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# Framework for COVID-19 testing for hospital patients in Wales

March 2021

The Welsh Government's refreshed testing strategy published in January 2021 retains our already established testing priorities. These include the need to support NHS clinical care, by diagnosing those infected so that clinical judgements can be made to ensure the best care, and to protect our NHS and social care services and individuals who are our most vulnerable. The refreshed strategy continues to focus on supporting people receiving care and/or being admitted to hospital. It includes testing to diagnose, to enable rapid identification of patients who are infectious, particularly those presenting to hospital so they can benefit from specific treatment for COVID-19. A confirmed diagnosis is also important to reduce uncertainty and the need for further investigations.

Safely maintaining a full range of clinical services depends on the prevention of nosocomial transmission of COVID-19. This requires the separation, as far as possible, of patients with COVID-19, even if asymptomatic, from those requiring care for other clinical conditions. This aim is more likely to be achieved by the regular and systematic testing of patients in hospitals. Transmission from and between staff should also be minimised by regular staff testing.

This paper discusses an approach to patient testing to prevent COVID-19 entering hospitals undetected, to prevent spread within hospitals, to reduce the risk to some particularly vulnerable cohorts of patients requiring treatment and to enable the safe discharge to home or community care. It is intended that the proposals will also have relevance to community hospitals, mental health facilities and independent hospitals (including hospices).

## **Purpose 1: to prevent COVID-19 in elective pathways**

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Where possible, patients with COVID-19 should not be admitted to hospital until they are non-infectious. This will not usually be possible to achieve when a patient presents with an emergency requiring immediate admission and care, but can be achieved for those being admitted on a planned basis for elective care.

There is evidence that patients who undergo surgery after contracting COVID-19 face a significantly increased risk with a post-operative mortality in one study of nearly 25%<sup>1</sup>. However, it has also been shown that mortality could be dramatically reduced by delivery of elective cancer surgery in 'COVID cold' sites or pathways, where services were redesigned, including the use of patient testing, to keep COVID-19 infection out as far as possible<sup>2</sup>.

The Nosocomial Transmission Group of Welsh Government has previously published 'A Principles Framework to assist the NHS in Wales to return urgent and planned services in hospital settings during COVID-19'<sup>3</sup>, including guidance for reverse transcription polymerase chain reaction (RT-PCR) testing of patients prior to elective admission. It advised that plans should be developed for pre-admission self-isolation with testing up to 72 hours in advance, taking into account the type of procedure/treatment to be undertaken. This requirement for extended self-isolation was reduced by the publication of the NICE rapid guideline<sup>4</sup>.

**NICE COVID-19 rapid guideline:  
arranging planned care in hospitals  
and diagnostic services (July 2020)**

All planned procedures needing anaesthesia (general, regional and local) or sedation, the service should:

3.7 Advise patients (and families and carers as appropriate) when and where they can have a SARS-CoV-2 test in line with local arrangements.

3.8 Advise patients to:

- follow comprehensive social-distancing and hand-hygiene measures for 14 days before admission (see government advice on social distancing)
- have a test for SARS-CoV-2 within 3 days before admission, (and the team should ensure the results are available before admission)
- self-isolate from the day of the test until admission.

This is a minimum suggested standard. In areas of higher prevalence or following discussion between patient and clinician, stricter isolation measures can be followed.

Discussions around quarterly planning indicate that all health boards have complied with this guidance in the re-establishment of some elective surgery.

## **Purpose 2: to prevent COVID-19 in elective pathways in those with previous COVID-19 infection**

It is now known that viral ribonucleic acid (RNA) may be detected by RT-PCR in upper respiratory samples for prolonged periods, in some cases more than 120 days, after an initial infection. However, the presence of viral RNA does not necessarily correlate with either the presence of live virus, or indeed infectivity. This can create the situation when a patient cannot be admitted for essential or urgent elective care because their RT-PCR test is positive, yet they are non-infectious. To avoid this, similar criteria can be applied to those used to establish a low risk of infectivity in hospital patients discharged to care homes after COVID-19 infection.

In November 2020 the Technical Advisory Group (TAG) to Welsh Government updated the consensus statement on testing criteria for the safe discharge of asymptomatic and non-infectious patients to care homes<sup>5</sup> and, following this in December 2020, the Minister for Health and Social Services issued a Written Statement: Discharge arrangements and duration of COVID-19 outbreaks in social care<sup>6</sup>.

The TAG advice states “Patients that have had COVID-19 during admission but who have had resolution of fever for at least three days and clinical improvement of symptoms other than fever, and are to be discharged from hospital to a care home or other step down care can be assumed to be non-infectious if:

- 20 days have elapsed since onset of symptoms, or first positive SARS-CoV-2 test, or
- 14 days have elapsed since onset of symptoms, or first positive SARS-CoV-2 test; AND an RT-PCR test is negative or ‘low positive’ with a CT [cycle threshold] value  $\geq 35$ .”

These are cautious criteria that can be used to enable a patient with a previous history of COVID-19 infection to be admitted safely to hospital for elective care.

In terms of admission of recovered COVID-19 from the community, Velindre University NHS Trust report that their current practice for oncology procedures, based upon pragmatic Public Health Wales (PHW) advice, is that if a patient tests positive, their treatment will be deferred for 14 days with the patient self-isolating. Assuming that the patient is symptom free after 14 days, treatment can proceed without a need for repeat testing.

### **Purpose 3: to identify COVID-19 in emergency care pathways**

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Acutely ill patients may require hospital admission whether or not they have COVID-19 infection. In this case the presence of COVID-19 cannot be prevented, but the isolation, segregation and safe management is significantly enabled if it can be identified, either by testing on admission or throughout the patient's stay.

Our first strategy for COVID-19 testing in Wales<sup>7</sup> and 'A Principles Framework to assist the NHS in Wales to return urgent and planned services in hospital settings during COVID-19'<sup>3</sup> both contained the expectation:

**"Emergency Admissions: test all patients on admission. For patients who test negative, further testing will be undertaken if COVID-19 symptoms are present or develop."**

This requirement has subsequently been reiterated in a letter from the Chief Nursing Officer and the Deputy Chief Medical Officer on COVID-19 testing on hospital admission. Despite this, the PHW Tableau database continues to indicate that only half of all admissions are tested, but this may be due to data definitions and collection issues. All Health Boards and Trusts should ensure they have robust data and that testing is being systematically deployed in all high risk settings.

One problem until recently has been delays caused by waiting for RT-PCR results. Patients may be isolated or cohorted in the emergency unit during this time, slowing the speed of admission and flow through the hospital, potentially exposing non-infected patients to transmission.

Such delays can now be in part avoided by the thoughtful use of rapid tests (rapid RT-PCR testing platforms, lateral flow devices or point of care test devices) to screen patients entering the hospital. Rapid RT-PCR testing has the same performance characteristics as routine RT-PCR but is a limited resource. Both lateral flow test devices (LFDs) and point of care tests have higher specificity than sensitivity, meaning that positive results tend to be more reliable than negative results.

An evaluation<sup>8</sup>, by PHW, of the Lumira DX point of care device in November 2020 found specificity of 99.6% and overall sensitivity of 73.3%. This increased to 87.8% for detection in samples with low CT values (<28) that come with higher viral load.

It is important to remember that the positive and negative predictive values of any test for COVID-19 depend on the likely prevalence of the disease in the population being tested. This means that when there is a lower likelihood of COVID-19, the probability of a positive being a false positive increases. Conversely, when there is a high likelihood of COVID-19, the probability of a negative being a false negative increases. The likelihood of any patient admitted as an emergency having COVID-19 will depend upon the prevalence of COVID-19 in the community and the individual characteristics, particularly symptoms.

These devices can therefore each be used to identify patients with COVID-19 in emergency care, accepting the need for careful interpretation of the result.

NHS England (NHSE) recently published a standard operating procedure (SOP)<sup>9</sup> for LFDs with the following guidance on action following the result in a patient with high likelihood of having COVID-19:

- Positive: treat patient as COVID-19 positive. There is no need to wait for the RT-PCR test result. However, as prevalence falls the definition of suspected COVID-19 will need to be sufficiently robust to avoid placing a patient in a COVID-19 stream inadvertently on the basis of a false positive result from a point of care test, for example lymphopenic, compatible radiological changes and absence of alternative diagnosis.
- Indeterminate: patient could be positive or negative. Isolate patient and wait for confirmatory RT-PCR test result.
- Negative: no change to current pathways. Patient could still be positive, isolate patient and wait for confirmatory RT-PCR result.

Emergency admissions to hospitals in Wales may be tested using a rapid technology, as well as by RT-PCR. The NHSE SOP and flow chart for testing of emergency patients and allocation to red, amber and green pathways may be followed, noting the caveats around the reliability of the result considering a pre-test probability changing with community prevalence.

Based on the Welsh Lumira DX evaluation (sensitivity 73.3%, specificity 99.6%), the predicted outcomes from testing for a population of 1,000 with prevalences of 2% and 25% are shown in the table.

| Specificity | Sensitivity | Prevalence | PPV  | 1000 tests             |                |                 | NPV  | 1000 tests             |                |                 |
|-------------|-------------|------------|------|------------------------|----------------|-----------------|------|------------------------|----------------|-----------------|
|             |             |            |      | Total positive results | True positives | False positives |      | Total negative results | True negatives | False negatives |
| 99.6%       | 73.3%       | 0.5%       | 0.48 | 8                      | 4              | 4               | 1.00 | 992                    | 991            | 1               |
|             |             | 2%         | 0.79 | 19                     | 15             | 4               | 0.99 | 981                    | 976            | 5               |
|             |             | 25%        | 0.98 | 186                    | 183            | 3               | 0.92 | 814                    | 747            | 67              |

This shows that in an asymptomatic population with low community prevalence (2%) a negative result is highly reliable (negative predictive value; NPV 99%), but a positive result is much less reliable (positive predictive value; PPV 79%). For a symptomatic population with high community prevalence (25%) a negative result is less reliable (NPV 92%), but a positive result is much more reliable (PPV 98%).

In a very low prevalence population (0.5%) the PPV is only 0.48 (48%), so approximately half of positives will be false positives, so such results must be confirmed by RT-PCR.

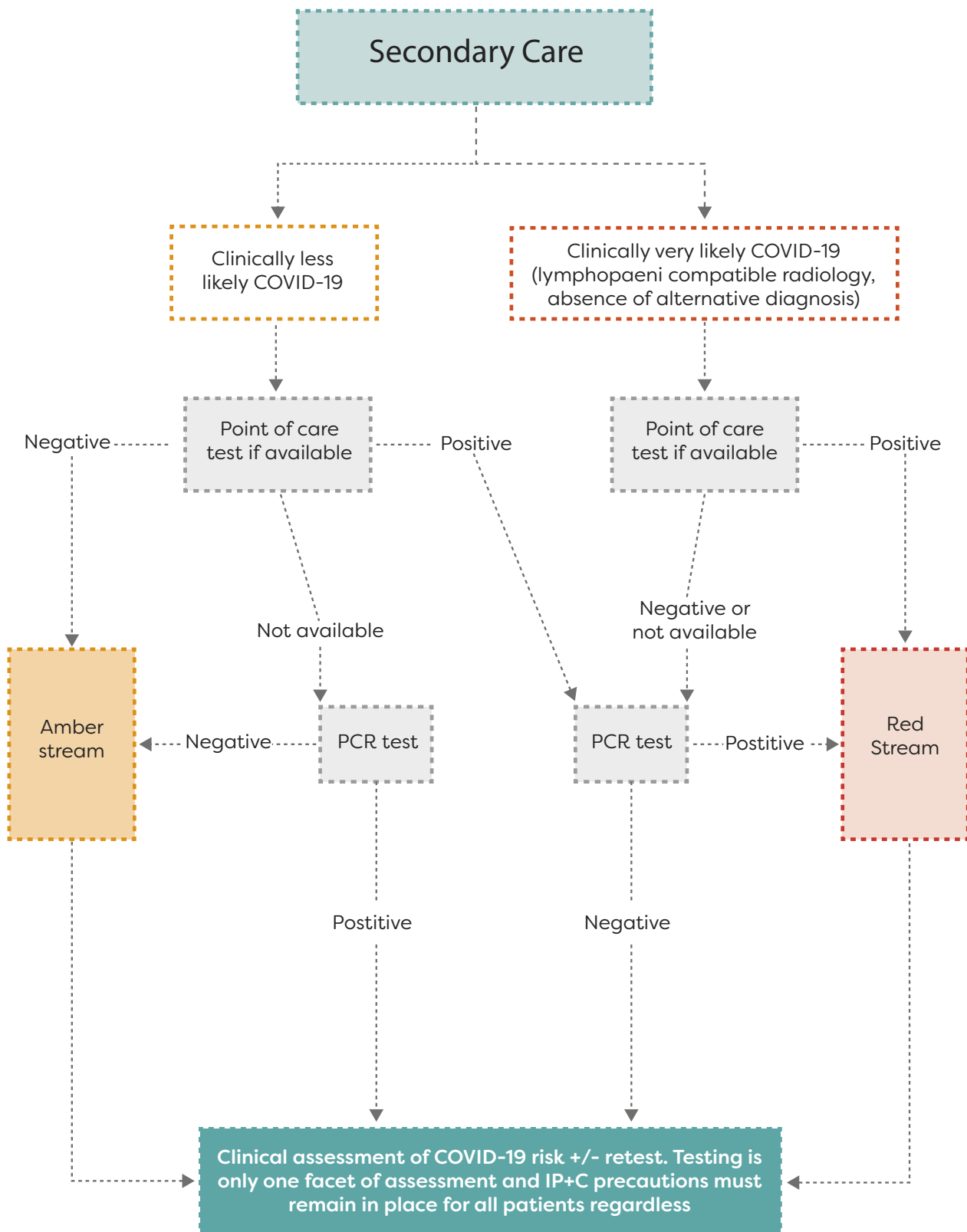
In a high prevalence population (25%) the NPV is only 0.92 (92%), so approximately 10% of negatives will be false negatives, so it will be advisable to confirm the negative results using RT-PCR.

So, in summary, patients being admitted may also be screened using validated point of care testing technology. During a period of low community prevalence, in patients without COVID-19 symptoms, a positive point of care test result must be confirmed by RT-PCR (with appropriate isolation of the patient whilst this result is awaited). A negative test has a similar utility to a negative RT-PCR test in asymptomatic screening, but neither results exclude the diagnosis of COVID-19 and full infection, prevention and control precautions must still be followed (see the flowchart on page 6).

All tests must be interpreted in the clinical context of the patient's symptoms, the background community prevalence and other available results. No decision should be made on the basis of the test result in isolation.

In those who test negative on admission, the revised Wales Testing Strategy recommends repeating RT-PCR testing at 5 days to ensure that patients have not become positive and infectious after their admission. It is suggested that further

retesting of inpatients should occur at 5 day intervals and, in areas with high rates of nosocomial transmission, an additional regimen of retesting at 3 and 7 days may be adopted.



## **Purpose 4: to reduce risk to patients at higher risk**

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Some patients may be at a particularly high risk of death after COVID-19 due to their pre-existing medical conditions. Some clinicians in Wales have argued that enhanced testing regimens in such patient groups may help to minimise their risk. Although testing does not in itself provide protection comparable to the standard infection prevention and control procedures that should operate in hospitals, it is accepted that there should be some local clinical discretion on the testing of those at highest risk.

Patients who might be considered for enhanced testing regimes should include those who are clinically extremely vulnerable and on the shielding patient list. The case has been made in this framework to include those with renal disease requiring dialysis and patients attending for treatment of cancer although the estimation of numbers in this section is indicative only.

It is also understood that there will be several patient groups, such as those waiting for transplant surgery or for therapeutic procedures, which are not specified here but for whom a similar provision will be made. This will be determined on a local or regional basis.

### **Patients undergoing renal dialysis**

In Wales there are 1,200 patients attending dialysis units for treatment, with approximately half aged 65 or below. In order to attend for treatment, many patients have to share ambulance transport and waiting areas before and after treatment. The risk for dialysis patients is further heightened by the fact that asymptomatic carriage and atypical disease presentation appears common within this population.

Renal Registry surveillance reports<sup>10</sup> show that around 12% of adult patients receiving haemodialysis in the UK have had confirmed symptomatic COVID-19 and 22% of these have died. Compared to the general population with COVID-19, the relative risk of death in dialysis patients with COVID-19 was 45.4<sup>11</sup>.

Testing of patients attending dialysis units in Wales before each treatment would require approximately  $1,200 \times 3 = 3,600$  tests/week, but may be considered justified for the protection of others if the identification of the asymptomatic patient with a positive test enables greater segregation of pathways.

### **Patients with cancer**

COVID-19 illness may be more serious in patients who are immunocompromised because of cancer and these patients still need to attend hospital for investigations and treatment. The original study in cancer patients from Wuhan identified a mortality rate of 28.6% in 28 cancer patients infected with COVID-19<sup>12</sup>. The Wales Cancer Network reports that in May 2020 the UK Coronavirus Cancer Monitoring Project had registered over 1,000 patients and demonstrated that while 55% have mild symptoms, 45% had severe or critical symptoms with 30.7% ultimately dying of COVID-19.

The evidence continues to highlight that cancer patients are at risk of severe infection and poor outcome but without anti-cancer treatment there will be an increased risk of cancer associated mortality.

Treating clinicians advise that rapid COVID-19 testing of staff and patients immediately prior to cancer treatment may help minimise exposure. Specifically it is suggested that asymptomatic patients with a positive test could be treated and transported home in isolation.



## **Purpose 5: To show non-infectivity prior to discharge of patients with a history of COVID-19**

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This has been covered in part in the preceding section on how to assess non-infectivity in patients with a prior history of COVID-19 due to be admitted for planned elective care. TAG criteria<sup>5</sup> for safe discharge to care homes are advised. These criteria seek to enable safe discharge which might be possible at an earlier date than from awaiting a negative test result.

To re-emphasise, patients can be discharged from hospital to other care settings when they are either:

- 20 days post symptom onset or first positive RT-PCR test (whichever is earlier) without the need for further testing and regardless of any test result if a test is done, or
- 14 days post symptom onset or first positive RT-PCR test, and a negative or low level RT-PCR result.

The only caveat to this is in those who are heavily immunosuppressed in whom individual risk assessment and/or discussion with infection specialist is required. The groups covered by this are defined here:

<https://www.gov.uk/government/publications/covid-19-guidance-for-stepdown-of-infection-control-precautions-within-hospitals-and-discharging-covid-19-patients-from-hospital-to-home-settings/guidance-for-stepdown-of-infection-control-precautions-and-discharging-covid-19-patients#immsupp>.

A negative RT-PCR test would still be required prior to discharge in a patient with no past history of COVID-19. This is illustrated in the discharge testing algorithm in the Appendix.

The above does not necessarily capture patients with transient visits or short stays in an Emergency Department/Admissions Unit. This patient movement undoubtedly creates a risk of acquiring COVID-19 and returning to the care setting whilst incubating infection, however testing will be uninformative in this situation.

A requirement for a negative test result in an asymptomatic patient which delays discharge increases the risk of COVID-19 acquisition by increasing length of stay in hospital, and should therefore be avoided wherever possible. This does not include patients with a presentation compatible with COVID-19 who will require testing and clinical assessment to exclude the diagnosis. The principal intervention to reduce risk to the care environment will be isolation of these patients on return from hospital, suggested for a minimum of 10 days.

Testing data is routinely monitored and is made publicly available via Public Health Wales and Welsh Government Official Statistics. The published information currently includes RT-PCR tests only as there are established flows of laboratory testing data. Point of care testing flows are in the process of being formally established and will be used to monitor compliance with this framework. Testing data and results are stored in the patient record according to local practices.



## Summary

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1. Undertake pre-admission RT-PCR testing in all patients due to be admitted for elective treatment.
2. Implement the 'discharge to care home' criteria of non-infectiousness for all planned elective admissions with previous history of COVID-19 infection.
3. Ensure robust and consistent data collection of testing practice for local and national assurance.
4. Emergency admissions may be tested using LFD or suitable rapid point of care devices like Lumira DX, in addition to RT-PCR, interpreting the results in the context of the likelihood of COVID-19 infection.
5. Follow the NHSE standard operating procedure for emergency admissions and pathways.
6. Repeat RT-PCR test at 5 days after an initial negative result and at 5 day intervals and consider retesting at 3 and 7 days in areas of high nosocomial transmission.
7. Consider enhanced testing of patients who are clinically extremely vulnerable or receiving dialysis and cancer care in hospital.
8. Follow published Welsh Government guidance on testing prior to discharge to care homes or other health or social care facility.

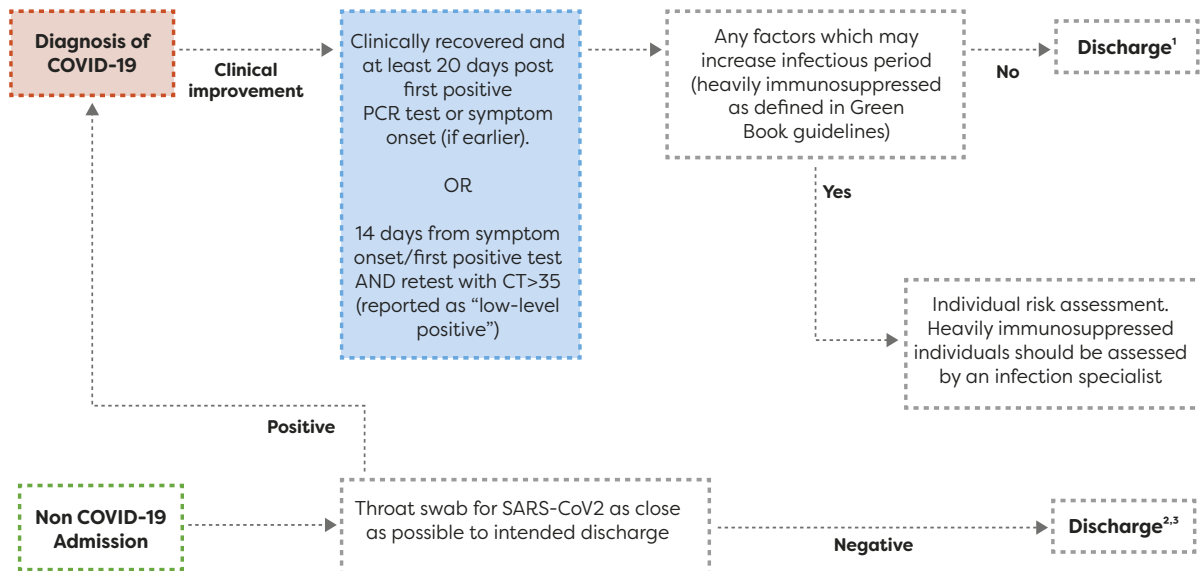
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# Appendix

## Testing algorithm to facilitate discharge to placement or care package



### NOTES:

1. Strong clinical evidence confirms that patients >20 days post symptom onset who have clinically recovered are not an infectious risk, but may have a significant delay before they achieve a negative PCR test. Repeat testing of individuals recovering from COVID-19 greater than 20 days post onset is rarely required and a positive test >20 days post symptom onset is not a contraindication to discharge.
2. Patients discharged who have not had COVID-19 and test negative on discharge should be isolated for 14 days in their destination setting. In a care home this means all personal care is provided in an individual's own room by staff wearing PPE and the home has been risk assessed as able to meet the standards of infection control able to support the quarantine period.
3. A negative swab in an asymptomatic individual who has never had COVID-19 provides only minimal reassurance, strict IP+C precautions and isolation must be observed as the patients may still develop symptoms after discharge and transmission may occur BEFORE symptoms develop.