of ELISA Reader is available. Similarly the

responsibility of antibody testing of all Heath Care Workers working in higher Institutions before 10th September 2020 shall lie upon the concerned Medical Superintendent of Hospital and concerned Principal of Medical College. The Antibody test kits shall be provided by the Directorate of Health Services for the purpose of surveillance. The results shall be compiled by the Community Medicine Departments of the attached Medical Colleges (as per Order bearing no. HFW-B(B)15-20/2017 dated 4th June 2020).

5. In addition, to undertake surveillance in a routine manner, all the secondary and tertiary care health Institutions of the State shall undertake sampling of all the outpatient attendees on 10th of every month and the results shall be compiled by the Community Medicine Departments of the attached Medical Colleges (as per Order bearing no. HFW-B(B)15-20/2017 dated 4th June 2020).
6. The IgG ELISA tests conducted and their results shall be uploaded onto the RATI Application, manual in respect of which is attached with this Circular. The Collection Centres for the purpose can be created at www.covid19cc.nic.in as already communicated vide correspondence no. NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP-Part (1)-3106 dated 30th April 2020.

For the purpose of training and capacity building of teams responsible for sample collection and testing, the faculty of Government Medical Colleges shall hand hold the District teams as per Districts allotted vide Order bearing no. HFW-B(B)15-20/2017 dated 4th June 2020.

It is further advised that massive IEC and advocacy needs to be carried out in the community that any ILI should not be underestimated and there is need to catch the ILI patients as early as possible to prevent further deterioration so that associated morbidity and mortality can be minimized to the extent possible.

Additional Chief Secretary (Health) to the
Government of Himachal Pradesh

Endst. No. As above Dated Shimla-9, the
Copy for information and necessary action to:

/25378/2020

1. Special Secretary (Health) to the Government of Himachal Pradesh
2. All Deputy Commissioners, Himachal Pradesh
3. Director Health Services, Himachal Pradesh
4. Director Medical Education, Himachal Pradesh
5. All Chief Medical Officers, Himachal Pradesh
6. All Principals, Government Medical Colleges in Himachal Pradesh
7. All Senior Medical Superintendents in Himachal Pradesh
8. District Surveillance Officers, Himachal Pradesh

Additional Chief Secretary (Health) to the
Government of Himachal Pradesh

ANNEXURE A

i) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile nasopharyngeal swab for sample collection.

ii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.

iii) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

iv) ***Once the sample is collected in the extraction buffer, it is stable only for one hour.*** Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. **Transportation to the lab is not recommended.**

v) Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.

vi) The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. **Maximum duration for interpreting a positive or negative test is 30 minutes.** After that the test strip should be discarded.

vii) The test kit should be stored between 2° to 30°C.

INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH

Advisory on Use of Rapid Antigen Detection Test for COVID-19

Dated: 14th June 2020

Background:

1. Real time RT-PCR is the gold standard frontline test for diagnosis of COVID19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in India. All these platforms require specialized laboratory facilities in-terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours including the time taken for sample transportation. These specifications limit the widespread use of the RT-PCR test and also impedes quick augmentation of testing capacity in various containment zones and hospital settings.

2. In view of this, there is urgent need of a reliable point-of-care rapid antigen detection test with good sensitivity and specificity for early detection of the disease.

3. There are no reliable antigen detection tests available worldwide, which could be used as rapid point of care tests for quick detection of COVID-19 positive patients. Such tests would help in proper implementation of the Govt. strategy to test, track and treat. Such tests will also help in allaying the anxiety and fear of healthcare workers and aid in better clinical management of the patients. In view of this, an independent two site evaluation of the only available or standalone antigen detection assay: **Standard Q COVID-19 Ag detection kit,** was conducted with an aim to evaluate its sensitivity, specificity and feasibility of use as a point-of-care test for early detection of SARS-CoV-2.

4. **Brief description of the Standard Q COVID-19 Ag detection:**

   i) **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. has been developed by SD Biosensor, a South Korea based company, having its manufacturing unit in Manesar, Gurugram, India.

   ii) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.

   iii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.

   iv) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing

biosafety and biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

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viii) The test kit should be stored between 2° to 30° C.

ix) Detailed instructions for use can be accessed through the video link: https://youtu.be/mBdaOHJWxI4

5. Validation of the Test:

I. Sites:

Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by the following agencies:

i) Indian Council of Medical Research, Delhi; and

ii) All India Institute of Medical Sciences, Delhi

II. Results:

i) Standard Q COVID-19 Ag rapid antigen detection test has a very high specificity (i.e. ability to detect true negatives). Specificity ranged from 99.3 to 100% at the two sites.

ii) Sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% to 84% in two independent evaluations, depending upon the viral load of the patient. Higher viral load correlated with higher sensitivity.

6. Conclusions and Recommendations:

i) Standard Q COVID-19 Ag detection assay by SD Biosensor is the standalone antigen detection test which is available in India and has been validated.

ii) ICMR encourages other manufacturers / developers who have antigen detection assays to come forward for validation.

iii) **<u>In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q COVID-19 Ag detection assay as a point of care diagnostic assay for testing in the following settings in combination with the gold standard RT-PCR test:</u>**

A. Containment zones or hotspots *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C.):*

i) All symptomatic Influenza Like Illness (ILI).

ii) Asymptomatic direct and high-risk contacts with co-morbidities (*lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders*) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. Healthcare settings *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):*

i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.

ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:

- Patients undergoing chemotherapy
- Immunosuppressed patients including those who are HIV+;
- Patients diagnosed with malignant disease;
- Transplant patients;
- Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)

iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:

- Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures;
- Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

****ILI case is defined as one with acute respiratory infection with fever ≥ 38°C AND cough.***

<u>Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:</u>

i) Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.

*ii) The test should be conducted **<u>onsite</u>** under strict medical supervision and within one hour of sample collection in extraction buffer.*

*iii) Suspected individuals **<u>who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR</u>** to rule out infection, **<u>whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test</u>**.*

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

ADVISORY

Newer Additional Strategies for COVID-19 Testing

Dated: 23/06/2020

Existing strategies for COVID-19 testing:

1. **Real Time RT-PCR** is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. In view of the specialized laboratory requirements, this test cannot be performed at every district level lab which do not have molecular virology facilities. However, wherever available, it is advised to use real time RT-PCR as the frontline test for diagnosis of SARS-CoV-2.

2. **The TrueNat and CBNAAT** systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges. These platforms have widespread availability even at district and primary health center level as these platforms are widely used for diagnosis of Tuberculosis and other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day only. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.

3. All COVID-19 tests conducted through RT-PCR, TrueNat and CBNAAT are reported on ICMR data entry portal which helps in drawing the National estimates on numbers of tests conducted, numbers of positives, tests conducted per million population etc. This data portal is the single National source of data entry which is accessed by all relevant Ministries / Departments for defining National strategies for COVID-19. ICMR urges all the laboratories to continue entering data into the ICMR portal https://cvstatus.icmr.gov.in/login.php to help in guiding the National strategies appropriately.

4. In an effort to ramp up testing capacity, ICMR has approved a total of 1000 COVID-19 testing labs in both public (730) and private sector (270). This includes RT-PCR labs (557); TrueNat Labs (363) and CBNAAT Labs (80). However, inspite of these developments, access to testing still remains a huge challenge in a large country like India. There is a definite need to increase the outreach of testing by introducing rapid point of care diagnostic tests. Also, there is value in conducting serosurveys with IgG based antibody tests in certain situations. In view of this, it is now suggested to include additional testing methods to improve the access and availability of testing in various parts of the country.

Newer additional strategies for COVID-19 Testing:

I. Rapid Point-of-Care (PoC) Antigen Detection Test (for diagnosis along with RT-PCR):

5. Since the entire public health machinery is focused to test, track and treat COVID-19 patients, it is imperative to explore the existing antigen-based assays as point-of-care tests for early detection of SARS-CoV-2. Such tests, if reliable would be valuable at field level for early detection of infection and quick containment. Availability of antigen-based detection tests is very limited all across the world. Most of such tests have relatively **moderate sensitivity but high specificity**. However, manufacturers of all antigen-based tests are encouraged to approach ICMR for validation and inclusion of their test in the wider testing approach of the country. A positive test should be considered as a true positive whereas all symptomatic individuals testing negative through the rapid antigen test should be confirmed with a real-time PCR test.

6. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay which **does not require a specialized machine** and can be interpreted with a naked eye. The test is a promising tool for quick diagnosis of SARS-CoV-2 in field settings. The assay is known as **Standard Q COVID-19 Ag kit** and has been developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. On validation, the test has been found to have a very high specificity with moderate sensitivity. It is now recommended to use Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the gold standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020 in this regard, which may be accessed at: https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test_14062020.pdf. The recommended use of the rapid antigen PoC as per the ICMR advisory is enclosed at **Annexure 1.**

7. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor.
   Contact details are as follows:
   Dr. CS Bedi.
   Mobile No: +919810426069; Email: drbedi@icloud.com

   For any technical assistance /clarifications regarding the performance of the test, details of the ICMR contact point are given below:
   Dr. Sidhartha Giri
   Email: sidhartha.g@icmr.gov.in

ICMR recommends deployment of the rapid antigen PoC test in the following settings:

i) All containment zones identified by the State Governments,
ii) All Central & State Government Medical Colleges and Government hospitals
iii) All private hospitals approved by National Accreditation Board for Hospitals & Healthcare (NABH).
iv) All private labs accredited by National Accreditation Board for Laboratories (NABL) and approved by ICMR as COVID-19 testing labs.

Rapid antigen PoC test is recommended for use subject to the following conditions:

i) All hospitals, labs, State Govts intending to perform the **PoC antigen test need to register with ICMR to obtain the login credentials for data entry. Interested Institutions may send their request on the following email id's:**

ag-pvthosp-nabh@icmr.gov.in
ag-govthosp@icmr.gov.in

ii) All data of testing needs to be entered into the ICMR portal on a real time basis. The ICMR portal has been modified to include a component on antigen testing. Detailed video is available on ICMR website at http://www.icmr.gov.in/video/Data_Entry_Antigen_v4.mp4.

iii) **All labs/hospitals initiating testing** through the rapid antigen PoC test need to ensure that **all symptomatic negative patients should be essentially referred to a real-time RT-PCR test for COVID-19**. This is particularly essential as the rapid antigen PoC test has a moderate sensitivity.

iv) All the entities using antigen PoC test are expected to tie up with the nearest RT-PCR COVID-19 testing lab to ensure that all symptomatic who are negative by the rapid antigen test get tested at the nearest facility.

v) The data of individuals tested by RT-PCR will need to be entered through the lab performing the RT-PCR test.

II. IgG Antibody test for COVID-19 (Only for surveillance and not diagnosis):

8. IgG antibodies generally start appearing after two weeks of onset of infection, once the individual has recovered after infection and last for several months. Therefore, the IgG test is not useful for detecting acute infection. However, detection of IgG antibodies for SARS-CoV-2 may be useful in the following situations:

   a. Serosurveys to understand the proportion of population exposed to infection with SARS-CoV-2 including asymptomatic individuals. Depending upon the level of seroprevalence of infection, appropriate public health interventions can be planned and implemented for prevention and control of the disease. Periodic serosurveys are useful to guide the policy makers.

   b. Survey in high risk or **vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc)** to know who has been infected in the past and has now recovered. The groups of individuals who should be prioritized for such serosurveys is enclosed at **Annexure 2.**

9. It is strictly advised to use IgG based ELISA and CLIA assays only for conduct of serosurveys. ICMR has validated and approved IgG ELISA kits for COVID-19. In addition, USFDA approved IgG ELISA and CLIA kits are also available and can be used. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf. It is advised to enable all **Government and Private Hospitals, Offices, Public Sector Units etc. to perform the antibody-based testing.** This will help in allaying the fear and anxiety of health care workers, office employees etc. As the apex research organization of the country, ICMR is mandated to review and

conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, it is advised to share the comprehensive report of antibody testing with ICMR at the email id given below: mmurhekar@gmail.com.

10. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to **all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened**. ICMR advises all concerned State Governments, Public and Private Institutions to take required steps to scale up testing for COVID-19 by deploying combination of various tests as advised above.

Annexure 1:

Use of Standard Q COVID-19 Ag a point of care diagnostic assay is recommended in the following settings in combination with the gold standard RT-PCR test:

A. **Containment zones or hotspots** *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):*

i) All symptomatic Influenza Like Illness (ILI).

ii) Asymptomatic direct and high-risk contacts with co-morbidities (*lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders*) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. **Healthcare settings** *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):*

i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.

ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:

- Patients undergoing chemotherapy
- Immunosuppressed patients including those who are HIV+;
- Patients diagnosed with malignant disease;
- Transplant patients;
- Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)

iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:

- Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures etc.
- Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis etc.

ILI case is defined as one with acute respiratory infection with fever ≥ 38°C AND cough.

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

i) Should be interpreted between 15 to 30 minutes with a naked eye. No interpretation should be made before 15 minutes of after 30 minutes.

ii) ***Symptomatic individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.***

iii) Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.

iv) The test should be conducted ***onsite*** *under strict medical supervision and within one hour of sample collection in extraction buffer.*

Annexure 2:

Possible groups/ community/ population based on specific requirement for sero-survey by using IgG ELISA test.

i.) **Immuno-compromised patients:** PLHIV, patients on immuno-suppressive treatment, TB, SARI, COPD, patients on dialysis to be considered for testing;

ii.) **Individuals in containment zones:** In identified containment zones and buffer zones where large number/ cluster of cases have been identified as demarcated geographical areas with residential, commercial structures;

iii.) **Health Care Workers:** Specifically, all doctors including specialists, nursing staff, support staff, sanitary and other staff including the staff at registration, pharmacists, client facing desk clerks etc. Those workers in health care settings who either faces patients (whether known COVID 19 +ve or not), involved in their care or are in environment of potentially shared spaces or handling fomites;

iv.) **Security personnel:** All security personnel facing the visitors, conducting their security screening, physical checking and thermal screening. This includes CISF personnel involved in security especially of offices;

v.) **Police and paramilitary personnel civil defense & volunteers:** police personnel and volunteers involved in duties facing large number of individuals or those coming in contact with potentially infected individuals, fomites or settings/ places;

vi.) **Press corps:** Press reporters covering field, interviews, press briefings, etc. and support staff;

vii.) **Rural, tribal population (after reverse migration):** Migrant workers who have travelled back from urban and peri-urban areas to rural, tribal, hard to reach areas in the country as well as natives after coming in contact with returned migrants.

viii.) **Industrial workers or labour force:** industry workers, daily wagers, migrant workers, temporary travel related workers, hospitality related works, service sector who are in large number or groups and has potential to spread transmission rapidly in workplace settings;

ix.) **Farmers, vendors visiting large markets:** Farmers, sellers, brokers, purchasing vendors, distributors and other persons including drivers and labor by virtue of visiting crowded places like main markets where large exchange of materials happen between farmers and vendors during purchase and sell of vegetables etc.;

x.) **Staff in municipal bodies:** Municipal staff working in areas like sanitation, water supply, electricity, etc. where interactions with citizens is expected; and

xi.) **Drivers:** Drivers of hospital ambulances, hearse, buses, auto, taxies, etc. who have been on work font faced large number of individual previously or going to face in future. Bus conductors, cleaners and helping staff also should be included;

xii.) **Banks, post, couriers, telecom offices:** public or private banks, small or large branches of banks and post, telecom offices as well as couriers;

xiii.) **Shops:** Vendors and/ or owners as well as staff working in shops for essential goods, groceries, vegetables, milk, bread, chemists working at pharmacies, eateries and take away restaurants, etc.;

xiv.) **Air travel related staff:** All ground staff, security staff, janitors, sanitation staff, flight captains and crew for domestic and international as well as cargo may be considered;

xv.) **International operations:** All members of overseas operations for evaluation;

xvi.) **Congregate settings:** People staying or working in slums with very high population density with poorly ventilated building, structures. Persons staying in institutional settings like old age homes, orphanage, asylums, shelters for homeless, hostels, etc. may also be considered;

xvii.) **Prisons:** All prisoners with or without symptoms whenever there is a batch transfer or reported symptomatic;

130382/2020/O/o-SSO

डॉ. जी. एस. टोटेजा
अपर महानिदेशक
Dr. G. S. Toteja
Additional Director General

ICMR
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर नई दिल्ली-110029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare, Govt. of India
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029

D.O.No.ECD/COVID-19/Misc./2020
6th July, 2020

Dear Sir/Madam,

This is in continuation to the earlier communication of ICMR and MoH&FWdated 1st July 2020 regarding "empowering citizens for testing of SARS-CoV-2".

Please find attached a self-explanatory algorithm for interpreting the test results of the rapid antigen point-of-care test.

With regards

Yours sincerely

(Dr. G.S. Toteja)

Enclosed: As above

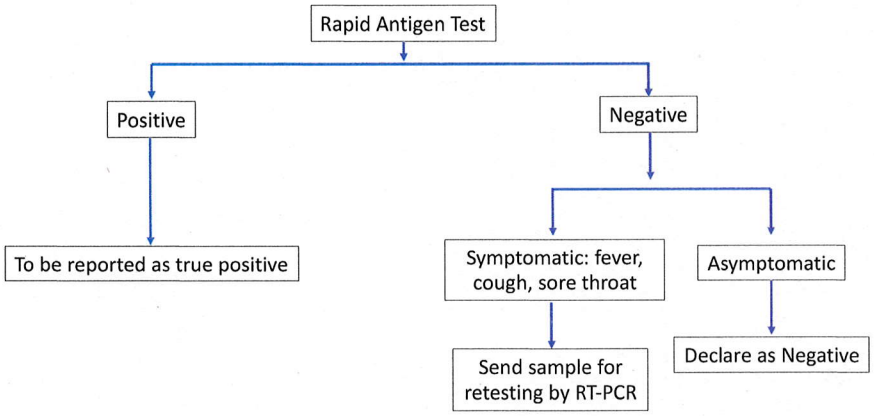
All Chief Secretaries (States)/Addl.Chief Secretaries/Secretaries/Commisioners/Principal Secretaries (Health & Family Welfare)

CC:

1. Ms. Preeti Sudan, Secretary, Health & F.W., Nirman Bhawan, New Delhi.
2. Shri Rajesh Bhushan, OSD, Ministry of Health & F.W., Nirman Bhawan, New Delhi.

Tel: (Off.) : 011-26589152, Fax: 011 26588762 **Web.** : www.icmr.nic.in
Email : gstoteja.addldg@gmail.com

Algorithm for COVID-19 testing using rapid antigen point-of-care test



- *All positive and negative results should be entered into the ICMR portal on a real time basis after performing the antigen test.*
- *Results of samples subjected to RT-PCR should be entered after the RT-PCR results are available.*

National Informatics Centre

Ministry of Electronics & Information Technology

Rapid Antibody Test of India (RATI)

(for capturing Test data/results)

https://covid19cc.nic.in

17-April-2020

Objective

- Quick mechanism for Data Collection of Rapid Anti Body Test and Results

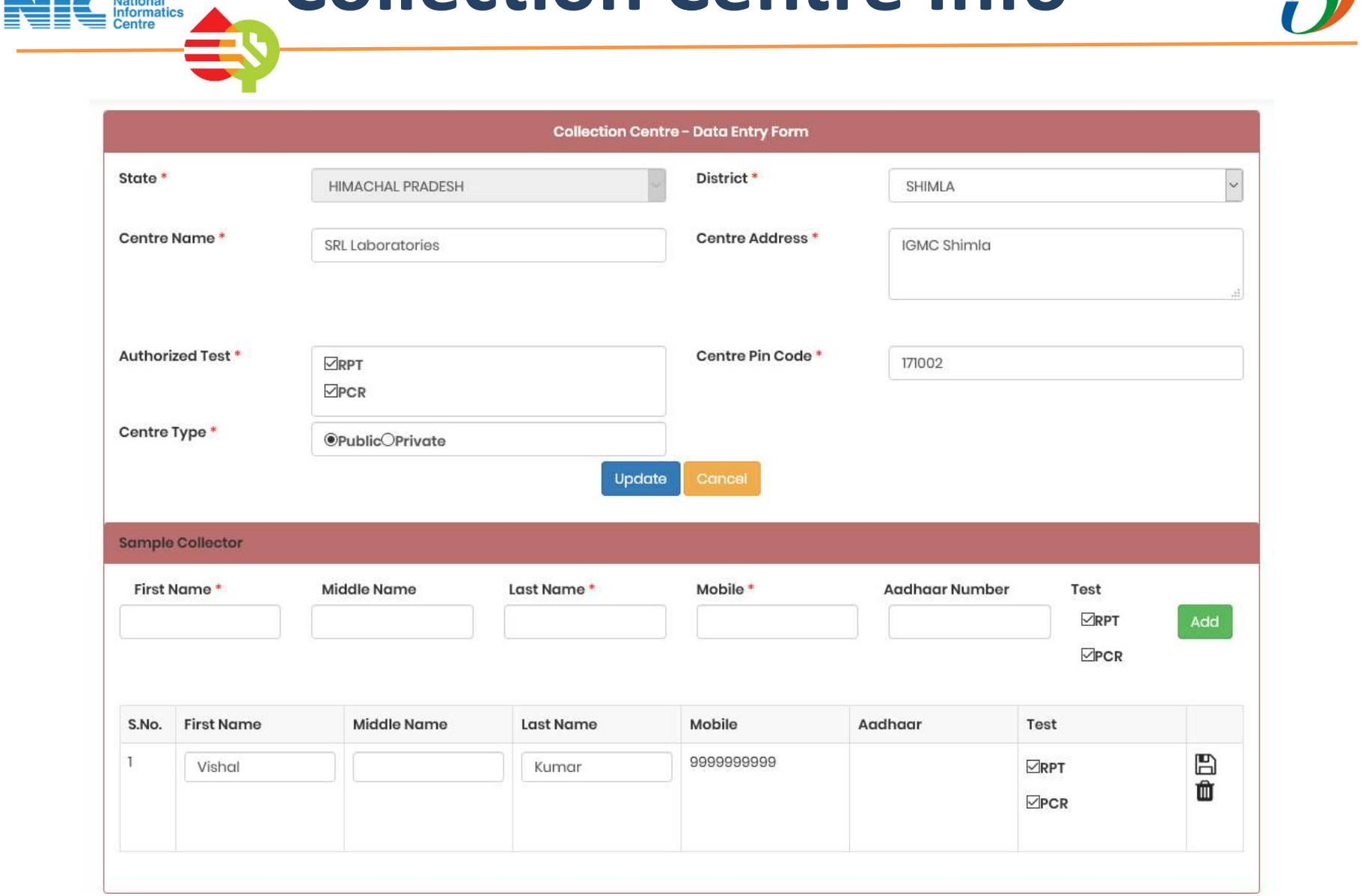
- Linkage with https://covid19cc.nic.in portal for authorizing Collection Centres/Testers and Viewing Test Reports

App Features

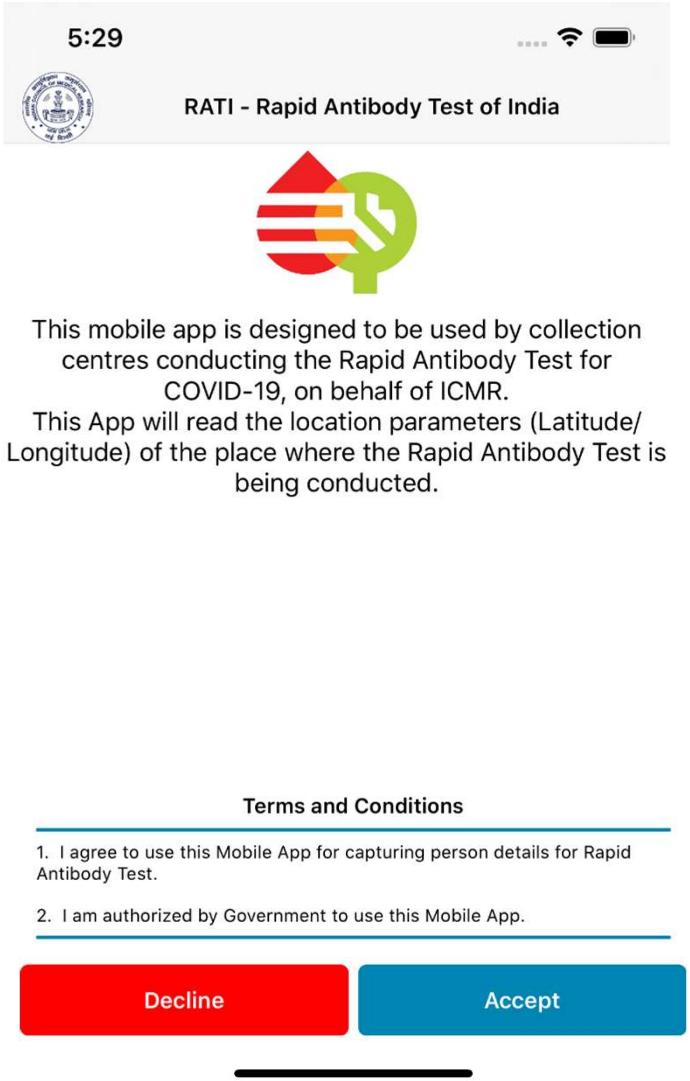
- Authentication with User Mobile/ OTP
- Linking user with State and District
- Person Mobile/OTP
- Geo-tagging
- Terms and Conditions Acceptance
- OTP based search of Test Reports on portal

https://covid19cc.nic.in

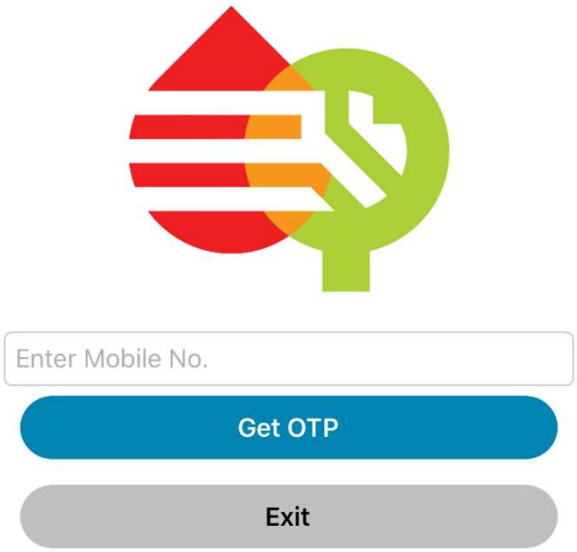
Collection Centre Info

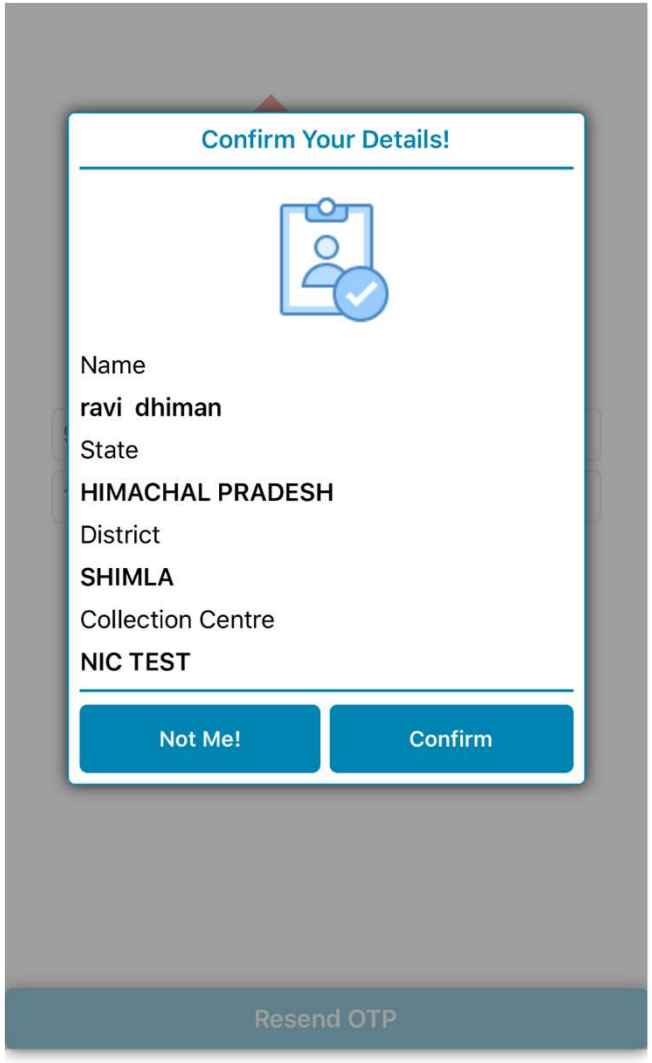


App Installation



User Authentication





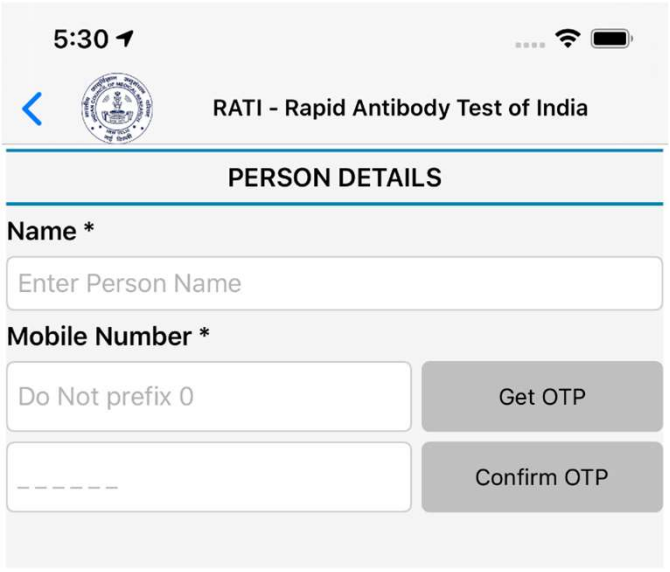
User Authentication

New Test

Repeat Test

Update Results

View Results



Select Gender

Male

Female

Others

Choose Occupation

Civil Security Personal

Drivers

Health Care Worker

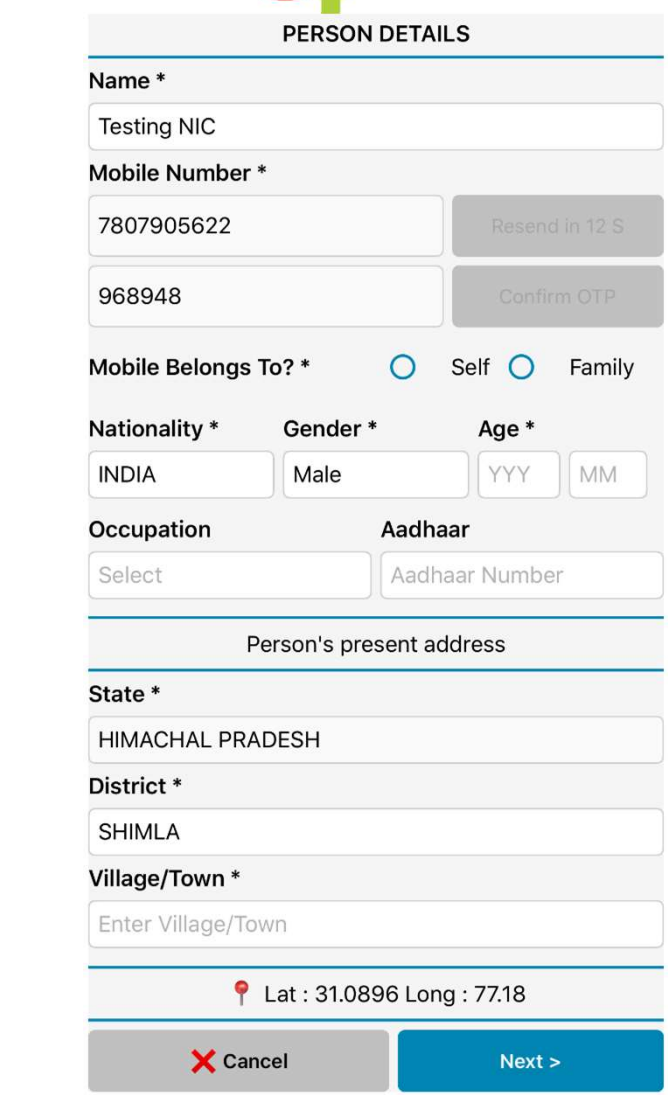
Not Applicable

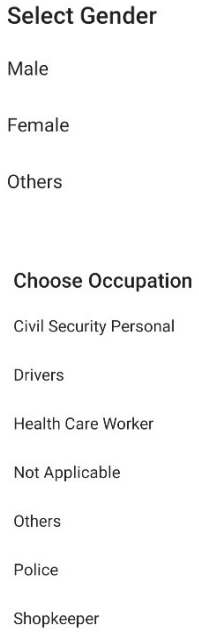
Others

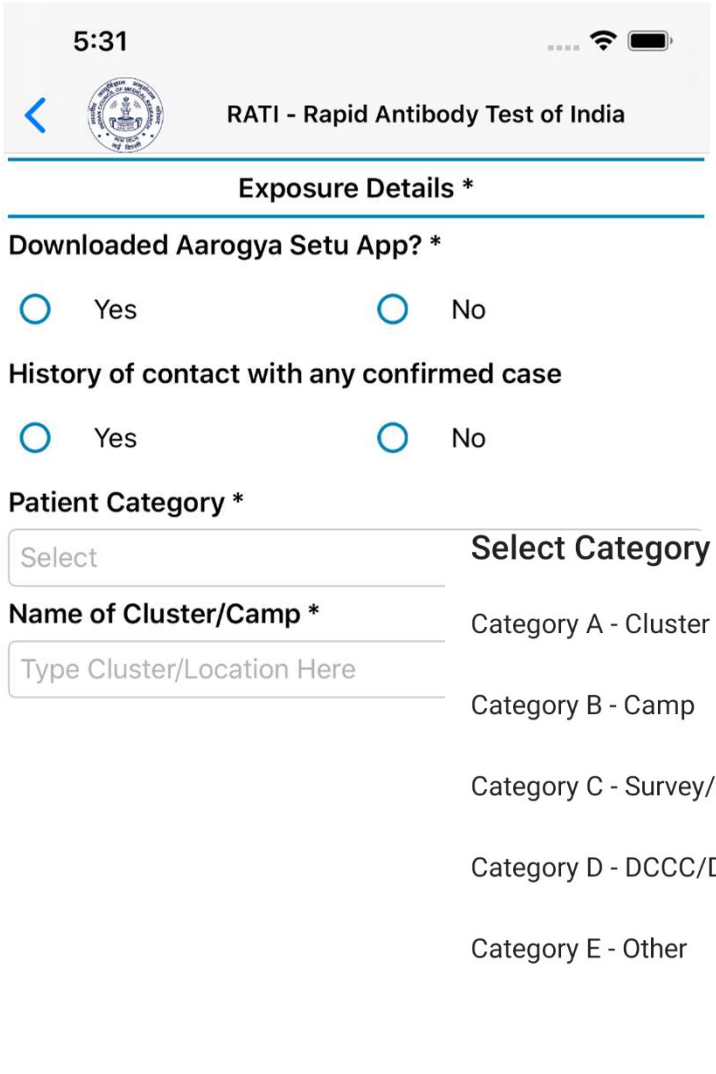
Police

Shopkeeper

App-New Individual







Kit Details, Symptoms

Test Kit Details

Test Date

17/04/2020

Test Time

5:31 PM

Scan Kit Bar Code

Scan Kit QR Code

Enter Kit Name & ID

Test Kit Type *

- ○ Combo kit
- ☑ Separate IGG and IGM band kit

Test Kit Name *

Testing Kit Name

Enter Test Kit ID *

Kit ID

Symptom Details

Respiratory illness *

NA

Symptom Present *

☑ Yes ○ No

Date of Onset of symptoms

17/04/2020

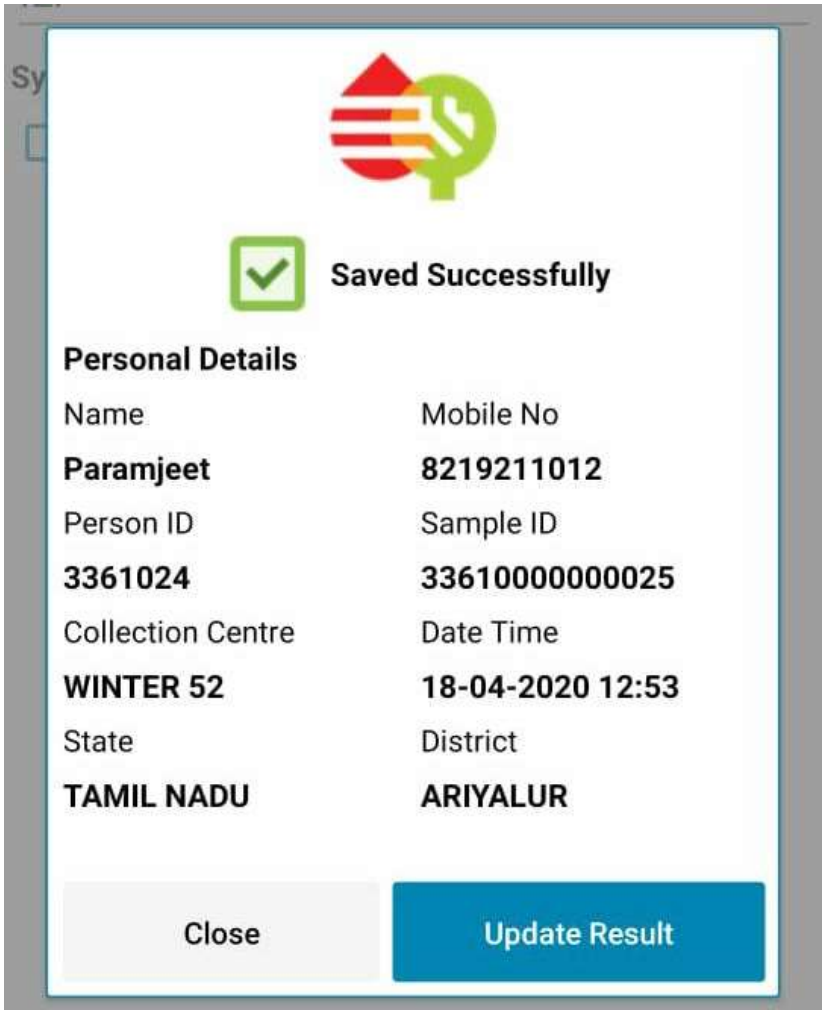
Select Symptom(s)

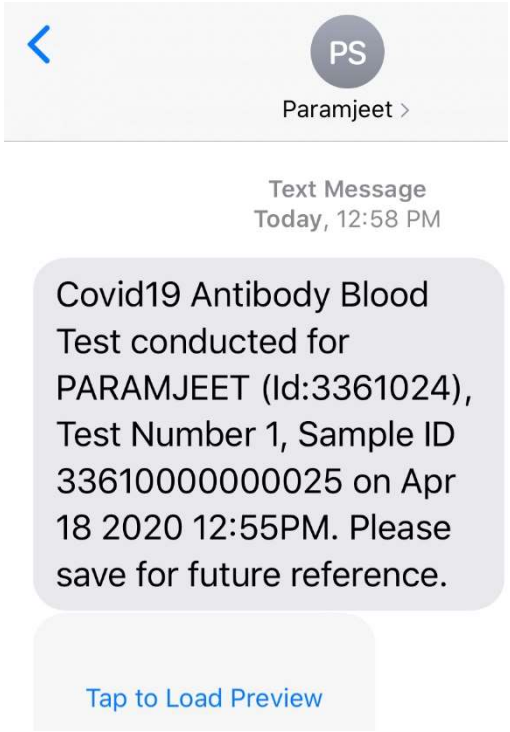
○ Fever at evaluation	○ Shortness of Breath
☑ Cough	○ Runny Nose
○ Headache	○ Body ache
○ Stomach ache	○ Tiredness
○ Loss of smell	○ Loss of taste
○ Sore Throat	

Any Other Symptoms

Testing for Other Symp

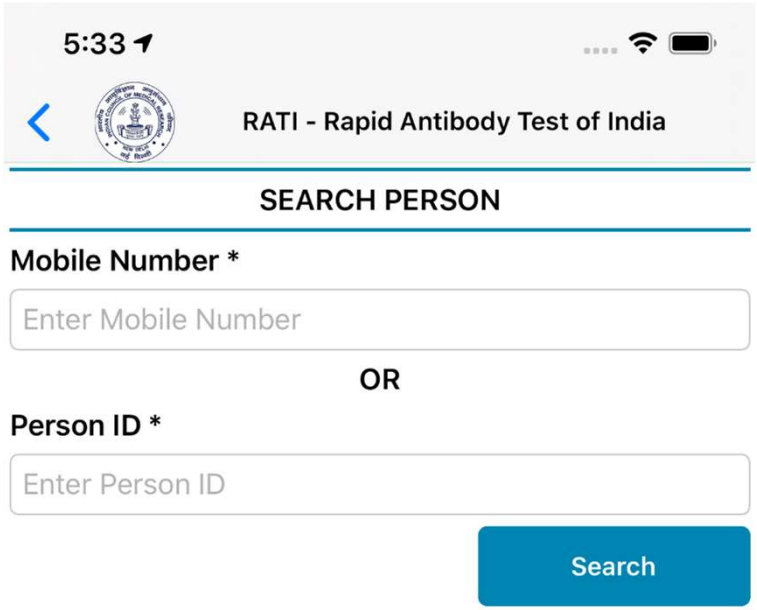
App-Saving Record





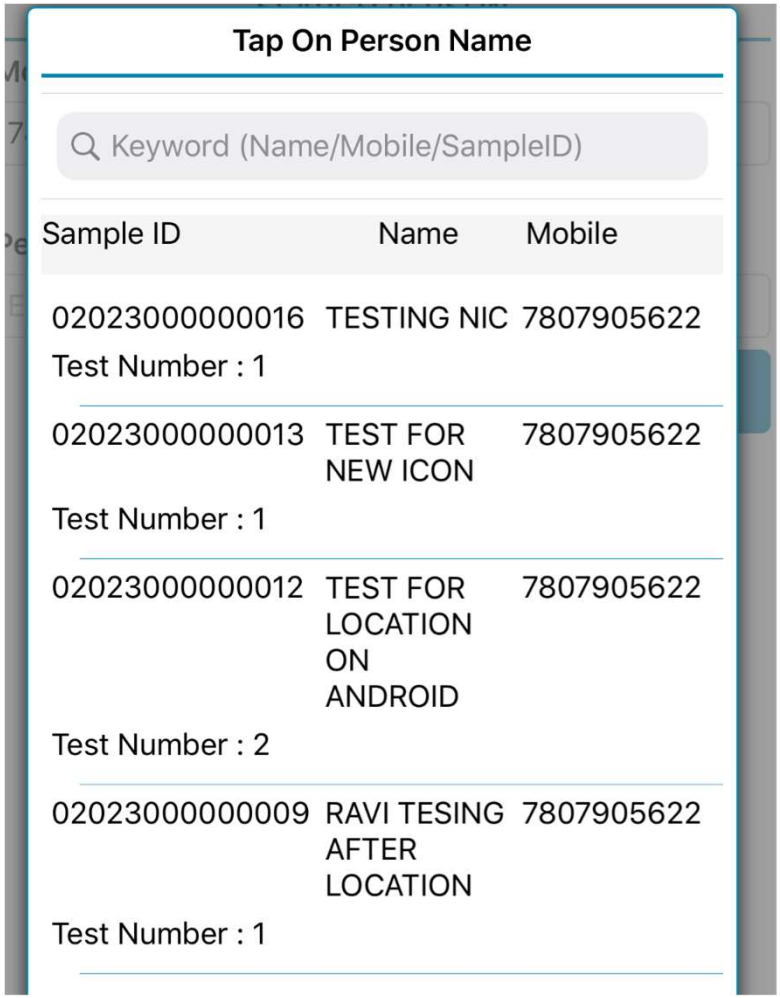
- **SMS** with IDs and Link to Report is sent to Person
- Update result option is available here too

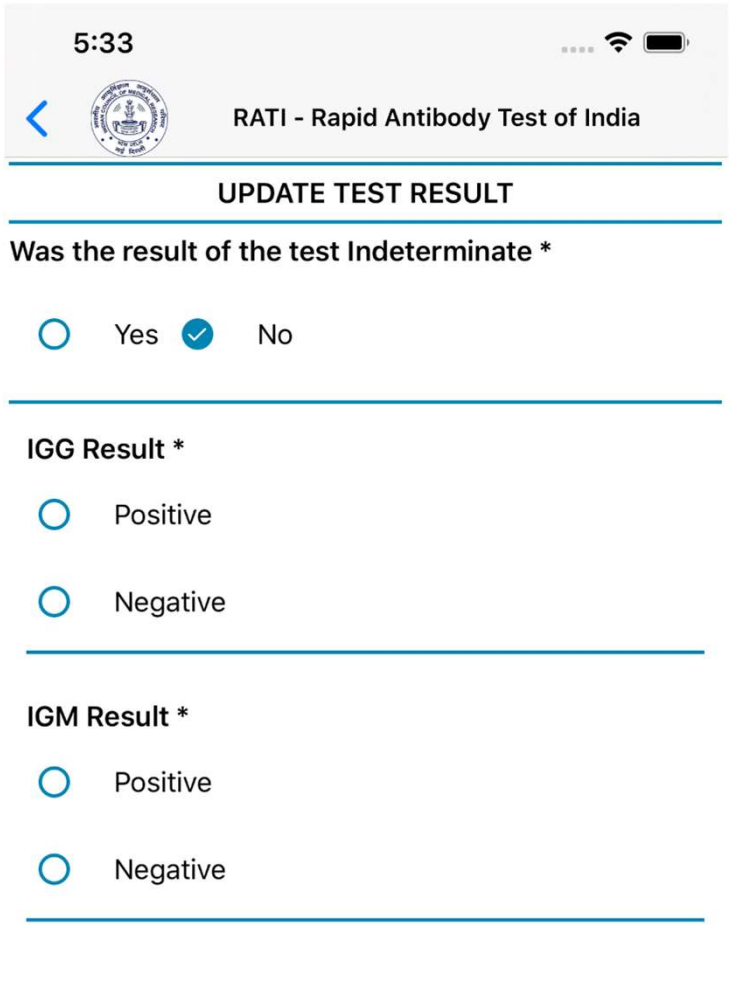
App-Update Result



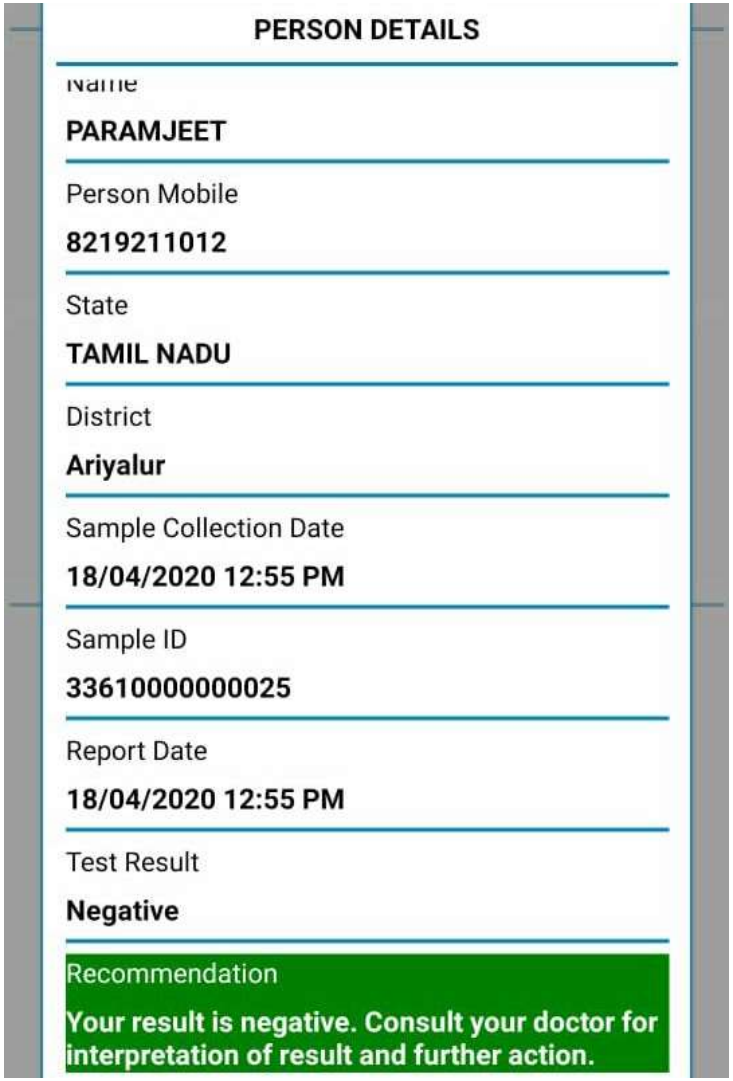
- Search person on Phone number or Person ID

App-Verify & Update





App-Verify & Update



PERSON DETAILS

Name

PARAMJEET

Person Mobile

8219211012

State

TAMIL NADU

District

Ariyalur

Sample Collection Date

18/04/2020 12:55 PM

Sample ID

33610000000025

Report Date

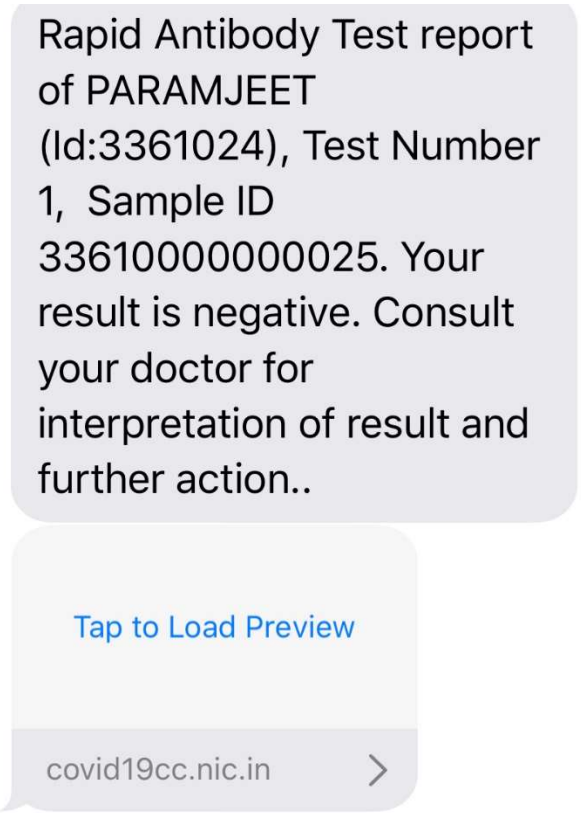
18/04/2020 12:55 PM

Test Result

Negative

Recommendation

Your result is negative. Consult your doctor for interpretation of result and further action.



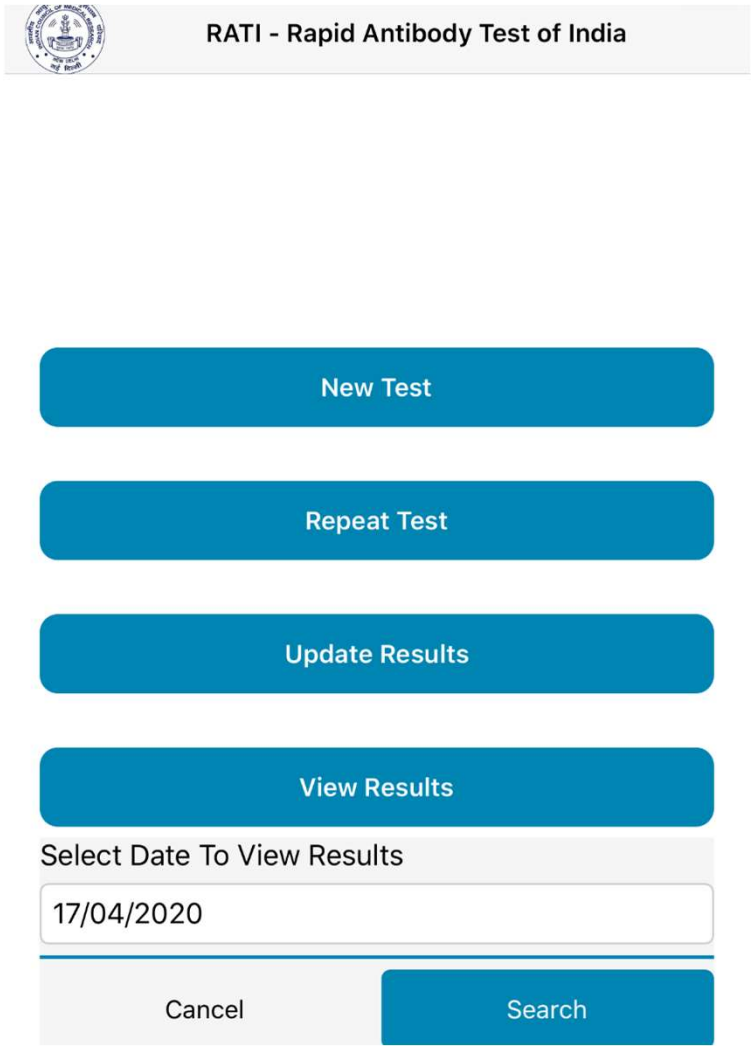
Rapid Antibody Test report of PARAMJEET (Id:3361024), Test Number 1, Sample ID 33610000000025. Your result is negative. Consult your doctor for interpretation of result and further action..

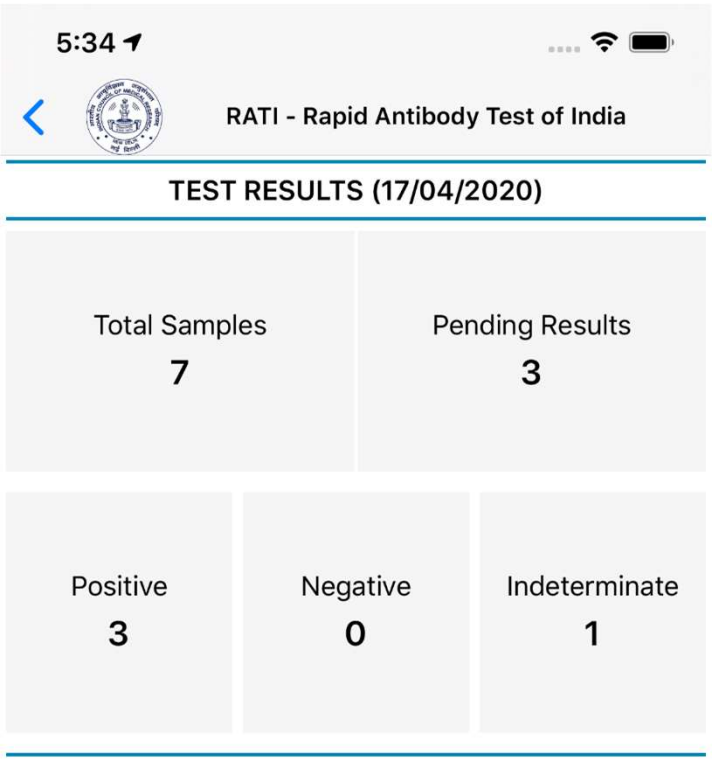
Tap to Load Preview

covid19cc.nic.in

- SMS Sent to user with link of Test report

App-View Own Tests





App-View Own Tests

Positive Results

Sample ID	Name	Mobile
02023000000011	SANDEEP SOOD	9418453053
02023000000014	BACK DISABLE ON UPDATE	7807905622
02023000000016	TESTING NIC	7807905622

PERSON DETAILS

Name
TESTING NIC

Person Mobile
7807905622

State
HIMACHAL PRADESH

District
SHIMLA

Sample Collection Date
17/04/2020 05:32 PM

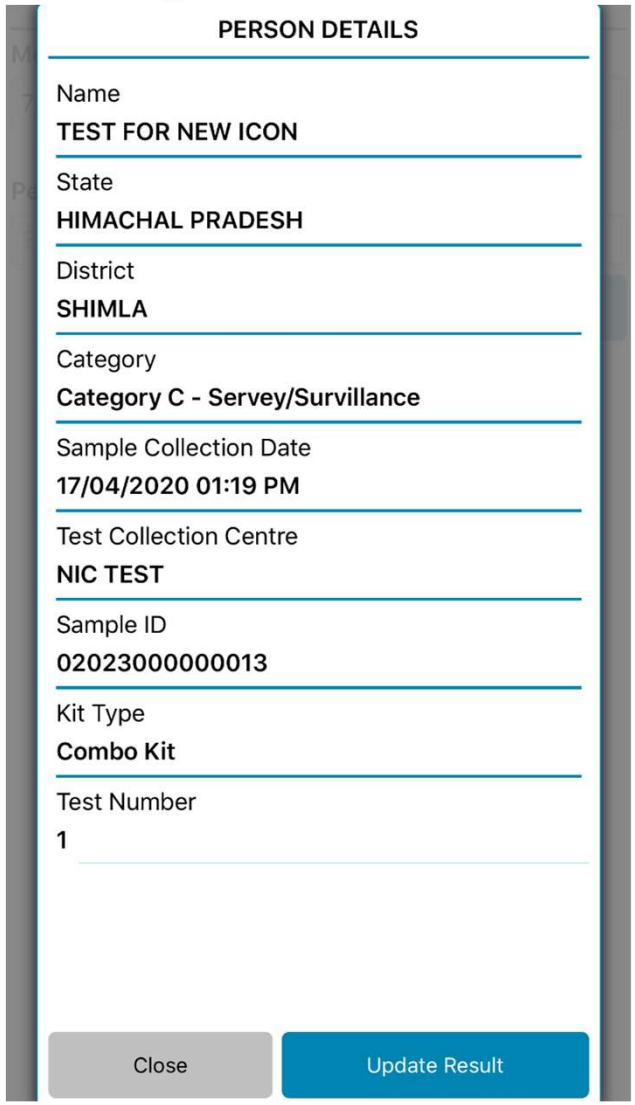
Sample ID
02023000000016

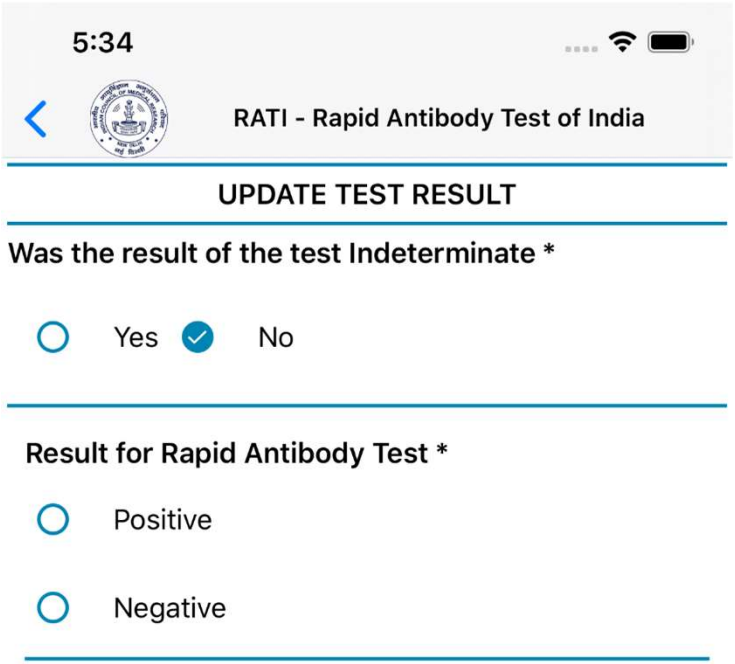
Report Date
17/04/2020 05:33 PM

Test Result
Positive

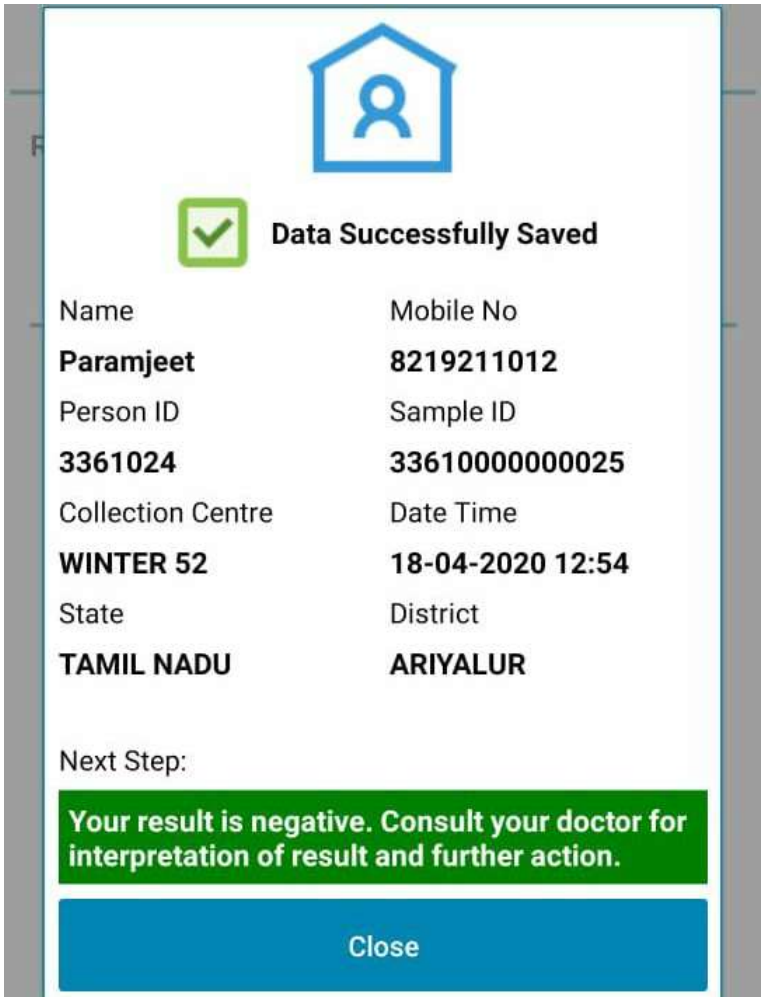
Recommendation
Consult your doctor for interpretation of result and further action.

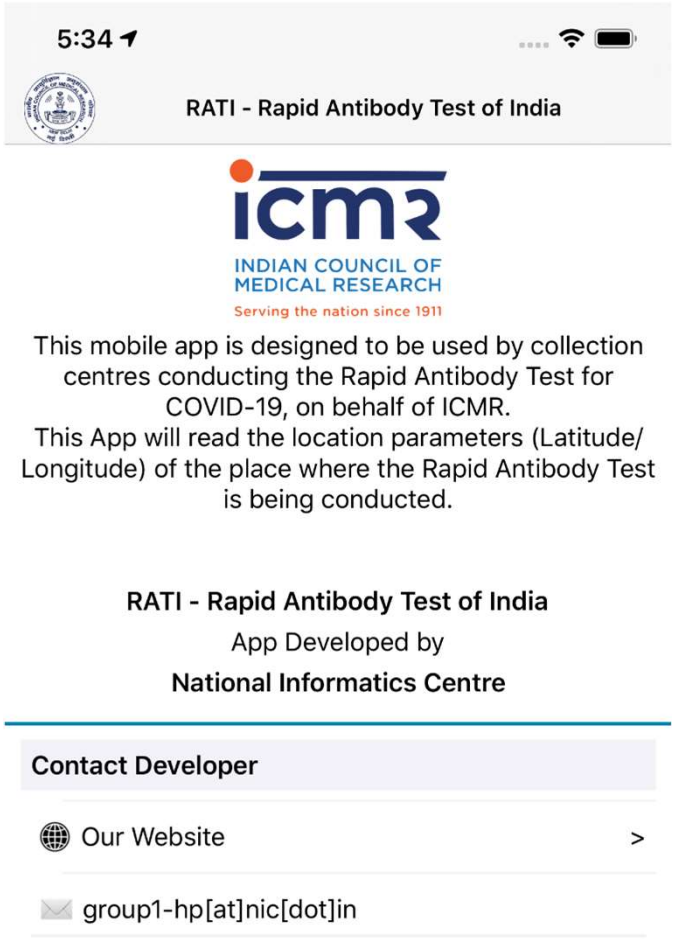
Menu-Update Result



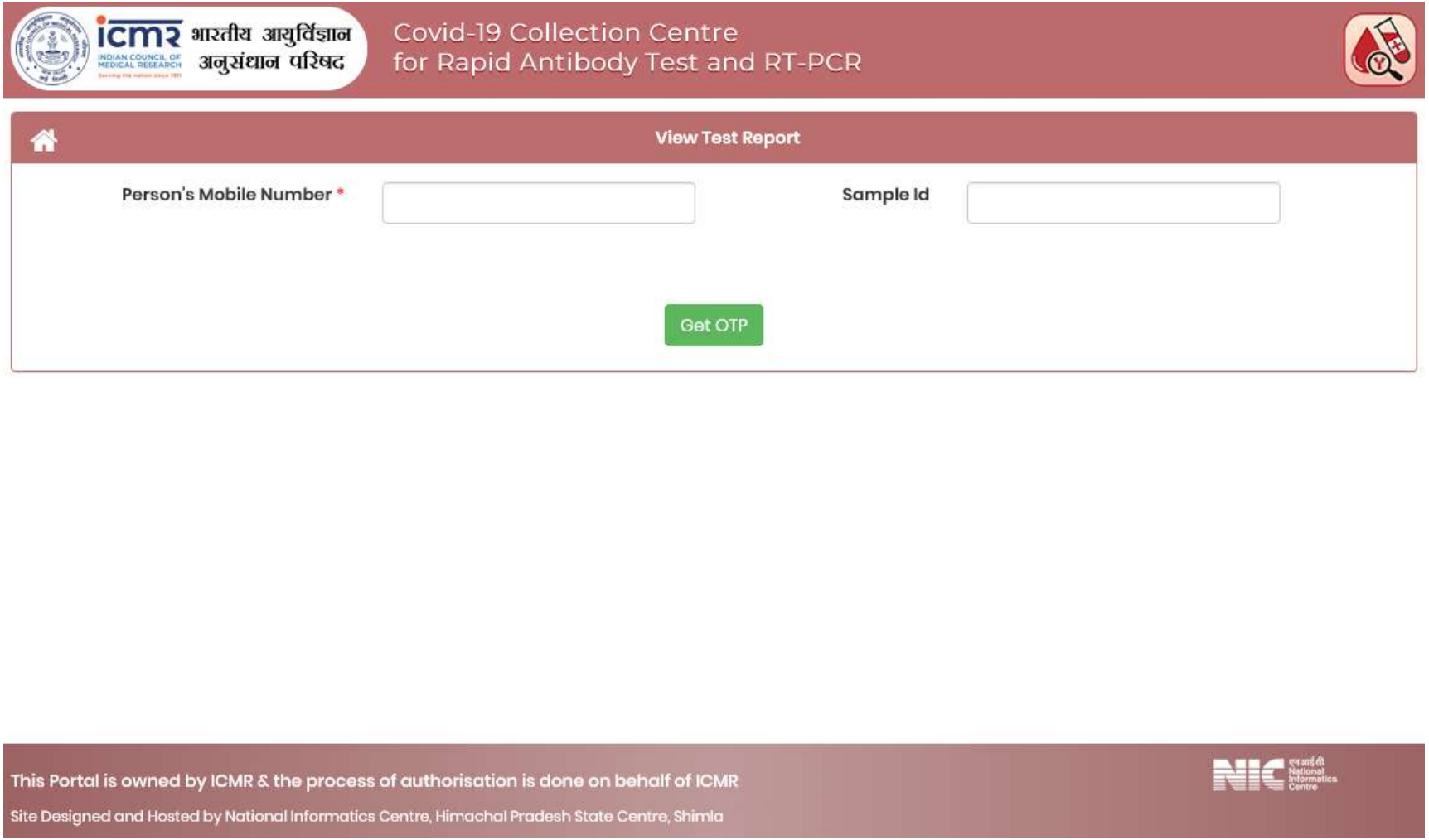


Menu-Update Saved





View on Portal



Test Report

OTP based only

Rapid Antibody Test of India Report for COVID-19

Sample ID: **33610000000025**
Test Sequence No.: **1**

PERSON DETAILS

Person ID:	**3361024**	Occupation:	**Others**	
Person Name:	**PARAMJEET**	Age:	**68** Years	Gender: **Male**
Present Village or Town:	**CSML**	Mobile Number:	**8219211012**	Belongs to: **Self**
District of present residence:	**Ariyalur**	Latitude :	**31.08830**	Longitude : **77.18044**
State of present residence:	**TAMIL NADU**	Nationality:	**INDIA**	
Pin Code:	**171002**	Passport No.:		
Downloaded Aarogya Setu App:	**Yes**	Aadhaar No.:	**999999999999**	

EXPOSURE DETAILS

History of contact with any confirmed case **No**
Category **C - Survey/Surveillance**
Name of Cluster / Camp : **SURVEY CLUSTER**

CLINICAL SYMPTOMS AND SIGNS

Respiratory Illness : **ILI** Symptom(s) Present : **No**

TESTING KIT DETAILS

Test Date : **18/04/2020** Test time : **12:55 PM** Kit Type : **Combo :** Kit Name : **COMBO KIT** Test Kit ID : **6789888**

TEST RESULT

Result : **Combo : Negative** Report Date : **18/04/2020** Time: **12:55 PM**
Recommendation : **Your result is negative. Consult your doctor for interpretation of result and further action.**

Sample Collector Detail

Name : **FIFTY TWO**	Mobile : **9111111152**	Center : **WINTER 52**
State : **TAMIL NADU**	District : **Ariyalur**	PinCode : **600005**

Scan to View Test Report

Thanks