



DIAGNOSTIC DILEMMAS IN COVID-19 TESTING IN PREGNANT WOMEN (EXPERIENCES FROM NON-COVID TERTIARY CARE CENTRE)

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ABSTRACT **BACKGROUND:** The COVID-19 pandemic is the biggest threat in living memory to the human race. We are not a designated COVID Hospital. Yet, as we complete more than 60 days since the pandemic was declared, we have screened (as per ICMR Guidelines) and managed many pregnant patients who later came out as COVID positive.

OBJECTIVES:

- To assess the impact of screening on detection of corona virus infection in obstetric patients.
- To analyse trend in detection and discuss challenges in implementation of testing.
- To find the incidence of COVID positive patients in symptomatic and asymptomatic pregnant women.

MATERIALS: Retrospective Observational Study was conducted in our admitted patients. As per the ICMR Guidelines for COVID-19 testing in pregnant women, all pregnant patients were tested at entry point in Labour ward casualty/triage area by collecting naso-pharyngeal swab for COVID-19.

RESULTS: In this study duration, we analysed total 829 pregnant patients including ANC/Delivered/Aborted. In these, 25 were symptomatic, of which 14 patients were COVID positive (56%). Of the 804 asymptomatic pregnant women, 86 patients were diagnosed as COVID positive (10.69%). The overall incidence of COVID-19 patients in our admitted obstetric patients was 12.06%. (Table 1) although the incidence of symptomatic positive patients was 1.68% of the total population tested. Of 2631 patients tested in our hospital, men were more prone for COVID infection (384) than women (323). 26.87 % of total swabs collected were positive and 10.56 % swabs were inconclusive or pending due to multiple reasons. (Table 2).

CONCLUSION: There is a need for testing all admitted pregnant women as many of COVID-19 positive pregnant women are asymptomatic. Meticulous filling of forms, careful sample collection and dispatch is important for accurate reports.

KEYWORDS : COVID Positive Pregnant, COVID-19 Swabs, Screening.

INTRODUCTION:

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus SARS-CoV-2. Coronaviruses are found in both avian and mammalian species. They resemble each other in morphology and chemical structure: for example, the corona viruses of humans and cattle are antigenically related. There is no evidence that human corona viruses can be transmitted by animals.^{1,2}

Corona viruses were originally grouped into the family Coronaviridae based on the crown or halo-like appearance of glycoprotein studded envelope on electron microscopy.

Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease and cancer are more likely to develop serious illness.³

After the declaration of the pandemic worldwide, a lockdown was declared in major cities of Maharashtra like Mumbai, Pune from 21st March 2020. At the beginning of the pandemic, our hospital had neither the facilities nor the necessary resources to test patients for COVID-19. As a result, we managed patients symptomatically and transferred high risk patients to designated COVID facilities for further management.

However, as the number of cases increased, COVID 19 testing was arranged by our hospital.

Initially, testing was available only in the Fever OPD and not in the obstetric department. The ICMR guidelines of April 2020 recommend testing of all pregnant women above 34 weeks of gestation and likely to be delivered in the next 5 days, or those hailing from hotspots/containment areas with likely contact to positive case, even if asymptomatic.⁴

Thus, after discussion with the administration and Microbiology

department, decision to take naso-pharyngeal swabs of all pregnant women at the entry point in the labour room or ANC Ward was taken by our department.

AIMS AND OBJECTIVES:

- To assess the impact of screening on detection of corona virus infection in obstetric patients.
- To analyse trend in detection and to discuss challenges in implementation of testing.
- To find the incidence of COVID positive patients in symptomatic and asymptomatic pregnant women.

METHODOLOGY:

Type Of Study: This is a Retrospective Observational Study.

Centre of Study: Hindu Hrudaysamrat Balasaheb Thakarey Medical College (HBTMC) and Dr R.N. Cooper Hospital, Mumbai.

Duration of Study: 16th March 2020 to 17th May 2020

Sample Size: All the patients admitted in Labour Ward, ANC and Gynaecology ward under Obstetrics and Gynaecology department.

Swab Collection Location And Technique:

As per the directives of the ICMR Guidelines for COVID-19 testing in pregnant women, our hospital, a Non COVID designated centre, started testing all pregnant patients at entry point in Labour ward casualty/triage area by collecting naso-pharyngeal swab for COVID-19. The swabs were collected with a swab stick and sent in transport medium for COVID-19 testing by Real time PCR. Samples were processed according to the standards prescribed by GOI. Based on the results, patients with positive results were triaged and managed as per the standard protocols for further care.

Inclusion Criteria:

- Pregnant patients registered in our hospital and admitted for antenatal care OR
- Pregnant patients registered with us and presenting in labour OR
- Unregistered patients presenting in labour (direct/ referred from

other health care facility)

AND

- Patients willing to get COVID swab testing.

Exclusion Criteria:

1. Patients refusing consent for swab test.
2. Patients who were already tested positive for COVID.

Patients were admitted and managed as per their symptoms according to standard protocols. Labour management was as per standard guidelines and Caesarean section was done only for obstetric indications.⁵

Symptomatic and suspected patients were delivered in a separate isolation room; operative procedures in suspected cases were performed in a separate designated operation theatre as per standard guidelines.⁶

Precautions as per standard protocols were implemented in Labour Ward and Operation Theatre viz wearing Personal Protective Equipment (PPE), N 95 masks and face shield.⁷

Patients with early pregnancy failure were managed by emergency check curettage in Operation Theatre. In order to reduce the risk of transmission to the healthcare workers, anaesthetists preferred Saddle block over intravenous sedation as the method of anaesthesia.

Symptomatic patients post-delivery or surgery were then shifted to designated isolation wards. Asymptomatic patients were shifted to respective post-natal Ward or Caesarean Section Ward. Neonatologists and anaesthetists were informed about symptomatic patients in advance of delivery or caesarean section to ensure proper care of patients, neonates and health care workers as per standard protocols⁸ Asymptomatic patients were discharged as per standard protocols. COVID-19 swab reports usually came in 3 days after dispatch of swabs.

Patients Were Triaged As Per Reports:

- Positive patients, if not discharged, were transferred to Isolation ward.
- Neonatologists were also informed.
- If positive patients were discharged before receipt of reports, the hospital administration and respective ward officers were informed about the final diagnosis of the patients along with their address, contact no and necessary details.

RESULTS:

1. We had a total of 808 deliveries between 16th March 2020 to 17th May 2020.
2. Testing of all pregnant women admitted to the obstetric department commenced from 22nd April 2020.
3. Of the 829 women including delivered/aborted or ANC patients, 25 had symptoms and the rest were asymptomatic (804) including ANC patients.
4. Out of the 25 symptomatic patients, 14 patients were diagnosed COVID positive based on naso-pharyngeal swab testing, incidence being 56%.
5. Of the 804 asymptomatic patients, 86 patients were diagnosed as COVID positive with incidence of 10.69%.

**Group A: Symptomatic Pregnant Patients Admitted To Hospital
Group B: Asymptomatic Pregnant Patients Admitted To Hospital**

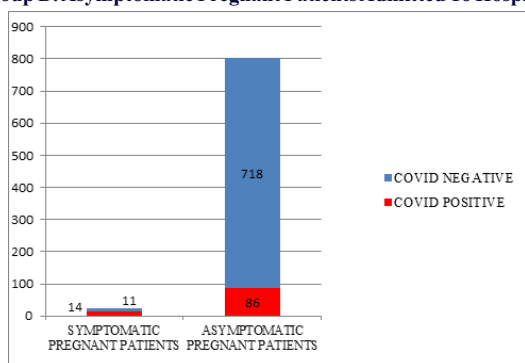


Chart 1: Symptomatic And Asymptomatic Patients Admitted In OBGY Department.

Table 1*: Symptomatic And Asymptomatic Pregnant Patients.

	SYMPTOMATIC (Group A)	ASYMPTOMATIC (Group B)	TOTAL
COVID POSITIVE (Including ANC, Abortion)	14	86	100
COVID NEGATIVE	11	718	729
Total	25	804	829

***Source: Department of OBGY and Microbiology, HBTMC and Dr RN Cooper Hospital, Mumbai**

- The total number of pregnant COVID positive women admitted in our hospital was 100 (retrospective diagnosis).
- Of these, there were 79 cases of deliveries (both vaginal and caesarean section), 8 cases of check curettages for first trimester miscarriages, 12 antenatal cases and 1 case of chronic ectopic pregnancy with tubal abortion.
- There was one case of maternal mortality (Indirect suicidal hanging)
- Besides the 88 delivered/aborted COVID positive patients, there were 12 ANC COVID positive patients which were either transferred to designated COVID Hospitals or managed conservatively in our hospital as per their diagnosis.
- Thus, the incidence of COVID positivity in the indoor obstetric patients including was 12.06% (100 out of 829).
- The incidence of symptomatic COVID positive patients was 1.68%.

Table 2 Overall COVID Testing Reports In Our Institute (men And Women)

	MEN	WOMEN	TOTAL
COVID Positive	384	323	707
COVID Negative	646	1000	1646
Pending/ Inconclusive	137	141	278
Total	1167	1464	2631
% Positive gender wise	384/1167 = 32.9%	323/1464 = 22.0%	707/2631 = 26.8%
% Positive of total population tested	384/2631 = 14.5%	323/2631 = 12.2%	

***Source: Department. Of Microbiology, HBTMC And Dr RN Cooper Hospital, Mumbai**

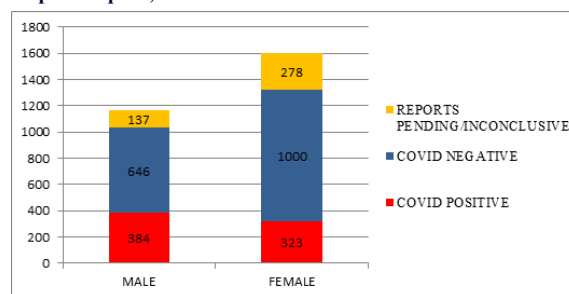


Chart 2: Overall COVID Testing Reports In Our Institute (male And Female)

Table 3*: Analysis Of Trends Based On COVID Testing In Admitted Pregnant Women (ANC, Delivered And Aborted Patients)

DURATION	COVID Positive Pregnant women	COVID Negative Pregnant women	TOTAL
16/3/2020 to 31/3/2020	0	152 (No testing)	152
01/04/2020 to 15/04/2020	0	203 (No testing)	203
16/04/2020 to 30/04/2020	22 (Testing from 22 nd)	119	142
01/05/2020 to 15/05/2020	72	168	240
16/05/2020 to 17/05/2020	6 (2 days)	35	41
TOTAL	100		

*Source: Department Of OBGY And Microbiology, HBTMC And Dr RN Cooper Hospital, Mumbai.

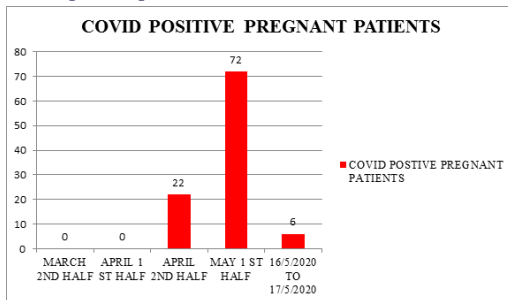


Chart 3: Analysis Of Trends Based On Covid Testing In Admitted Pregnant Women (ANC, Delivered And Aborted Patients)

DISCUSSION:

At the beginning, when the WHO declared COVID-19 a pandemic and lockdown was implemented in India, the COVID-19 swab testing facility was not available at our tertiary care institute. As the number of cases started rising in Mumbai, swab testing for COVID-19 was made available in our hospital. Initially, the testing was limited to Fever OPD, so testing of asymptomatic pregnant patients could not be done. Only pregnant women with symptoms of COVID 19 infection were tested in the Fever OPD and managed as per the standard protocol.

From 22nd April 2020, testing of all admitted pregnant patients for COVID-19 was started in our OBGY Department as per ICMR guidelines. The swabs were collected in the Labour ward Casualty area on admission of pregnant women.

The various issues about sample collection that we encountered were:

- Incomplete form filling
- Illiterate patients unable to give accurate information
- Patients and relatives not knowing the exact address
- Language barrier
- Patients could not or choose not to give correct contact numbers.
- Sample spillage

Residents were trained accordingly to fill forms accurately and avoid spillage of samples. Filling the proforma correctly and daily reporting of the collected samples according to the new guidelines is being followed.

Initially, the samples were tested in one designated MCGM COVID-19 laboratory. However, due to heavy workload, ICMR then permitted private laboratories to test the COVID-19 samples. Since then, samples are now sent to other private laboratories providing free testing for MCGM patients.

The incidence of COVID-19 patients in our admitted obstetric patients was 12.06%. It is likely that the real incidence may be slightly higher as some pregnant COVID-19 positive patients were missed as the testing was started only from 22nd April as per the revised ICMR guidelines.

The incidence of symptomatic COVID-19 positive patients was 1.68%. Symptoms included fever, sore throat, cough, breathlessness, running nose, headache, weakness, fatigue, diarrhea, loss of smell etc. Thus, despite the large number of COVID-19 positive patients, the prevalence of symptomatic patients was less. Further, most of the symptomatic patients had symptoms that were mild in nature; one patient had persistent fever had mastitis. One patient, a case of eclampsia with caesarean section had severe symptoms of fever and breathlessness with X Ray suggestive of early ARDS and cardiomegaly. The patient is currently on anticoagulants, higher antibiotics, steroids and diuretics and is presently stable. Fortunately, no obstetric complication like DIC, renal failure, HELLP syndrome. etc. were seen in the positive symptomatic patients till now. One case of COVID-19 positive maternal mortality was seen in a second trimester antenatal case with suicide attempt due to hanging (indirect cause).

26.87 % of total swabs collected in our hospital for testing were positive. Swabs for COVID testing in males were taken in Fever OPD or in admitted symptomatic cases, and the incidence of COVID-19 positive swabs among the males was 32.9%. Incidence of positive swabs in females was 22.06% overall but this also includes asymptomatic pregnant women screened. The incidence of COVID-19

infection is seen more often in men as compared to women in many studies, including ours - both when analyzed gender-wise or as percentage of the total tests (Table 2).⁹ Studies have shown men are more vulnerable to COVID 19 infection than women as men have a higher amount of Angiotensin Converting Enzyme II in their plasma and the outcome in males is worse as compared to females.⁹

The management of COVID positive men was done by respective departments in which they were admitted like medicine, surgery etc.

10.56 % of reports of total swabs sent were inconclusive or pending due to multiple reasons like incomplete form filling, spillage of samples, time duration for testing, etc. These issues were solved over the period by proper training of the residents and reducing the turnaround time for the tests.

Out of total COVID-19 positive women tested in our hospital, 31.2 % of women were pregnant but this data is inconclusive as the samples of only symptomatic non-pregnant patients are being sent, while samples of all pregnant patients (symptomatic and asymptomatic) are being sent as per ICMR Guidelines⁴.

In our hospital, all pregnant women were not tested for COVID-19 till 20th April, when the first case, a case of chronic ectopic was diagnosed to be positive. It was only with the revised ICMR guidelines that universal testing of all admitted pregnant women was started from 22nd April with administrative sanction. Reflecting on the trends in COVID-19 positivity among the pregnant women since then, 22 pregnant patients were diagnosed positive till 30th April but in first half of May the number of positive patients shot up to 72 in just 15 days, the rate thereafter increasing day by day. Thus, implementing testing for all pregnant patients has helped us identify 100 COVID positive patients.

Although our hospital is not a designated COVID-19 centre, our study revealed that there was a high incidence of asymptomatic positive pregnant women. The diagnosis in almost all cases was made retrospectively post-delivery. We are currently treating all patients with proper precautions due to high incidence of asymptomatic positive, diagnosed positive post-delivery.

Measures Adopted Include:

- Clinical assessment of patients in triage area and admitting only if strongly indicated,
- Collecting COVID-19 swabs of all admitted patients and isolating symptomatic patients,
- Delivering symptomatic labor cases in separate area (pending swab reports),
- Making sure that list of all collected swabs with requisite patient details is maintained and reports are traced.
- Making it mandatory for all residents/ staff to wear appropriate PPE kit, N95 mask, face shield and gloves in the triage area, labour ward and during delivery by vaginal delivery or by caesarean section.

Recent updates on ICMR Guidelines of 18th May:¹⁰

The updated ICMR guideline (version 5) does not specify any further modifications regarding testing for pregnant women than the previous guideline, and we continue to test pregnant women as advised previously, with inputs from our Microbiology Department and Administration since we cater to patients coming from RED/ HIGH Risk zones.

CONCLUSION:

Based on our experience, we find that there is a need for testing all admitted pregnant women as most of COVID-19 positive pregnant women are asymptomatic and come from containment areas/ red zones. By testing all pregnant women requiring admission, although the reports of the test are available after 1-2 days, proper management of patients, neonates and other pregnant women can be ensured. This eventually benefits everyone: patients, health care workers and society. Meticulous filling of forms and careful sample collection and dispatch is important for accurate reports.

Conflicts Of Interest: Nil

Acknowledgement:

We are very thankful to Dean sir Dr Pinakin Gujjar, Academic Dean and I/C HICC Dr Kishore Bisure and Head of Department Dr Sneha

Shirodkar Madam for the support, guidance and permission to use the hospital data.

**APPENDIX:
FORM:**

ICMR Specimen Referral Form for COVID-19 (SARS-CoV2)

INTRODUCTION
This form is for collection centres/ labs to enter details of the samples being tested for Covid-19. It is mandatory to fill this form for each and every sample being tested. It is essential that the collection centres/ labs exercise caution to ensure that correct information is captured in the form.

INSTRUCTIONS:
 1. Inform the local / district / state health authorities, especially surveillance officer for further guidance
 2. Seek guidance on requirements for the clinical specimens collection and transport from nodal officer
 3. This form may be filled in and shared with the IDSP and forwarded to a lab where testing is planned
 4. Fields marked with asterisk (*) are mandatory to be filled

SECTION A – PATIENT DETAILS

A.1 TEST INITIATION DETAILS
 *Doctor Prescription: Yes No *Repeat Sample: Yes No
 (If yes, attach prescription, if No, test cannot be conducted) If Yes, Patient ID:

A.2 PERSONAL DETAILS
 *Patient Name: *Age: ... Years/Months (If age <1 yr, pls. tick months checkbox)
 *Present Village or Town: *Gender: Male Female Others
 *District of Present Residence: *Mobile Number:
 *State of Present Residence: *Nationality: Self Family
 *Present patient address: *Downloaded Aarogya Setu App: Yes No
 *Pincode: (These fields to be filled for all patients including foreigners)
 Email: Passport No. (For Foreign Nationals):
 Aadhar No. (For Indians):

A.3 SPECIMEN INFORMATION FROM REFERRING AGENCY
 *Specimen type TS/NPS/NS BAL/ETA Blood in EDTA Acute sera Covalent sera Other
 *Collection date
 *Sample ID (Label)

A.4 PATIENT CATEGORY (PLEASE SELECT ONLY ONE)
 Cat 1: Symptomatic international traveller in last 14 days
 Cat 2: Symptomatic contact of lab confirmed case
 Cat 3: Symptomatic healthcare worker
 Cat 4: Hospitalized SARI (Severe Acute Respiratory Illness) patient
 Cat 5a: Asymptomatic direct and high risk contact of lab confirmed case
 Cat 5b: Asymptomatic healthcare worker in contact with confirmed case without adequate protection
 Cat 6: Symptomatic influenza like illness (ILI) patient in hospital/ MoHPW identified clusters
 Other:
 (Please select "other" only if the patient doesn't fall in any other category)

A.5 STATUS OF CURRENT RESPIRATORY INFECTION
 *Respiratory Infection: Severe Acute Respiratory Illness (SARI): Yes No , Influenza Like Illness (ILI): Yes No

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SECTION B- MEDICAL INFORMATION

B.1 EXPOSURE HISTORY (2 WEEKS BEFORE THE ONSET OF SYMPTOMS)
 1. Did you travel to foreign country in last 14 days: Yes No
 If yes, place(s) of travel:
 2. Have you been in contact with lab confirmed COVID-19 patient: Yes No
 If yes, name of confirmed patient:
 3. *Were you Quarantined?: Yes No *If yes, where were you quarantined: Home Facility
 4. Are you a health care worker working in hospital involved in managing patients: Yes No

B.2 CLINICAL SYMPTOMS AND SIGNS
 Date of onset of symptoms: (dd/mm/yy) First Symptom:

Symptoms	Yes	Symptoms	Yes	Symptoms	Yes	Symptoms	Yes
Cough	<input type="checkbox"/>	Diarrhoea	<input type="checkbox"/>	Vomiting	<input type="checkbox"/>	Fever at evaluation	<input type="checkbox"/>
Breathlessness	<input type="checkbox"/>	Nausea	<input type="checkbox"/>	Haemoptysis	<input type="checkbox"/>	Body ache	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>	Chest pain	<input type="checkbox"/>	Nasal discharge	<input type="checkbox"/>	Sputum	<input type="checkbox"/>
						Abdominal pain	<input type="checkbox"/>

B.3 PRE-EXISTING MEDICAL CONDITIONS

Condition	Yes	Condition	Yes	Condition	Yes	Condition	Yes
Chronic lung disease	<input type="checkbox"/>	Malignancy	<input type="checkbox"/>	Heart disease	<input type="checkbox"/>	Chronic liver disease	<input type="checkbox"/>
Chronic renal disease	<input type="checkbox"/>	Diabetes	<input type="checkbox"/>	Hypertension	<input type="checkbox"/>		

 Immunocompromised condition: YES NO Other underlying conditions:

B.4 HOSPITALIZATION DETAILS
 Hospitalized: Yes No Hospital State:
 Hospitalization Date: (dd/mm/yy) Hospital District:
 Hospital Name:

B.5 REFERRING DOCTOR DETAILS
 *Name of Doctor: Doctor Mobile No:
 Doctor Email ID:

*Fields marked with asterisk are mandatory to be filled

- a-coronaviruses#
- 2. Questions and Answers on the COVID-19: OIE - World Organisation for Animal Health [Internet]. OIE. [cited 2020May23]. Available from: <https://www.oie.int/en/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019-novel-coronavirus/>
- 3. Coronavirus [Internet]. World Health Organization. World Health Organization; [cited 2020May23]. Available from: <https://www.who.int/health-topics/coronavirus/coronavirus>
- 4. Pti. ICMR issues testing strategy for pregnant women in hotspot districts [Internet]. <https://www.oneindia.com.2020> [cited 2020May23]. Available from: <https://www.oneindia.com/india/icmr-issues-testing-strategy-for-pregnant-women-in-hotspot-districts-3075921.html>
- 5. FOGSI's GCPR on Pregnancy with COVID-19 Infection - for your valuable suggestions [Internet]. The Federation of Obstetric & Gynecological Societies of India. 2020 [cited 2020May23]. Available from: <https://www.fogsi.org/fogsi-gcpr-on-pregnancy-with-covid-19-infection-version-2/>
- 6. WANI RJ. COVID-19 and Women's Health – Conception to Delivery. the indian practitioner [Internet]. 2020May6; Available from: <https://theindianpractitioner.com/2020/05/06/covid-19-and-womens-health-conception-to-delivery>
- 7. COVID -19 Outbreak - ncdc.gov.in [Internet]. [cited 2020May23]. Available from: <https://ncdc.gov.in/WriteReadData/1892s/42417646181584529159.pdf>
- 8. Coronavirus (COVID-19) Infection in Pregnancy [Internet]. [cited 2020May23]. Available from: <https://www.rcog.org.uk/globalassets/documents/guidelines/2020-04-17-coronavirus-covid-19-infection-in-pregnancy.pdf>
- 9. Sama, Izhah, Ravera, Alice, T B, Harry, et al. Circulating plasma concentrations of angiotensin-converting enzyme 2 in men and women with heart failure and effects of renin-angiotensin-aldosterone inhibitors [Internet]. OUP Academic. Oxford University Press; 2020 [cited 2020Jun16]. Available from: <https://doi.org/10.1093/eurheartj/ehaa373>
- 10. COVID-19: Indian Council of Medical Research: Government of India [Internet]. COVID-19 | Indian Council of Medical Research | Government of India. [cited 2020May23]. Available from: https://main.icmr.nic.in/sites/default/files/upload_documents/Testing_Strategy_v5_18052020.pdf

TEST RESULT (To be filled by Covid-19 testing lab facility)

Date of sample receipt(dd/mm/yy)	Sample accepted/ Rejected	Date of Testing (dd/mm/yy)	Test result (Positive / Negative)	Repeat Sample required (Yes / No)	Sign of Authority (Lab in charge)

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COLLECTION KIT:

REFERENCES:

- 1. Q&A on coronaviruses (COVID-19) [Internet]. World Health Organization. World Health Organization; [cited 2020May23]. Available from: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q>