

**Options for the use of rapid antigen tests for COVID-19**

11 November 2020

Scope of this document

On 28 October 2020, a European Commission Recommendation on COVID-19 testing strategies, including the use of rapid antigen tests (RATs) was published [1]. That recommendation calls for EU/EEA Member States to agree on criteria to be used for the selection of RATs, to share and discuss information on results of validation studies. This ECDC document is intended to facilitate further discussions between Member States with the aim to reach agreement on criteria to be used for the selection of RATs, as well as scenarios and settings during which rapid antigen tests are appropriate to be used. Furthermore, the document is intended to support clinical validations of RATs.

Summary [to be developed]

Background

Timely and accurate COVID-19 testing is an essential part of surveillance, contact tracing, infection prevention and control, and clinical management of COVID-19. ECDC proposed an objective-driven testing strategy for the EU with specific recommendations by level of virus circulation in the community, taking into account available public health resources and testing capacities [2].

To date, testing for SARS-CoV-2 infection mostly relies on reverse transcription polymerase chain reaction (RT-PCR) performed on a nasopharyngeal specimen. This testing method remains the gold standard for detecting SARS-CoV-2 and is characterised by both high sensitivity and specificity to detect viral ribonucleic acid (RNA). The current EU level case definition of a confirmed COVID-19 case relies on detection of SARS-CoV-2 RNA in a clinical specimen by RT-PCR [3], however, there are intentions to update the case definition shortly.

Diagnostic laboratories routinely perform RT-PCR tests, which require extraction of viral RNA as well as stationary instrumentation for nucleic acid amplification and detection. Theoretically, the time required to perform the RT-PCR test is few hours, however, specimens often need to be transported from the place of sampling to the laboratory, and then additional time elapses until the specimen is actually processed. Additionally, limited internal laboratory capacity, including trained staff, as well as high sample volumes may contribute to the delayed processing of samples. Hence, the turn-around time can easily increase to several days. Early in the pandemic, most of the testing capacity was reserved to identifying cases in hospitals and high risk-settings. Since then, laboratory capacity has increased and testing been extended to comprehensively identify symptomatic cases and contacts of cases, and to perform screening programmes. The current upsurge of COVID-19 cases in Europe, coupled with the usual rise of other respiratory infections during autumn, has led to a dramatic increase in the demand for COVID-19 tests. The high volume of samples reaching the laboratories could lead to a shortage of reagents and disposables as already reported by some countries, and to a further increase in the turn-around time for RT-PCR tests.

To complement RT-PCR testing, several countries have already started clinical validation of RATs performance and some have integrated RATs use in their national testing strategies [4-10]. World Health Organization [11], Health Canada [12] and the US Centre for Disease Control and Prevention (CDC) have recently issued guidelines for the use of RATs [13].

Benefits and challenges with use of RATs

RATs offer multiple benefits in comparison to RT-PCR tests for detection of SARS-CoV-2. RATs have been developed as both laboratory-based tests and for near-patient use (point-of-care), and results are normally generated in 10-30 minutes after start of the analysis. Some of the RATs require a laboratory instrument for the analysis, but others do not as the analysis is performed on a handheld cartridge with visual readout (Annex 1). RATs generally offer low cost testing and relatively simple handling. Due to the timeliness of results, RATs can provide added value e.g. in patient triage process in the health care settings at admission. In the context of contact tracing, RATs can allow for a more rapid identification of contacts and a more frequent monitoring of their infectious status while in quarantine through recurring testing by RATs.

Sampling for detection of SARS-CoV-2 relies mostly on nasopharyngeal, throat or nasal swab specimen. These specimens require professional sampling, including sample taker using the appropriate personal protective equipment. Mostly nasopharyngeal specimens have been indicated for use in RATs by the manufacturers. The option for reliable self-sampling is not yet clinically validated for RATs. RATs lack internal controls for confirmation of proper inclusion of human cells to confirm appropriate sampling. As many of the RATs are processed individually, analysis of large volumes of specimens simultaneously is not possible and multiplex analysis of other respiratory pathogenesis is not possible either. An additional drawback with the RATs is that the specimens are not necessarily shipped to public health laboratories for further characterisation, such as sequencing.

In contrast to RT-PCR, which amplifies the virus target sequences and has generally a high sensitivity, RATs detect the presence of a viral antigen in the patient’s specimen without amplification. Most of the currently available RATs show a lower sensitivity as compared to the standard RT-PCR test (Annex 1); however, their specificity is generally reported to be high (Annex 1) [14,15]. Important to state, RATs may be sensitive enough to detect cases with high viral load, i.e. pre-symptomatic and early symptomatic cases (up to 5 days from symptom onset; or low RT-PCR cycle threshold (Ct) value <25), which likely account for a significant proportion of transmission (Annex 1). Ct value of 25 correlates with approximately 10e6 viral RNA copies per millilitre [15], depending on the technical setup of the RT-PCR. Several countries that started to use RATs, therefore target early detection of COVID-19 cases, i.e. testing individuals with COVID-19 compatible symptoms early after disease onset.

Regulatory considerations for diagnostic tests

Commercial reagents, control materials, testing kits, and instruments intended for diagnostic use are referred to as *in vitro* diagnostic medical devices (IVDs). To be placed on the EU market, these devices must be affixed the CE-IVD label in compliance with the European in vitro diagnostics directive (98/79/EC). It is, however, important to note that the CE-marking is based on a self-declaration by the test manufacturer, including the claims on test performance. Independent information on the clinical performance of these tests in terms of sensitivity and specificity is often limited, and yet this is critical for proper interpretation of results. Under the current directive, it is up to the individual Member State to grant final authorisation to use a specific device for diagnostic purposes.

The determination of diagnostic accuracy should be performed in clinical studies using head-to-head comparison with the gold standard reference RT-PCR test in the target population intended to be tested, see below. Preferably, such validation studies would be complemented with virus cultivation data from patient samples.

**Current data on RAT performance and use**

The World Health Organization (WHO) initiative FIND (Foundation for Innovative New Diagnostics) gives an overview of SARS-CoV-2 tests that are commercially available or in development for the diagnosis of COVID-19, including an indication if they are CE-IVD marked [16]. As of 11 November 2020, there are 56 antigen tests with a CE-IVD label listed on the FIND database.

Both WHO and the United States Food and Drug Administration (FDA) have provided emergency use listings or authorisations, respectively, for RATs. WHO has listed two [17] and FDA seven RATs [12,18].

ECDC has performed a meta-analysis of the clinical performance of commercial SARS-CoV-2 tests, including four rapid antigen tests, up until 22 August 2020 [14]. Searching literature (pre-prints and peer-reviewed articles and including personal information from the European COVID-19 laboratory network partners) for RATs with a CE-IVD mark, we could retrieve additional results of clinical evaluation studies for 9 RATs from 8 companies by October 23rd, 2020. Independent evaluations were performed in several countries, predominantly in symptomatic populations. The sensitivities and specificities were calculated against the RT-PCR tests and ranged between 29% (95%CI 15.7-42.3) and 93.9% (95% CI 86.5-97.4) for test sensitivity and between 80.2% (95% CI 71.1-86.7) and 100% (95% CI 98.8-100) for test specificity. The substantial differences in performance noted between the tests and between the studies can be partially explained by different populations and time of testing (proportion of persons that were tested early versus late in the course of the disease). Some studies confirmed that the sensitivity of tests was higher in specimens obtained within 7 days after onset of symptoms and for samples with lower Ct value and indicating higher viral load. The data collected from validations of CE-IVD marked tests in Annex 1 contains available information on time point of sampling and stratification by Ct values if those were reported.

Infectivity is associated with high viral loads resulting in RT-PCR Ct values below 25-30 [19]. Cases positive in RT-PCR with higher Ct values have been considered non-infectious in one study [13]. Since positivity by RAT generally requires samples of high viral load identification of potentially infectious cases is a possible use for RATs. False negative RAT-results have been identified in samples with a low viral load, consistent with low number of viable virus and low infectiousness.

Most available RATs on the market are developed for testing in symptomatic persons and are not currently recommended for use in asymptomatic persons.

The use of RATs in the EU/EEA Member States

A survey, conducted by the European Commission Health Security Committee in September 2020, investigated the Member States’ practices in using RATs. Overall, of the fifteen EU Member States that responded to the survey, five EU Member States are using RATs for some aspect of the response to the COVID-19 pandemic. Nine out of the fifteen countries are currently carrying out clinical validation studies or pilots to assess the clinical/diagnostic performance and potential use of rapid antigen tests. However, two Member States are not considering the use of RATs [personal communication[[1]](#footnote-2)]. The context of applying the tests vary. Some countries use the tests as part of their testing strategy for early identification of cases, conducting contact tracing, and/or implementing rapid isolation and quarantine of detected cases and their contacts. Other countries use RATs specifically to ensure laboratory testing in remote areas where the gold standard RT-PCR is not available or timely enough. One country uses them for testing travellers and in schools.

Options for the use of RAT

Besides the performance of the test, other practical and strategic aspects play a significant role in deciding if a test can be used and with which indications. Examples of considerations are for example timeliness of test results, the scalability, the simplicity of use, instrumentation availability, human and material resources, and overall logistical arrangements for sampling and testing and costs. The epidemiological situation per setting, local area, region and nationwide affects the testing strategy. In this section we outline some generic aspects that countries meet when deciding to use a RAT.

**Minimum performance requirements**

WHO recommends that RATs which meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity, compared to a RT-PCR, can be used to diagnose SARS-CoV-2 infection in a range of settings where RT-PCR is unavailable or where prolonged turnaround times preclude clinical utility [19]. ECDC agrees with the WHO minimal criteria and acknowledges that the tests need to be validated for the intended setting and situation. RATs should be applied in a way, which compensates for the lower performance as compared to RT-PCR, i.e. by including repeat testing for screening purposes and confirming test results by RT-PCR (see description for settings and Figure for more details). As the positive (PPV) and negative (NPV) predictive values of all tests are dependent on the epidemiological situation in combination with test performance, ECDC would strongly suggest to aim for use of tests with performance closer to RT-PCR, i.e. ≥90% sensitivity and ≥97% specificity. Certain testing scenarios would probably allow for RATs which only meet the minimum performance criteria. A risk analysis should be performed that includes the probability of incorrect results, and the potential impact of these on the population or individuals tested. Sub-optimal performance of tests can be mitigated by confirmatory testing by RT-PCR (see below for examples of settings and needs for confirmatory testing; Figure) or using a scheme of repeated testing that maximizes the possibility to test individuals when viral loads are within the sensitivity range of the tests.

**Considerations for test validations**

The clinical performance of a test should be evaluated for the intended use and conditions, e.g. target population, type of specimen, sampling method and pre-analytical factors. A test intended for early detection of cases with presumed high viral load needs to be validated using samples from cases in this phase of infection. A validation exercise using a sample collection covering the full spectrum of infected individuals in different stages of infection would not be useful here. In addition, the manufacturer instructions should be carefully followed for validation and practical use of the test [20,21].

ECDC concur with the validation model for RATs presented by FIND [21]. In the validation study, the performance of the new test should be compared the current gold standard RT-PCR. Prospective clinical comparison using fresh respiratory swabs is the preferred study model, however, a retrospective approach using stored respiratory specimens can also be used, provided that equivalence between fresh and stored samples is demonstrated.

In the prospective study design, two respiratory swabs are collected per participant: one for RT-PCR testing and diagnosis, and one for RAT. If it can be demonstrated that swabs in viral transport medium are of equivalent quality as fresh swabs, one swab can be used for both RT-PCR and RAT testing. Data collection should continue until a minimum of 100 COVID-19 RT-PCR positives and 100 COVID-19 RT-PCR negatives are included in the study. Preferably, a total of 300 negative samples should be included.

For retrospective study design, remnant swab specimens which have been collected from individuals suspected to have COVID-19 are used. Samples should represent different days from symptom onset and span specimens from pre- or asymptomatic individuals to severe infections. A minimum of 100 COVID-19 RT-PCR positive and 100 PCR negative samples should be included in the study. For full description of study design, please see FIND webpage [21].

Dependent on the target population or situation the test is to be validated for, the laboratories need to ensure for correct stratification of specimens and ensure they correspond to the intended use. Example of stratification can be by days post onset of symptoms or viral load characterised by Ct values or viral copy number.

**Target population and epidemiological situation**

PPV and NPV of a test depend on disease prevalence in the target population and the test performance and should be considered when choosing to use a RAT with suboptimal sensitivity and specificity.

Table 1 shows the estimated prevalence of COVID-19 in different target populations in different situations. Table 2 shows the corresponding NPV and PPV when applying two example tests of sensitivity/specificity of 80/98% and 98/98%, respectively, that are shown as examples for a RAT and RT-PCR test.

**Table 1:** Estimated prevalence ranges in different target populations in different settings (Modified from, Find [16]).

|  |  |
| --- | --- |
| Target population | Example prevalence rage |
| Symptomatic healthcare workers, community with high prevalence, outbreak setting | High to very high (10-≥30%) |
| Healthcare workers with significant exposure, community with high prevalence | High (10%) |
| Contacts of index patient | Low to high (2-10%) |
| Community testing/contact tracing hotspots | Medium to high (5-≥10%) |
| Symptomatic general population | Low to high (2-10%) |
| Asymptomatic general population | Very low to low (≤2%) |

Public health objectives for using RATs

The public health objectives, based on the ECDC COVID-19 testing strategy [2], for which the testing by RATs may be beneficial, are the following:

* control transmission: early detection of cases, contact tracing
* mitigate the impact of COVID-19 in healthcare and social-care settings: triage at admission, early detection and isolation
* identify clusters or outbreaks in specific settings: early detection and isolation
* monitor incidence and trends, assess severity over time: population-wide testing

RATs can be used for early detection of cases where RT-PCR testing capacities are not available and where receiving timely results are critical, e.g. for contact tracing purposes. RATs can offer a significant advantage over RT-PCR in terms of timeliness of results. Therefore, the use of RATs can allow for rapid identification of individuals with high transmission potential, particularly in circumstances of high community transmission.

Settings for use of RATs

Figure and Annex 2 show different settings, where use of RATs could be considered and where RT-PCR is suggested to be used. The flowchart (Figure) gives a simple overview to guide the use of RATs for symptomatic and asymptomatic persons by high or low prevalence situation.

When the availability of RT-PCR tests is temporarily limited, rapid antigen test use can be considered for individuals with COVID-19 compatible symptoms for up to 5 days since symptom onset, in areas where the proportion of test positivity is high or very high, ≥10%.

For outbreak investigation purposes, where the outbreak is already RT-PCR confirmed, RATs could be used for early detection of further cases. RATs could be also used to rapidly screen residents of closed settings to identify SARS-CoV-2 positive individuals and rapidly quarantine/isolate them to protect remaining residents and staff from infection. In such situations, negative results would need to be confirmed by RT-PCR to avoid false negatives.

For contact tracing, RAT use can be considered for individuals with symptoms up to 5 days since symptom onset. In settings prone to transmission, for further contact tracing purposes, asymptomatic high-risk (close) contacts and low risk exposure contacts can be tested by RAT up to 7 days post known exposure. With unknown exposure time, testing is to be performed as soon as possible as it can be assumed that several days have elapsed since exposure. Negative test results are to be followed up with a RT-PCR test on or after day 10 following the last exposure for releasing from quarantine earlier than 14 days. Early release from quarantine needs to be assessed on a case-by-case basis, especially for contacts working with vulnerable populations or contacts in high risk settings such as long-term care facilities or prisons.

To mitigate the impact of COVID-19 in healthcare and social-care settings, use of RAT use can be considered for triage of symptomatic patients or residents (up to 5 days since symptom onset) at admission. Results of testing can guide the need for isolation and use of personal protective equipment. In a high prevalence situation, in the context of circuit breaker strategies to detect the individuals with high transmission potential in the community and to lower the pressure on health-care settings and laboratories, RAT use can be considered for a targeted population-wide testing approach, e.g. in a local community. In such situation, the risk of not detecting all cases or risk of false negative results is balanced out by the timeliness of results and the possibility of recurring testing of initially negative individuals. The repeat testing with RATs should occur every 2-3 days to compare with the detection potential of RT-PCR by every 5 days[[2]](#footnote-3).

In a high prevalence situation and with limited RT-PCR testing capacity to detect the individuals with high transmission potential, RAT use can be considered for recurring testing (every 2-3 days) of staff of health-care, home care, long-term care facilities, closed settings (e.g. prisons, migrant detention and reception centres) and occupational settings. Negative RAT tests need to be confirmed with RT-PCR. If RT-PCR testing capacity is limited, the RAT needs to be repeated after 2-3 days.

Furthermore, monitoring of incidence and trends through population-wide testing approaches can be achieved through use of RATs if RT-PCR capacities are limited.

RATs are not suited to screen persons to prevent (re-) introduction into regions/countries with sustained control over the virus and for such uses. In these situations, only RT-PCR should be used not to risk any false positive or negative results., RT-PCR testing capacities should be readily available as prevalence of COVID-19 in such situations would be very low. Further settings, where RT-PCR should be the preferred option are diagnostic testing of patients with COVID-19 compatible symptoms in hospitals, long-term care facilities or other social care settings to avoid false negative results. If RATs are used in these occasion, negative tests need to be confirmed with RT-PCR. In specimens for sentinel surveillance from patients with acute respiratory infection, influenza-like illness, severe acute respiratory infection or COVID-19 compatible symptoms tested in sentinel surveillance in primary or secondary care, RT-PCR test is preferred. If RAT is used for sentinel surveillance specimen analysis, parallel testing for influenza including subtyping and lineage determination during the influenza season, and other respiratory viruses, is recommended.

Considerations for use of RATs in settings of low and high infection prevalence and the need for confirmatory testing

In a **high prevalence setting**, RATs will have a high PPV (Table 2).In such a situation,a positive result from a RAT (even with a lower specificity than in RT-PCR tests and thus a higher probability of false positivity) is likely to indicate a true infection and may not require confirmation by RT-PCR. On the other hand, any negative test result should be confirmed by RT-PCR immediately or, in case of unavailability of RT-PCR, with another RAT a few days later (to allow the viral load to increase). This is particularly true for asymptomatic cases with a known history of exposure. In any high-risk settings with vulnerable populations only RT-PCR should be used. In vulnerable populations with symptoms, multiplex RT-PCR would be best suited for confirmation to exclude symptoms caused by other respiratory pathogens.

In a **low prevalence setting**, RATs will have a high NPV but a low PPV (Table 2). Therefore, if used correctly, RATs should be able to rule out a highly infectious case in such a setting. A negative test result may not require confirmation by RT-PCR, whereas a positive test will need confirmation by RT-PCR. Recurring testing by RAT every 2-3 days with the aim to identify infectious cases in a population can partly mitigate the lower sensitivity of the test and can be used in certain settings (see frequency column in Annex 2) such as in staff of health care settings.

In low prevalence settings, sufficient RT-PCR and logistics capacity will probably be in place to ensure a rapid turnaround of results. However, there still might be an added value to the use of RATs because of low cost and rapid turn-around time of analysis. Here, a careful cost-benefit calculation has to be made in order not to exhaust the overall testing capacity in settings, which have low impact on the course of the epidemic and the resources should rather be reserved for settings, where highly infectious persons can and need to be detected.

**Table 2:** NPV and PPV at 0.5, 1.0, 10 and 20% Covid-19 prevalence using test with two different sensitivities and specificities, for comparison of typical performance of rapid antigen and RT-PCR tests (conceptual example).

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Example prevalence | Example prevalence (%) | Sensitivity | Specificity | NPV | PPV | True positive | False positive | True negative | False negative | Nr with disease | Nr of positive tests in total |
| 50/100000 | 0.0005 | 0.8 | 0.98 | 1.000 | 0.020 | 40 | 1999 | 97951 | 10 | 50 | 2039 |
| 50/100000 | 0.0005 | 0.98 | 0.999 | 1.000 | 0.329 | 49 | 100 | 99850 | 1 | 50 | 149 |
| 100/100000 | 0.001 | 0.8 | 0.98 | 1.000 | 0.038 | 80 | 1998 | 97902 | 20 | 100 | 2078 |
| 100/100000 | 0.001 | 0.98 | 0.999 | 1.000 | 0.495 | 98 | 100 | 99800 | 2 | 100 | 198 |
| 500/100000 | 0.005 | 0.8 | 0.98 | 0.999 | 0.167 | 400 | 1990 | 97510 | 100 | 500 | 2390 |
| 500/100000 | 0.005 | 0.98 | 0.999 | 1.000 | 0.831 | 490 | 100 | 99401 | 10 | 500 | 590 |
| 1000/100000 | 0.01 | 0.8 | 0.98 | 0.998 | 0.288 | 800 | 1980 | 97020 | 200 | 1000 | 2780 |
| 1000/100000 | 0.01 | 0.98 | 0.999 | 1.000 | 0.908 | 980 | 99 | 98901 | 20 | 1000 | 1079 |
| 5000/100000 | 0.05 | 0.8 | 0.98 | 0.989 | 0.678 | 4000 | 1900 | 93100 | 1000 | 5000 | 5900 |
| 5000/100000 | 0.05 | 0.98 | 0.999 | 0.999 | 0.981 | 4900 | 95 | 94905 | 100 | 5000 | 4995 |
| 10000/100000 | 0.1 | 0.8 | 0.98 | 0.978 | 0.816 | 8000 | 1800 | 88200 | 2000 | 10000 | 9800 |
| 10000/100000 | 0.1 | 0.98 | 0.999 | 0.998 | 0.991 | 9800 | 90 | 89910 | 200 | 10000 | 9890 |
| 20000/100000 | 0.2 | 0.8 | 0.98 | 0.951 | 0.909 | 16000 | 1600 | 78400 | 4000 | 20000 | 17600 |
| 20000/100000 | 0.2 | 0.98 | 0.999 | 0.995 | 0.996 | 19600 | 80 | 79920 | 400 | 20000 | 19680 |
| 50000/100000 | 0.5 | 0.8 | 0.98 | 0.831 | 0.976 | 40000 | 1000 | 49000 | 10000 | 50000 | 41000 |
| 50000/100000 | 0.5 | 0.98 | 0.999 | 0.980 | 0.999 | 49000 | 50 | 49950 | 1000 | 50000 | 49050 |

**Time of sampling**

Based on the available evidence, replicating virus can be isolated from the nasopharyngeal specimens collected six days before to nine days after the first evidence of typical symptoms [22]. The highest viral load has been observed in respiratory samples collected three days before to three days after the symptom onset [23].

As mentioned above, RATs have been shown to be more efficient in detecting cases in the days around the onset of symptoms, when the viral load is highest. Hence, a RAT should be used within five days after the onset of symptoms or no later than seven days after exposure.

**Testing capacities and availability of resources**

The processing time for a sample analysed with a RAT is less than half an hour, thus it is considerably shorter than that of RT-PCR. However, RATs are run individually and some RATs require an instrument for the read-out of the result. For some handheld RAT devices with visual readout, a small number (up to 10) specimens can be analysed in parallel. Hence, completing a large number of tests might be prohibitively time consuming. In contrast, diagnostic laboratories are able to conduct RT-PCR testing on multiple samples simultaneously and the turn-around time, when managing a very large number of samples, might be shorter.

When considering RAT, a careful analysis of the expected sample volumes, availability of resources, equipment and supplies, logistical arrangements including the expected need for confirmatory testing and supplies for those, needs to be done.

**Biosafety considerations**

Until today, there is not enough evidence that buffers in the RAT testing systems are reliably inactivating SARS-CoV-2 within the short processing time. Therefore, appropriate biosafety measures must be in place when sampling, handling and processing specimens and tests. Such additional protective measures include adequate personal protective equipment or, alternatively, that the sample processing is done in a biosafety cabinet.

Manufacturer instructions for sample collection, safe handling, waste management and use need to be followed precisely, including specimen type.

**User considerations**

For RATs intended for use in point-of-care setting, trained healthcare and laboratory staff are needed to carry out sampling, testing, test analysis and reporting of test results to clinical staff and public health authorities at local, regional, national and international level. Member States need to ensure sufficient capacities and resources for sampling, testing and reporting. To ensure these capacities, additional healthcare personnel needs to be trained [24].

**External quality assessment**

In keeping with the ECDC strategy for the external quality assessment (EQA) of public health microbiology laboratories [25], EQAs improve and maintain high quality and comparability of key laboratory surveillance data reported at the European level. One of the aims with EQAs is also to foster capabilities to detect emerging and epidemic diseases across the EU/EEA Member States. To establish high quality and comparability of rapid antigen test results for SARS-CoV-2, EQAs suitable for RATs should be used in the diagnostic laboratories in regular intervals.

**Interpretation of test results and implications for surveillance**

Interpretation of RAT results and the need for confirmatory testing of results need to be agreed upon for clinical decision-making, surveillance and acceptance between regions and countries. At the moment, the EU/EEA COVID-19 case definition only includes cases with RT-PCR confirmation. The EU/EEA case definition will be updated to include positive results obtained in RATs for surveillance reporting.

ECDC proposes that a positive antigen test in a symptomatic person and/or a person with a clear exposure history and/or X-ray characteristic for COVID-19 should be considered as a laboratory confirmed case. RAT should then also be included when computing testing rates and test positivity rates. Positive confirmatory PCR or recurring RAT in the same individual should not be included in these counts. If confirmatory RT-PCR remains negative, those results should be reported negative even if the RAT result would be positive. If RAT is used for SARS-CoV-2 detection, parallel testing for influenza viruses as well as subtyping and lineage determination during influenza season, and other respiratory viruses, should be performed.

The countries applying RATs would need to ensure at least representative sample of specimens to be shipped to national reference laboratories to ensure characterisation of circulating viruses for surveillance purposes.

Conclusions

RATs can contribute to the overall COVID-19 testing capacity offering an advantage in terms of shorter turnaround time and reduced cost, especially in situations where RT-PCR testing capacity is reduced. Together, these benefits of RATs can contribute to more efficient interruption of transmission through more timely identification of cases and faster contact tracing. The currently available data shows that RATs can best be used in settings where the time of symptom onset or exposure time is known and is up to five days after symptom onset or seven days after exposure. After that it becomes more unlikely that RATs will perform well.

At the moment, there are several RATs on the EU/EEA market, but there is limited data on their clinical performance and many of those data are based on limited number of mostly symptomatic individuals. In addition, many of the reports are still preprints and have not been peer-reviewed and therefore the data should be interpreted cautiously at this stage. In addition, only one test is intended for use in nasal swabs when all others are intended to be used with nasopharyngeal swab which is a more invasive specimen type and may not be suited to be used for some individuals.

The validation studies conducted so far show variable performance between tests. ECDC recommends Member States to perform independent validations of the RATs against RT-PCR on specimens collected from patients around the onset of disease or within seven days after exposure and to conduct setting-specific validation of tests before deciding on any rapid test to be used. From such validation studies, ECDC recommends the use of tests that have a sensitivity of 90% or above and minimum specificity of 97%.

Confirmation of RAT results by RT-PCR should be conducted taking the performance of the test and prevalence in target population into consideration as there continues to be a considerable risk of false negative and positive results with RATs. This risk needs to be taken into account when considering the use of RATs in specific settings. The use of RATs changes also the logistical arrangements for testing and the resources for applying RATs and the needs for confirmatory testing need to be carefully considered.

With all the caveats of RATs to be taken into account, RATs may support early identification of individuals that would likely transmit the SARS-CoV-2 infection onward. RATs may alleviate pressures in testing when RT-PCR testing capacity has become limited or needs to be prioritised. RATs can support outbreak investigations and contact tracing as they will return the results quickly and make further contact tracing more timely than with RT-PCR where the turnaround times are from one to several days. In addition, RATs can be used for screening staff or persons in high-risk settings in which recurring testing could quickly identify persons with a SARS-CoV-2 infection to inform infection prevention and control measures, thus preventing further transmission.

A test that is able to detect infectious cases whether symptomatic or not, and that is sufficiently rapid to maximise the effectiveness of case isolation and contact tracing, would significantly improve COVID-19 prevention and control strategies. Further clinical validation studies, especially in asymptomatic persons and with different specimen types and comparing head-to-head with quantitative RT-PCR test, need to be conducted to show, if RATs can be applied for further screening purposes, e.g. of asymptomatic travellers, in the future.

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Disclaimer

All data published in this document are correct to the best of our knowledge at the time of publication.

[Add disclaimer on DOIs of external experts as needed]

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Annex 1: Overview of available clinical validation results by antigen test by 06 November 2020

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Antigen Test | Manufacturer | Type of interpretation | Authorization/certification | Country tested | Type of specimen | Population | Stratified analysis | Sensitivity % a  (95%CI) | Specificity % (95%CI) | Ref. |
| BD Veritor™ System for Rapid Detection of SARS-CoV-2 | [Becton, Dickinson and Company, BD Life Sciences—Integrated Diagnostics Solutions, Sparks, MD, USA](https://www.bd.com/en-us/offerings/capabilities/microbiology-solutions/point-of-care-testing/bd-veritor-plus-system-for-rapid-covid-19-sars-cov-2-testing) [26] |  | CE-IVD  Brazil ANVISA  FDA-USA | USA | Nasopharyngeal or oropharyngeal swabs | Symptomatic (n= 251) | By symptoms onset  1 dpo  2 dpo  3 dpo  4 dpo  5 dpo  6 dpo  ≤ 7 dpo | 76.3 (60.8-87.0)  87.5 (52.9 – 97.8)  85.0 (64.0 – 94.8)  81.8 (61.5 – 92.7)  85.2 (67.5 – 94.1)  83.9 (67.4 – 92.9)  82.4 (66.5 – 91.7)  76.3 (60.8 – 87.0) | 99.5 (97.7-99.9)  100 (88.6 – 100)  100 (95.1 – 100)  100 (97.1 – 100)  100 (97.7 – 100)  100 (98.1 – 100)  99.5 (97.4 – 99.9)  99.5 (97.4 – 99.9) | [27] |
|  |  |  |  | The Netherlands | Nasal swabs | Symptomatic adults (n=352) | By symptoms onset  < 7 dpo  ≥ 7 dpo  By symptoms onset and Ct values  < 7 dpo, Ct < 20  < 7 dpo, Ct 20-25  < 7 dpo, Ct 25- 30  < 7 dpo, Ct ≥ 30  < 7 dpo, Ct < 30  ≥ 7 dpo, Ct < 20  ≥ 7 dpo, Ct 20-25  ≥ 7 dpo, Ct 25- 30  ≥ 7 dpo, Ct ≥ 30  < 7 dpo, Ct < 30 | 80.7 (73.2-86.9)  91.0 (82.4-96.3)  67.2 (53.7 - 79.0)  100 (85.2-100)  100 (89.7- 100)  92.3 (64.0 – 99.8)  25.0 (3.2 – 65.1)  98.6 (92.3 -100)  100 (29.2 -100)  81.3 (54.4- 96.0)  87.0 (66.4- 97.2)  18.8 (4.1 – 45.7)  85.7 (71.5 – 94.6) | 100(98.9-100)  NR  NR  NR  NR  NR  NR  NR  NR  NR  NR  NR  NR | [28] |
| RapiGen Biocredit COVID-19 Ag One 90 Step SARS-CoV-2 | [RapiGEN Inc., Anyang-si, Gyeonggi-do, Republic of Korea](https://www.biovendor.com/file/13419/1-2%20IFU_Covid-19_Ag_Antigen_Multi%20Language%20SEP2020Watermarked.pdf?version=202009300841) [29] | Visual | CE-IVD  Brazil  Philippines | Chile | Nasopharyngeal or oropharyngeal swabs | Symptomatic (n=111) | By Ct values  Ct < 25  Ct > 25 | 62.0 (51.0-71.9)  84.9 (72 - 92)  15.4 (6 - 34) | 100 (88.7-100)  NR  NR | [30] |
|  |  |  |  | Hong Kong | Respiratory samples | NR (n= 336)  NPA-TS (n=81)  NPS-TS (n=103) Sputum(n= 62)  Saliva(n= 122) | By type of samples  NPA-TS  NPS-TS Sputum  Saliva  By type of samples and Ct values b  NPA-TS, Ct < 18.57  NPS-TS, Ct < 18.57 Sputum, Ct < 18.57  Saliva, Ct < 18.57  NPA-TS, Ct >18.57  NPS-TS, Ct > 18.57 Sputum, Ct > 18.57  Saliva, Ct > 18.57 | 34.3 (NR)  45.7 (NR)  11.1 (NR)  40.0 (NR)  81.8 (NR)  80.0 (NR)  28.6 (NR)  53.8 (NR)  12.5 (NR)  0 c  7.9 (NR)  21.1 (NR) | NR  NR  NR  NR  NR  NR  NR  NR  NR  NR  NR  NR | [31] |
|  |  |  |  | Brazil | Nasopharyngeal swabs | Symptomatic (n=476) | By symptoms onset  < 7 dpo  By Ct values  Ct < 25  Ct < 33 | 74.4 (65.8-81.4)  77.6 (68.3-84.7)  90.9 (80.5-96.1)  82.5 (73.7-88.8) | 98.9 (97.2-99.6)  NR  NR  NR | [32] |
| Bioeasy 2019-nCoV Ag Fluorescence Rapid Test Kit | [Shenzhen Bioeasy Biotechnology Co. Lt. Guangdong Province, China](http://en.bioeasy.com/?page_id=1002) [33] | Reader | CE-IVD | Germany and UK | Nasopharyngeal or oropharyngeal swabs | Symptomatic  (n=727) | By Ct values  Ct < 25  Ct ≥ 25 | 66.7 (41.7-84.8)  88.9 (56.5 -99.4)  33.3 (9.7-70.0) | 93.1 (91.0-94.8)  NR  NR | [34] |
| Chile | Nasopharyngeal or oropharyngeal swabs | Symptomatic (n=127) | By symptoms onset  0-7 dpo  8-12 dpo  By Ct values d  Ct < 25.1  Ct ≥ 25.1 | 93.9 (86.5-97.4)  94.7 (87.2 -97.9)  80.0 (37.6 – 96.4)  100 (89.8-100)  49.1 – 87.5 | 100 (92.1-100)  100 (NR)  100 (NR)  NR  NR | [35] |
| Chile | Nasopharyngeal or oropharyngeal swabs | Symptomatic (n=111) | By Ct values  Ct < 25  Ct > 25 | 85.0 (75.6-91.2)  100 (94 -100)  54 (35 - 71) | 100 (89.0-100)  NR  NR | [30] |
| Coris COVID-19 Ag Respi-Strip | [Coris Bioconcept, Gembloux, Belgium](https://www.corisbio.com/Products/Human-Field/Covid-19.php) [36] | Visual | CE-IVD | Belgium | Nasopharyngeal swabs | Symptomatic  (n= 328)  HCW (n=53) | By Ct values  Ct < 25  By sub-population and Ct values  HCW, Ct < 25 | 57.6 (NR)  73.9 (NR)  92.9 (NR) | 99.5 (NR)  NR  NR | [37] |
| France | Nasopharyngeal swabs | NR (n= 138) | By Ct values  Ct < 25 | 50.0 (39.5-60.5)  82.2 (NR) | 100 (91.8-100)  NR | [38] |
| Belgium | Nasopharyngeal swabs | NR (n= 56) |  | 30 (16.7–47.9) | 100 (NR) | [39] |
| France | Nasopharyngeal swabs | Symptomatic (n=45) | By Ct values  Ct ≤ 25  Ct 25-34  Ct ≥ 35  By symptoms onset  ≤ 7 dpo  7- 14 dpo  > 14 dpo | 29.0 (15.7-42.3)  87 (70-100)  0  0  41.0 (20.4 – 61.6)  29.0 (5.2 – 52.8)  0 | 100 (NR)  100 (NR)  100 (NR)  100 (NR)  100 (NR)  100 (NR)  100 (NR) | [40] |
| Belgium | Nasopharyngeal swabs | NR (n=148) | By Ct values  Ct < 25  Ct < 30  Ct < 35 | 30.2 (21.7-39.9)  100 (NR)  70.6 (NR)  46.9 (NR) | 100 (NR)  NR  NR  NR | [41] |
| Germany and UK | Nasopharyngeal or combined nasopharyngeal and oropharyngeal swabs | Symptomatic  (n=425) | By symptoms onset  <7 dpo | 50 (21.5-78.5)  42.9 (15.8-75.0) | 95.8 (93.4-97.4)  NR  NR  NR | [42] |
| LUMIPULSE SARS-CoV-2 Ag kit | [Fujirebio, Japan](https://www.fujirebio.com/en/products-solutions/lumipulse-g-sars-cov2-ag) [43] |  | CE--IVD | Japan | Nasopharyngeal swabs | NR  (n= 313) | By viral load  > 100 copies  10-100 copies  1 – 10 copies  < 1 copy | 55.2 (41.5-68.2)  100 (NR)  60 (NR)  33 (NR)  26 (NR) | 99.6 (97.8-99.9)  NR  NR  NR  NR | [44] |
| Abbott Panbio™ COVID-19 Ag Rapid Test | [Abbott Rapid Diagnostics, Chicago, US](https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html) [45] | Visual | CE-IVD  WHO EUL | Spain | Nasopharyngeal swabs | Symptomatic (n= 412)  Adults (n= 387)  Children (n=85) | By sub-population  Adults  Children  By symptoms onset  < 5 dpo  By Ct values  Ct < 25 | 79.6 (67.0-88.8)  82.6 (69.3 -90.9)  62.5 (30.6-86.3)  80.4 (66.8-89.3)  100 (NR) | 100 (98.7-100)  NR  NR  NR  NR | [46] |
|  |  |  |  | The Netherlands | Nasopharyngeal swabs | Symptomatic (n= 1367) | By Ct value  Ct < 32 | 72.6 (64.5-79.9)  95.2 (89.3-98.5) | 100 (99.7-100)  NR | [47] |
|  |  |  |  | Aruba | Nasopharyngeal swabs | Symptomatic  (n= 208) | By Ct value  Ct < 32 | 81.0 (69.0 -89.8)  98.0 (89.2–99.95) | 100 (97.5-100)  NR | [47] |
|  |  |  |  | Chile | Nasopharyngeal swabs | Symptomatic (n= 185) Asymptomatic (n= 55) Total  (n= 240) | By symptoms onset  < 7 dpo  By Ct values  Ct<25  Ct<30  Ct<35 | 73.3 (62.2-83.8)  86.5 (75.0 – 97.0)    100 (NR)  87.5 (NR)  25 (NR) | 100 (NR)  NR  NR  NR  NR | [48] |
| SD Biosensor Standard F COVID-19 Ag FIA | [SD Biosensor, Inc. Gyeonggi-doo, Korea](http://www.sdbiosensor.com/xe/)  [F. Hoffmann-La Roche LTD, Basel, Switzerland](https://www.roche.com/media/releases/med-cor-2020-09-01b.htm) | Reader | CE-IVD | Brazil | Nasopharyngeal swabs | Symptomatic  (n= 421)  Asymptomatic (n=29)  Total (n= 453) | By symptoms onset  ≤ 7 dpo  By Ct value  Ct ≤ 25  Ct ≤ 33 | 77.5 (69.2-84.1)  80.2% (71.1, 86.7)  87.9% (77.9, 93.7)  80.9% (72.6, 87.2) | 80.2 (71.1-86.7)  NR  NR  NR | [49] |
| SD Biosensor  Standard Q COVID-19 Ag Test | [SD Biosensor, Inc. Gyeonggi-doo, Korea](http://www.sdbiosensor.com/xe/)  [50]  [F. Hoffmann-La Roche LTD, Basel, Switzerland](https://www.roche.com/media/releases/med-cor-2020-09-01b.htm) [51] | Visual  With F2400 device | CE-IVD  Brazil  WHO  FDA USA - EUA | Germany and UK | Nasopharyngeal or oropharyngeal swabs | Symptomatic  (n=2417) | By type of specimen  NPS  OPS  NPS/OPS (Berlin)  NPS/ OPS (Liverpool)  By symptoms onset  0-7 dpo  8- 14 dpo  >14 dpo  By disease severity  Category 1 f  Category 2 g  Category 3 h  By Ct values  Ct < 25  Ct ≥ 25 | 76.6 (62.8-86.4)  57.1(25.0-84.1)  NAe  79.5 (64.5 -89.2)  NA  80.0 (64.1 -90.0)  100 (51.0- 100)  NA  58.8 (36.0 -78.4)  85.7 (65.4 -95.0)  100 (51.0-100)  100 (82.4 -100)  62.1 (44.0 -77.3) | 99.3 (98.6-99.6)  97.9 (95.6 -99.1)  100 (90.1 -100)  99.7 (99.0-99.9)  100 (83.2 -100)  99.2 (98.4 -99.6)  100 (93.0 – 100)  100 (74.1 -100)  99.2 (97.9 -99.7)  99.2 (98.2 – 99.7)  100 (84.5 – 100)  NR  NR | [34] |
|  |  |  |  | Italy | Nasopharyngeal swabs | Symptomatic (n= 185) Travellers (n= 145) Total  (n= 330) | By Ct value  Ct < 28  Ct < 28-30  Ct < 31-34  Ct > 34 | 70.6 (NR)  100 (NR)  38.5 (NR)  26.7 (NR)  9.1 (NR) | 100 (NR)  NR  NR  NR  NR | [52] |
|  |  |  |  | Italy | Nasopharyngeal swabs | NR (n= 359) |  | 47.1 (37.1-57.1) | 98.4 (96.0-99.6) | [53] |
|  |  |  |  | Netherlands | Nasopharyngeal swabs | Mild symptomatic (n=521) | By Ct value  Ct < 20  Ct < 25  Ct < 30 | 87.14 (77-93.95)  100 (NR)  95 (NR)  67 (NR) | 100 (99.2- 100)  NR  NR  NR | Personal communication[[3]](#footnote-4) |
|  |  |  |  | Netherlands | Nasopharyngeal swabs | Mild symptomatic (n=798) | By Ct value  Ct <30 | 83.6 (NR)  93.7 (NR) | 99.5  NR | Personal communication[[4]](#footnote-5) |
|  |  |  |  | Netherlands | Nasopharyngeal swabs | Total (n= 977)  Symptomatic 92% | By symptoms onset and Ct values  ≤3 dpo, Overall  ≤3 dpo; Ct < 25  ≤3 dpo; Ct<30  ≤7 dpo; Overall;  ≤7 dpo; Ct < 25;  ≤7 dpo; Ct<30) | 84.0 (78.1-88.6)  99.3 (84.1-97.4)  100 (92.1-100)  96.5 (88.1-99.0)  89.9 (83.5-94.0)  98.8 (93.7-99.9)  95.0 (89.4-97.7) | 99.5 (98.7-99.8)  96.6 (97.9-100)  NR  NR  96.6 (95.9-98.6) | Personal communication[[5]](#footnote-6) |
|  |  |  |  | Netherlands | Nasopharyngeal swabs | Mild symptomatic  (n=628) | By Ct values:  Ct < 20  Ct < 25  Ct < 30 | 78.0 (69.4-85.1)  92.7 (NR)  90.3 (NR)  84.4 (NR) | 99.6 (98.6-99.9) | Personal communication[[6]](#footnote-7) |
| Quidel, SARS Ag Test with Sofia 2 device | [Quidel Corporation, San Diego, US](https://www.quidel.com/immunoassays/rapid-sars-tests/sofia-sars-antigen-fia) **[54]** |  |  | Netherlands | Nasopharyngeal swabs | Mild symptomatic (n=733) | By Ct values:  Ct < 20  Ct < 25  Ct < 30 | 84.0 (77-89.6)  91.8 (NR)  93.5 (NR)  79.2 (NR) | 99.0 (99.1-100) | Personal communication[[7]](#footnote-8) |

CE-IVD = CE Marking according to the Requirements of European Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices (IVDD) or its successor Directive; Ct= cycle threshold; Brazil ANVISA= Brazil National Health Surveillance Agency; dpo= days post symptoms onset; FDA = United States Federal Drug Agency; NA = not applicable; NPA-TS= Nasopharyngeal aspirate and throat swab; NPS= Nasopharyngeal swab; NPS-TS= Nasopharyngeal swab and throat swab; NR= not reported, OPS= oropharyngeal swab;

a Results >90% sensitivity are presented in bold.

b The Ct threshold was defined by the limit of detection between the antigen test, viral culture and RT-PCR calculated in this study.

c none of the positive samples tested were detected by the antigen test.

d Ct values was defined by using the upper limit of the interquartile range of the Ct values of all samples tested.

e No positive PCR results in this category.

f Category 1: normal activity possible

g Category 2: light restrictions and able to walk

h Category 3: limited self-sufficiency and completely need of care

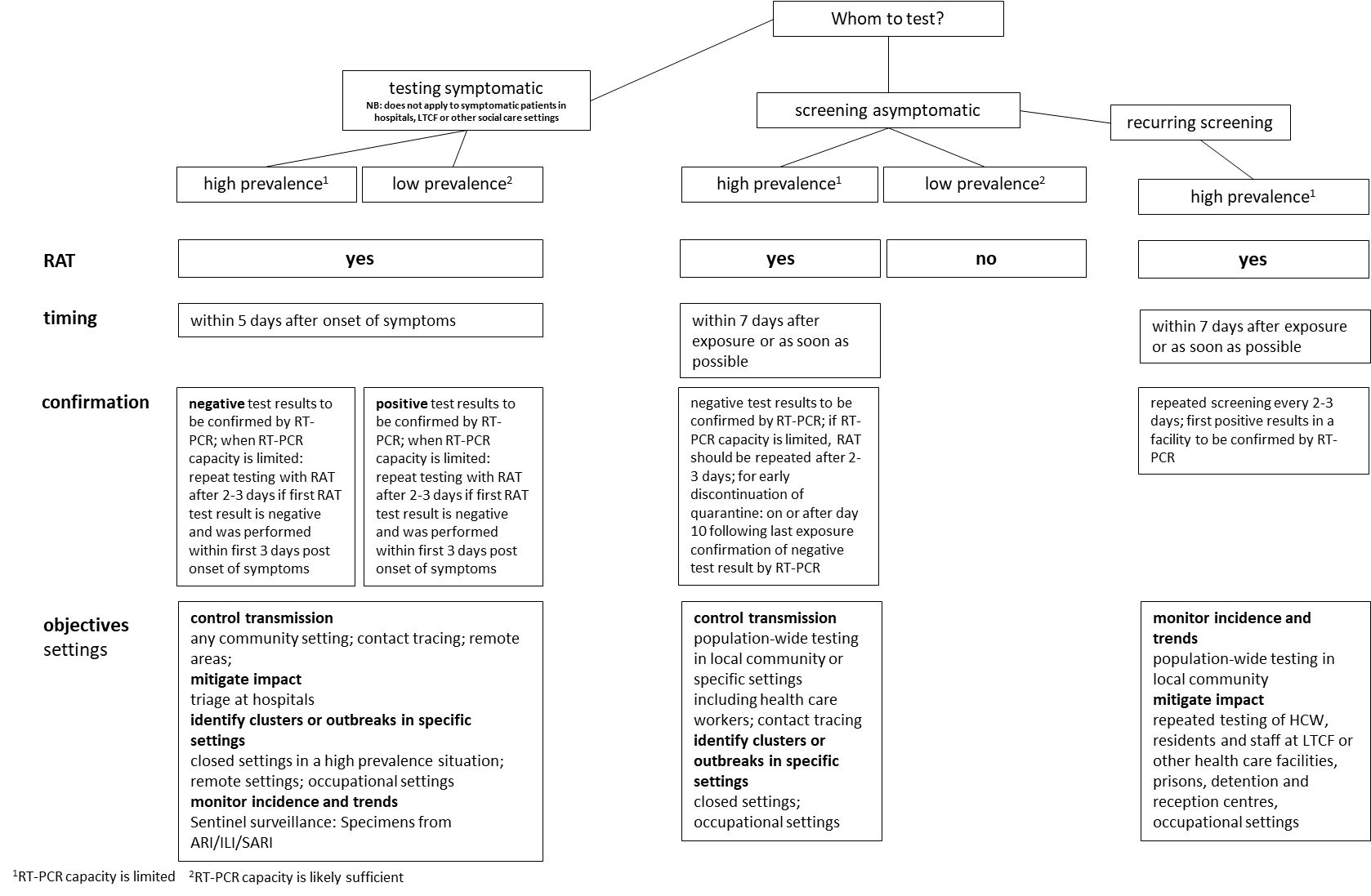
Annex 2: Options for use of RATs in different settings

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **type of population** | **Objective1** | **setting** | **target population** | **pre-test probability2** | **preferred test type** | **time point of testing** | **test frequency** | **confirmatory testing** | **Priority for testing3** |
| symptomatic | control transmission - early detection of cases | community, e.g. drive-in testing stations | symptomatic persons | high | RT-PCR, RAT | as soon as possible | once | confirmation of negative RAT results by RT-PCR | 1 |
| control transmission – contract tracing | community | high and low risk exposure | high | RT-PCR, RAT | as soon as possible; for RAT no later than 7 days post onset of symptoms | once | if RT-PCR available, confirmatory testing of negative RAT results by RT-PCR;  If only RATs are available, repeat testing after 2-4 days if first RAT test result is negative and was performed within first 3 days post onset of symptoms | 1 |
| control transmission, identify clusters or outbreaks in specific settings | remote areas | symptomatic persons | medium | RT-PCR, RAT | as soon as possible; for RAT no later than 7 days post onset of symptoms | once (with possible repetition) | if RT-PCR available, confirmatory testing of negative RAT results by RT-PCR;  if only RATs are available, repeat testing after 2-4 days if first RAT test result is negative and was performed within first 3 days post onset of symptoms | 1 |
| control transmission, identify clusters or outbreaks in specific settings | closed setting, e.g. prisons, migrant detention and reception centres | symptomatic persons | medium | RT-PCR, RAT | as soon as possible; for RAT no later than 7 days post onset of symptoms | once (with possible repetition) | if RT-PCR available, confirmatory testing of negative RAT results by RT-PCR;  If only RATs are available, repeat testing after 2-4 days if first RAT test result is negative and was performed within first 3 days post onset of symptoms | 1 |
| control transmission – end isolation earlier than 10 days after resolution of symptoms | Hospitals, LTCF, community, any setting | patients | low | RT-PCR | any time after resolution of symptoms | two consecutive negative SARS-CoV-2 RT-PCR tests in a 24-hour  interval from respiratory specimens | N/A | 3 |
| monitor incidence and trends, assess severity over time | sentinel surveillance in primary or secondary care | patients with ILI/ARI/SARI | high | RT-PCR, RAT | as soon as possible | once | should ideally be tested for influenza or other respiratory pathogens in parallel | 1 |
| mitigate the impact of  COVID-19 in healthcare  and social-care settings - triage at admission | hospital | HCWs and patients | medium to high | RT-PCR, RAT | as soon as possible; for RAT no later than 7 days post onset of symptoms | once | confirmation of negative RAT results by RT-PCR | 1 |
| mitigate the impact of  COVID-19 in healthcare  and social-care settings – early detection and isolation | LTCF | vulnerable | high | RT-PCR, RAT | as soon as possible | once (with possible repetition) | negative RT-PCR test for SARS-CoV-2 should be tested for influenza or other respiratory pathogens; confirmatory testing of negative RAT results by RT-PCR;  If only RATs are available, repeat testing after 2-4 days if first RAT test result is negative and was performed within first 3 days post onset of symptoms | 1 |
| identify clusters or outbreaks in specific settings | outbreak population, any setting | symptomatic persons | high | RT-PCR, RAT | as soon as possible; for RAT no later than 7 days post onset of symptoms | once | confirmation of negative RAT results by RT-PCR | 1 |
| asymptomatic | control transmission – contact tracing | community | high-risk exposure (close contacts) | medium | RT-PCR, RAT | as soon as possible the contact has been traced, for RAT no later than 7 days post known exposure; with unknown exposure time, testing to be performed as soon as possible | once | confirmatory testing of negative results by RT-PCR for further contact tracing purposes;  negative test results to be followed up with a secondary RT-PCR test on or after day 10 following the last exposure for releasing from quarantine | 2 |
| control transmission – contact tracing | LTCF, closed settings | low-risk exposure | low | RT-PCR, RAT | as soon as possible after the contact has been traced | once | confirmation of negative RAT result by RT-PCR; if only RATs are available, repeat testing after 2-4 days if first RAT test result is negative and was performed within first 3 days post onset of symptoms | 3 |
| control transmission - screening for infectious travellers ***(not recommended)*** | airports and other ports of entry | travellers | low | RT-PCR, RAT | upon entry | once (with possible repetition) | confirmatory testing of positive RAT results by RT-PCR | - |
| monitor incidence and trends - population-wide testing | Community, e.g. in  regions of widespread community transmission or among  HCWs during outbreaks | , health care workersInhabitants and staf | low | RT-PCR, RAT | as scheduled | once or recurring | if capacity allows, confirmatory testing of representative samples of RAT-tested specimens by RT-PCR for calculation of predictive values | 4 |

1Objectives defined as in ECDC testing strategies and objectives [2] [ref].

2Pretest probability: Probability of a patient having an infection before the test result is known; based on the proportion of people in a community with the disease at a given time (prevalence) and the clinical presentation of the patient [13] [ref].

3Priority for testing: Scale of 1-4; 1, highest priority; 2, high priority; 3, lower priority, indicated if resources allow; 4, lowest priority, indicated if resources allow.

**Figure 1: Flowchart describing objectives and settings when to use rapid antigen tests.** 

1. Health Security Committee Secretariat (email communication, October 2020) [↑](#footnote-ref-2)
2. Billy J Quilty MSc, London School of Hygiene and Tropical Medicine, United Kingdom (email communication, November 2020) [↑](#footnote-ref-3)
3. Chantal Reusken PHD, RIVM, The Netherlands (email communication, November 2020) [↑](#footnote-ref-4)
4. Chantal Reusken PHD, RIVM, The Netherlands (email communication, November 2020) [↑](#footnote-ref-5)
5. Zsofia Igloi PHD, Erasmus Medical Centre, The Netherlands (oral communication, November 2020) [↑](#footnote-ref-6)
6. Chantal Reusken PHD, RIVM, The Netherlands (email communication, November 2020) [↑](#footnote-ref-7)
7. Chantal Reusken PHD, RIVM, The Netherlands (email communication, November 2020) [↑](#footnote-ref-8)