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சுகாதார அமைச்சு
Ministry of Health

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எனது இல)
My No.) DDG/LS/ED/Testing-Strategy/106/2021

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Your No. :)

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திகதி) 9 -06-2021
Date)


DDG, NHSL,
DDG, NH Kandy,
Directors of All Hospitals,
Provincial and Regional Directors of Health Service,
Heads of Institutions of dedicated COVID-19 treatment facilities,
All other Heads of Institutions

Revised Guidelines on Laboratory Testing Strategy for COVID-19

This is further to my letter No. DDG/LS ARDT-GL/2020) dated 03/12/2020 regarding 'Guideline for use of Ag-RAT in testing policy for COVID-19', Please find the revised guidelines (including flowcharts - Annexes 1-7) for COVID-19 RT-PCR and Ag-RAT testing in Sri Lanka, as listed below:

1. Testing strategy for health care settings
2. Community based COVID -19 testing strategy
3. Testing for Overseas returnees and foreign travelers
4. Testing Strategy for Employees in workplaces
5. Addendum for interpretation of COVID -19 RAT results

I hereby instruct to adhere to these guidelines strictly as indicated in each setting and appropriate testing strategy must be implemented. Further review of the guideline will take place with information gathered through ongoing usage and evidence.


Dr Asela Gunawardena,
Director General of Health Services

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Cc:

- 1) Hon. Minister of Health
- 2) Secretary of Health
- 3) Additional Secretaries
- 4) All DDGs
- 5) Chairman, NMRA
- 6) Director, LS
- 7) Chief Epidemiologist
- 8) Director, MRI
- 9) Technical heads of designated laboratories

Revised Guidelines on Laboratory Testing Strategy for COVID-19

These guidelines will be reviewed according to the COVID-19 situation in the country. Please ensure that the content of this document is circulated to all relevant categories of staff, in order to take appropriate action.

1. Testing Strategy for Healthcare Settings

1.1 Indications for COVID-19 PCR Testing (RT-PCR)

- Symptomatic patients suspected of having COVID-19 (As the initial test or the secondary test following negative COVID-19 Rapid Antigen Test)
- Symptomatic patients with high degree of clinical suspicion need repeat PCR test when the initial PCR test is negative (lower respiratory sample is preferred with lower respiratory tract involvement)
- Symptomatic surveillance for COVID 19 at fever corner/ILI surveillance (As the initial test or the secondary test following Negative COVID-19 Rapid Antigen Test)
- Before high-risk surgeries such as head and neck, ENT, OMF and cardiothoracic and procedures such as elective bronchoscopy.
- Quarantined individuals who are getting admitted for non-COVID conditions and procedures (when to test should be decided on case-by-case basis)

1.2 Indications for COVID-19 Rapid Antigen Testing (RAT)

- RAT can be considered as the initial test in patients with COVID suspected symptoms (for early diagnosis), but secondary PCR is indicated on Ag negative cases to exclude the infection.
- Surgeries under GA in the absence of suspected symptoms (cases other than mentioned in 1.1 as high-risk surgeries and procedures indicated for PCR testing)
- High risk dental procedures such as scaling and filling or any procedure using air rotors in the absence of suspected symptoms
- Day procedures such as endoscopy, dialysis and surgeries under local and spinal anesthesia, in the absence of suspected symptoms
- Suspected patients needing emergency procedures or transfer to ICU (Secondary PCR can be considered by the treating clinician and virologist/microbiologist, but should not delay the emergency procedure waiting for PCR results)

1.3 Definition for Confirmed COVID-19 Case

- A person with positive COVID-19 RT-PCR test result
- A person with a positive COVID-19 RAT test result and meeting either clinical or epidemiological criteria for suspected COVID-19
- An asymptomatic person with a positive COVID-19 RAT test result who has epidemiological link for COVID-19.

1.4 Contact Tracing in Healthcare Settings

- Risk assessment should be done according to the relevant protocol.
- Consider the COVID vaccination history of 1st contact health care staff to take decisions on further follow up work on contact tracing and quarantine
- First contact health care staff who **have completed 2 weeks period after second dose of COVID vaccination need not to undergo quarantine process** after an COVID exposure, but can continue work (if they are asymptomatic) with recommended infection prevention precautions. But they **need to be tested with COVID RAT on Day 3, 7 and 10** while continuing the work and with PCR if they become symptomatic
- **First contact health care staff without vaccination or with partial vaccination history** (including staff before completing 2 weeks period after vaccination) need to **undergo quarantine for 10 days** after the last date of exposure to COVID-19 patient. They can be tested with RAT initially in the beginning of quarantine if indicated by infection control team of the hospital for further contact tracing purposes.
- If additional asymptomatic surveillance is planned by the infection control team beyond 1st contacts, RAT or RT-PCR can be utilized in a tailored approach.
- All 1st contacts quarantined for 10 days should inform the infection control team if they become symptomatic to arrange PCR for them
- Quarantined healthcare workers can return to work with a negative PCR result on a sample collected on day 10 of quarantine period from the last exposure date to the COVID-19 positive person

1.5 Psychiatric patients and similar patients in long-term care facilities

- All such patients should be tested with COVID-19 PCR on admission to the facility
- Regular symptomatic surveillance (with RT-PCR) and random asymptomatic surveillance (with RAT/RT-PCR) can be carried out under the instructions from the infection control team of the hospital
- On detecting a positive case or cases, further outbreak investigation should be done using RAT/RT-PCR under the instructions from the infection control team of the hospital

1.6 Postmortem testing

In addition to the DGHS circular Number DGHS/COVID-19 /347-2020 (dated 17/11/2020) ‘Guideline On management of dead during current pandemic of COVID-19’, the following is recommended.

- Clinicians, JMO or the public health medical staff should determine the indication for PCR testing for COVID-19 on dead bodies (with signs and symptoms compatible with COVID-19 during life and/or epidemiological link).
- The recommended test for post mortem diagnosis of COVID-19 is PCR. Nevertheless, samples of dead bodies can be tested with RAT if performed during the stipulated period which is at the discretion of the JMO. If RAT is positive, it is confirmed as a positive case of COVID-19 and follow the recommended protocols and guidelines on management of dead. If negative, should be followed by PCR. Therefore, if to perform RAT, parallel sampling must be obtained anticipating a follow up PCR if RAT is negative (If to perform RAT as an initial investigation, samples must be obtained in duplicate for both RAT and PCR where sample for PCR can be discarded with standard precautions if RAT is positive).
- It is encouraged for clinicians to perform RAT in ward set up or where the person is admitted in a terminal stage and died at OPD/PCU/ETU. However, RAT is not recommended on persons brought dead to the hospital.
- **Routine testing for COVID-19 on all dead bodies is not recommended.** However, this is mandatory in “lock down and “high-risk” areas.

2. Community Based COVID-19 Testing Strategy

At this stage of COVID-19 community prevalence, the following testing strategy should be coupled with the appropriate isolation and quarantine policy.

Symptomatic surveillance should be a priority in community setting with prioritized testing for symptomatic individuals all over the country with early intervention for isolation and quarantine.

2.1 Symptomatic surveillance in community with COVID-19 Rapid Antigen Test (RAT) and RT-PCR

1. All symptomatic cases with suspected COVID-19 symptoms should be tested with either COVID-19 Rapid Antigen Test (RAT) or COVID-19 RT-PCR.
2. All symptomatic individuals with RAT negative results should be retested with COVID-19 RT-PCR.
 - If the COVID-19 RAT or RT-PCR is positive do the recommended clinical and infection control management according to the relevant updated guidelines.
 - Even if the COVID-19 PCR is negative advise the symptomatic individual to remain in home isolation **till recovery** regardless of negative results and to take infection prevention precautions. If progressive symptoms are developed, they need to present to the nearby hospital adhering to infection prevention measures.
 - On sending samples to COVID PCR labs, local public health officers should send samples (combined nasopharyngeal and throat swab in VTM) of symptomatic individuals in a separate list (labelling the list as symptomatic) and a separate package with triple packaging and ice. Then the laboratories are able to arrange priority testing on symptomatic samples. (Do NOT mix symptomatic and asymptomatic samples together in the same package)

2.2 Testing for contact tracing at community level

- Symptomatic contacts should be tested by RAT and all symptomatic individuals with RAT negative results should be retested with COVID-19 RT-PCR. If RAT or RT-PCR positive, do the recommended clinical and infection control management according to the updated relevant guidelines.
- Asymptomatic first contacts should be tested **only** if there was a risk of spread from that contact to other persons according to the risk assessment with COVID-19 RAT initially (**NOT PCR**). When first contacts are positive do the recommended clinical and infection control management according to the updated relevant guidelines and do further contact tracing.
- Asymptomatic contacts with COVID-19 RAT negative should be advised for home quarantine for 14 days. If they become symptomatic, follow the above testing protocol for symptomatic individuals in 2.1

- Contacts who are under home quarantine process can be released after 14 days using either of two options mentioned below;
 1. A negative COVID PCR result on a sample collected on day 12 from the last significant exposure date to COVID positive case
 2. A negative COVID RAT result on a sample collected on day 14 from the last significant exposure date to COVID positive case. In addition, other household members should be tested with RAT on the same day. If any of the household members is positive, it is necessary to further extend the quarantine period for 14 days. Exit RAT should be done for other negative members at the end of extended quarantine period.
(In case of RT-PCR or RAT cannot be done during the stipulated period, the asymptomatic contacts can be released on Day 21 without further testing)

Exit RT-PCR is exclusively recommended for overseas returnees and foreign travellers under quarantine process on a sample collected on or later the day 12 after arrival, but **NOT** the RAT.

2.3 Random asymptomatic surveillance at community level

- Should be considered only in settings vulnerable for super spreading events in the absence of any detected COVID-19 cases during last 2 weeks period or in the absence of an ongoing contact tracing process in the locality.
- COVID-19 RT-PCR assay should be used.
- On sending samples to a PCR lab, prepare a separate list and a package and label them as for “Random asymptomatic surveillance”.
- When cases are detected in a random surveillance, follow-up testing should be done according to the protocols for symptomatic surveillance and contact tracing. (After detecting new cases random surveillance testing protocol is not further applicable for the setting, but the protocol for contact tracing should be applied, thereafter)

2.4 Prisoners and residents of care homes

- All prisoners and residents should be tested with COVID-19 RT PCR after staying 2 weeks in isolation facility before entering the prison or care home
- Regular symptomatic surveillance (with RT-PCR) and random asymptomatic surveillance (with RAT/RT-PCR) can be carried out accordingly in tailored strategy in consultation with Consultant Community Physician/ Regional Epidemiologist/ Medical Officer of Health or the public health officer in-charge.
- On detecting a positive case or cases, further outbreak investigation should be done using RAT/RT-PCR under the coordination of a Consultant Community Physician/ Regional Epidemiologists.

3. Testing for Overseas returnees and foreign travellers

- All overseas returnees and foreign travellers should be tested on arrival with RT- PCR
- If RT-PCR is positive, refer the person for isolation according to the updated relevant protocol.
- Institutionalized quarantine is recommended for RT- PCR negative individuals for 14 days.
- Symptomatic but RT-PCR negative individuals should be admitted to isolation wards for further monitoring and follow up testing.
- Combined nasopharyngeal and throat swabs can be collected on day 12 for RT- PCR when they remain asymptomatic throughout the quarantine period. If the RT-PCR result is negative, then the individuals can be released on day 14.
- **Irrespective of vaccination status** of overseas returnees and foreign travellers, the above protocol should be adhered to considering the prevention of importation of existing and emerging SARS CoV-2 variants.

4. Testing Strategy for Employees in workplaces

(This is the revision of ‘Workplace testing Strategy for COVID-19 guideline - DDG/LS/CV19-RT /2020 dated 30/11/2020, First revision- 14th March 2021 and 2nd revision on 12th May 2021)

Revised laboratory testing strategy for COVID-19 for employees in workplaces have been developed to cover the following components.

1. Screening and testing of symptomatic employees
2. Testing during an outbreak of COVID 19 at workplaces
 - a. Testing of close contacts (1st line contacts)
 - b. Further random testing of small groups of employees
 - c. Conducting exit PCR for close contacts (1st line contacts) undergoing home quarantine for returning to work
3. Testing of asymptomatic employees for routine surveillance

4.1 Screening and testing of symptomatic employees

- All workplaces should strictly conduct screening of symptomatic employees suspected of COVID-19 on a daily basis.
- The focal point in all workplaces shall maintain daily records of employees with suspected symptoms of COVID-19 during the last 24 hours and send these records to the area Medical Officer of Health via email on a daily basis.
- If there are employees with symptoms suspicious of COVID-19, they should not be allowed to work. They should be sent to the nearest government hospital (Divisional hospitals or above) for testing with Rapid Antigen and for further management.
- If the Rapid Antigen test is positive, they will be referred to follow the treatment protocol.
- If the Rapid Antigen test is negative, the symptomatic employees will be subjected to RT-PCR immediately at the hospital. They should be kept in the hospital or self-isolation at home adhering to proper infection prevention control methods till the results of RT-PCR is available. Employees in boarding houses need to be kept in a secure place where they can self-isolate adhering to proper infection prevention control methods till the results of RT-PCR is available. If the subsequent RT-PCR test is positive they will be referred for treatment. If RT-PCR is negative they can resume work, once they have recovered from symptoms. However, if symptoms persist or worsen, a repeat test is indicated, if there is strong clinical or epidemiological suspicion.
- Focal points of workplaces should inform about all COVID-19 positive employees to the area Medical Officer of Health by telephone/fax/email as soon as possible of receiving such information.

4.2 Testing during an outbreak of COVID 19 at workplaces

a. Testing of close contacts (1st line contacts) of confirmed COVID-19 employees

- On detecting a positive employee with COVID-19, all identified close contacts (1st line contacts) need to be screened with rapid antigen test strictly under the guidance of the area MOH /Regional Epidemiologist/ District/ Provincial Consultant Community Physician at the earliest. If the test is positive, they should undergo the treatment protocol. The contact tracing to detect the close contacts (1st line contacts) of the identified positive employees and screening as mentioned above need to be conducted.

If the test is negative, they should undergo home quarantine and testing to exit the quarantine period should be done as per the current protocol.

- Tracing of first line contacts on detection of symptomatic COVID-19 cases and asymptomatic COVID-19 cases need to be done as outlined in the below table.

Table 1: Tracing of first line contacts on detection of symptomatic and asymptomatic COVID-19 cases

Status of employees having COVID-19	Start date	End date
Symptomatic	Two days before the symptoms appear	The last date the COVID-19 positive employee was at work
Asymptomatic	Two days before the date on which the sample that led to confirmation of COVID-19 was taken	The last date the COVID-19 positive employee was at work

- Workplaces can resume work with the remaining employees (those not identified as 1st line contacts and those not infected with COVID-19) with strict symptomatic screening conducted on a daily basis as mentioned in this guideline.
- **Conducting large numbers of RAT/RT-PCR tests among employees not identified as close contacts (1st line contacts) in a workplace at one point of time during an outbreak is not recommended.**
 - Further random testing of small groups of employees during the outbreak**
 - The MOH can decide about this approach in consultation with Consultant Community Physicians and Regional Epidemiologist. RAT can be used for this purpose in a staggered manner.
 - Conducting exit PCR for close contacts (1st line contacts) undergoing home quarantine for returning to work**
 - Resuming duty of quarantined close contacts (1st line contacts) -Employees can return to work with a negative PCR result on a sample collected on day 10 of quarantine from the last exposure to the COVID-19 positive person

4.3 Routine asymptomatic testing for surveillance

- Routine asymptomatic testing of employees for surveillance of COVID-19 at workplaces, should be carried out using Rapid Antigen Test (RAT) (WHO approved, locally validated, NMRA registered assays) under the strict guidance of the MOH/Regional Epidemiologist as follows.
 - i. All workplaces, without an ongoing COVID-19 outbreak or no COVID-19 positive cases identified in the workplace during the last 2 weeks need to conduct COVID-19 testing among asymptomatic employees using RAT on a weekly basis as per the instructions outlined in the following table.

Table 2: COVID-19 testing among asymptomatic employees using RAT on a weekly basis

Scale of the workplace	Number or % testing to be done with the Rapid Antigen Test
Large scale: 250 or more employees	1% of the total workforce or 15 employees whichever is the higher number
Medium scale: Between 50 -249 employees	10 employees
Small scale: less than 50 employees	5 employees

- ii. Employees coming from high-risk areas/settings and employees generally exposed to settings where there are COVID-19 positive cases should be considered when choosing the sample for testing.
- The results of the RAT should be notified to the area MOH immediately for further action. The first few sporadic cases detected by RAT in a routine asymptomatic surveillance (in the absence of epidemiological link) need to be reconfirmed with secondary COVID-19 RT-PCR from the government sector under the guidance of the area MOH/RE. The RAT positive asymptomatic employees need to undergo home isolation/isolated in a place provided by the workplace till subsequent confirmation with RT-PCR is done. The RAT positive employees need to be advised to practice infection prevention and control measures strictly while in isolation. COVID-19 prevention measures in the workplace need to be practiced strictly at all times.

Indications for RT-PCR testing in a workplace setting

1. For a symptomatic employee testing negative with Rapid Antigen Test (RAT)
2. For an employee undergoing quarantine to exit quarantine RT- PCR to be done on the 10th day
3. If there are no COVID -19 positive employees for the past 2 weeks, asymptomatic random testing is to be conducted with RAT. If any employees are tested positive, the initial few RAT positive employees in the absence of an epidemiological link have to be tested with RT-PCR and confirmed.

Special Note

- On sending sample lists for COVID-19 RT-PCR, please adhere to preparing separate list and packages in the following categories without mixing samples with each other.
 - Samples from symptomatic individuals in a separate list and package (Indicate same household members together in the list)
 - Samples from asymptomatic surveillance in a separate list and package (Indicate same household members together in the list)
 - Samples for quarantine entry or exit PCR in a separate list and package (Indicate same household members together in the list)
- Refer the addendum for COVID-19 RAT result interpretation if necessary. PCR confirmation should be considered when necessary, according to the indications in the addendum for COVID-19 rapid antigen test (RAT)
- In general, the COVID-19 RAT and RT-PCR test results are valid for 3 days (72 hours) but there could be exceptions to this rule according to the context where additional testing can be recommended by the treating physician or virologist/microbiologist
- NMRA approved COVID Rapid Antigen Test (RAT) kits should be used always after proper training and under appropriate technical guidance and supervision

5. Addendum to the Revised Guidelines (Version 1.0) for SARS-CoV-2 Rapid Antigen Test (RAT)

The RAT is a useful diagnostic test for detection of SARS-CoV-2 infection in certain settings such as an urgent requirement of results or in a field setting. These tests have a shorter turn-around-time (15-30 minutes) compared to that of real-time RT-PCR (PCR) but sensitivity and specificity is relatively less. Positive predictive value for infectivity is relatively high in positive RAT results compared to positive PCR results.

Therefore, this guideline is revised to optimize detection of true positives considering pretest probabilities using clinical (i.e., asymptomatic or symptomatic) and epidemiological criteria (i.e., exposure) and also the current level of community prevalence of COVID-19.

General recommendations:

- Only NMRA authorized RAT kits should be used.
- Prescribed storage conditions must be maintained.
- Manufacturer instructions must be strictly adhered to at all times, with special emphasis on the prescribed reading time of results.
- For interpretation of RAT results, please refer “Practical considerations on conducting Ag RDT” in the guideline.

Interpretation of Results

(1) Asymptomatic persons without a known epidemiological link to SARS-CoV-2 infection within last 14 days (eg: Screening before endoscopy)

- **If RAT negative:** to be interpreted as not infected with SARS-CoV-2
- **If RAT positive:** to be confirmed with a PCR (if PCR negative, consider the patient as negative) (refer to specific recommendation #03)

(2) Asymptomatic persons with an epidemiological link to SARS-CoV-2 infection within last 14 days (eg: Contact screening in the community)

- **If RAT negative:** to be interpreted as no current evidence of SARS-CoV-2 infection (refer to specific recommendation #02)
- **If RAT positive:** to be interpreted as infected with SARS-CoV-2

(3) **Symptomatic person without known epidemiological link to SARS-CoV-2 infection within last 14 days (eg: ILI surveillance at OPD)**

- **If RAT negative:** be interpreted as no current evidence of SARS-CoV-2 infection (refer to specific recommendation #02)
- **If RAT positive:** to be interpreted as infected with SARS-CoV-2

(4) **Symptomatic person with an epidemiological link to SARS-CoV-2 infection within last 14 days (e.g.: first line symptomatic patients)**

- **If RAT negative:** to be confirmed with a PCR (refer to specific recommendation #03)
- **If RAT positive:** to be interpreted as infected with SARS-CoV-2

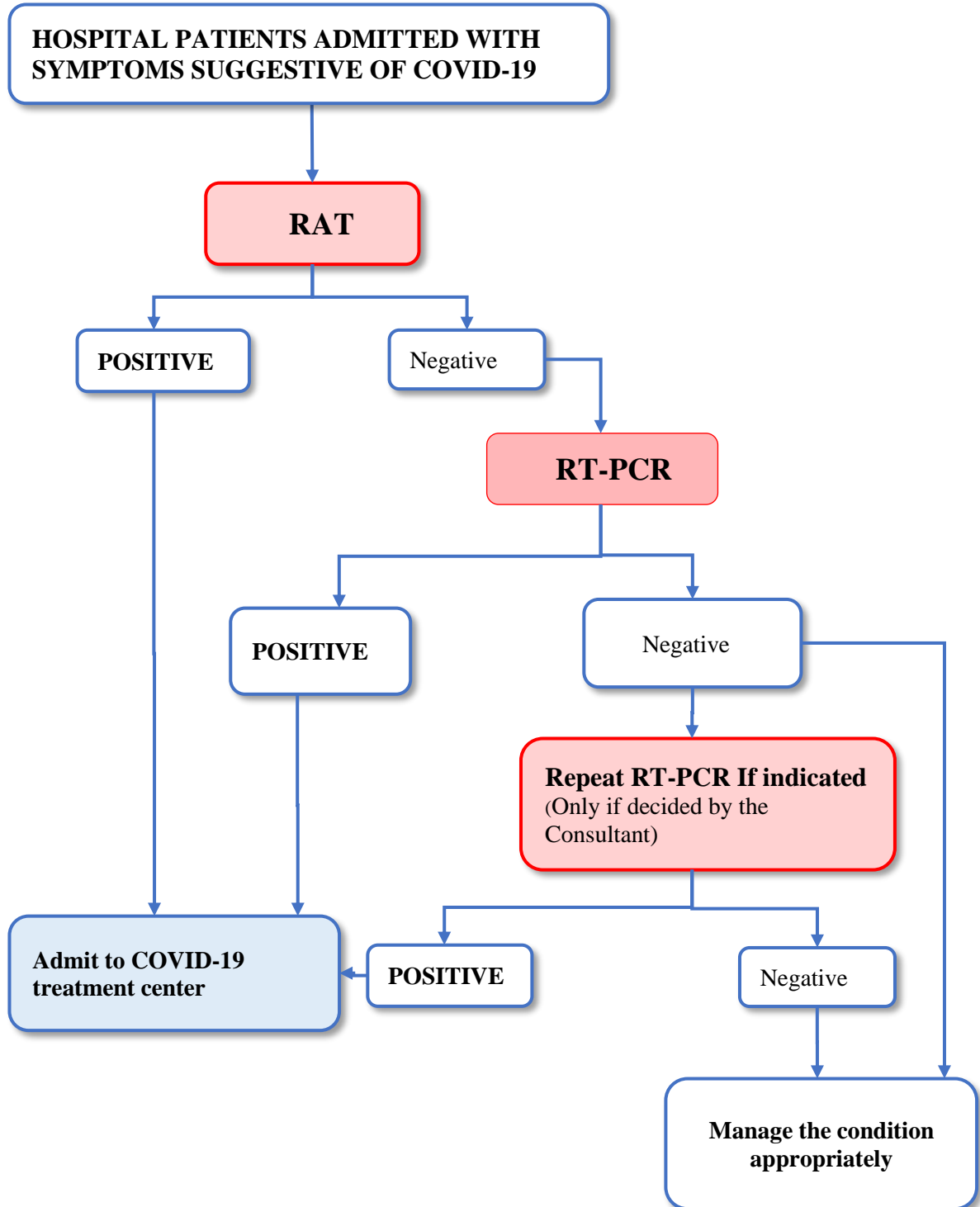
Specific recommendations:

1. Doubtful RAT results (e.g., faint test result bands, late appearance of test result bands) should be confirmed with a RT- PCR
2. Negative RAT results may be followed up with a RT- PCR if indicated for clinical and infection control purposes. (To be decided by either a consultant epidemiologist or microbiologist or virologist)
3. Samples taken for any confirmatory RT-PCR should be taken within 48 hours of the RAT to verify the RAT results. Even if 48 hours has passed, it is still necessary to do RT-PCR and confirm the status of the infection

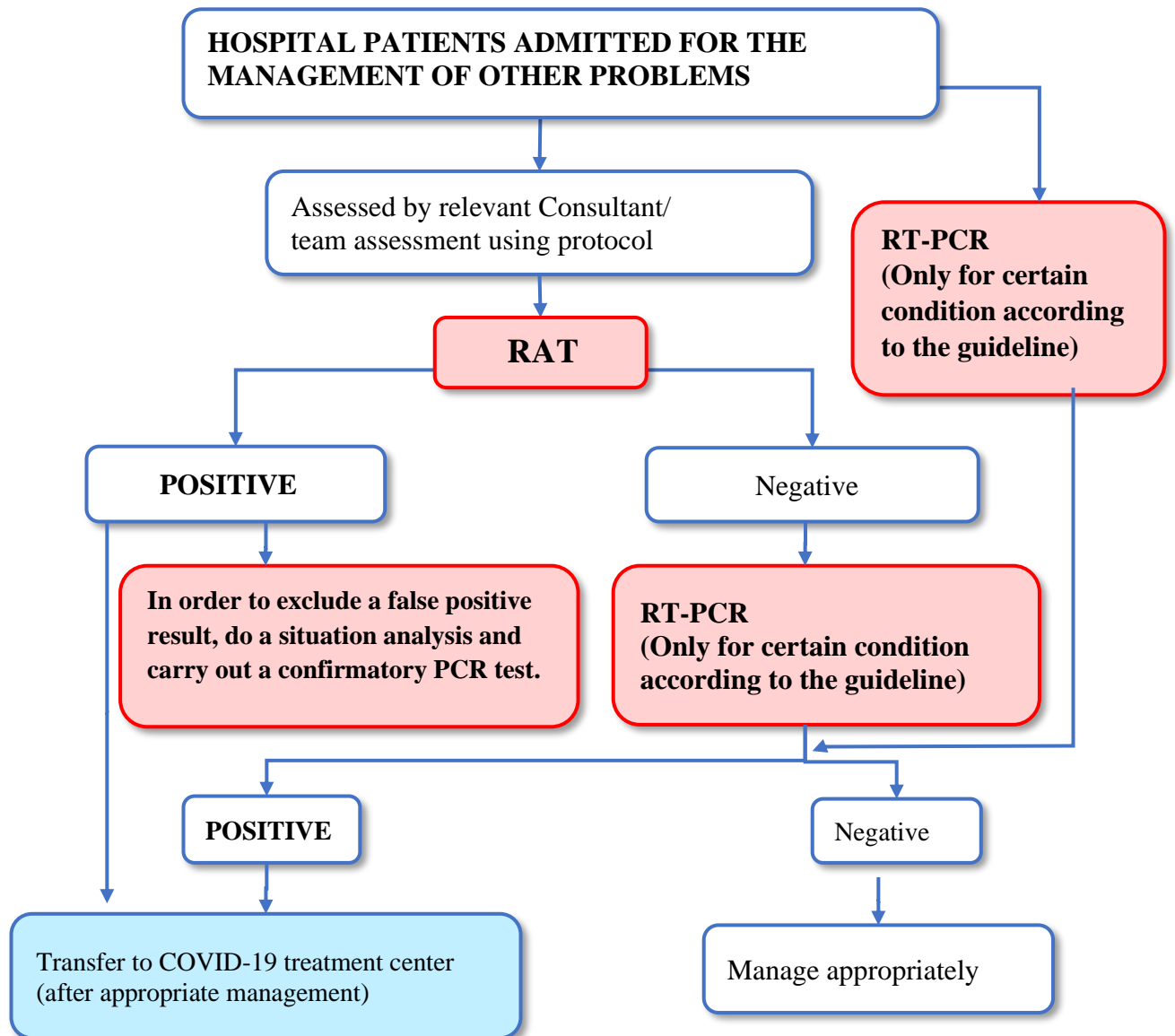
References:

1. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html> (accessed on 05.01.2021)
2. World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 2020.
3. <https://www.rcpath.org/discover-pathology/news/accuracy-of-lateral-flow-antigen-tests-for-covid-19.html> (accessed on 05.01.2021)

Annex 1(a) - HOSPITAL PATIENTS ADMITTED WITH SYMPTOMS OF SUSPECTED COVID-19

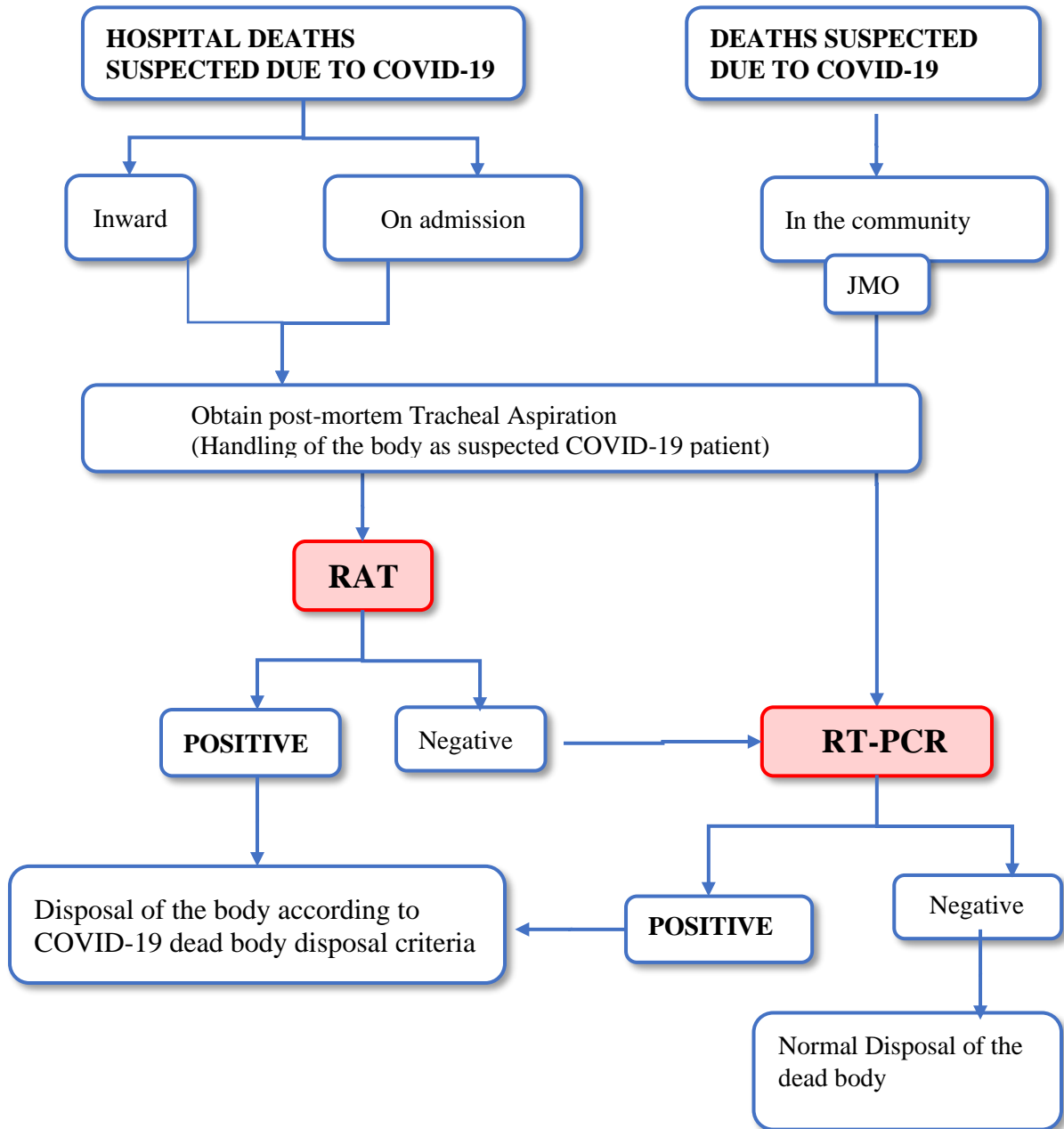


Annex 1(b) - HOSPITAL PATIENTS ADMITTED FOR THE MANAGEMENT OF OTHER



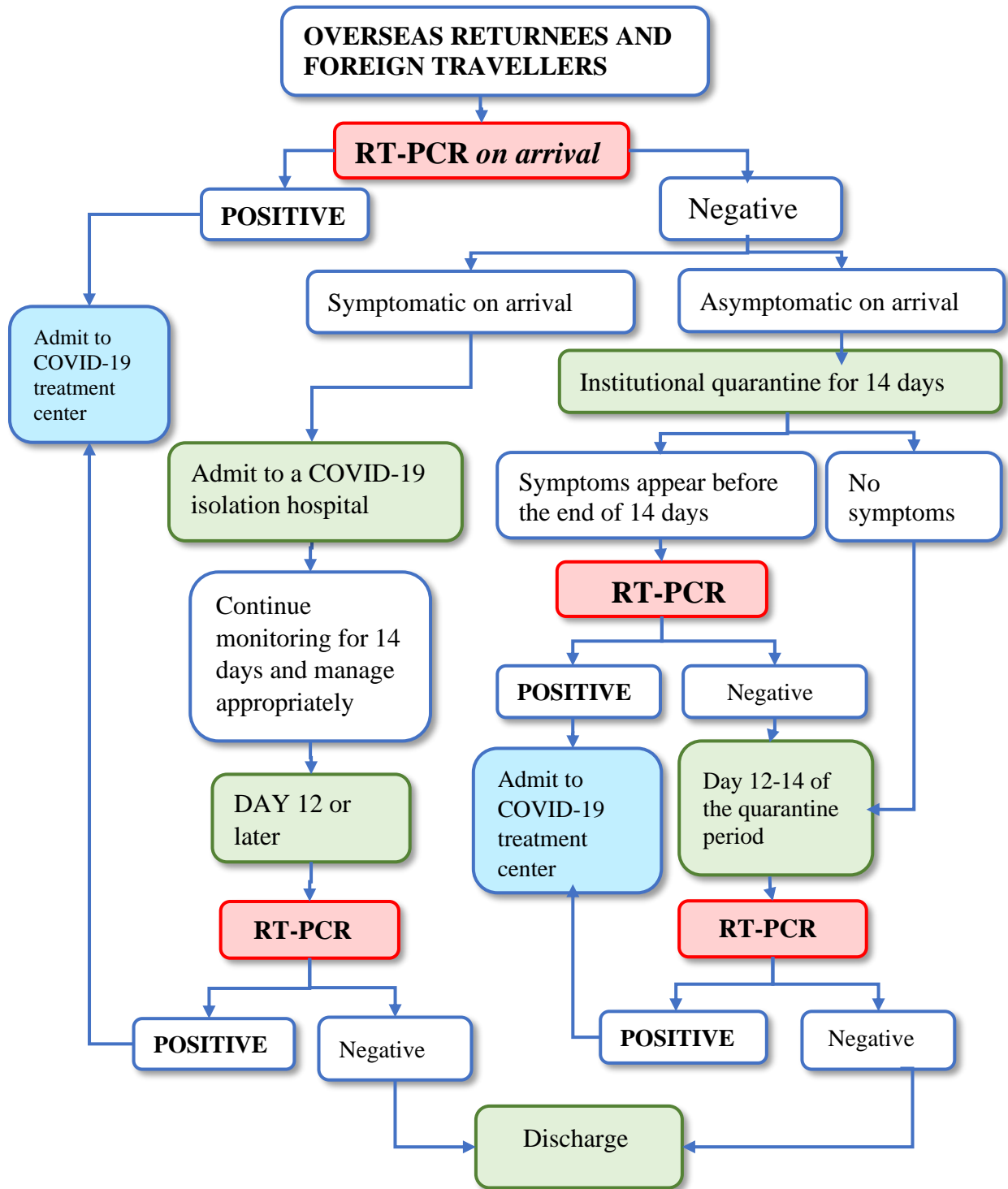
Annex 2 - DEATHS SUSPECTED DUE TO COVID-19

Adhere the steps on deciding testing for COVID-19 for Death Persons



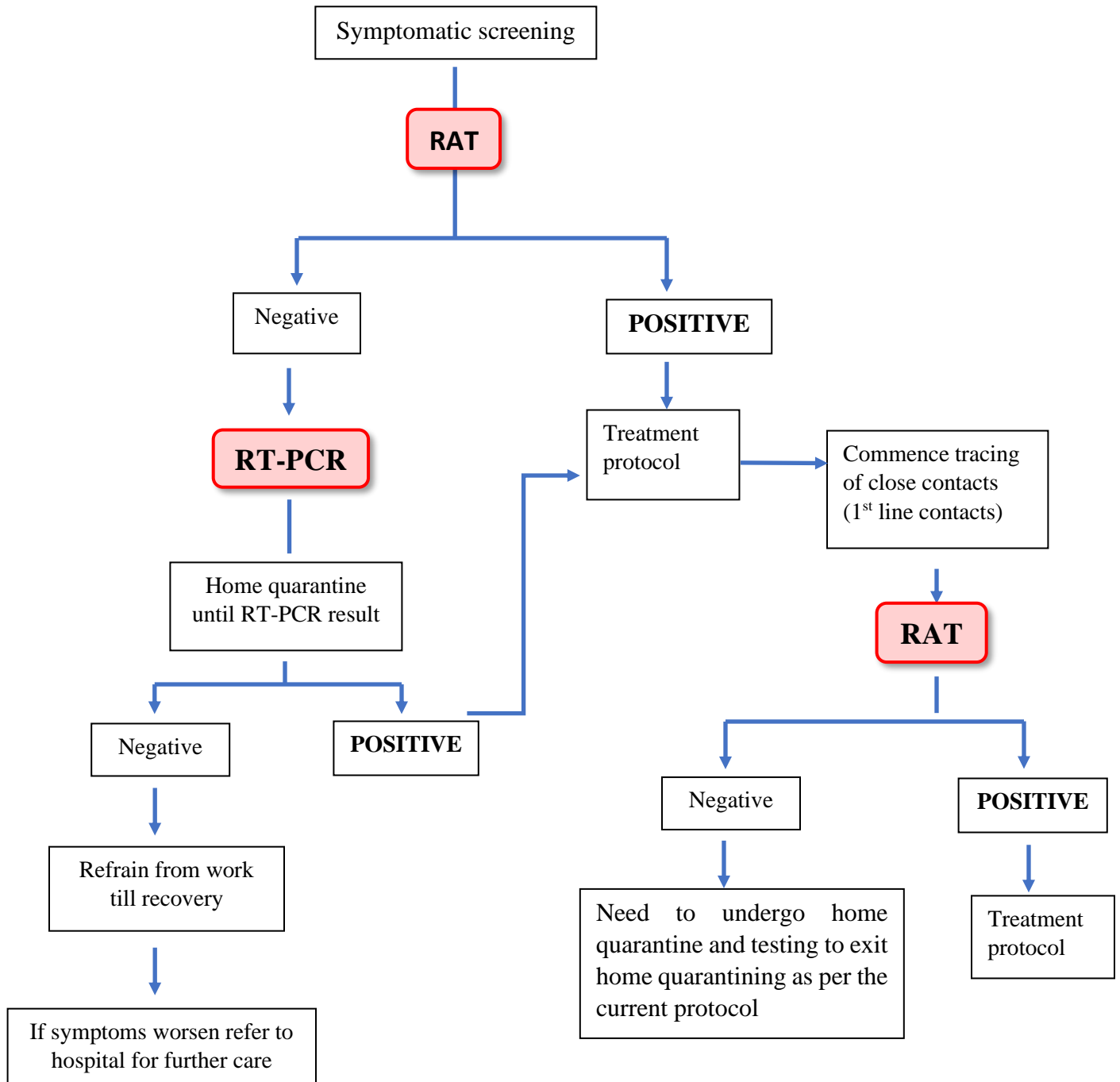
For handling and disposal of dead bodies of confirmed/ suspected COVID-19 patients - Refer **Provisional Clinical Practice Guidelines on COVID-19 suspected and confirmed patients.**
[Available at: www.epid.gov.lk]

Annex 3 - OVERSEAS RETURNEES AND FOREIGN TRAVELLERS



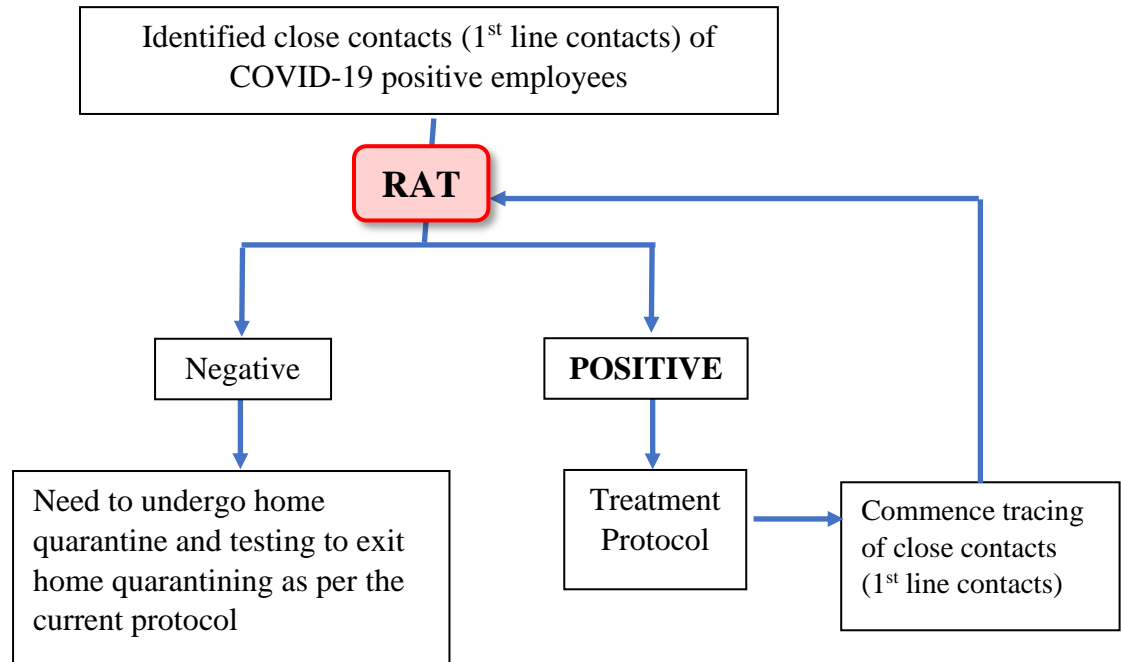
Annex 4(a) - EMPLOYEES IN WORKPLACES - I

Testing of all symptomatic employees to prevent the spread of COVID-19 and contain the disease

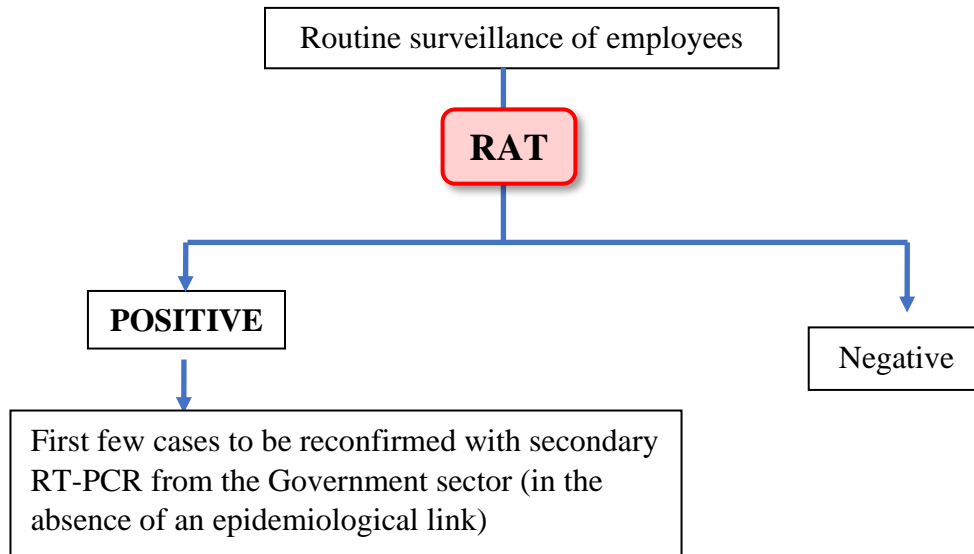


Annex 4(b) - EMPLOYEES IN WORKPLACES - II

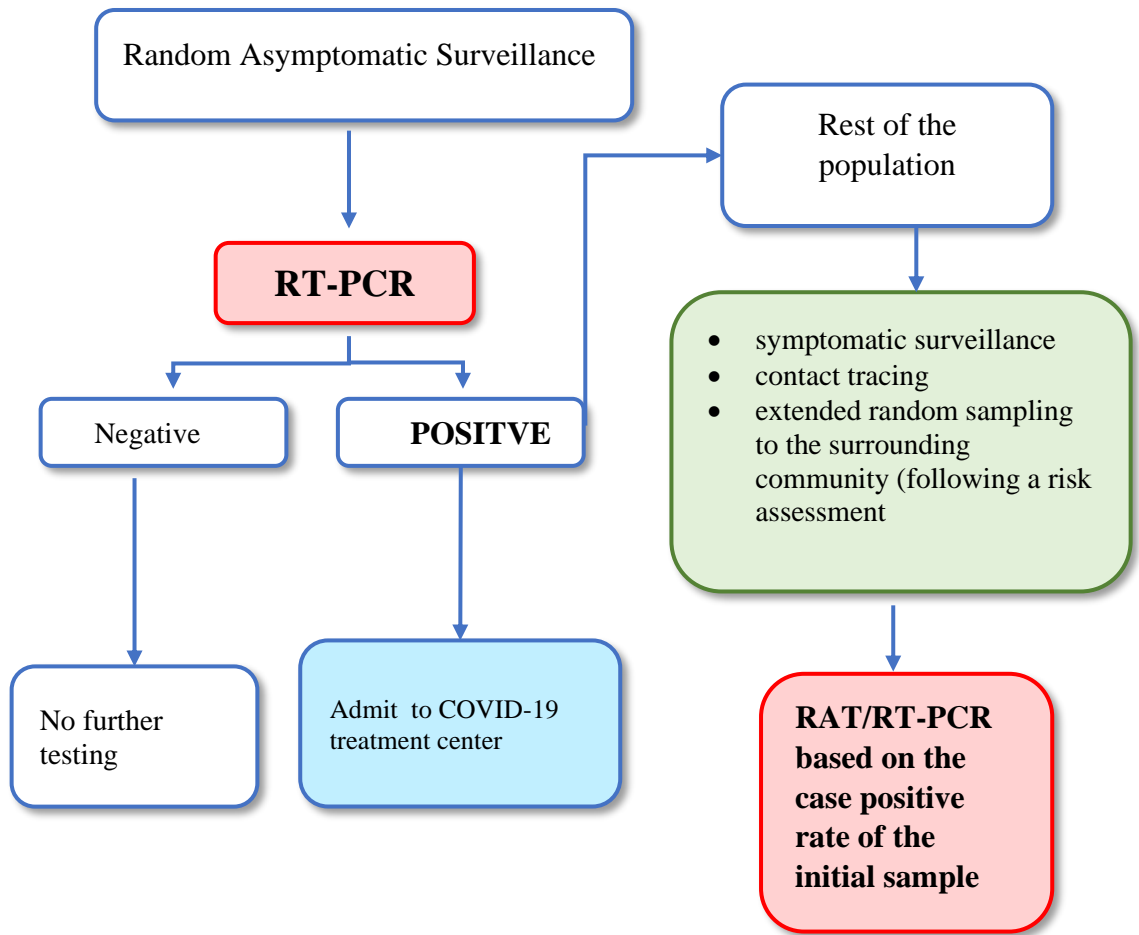
Testing of close contacts (1st line contacts) of confirmed COVID-19 employees



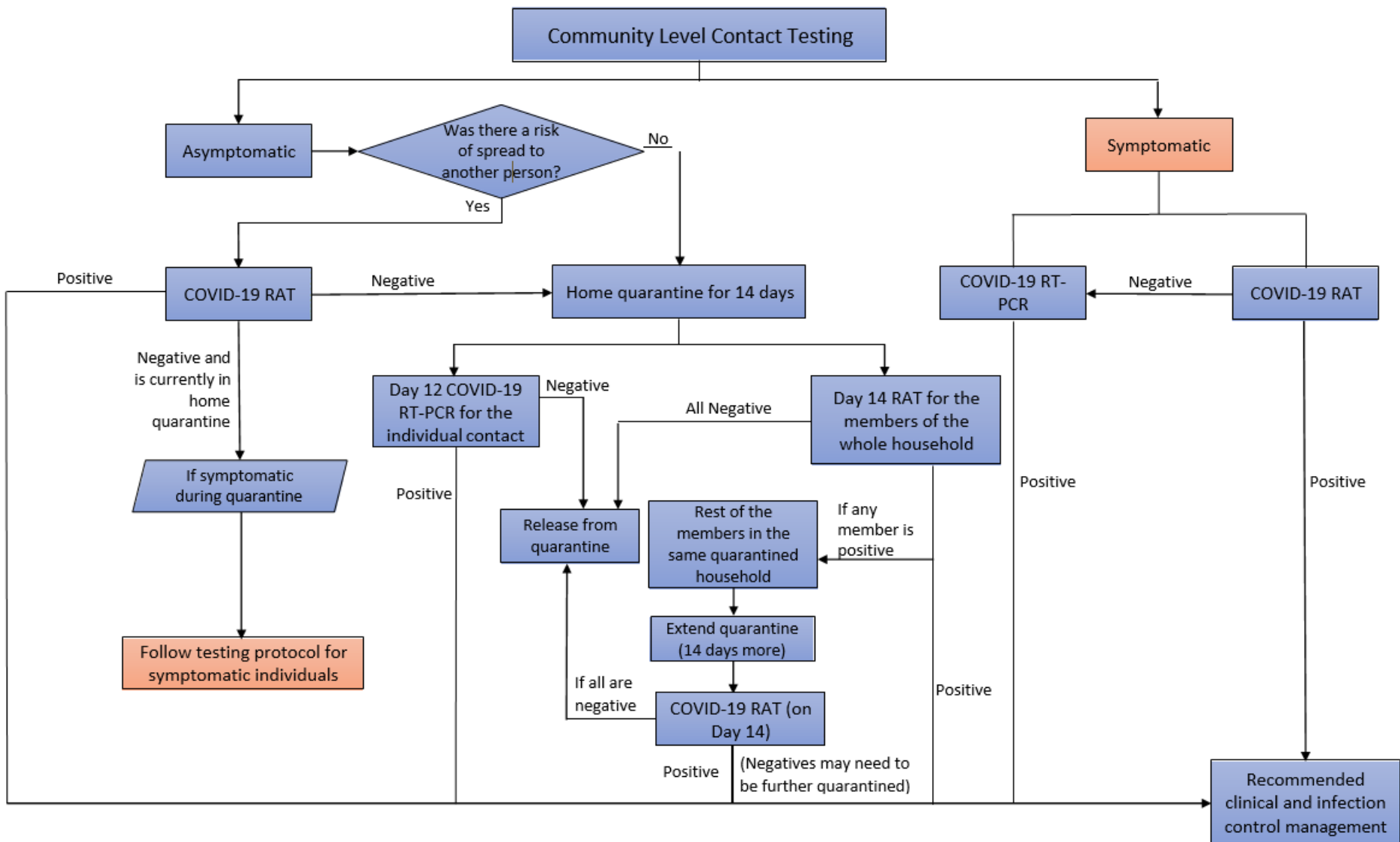
Routine asymptomatic testing for surveillance



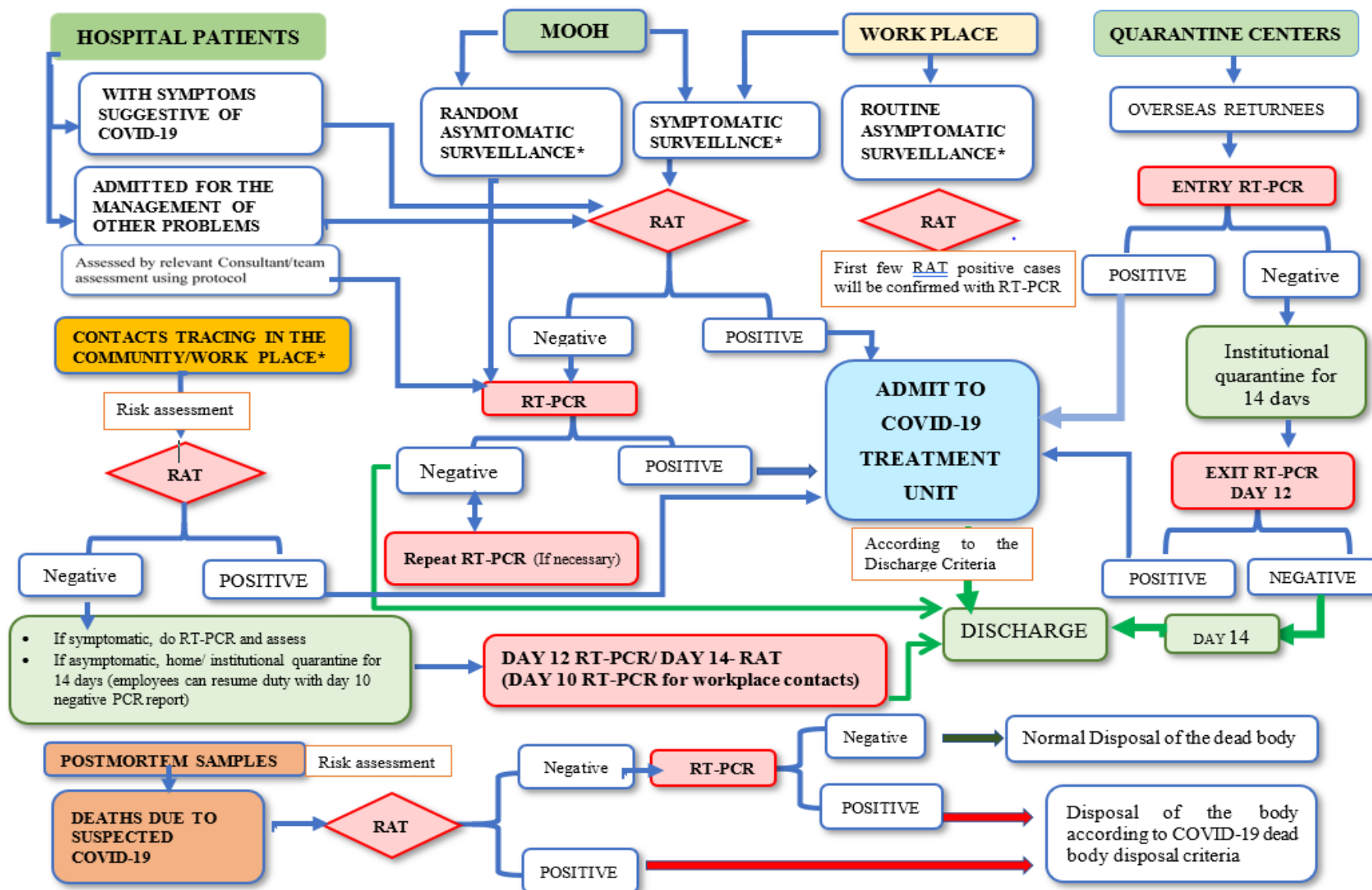
Annex 5 - RANDOM ASYMPTOMATIC SURVEILLANCE



Annex 6 – COMMUNITY LEVEL CONTACT TRACING



ANNEX 7- COVID-19 LABORATORY TESTING ALGORITHM*



*For details refer the relevant guidelines and flowcharts