



### ECDC/EU-OSHA TECHNICAL REPORT

## **Considerations on the use of rapid antigen detection (including self-) tests for SARS-CoV-2 in occupational settings**

5 May 2021

### **Key messages**

The use of rapid antigen detection tests (RADTs) and/or self-test RADTs in occupational settings can complement, but not replace, occupational safety and health measures and existing non-pharmaceutical interventions at the workplace aimed at preventing the introduction and spread of SARS-CoV-2. Most importantly, any individual exhibiting COVID-19-like symptoms should stay at home/self-isolate and access testing as soon as possible.

This document outlines the public health and occupational safety and health considerations for the use of RADTs, including self-test RADTs, to detect SARS-CoV-2 in individuals in occupational settings in the European Union/European Economic Area (EU/EEA).

The use of RADTs and/or self-test RADTs is appropriate in settings with high COVID-19 prevalence when a positive result is likely to indicate true infection, as well as in low prevalence settings for rapid identification of highly infectious individuals. In a low prevalence setting, however, caution is needed, as the use of RADTs could result in a high number of false positive test results.

There are different legal frameworks and requirements in the different EU/EEA countries concerning testing in the workplace. Several EU/EEA countries have introduced the use of RADTs at the workplace. However, a recent EU-OSHA survey indicates that the use of self-test RADTs is limited in occupational settings in most EU/EEA countries.

When considering the use of RADTs and/or self-test RADTs in occupational settings, having a clear testing strategy promotes occupational safety and health and facilitates meeting the public health objectives of testing. Within the strategy, the test performance must be considered as well as the prevalence of COVID-19 and the transmission dynamics in the occupational setting at hand.

Discussions on the appropriate testing strategy should be initiated between all relevant stakeholders before their implementation, including employers, workers, occupational safety and health authorities, and public health authorities. When testing strategies are designed and implemented at enterprise level, workers (or their representatives) should be consulted and clearly informed, in a language they can understand, about the procedures set out in the enterprise. The health and safety committee, where available, the occupational physicians or occupational health services should be involved in designing and implementing it. Furthermore, testing at the workplace should be clearly embedded in the occupational safety and health management approach according to the hierarchy of control, and the results of testing should be considered in the regular revision of the workplace risk assessment.

The cost of testing is an issue for enterprises when setting up testing programmes. Funding opportunities may be an important incentive to implement testing at workplaces.

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## **Scope of this document**

This document outlines the public health considerations for the use of rapid antigen detection tests (RADTs), including self-test RADTs to detect SARS-CoV-2 in individuals in occupational settings in the European Union/European Economic Area (EU/EEA), and provides information on the use of such tests in an occupational safety and health at work context.

This document is not intended to provide recommendations, but to outline the available options for rapid testing to assist public health and occupational safety and health authorities in EU/EEA countries when developing their national guidelines for the prevention of SARS-CoV-2 infection in the workplace, building and consolidating information from previously published ECDC material, including:

- COVID-19 clusters and outbreaks in occupational settings in the EU/EEA and the UK [1];
- <u>COVID-19 testing strategies and objectives</u> [2];
- Infection prevention and control and preparedness for COVID-19 in healthcare settings sixth update [3];
- Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK [4]; and
- <u>Considerations on the use of self-tests for COVID-19 in the EU/EEA</u> [5].

In addition, this document provides a status report of policies implemented in an occupational safety and health context in EU/EEA countries, through an online survey distributed to the national Focal Points of the European Agency for Safety and Health at Work (EU-OSHA) in April 2021.

## **Target audience**

Occupational safety and health and public health authorities in EU/EEA countries.

### Glossary

- Asymptomatic: refers to a person with a disease who does not exhibit any symptoms, e.g. COVID-19 symptoms: fever, cough, gastrointestinal symptoms, sudden loss of taste or smell, etc.
- Incidence: refers to the number of new COVID-19 cases during a specified period e.g. seven or 14 days.
- Negative predictive value (NPV): refers to the likelihood of a negative test being truly negative.
- Occupational Safety and Health (OSH): refers to safety, health, and well-being of people at work.
- Positive predictive value (PPV): refers to the likelihood of a positive test being truly positive.
- Prevalence: the proportion of the population with a disease/condition at a specific point or period expressed as a percentage or rate with the total population as the denominator. In this document, the 14-day notification rate of reported COVID-19 cases per 100 000 population provides an estimate of the prevalence of active cases in the population.
- Rapid antigen detection tests (RADTs): these have been developed as both laboratory-based tests (requiring specialised equipment for analysis) as well as for "near-patient" or "point-of-care" use, for which the analysis is performed on a handheld cartridge with a visual readout. RADT results are usually obtained 10 to 30 minutes after the start of the analysis [4]. For the purposes of this document, when referring to RADTs it is implied that it is a rapid antigen test performed and/or interpreted by trained personnel (i.e. including when persons being tested take a swab themselves). Within this document, the phrase "rapid antigen testing" refers to testing for antigens through the use of RADTs (i.e. rapid antigen detection test (RADT) testing).
- RT-PCR: reverse transcription polymerase chain reaction. It is considered the gold standard for the detection of SARS-CoV-2 RNA.
- Self-test RADT: requires an individual to collect a specimen from their own nose/throat (can be a nose swab, throat swab, or a combination of both), conduct the test and interpret the results according to the instructions provided. This is done with a single-use self-test kit that can be used at home (or in another setting) and without any specialised laboratory equipment or training. Self-tests are essentially RADTs (see above) for which the analysis is performed on a handheld cartridge with a visual readout within 10 to 30 minutes.
- Sensitivity: a qualifier of the accuracy of a testing method and represents the probability of a true positive result when using the test.
- A true positive: when an infected individual correctly tests positive when using a particular test.
- A false positive: when a non-infected individual (a non-case) incorrectly tests positive when using a particular test.
- Specificity: a qualifier of the accuracy of a testing method that represents the probability of a true negative test when using this test.
- A true negative: when a non-infected individual correctly tests negative when using a particular test.
- A false negative: when an infected individual (a case) incorrectly tests negative when using a particular test.

## Background

Since the beginning of the COVID-19 pandemic, guidelines at EU/EEA and national levels have consistently recommended and underlined the importance that individuals stay at home (self-isolate) upon any COVID-19 compatible signs or symptoms [6,7], and that they are tested as soon as possible. During this time, according to existing guidelines, public health authorities initiate tracing of their contacts [8]. Working from home (teleworking) has also been recommended among the workforce to reduce exposure on public transport on the way to work, as well as at the workplace itself [6,9-11]. Teleworking is not possible for some occupations, so in these instances additional interventions are recommended, e.g. physical distancing, use of face masks when physical distancing is not possible, appropriate respiratory and hand hygiene, and sufficient cleaning and disinfection at the workplace, in addition to the preventive measures set out by the occupational safety and health legislation [10]. There is a comprehensive body of occupational safety and health regulations in place [7,12] that sets out employers' obligations to carry out a workplace risk assessment and set preventive measures to protect workers if the risks cannot be eliminated, including, technical, organisational, and personal protective measures. In addition, EU-OSHA has issued guidance on the protection of workers in the context of the COVID-19 pandemic [7][10,11] and developed an electronic tool for employers' workplace risk assessment [13]. Sector-dedicated guidance on these topics is available [14,15] in many countries and referenced in EU-OSHA guidance [11].

To date, diagnostic and confirmatory testing for SARS-CoV-2 infection primarily refers to 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 in detecting the genetic material (ribonucleic acid, RNA) of the virus [4].

Rapid antigen detection tests (RADTs), however, are currently contributing significantly to the overall COVID-19 testing capacity, offering advantages in terms of shorter turnaround times and reduced costs, especially in situations in which RT-PCR testing capacity is limited. Test sensitivity for RADTs is generally lower than that for RT-PCR, and they perform best in cases with high viral load (i.e. likely highly infectious individuals), as is the case for individuals who are pre-symptomatic (the period just before they would start to exhibit symptoms) or at the early stages of presenting symptoms (up to five days from symptom onset) [4].

RADTs were initially approved to be performed by trained personnel (both sampling and test performance). In some EU/EEA countries, the specimen collection can also be performed by the individual through self-swabbing.

More recently, the use of self-test RADTs has started in some sectors, where the sampling, testing and resultinterpretation is completed by the test-individuals themselves, using RADTs that have been approved for this purpose. Self-test RADTs can be performed in any setting without specialised laboratory equipment and professional training.

In areas where widespread community SARS-CoV-2 transmission is on-going (and there is subsequently a high COVID-19 disease prevalence), the detection of cases in workplaces is to be expected. Providing testing at the workplace for early identification of cases could be an option as an add-on to the above-described interventions/approaches. However, it is crucial that any testing strategy is developed in close collaboration with public health authorities and occupational health services to ensure the appropriate approaches and tests are used, and that they are used in a situation and setting where they are known to be effective. The remainder of this document aims to provide guidance on this.

### **Occupations at higher risk of SARS-CoV-2 exposure**

Work is a social determinant of health, with evidence linking certain occupations to poorer health status. It is therefore important to better understand which population groups are employed in occupations that place them at higher risk during an emergency, such as the ongoing COVID-19 pandemic [16,17], whether due to the working conditions or the occupation itself.

Outbreaks and clusters of COVID-19 in occupational settings have been reported since the start of the pandemic. In the absence of mitigation measures, workers in some occupations are at higher risk of exposure to SARS-CoV-2. These include occupations that require close physical proximity to other people (co-workers, patients, customers, etc.), particularly when the work takes place in an indoor setting and/or where transport/accommodation is shared [1].

From an ECDC survey on outbreak in occupational settings, circulated in July 2020 to EU/EEA countries, most clusters of COVID-19 cases were reported in health and social care work settings, followed by food processing-related occupational settings, mines, and factories/manufacturing settings, and lastly by military/law enforcement settings, building/construction sites, education facilities, sales and retail [1]. Outbreaks were also reported in the transportation sector and packaging/mail distribution centres, as well as bars and restaurants. It is important to note that the vast majority (95%) of outbreaks were reported in indoor settings for all the professional categories, pointing to the significance of confined indoor spaces as a risk for occupational transmission.

An EU-OSHA survey on occupations and groups at high risk of COVID-19, including seasonal or temporary migrant workers, to its national focal points in August 2020 noted that the health and social care sector was considered

high risk by virtually all respondents. The construction, food, wholesale and retail, agriculture, and transport sectors were also often identified. Other sectors identified included education, tourism, public transport, and public services sectors.

A lack of sufficient physical distancing, prolonged contact, and poor ventilation are the most significant contributing factors for SARS-CoV-2 transmission, including in occupational settings. In addition to not being able to respect physical distancing because of the nature of the work and/or the housing or transport conditions, employees may also find themselves in a situation where they feel that they must attend work, regardless of potential symptoms or contact with a confirmed case, for fear of losing their job due to absence. This will in itself increase the potential risk for the occupational spread of SARS-CoV-2. This has in some cases been associated with vulnerable groups, where there will be a fear of loss of income or employment if absent from work [1].

### Rapid antigen testing at workplaces, results from the EU-OSHA survey

In April 2021, EU-OSHA conducted a survey among its national Focal Points (FOPs, typically the competent national occupational safety and health authority or a national institution designated by them) to gather information on the use of rapid antigen tests in a workplace context (Annex 2).

#### **Availability of RADTs**

RADTs were available to employers in all 19 EU and EEA countries that replied to the full survey (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Estonia, Finland, Germany, Hungary, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, and Slovenia). Denmark, Greece, and Ireland provided partial input.

In some countries, RADTs were made available to either all employers or employers in specific sectors. Some countries had implemented financial support schemes to cover all or part of the costs for enterprises, while others provided free access to rapid tests to some sectors, e.g. healthcare or social care. In some countries, such as Denmark, the premises set up for free general population testing were also made available to employers for free testing of workers, and tests could be carried out by mobile units or at healthcare centres for mass-testing. A few countries reported limited use of RADTs. Testing strategies in countries may depend on the availability of resources, for example occupational health services.

Common criteria mentioned by the FOPs for the choice of RADTs that were currently in use included test sensitivity  $\geq$  90% and CE certification (please see the section 'RADT as tools for SARS-CoV-2 detection in occupational settings' for information on CE certification). Some countries provided lists of approved tests at the national level, e.g. through employers' organisations or through their public health institutions.

RADTs were also reported to be available to the general public in nearly all countries that replied to the survey. There were settings where clients, customers, patients, or pupils are required to show a negative RADT or RT-PCR to access services, a measure that in a wider sense also provides a degree of protection for workers in these services from the risk of infection. Such requirements were reported for transport (e.g. airports, bus, and rail services), education (kindergartens, schools, universities) including those who attend examinations, healthcare (e.g. hospitals), care homes and similar social services, shops (retail), hairdressers and beauty salons, gyms, restaurants and hotels, participants in sports events, access to skiing resorts or cultural events, or generally in industry. Some of these sectors may have been closed or provided limited services at the time of the survey and such testing may have been required in the context of reopening.

#### **Use of RADTs in workplaces**

Testing for SARS-CoV-2 infection in workplaces was reported in the survey to be mostly carried out by occupational health services, occupational physicians or private services and is largely intended to prevent transmission at the workplace through early detection of asymptomatic cases. These tests could also be carried out by public health institutions, as mentioned above. Testing services could be established at the enterprise and such test centres were typically organised by larger enterprises. In case of offshore workers testing stations had been set up at the helicopter base from where the workers travel, for example.

Workers with COVID-19-compatible symptoms were usually referred to public health authorities or the national health system. Public health interventions could be implemented in cases of outbreaks (investigation together with contact tracing activities). In addition to suspected cases, employees with a known history of contact with a confirmed COVID-19 case were usually referred for testing in every sector. Regular testing could also be carried out in companies located in regions with increased incidence or where clusters had been observed on a regular basis.

The survey showed that employers both in public and private sectors implemented routine rapid antigen testing in a varying number of sectors depending on the country. These could include health and social care (in practically all countries), education (in particular schools and kindergartens), retail services, hotels and restaurants, and to a lesser extent universities, hairdressers and beauty salons, gyms, cleaning services, delivery services, public transport, taxi drivers, law enforcement, military personnel, prisons, manufacturing, the energy sector, the

maritime sector, agriculture, food preparation and processing, and the meat sector. Other specific examples of RADT testing included the oil and gas industry (Annex 1). Seasonal or migrant workers were targeted for testing in several countries, and their access to the workplace could depend on a negative test.

The size of the enterprise could also determine the extent of testing coverage. In Cyprus, for example, businesses/services that employed up to three workers were required to test all employees, those that employed four to 10 workers needed to test at least four employees, and those that employed more than 11 employees needed to test at least five workers, or 30% of the workforce, whichever is the greater in number. In the education sector, all employees had to be tested.

According to the answers to the EU-OSHA survey, the use of self-test RADTs was limited in the workplace context. Self-administered tests may be used in some countries, and this was reported explicitly in two of the respondent countries (Germany and the Netherlands), but only in one country were they reported to be used at workers' homes. Healthcare and the education sector were the only sectors referenced using self-test RADTs. In Greece, a new obligation for the use of at-home self-test RADTs had been set out very recently in order for workers to access workplaces; the sectors concerned were retail, tourism, manufacturing, food industry, and transportation. Self- testing is also mandatory for students, teachers and other staff in secondary education establishments including vocational education in order to access schools in Greece. Results of self-test RADTs need to be registered on a dedicated platform that issues the necessary certificate [18].

One issue, however, that needs to be considered when assessing the extent to which RADTs are used and the range of sectors where they are applied, is that many countries had implemented strict lockdown measures in the last months, and therefore testing may only have been started when enterprises were allowed to reopen. The use of testing, including the application of RADTs, may very well increase in the framework of reopening and return to the workplace. Testing may also be applied in a wider range of sectors under these circumstances. EU-OSHA has provided guidance for return to work that outlines the basic OSH issues to be considered [11] and this is also included in the OiRA COVID-19 tool for workplace risk assessment [13].

#### Legal requirements for the use of RADTs at workplaces

Fourteen of the surveyed countries reported that there were regulatory measures on the use of RADTs in the workplace context, of which less than half under the occupational safety and health framework. In six countries, regulations required employers to offer RADTs for workers in specific sectors, that include the health (e.g. hospitals, clinics, including private practice) and social service sectors (in all countries), education (e.g. kindergarten, schools, universities), retail (e.g. shops, markets), personal care (e.g. hairdressers, beauty salons, cleaning services, delivery services), food preparation and manufacture, hotels, catering and restaurants, agriculture, transport (e.g. airlines, railways, taxi, bus and coach services), public and emergency services (e.g. police, fire brigade, prisons), meat processing, and workplaces employing seasonal or migrant workers. Some countries also relied on the input of a committee or an expert group to design their national testing strategies and regulations, for example Ireland [19].

In Germany, for example, according to the second amendment to the SARS-CoV-2 Occupational Health and Safety Regulation from 20 April 2021 [20], employers were obliged to offer those employees that are not teleworking a RADT for SARS-CoV-2 at least once a week. Certain groups of workers needed to be offered at least two tests per week according to this regulation. The latter applied to workers using collective accommodation provided by or at the initiative of the employer, workers who work in enclosed spaces under conditions favouring transmission of SARS-CoV-2, workers in companies providing personal services with direct physical contact, or those who have frequent contact with others.

Intervals for regular testing organised by employers in a workplace context were reported to usually be weekly, but could also range from twice a week to a 21-day interval and could depend on the judgement of the employer following a workplace risk assessment or an assessment by the occupational health physician or service. One country reported that testing was restricted to a maximum of once a day. Workplace risk assessment and judgement of occupational physicians could also determine who in an enterprise had to be tested and how frequently. Furthermore, testing was conducted as needed, after public holidays, vacations, and upon new recruitments.

Testing was reported to normally be voluntary for workers, with a few exceptions reported, for example for workers in the health or social care sectors, who would not be allowed to access the workplace without a negative test. One country reported that the workplace risk assessment could determine that testing be obligatory for workers, and another country reported that workers could face disciplinary action if they refused to undergo a SARS-CoV-2 screening test; dismissal as a possible consequence of not taking a test was mentioned by four countries. Workers with a positive test result would normally have to take a PCR test and, if positive, quarantine; dismissal as a consequence of testing positive was only mentioned once. However, it could be an issue for seasonal or migrant workers who are required to provide a negative test result in order to access the workplace or enter the country. Countries reported that testing required by employers should also be cost-free to workers and that it should ideally be done within working time. Furthermore, generally, any positive tests would have to be reported to public health authorities, either directly or indirectly, and this was reported to be done by healthcare actors, whether occupational or public health services, as the employer would not be allowed to process sensitive

health data and was likely to receive information on the measures to be taken (isolation, collective PCR testing, adaptation of workplace measures) and the absence of a worker rather than health-related information, for instance if a worker has tested positive or negative. However, the employer could be informed of a positive test after consent from the workers. There may also be no direct reporting to public health authorities based on RADT as they are not considered conclusive to the same extent as PCR because of moderate sensitivity, especially in the case of negative tests.

#### Social partners' position on the use of RADTs

Social partners (representing workers' and employers' interests) in the countries that answered the survey were generally positive about the application of rapid tests in a workplace context. The social partners could not be consulted in all countries. In those countries where they were, providing testing opportunities was seen as an important component of the strategy to reduce the incidence of infection and protect workers. However, reservations were expressed on the workers' side about confidentiality of results and how confidential data would be handled at the enterprise level. They pointed out the need for proper procedures that would ensure that testing was offered for free to workers, including further testing after a positive RADT, was voluntary for workers, and performed by trained professionals, preferably by occupational physicians. Workers was foreseen, it should be regulated at the national level rather than at enterprise level, depending on the type of work performed, to prevent unequal treatment and to remove ambiguities. Also, it was seen as important that clear processes were outlined at enterprise level that would be informed of the companies' procedures. Worker consultation on these procedures was also seen as an important element of setting up testing policies in a workplace context including those at companies' or sectoral level.

The access to rapid antigen testing was seen as an important element to enable opening of enterprises after lockdown by both social partners, for example regarding sectors involved in tourism, museums and cultural events. However, as a test result is only a snapshot and testing is no substitute for occupational safety and health measures in the workplace, social partners insisted on the need for appropriate occupational safety and health measures.

Employers' organisations pointed out that considerable efforts had been made by companies to put in place additional measures at workplaces to protect workers from COVID-19. They raised concerns about the possible cost to enterprises, in particular SMEs, self-employed and public administrations, and the reliability of rapid antigen testing. Another issue mentioned by several countries was the importance of recognising tests in companies within the national testing strategy (for example, enabling a person who tests negative to access other services). Furthermore, the compensation of workers in case they test positive and in cases of precautionary confinement should be secured. Coverage of the latter was foreseen in Germany, for example. Funding seemed to be an essential prerequisite to implement rapid testing programmes at enterprises. For example, the funding programme put in place in Austria had incentivised testing programmes in nearly 2 000 companies covering about 900 000 workers who could get tested up to 2-3 times a week.

Only one country reported a social partner agreement on testing, including rapid antigen testing [21]. In Austria, there was a general collective agreement between social partners that covered testing at the workplace, testing at other facilities, consequences in case of a positive test result, wearing of masks at the workplace, and recreational breaks if wearing a mask was mandatory among others. It was applicable to all members of the Austrian Federal Economic Chamber (public law chamber) and thus to the (quasi-)entirety of the Austrian economy (agreement not specifically on the use of rapid antigen testing).

Other approaches included a national [22] or branch [23] organisation providing model agreements for enterprises on testing. A joint position of social partners was reported by Belgium [24], and it differentiated between testing in the context of an outbreak or high transmission, routine testing, and testing in small- and medium sizedenterprises, particularly in personal services.

#### Guidance on rapid antigen testing in a workplace context

Ten countries reported that guidance had been issued for rapid antigen testing in a workplace context. Guidance was national in most cases, but could also be directed at specific sectors, for example the health and social care sectors. The approaches were diverse, although it was reported that in most cases employers and those who were performing the testing (e.g. occupational health services) were addressed: in Austria, for instance, guidance had been prepared by the employers' organisation [25], while in Estonia such guidance was prepared by public health authorities but provided instructions for using SARS-CoV-2 RADTs in work collectives [26]. The German social accident insurance (DGUV) provided an FAQ feature on the application of RADTs in a workplace context [27], while in the Netherlands guidance was available for enterprises on how to organise rapid testing or self-testing under supervision, which provided toolkits for enterprises and informed about funding opportunities [28].

# RADTs as tools for SARS-CoV-2 detection in occupational settings

Several RADTs and self-test RADTs to detect SARS-CoV-2 infection are available and being used to a varying extent in different settings in several EU/EEA countries, including the occupational setting as described above. For the purposes of this document, when referring to RADTs it is implied that it is a RADT performed and/or confirmed by trained personnel. When referring to self-test RADTs, we are referring to tests that are performed and interpreted by the tested individual themselves.

To place a diagnostic test on the EU market, the manufacturer must demonstrate compliance with the applicable legal requirements of EU Directive 98/79/EC for in vitro diagnostic medical devices [29]. This includes carrying out a performance evaluation of the device. Furthermore, for any devices intended for non-medically trained persons, the manufacturer must also apply to a third-party body (called a notified body), which will examine the design aspects of the device and issue a corresponding certificate. Once the manufacturer has declared conformity of the device with the legal requirements, they may affix the "CE" marking to the device and place it on the EU market [4]. A list of CE-marked and commercially available RADTs and self-test RADTs for SARS-CoV-2 in the EU/EEA can be found on the relevant Joint Research Centre (JRC) database [30]. Some EU/EEA countries also provide lists of approved tests at national level.

RADTs, including self-test RADTs, perform best in cases with high viral load, in pre-symptomatic and early symptomatic cases up to five days from symptom onset [4,5]. They can therefore help reduce further transmission through early detection of highly infectious cases, enabling a rapid start of contact tracing. When considering the use of a test, the prevalence of the disease needs to also be taken into consideration, as it will impact the reliability of the tests results.

In some occupational settings, the prevalence of COVID-19 disease will reflect that of the community (i.e. employees in the workplace can be considered as having the same risk of being infected with the virus as anyone in the community). In other settings, the prevalence of the disease could differ from that of the community, as there will be other risk factors to take into consideration (such as in healthcare). The support provided by a diagnostic tool (e.g. RADT, self-test RADTs) in correctly identifying positive individuals (in this case SARS-CoV-2 infection) will depend on how common the disease is in the specific setting (i.e. how *prevalent* the disease is). Table 1 provides some considerations for how accurate RADT and self-test RADTs would be in high and low prevalence settings.

	Positive predictive value (PPV)	Negative predictive value (NPV)
High prevalence <sup>a</sup>	High PPV – a positive result is most likely truly positive	Low NPV –a negative result may not be truly negative and therefore it is important to follow up with a confirmatory test (PCR and/or RADT a few days later)
Low prevalence <sup>b</sup>	Low PPV – a positive result may not be truly positive and therefore it is important to follow up with a confirmatory test (PCR and/or RADT)	High NPV – a negative result is most likely truly negative

#### Table 1. Predictive value of RADTs and self-test RADTs in high versus low prevalence settings

<sup>a</sup> Conceptual example: high prevalence e.g. estimated 10 000/100 000 and a sensitivity of 0.8 and a specificity of 0.98 the NPV will be 0.978 and PPV will be 0.816. With a sensitivity of 0.98 and specificity of 0.999 the NPV and PPV are 0.998 and 0.991, respectively. For more conceptual examples with different prevalence see Table 2 in [4].

<sup>b</sup> Conceptual example: low prevalence e.g. estimated 50/100 000 and a sensitivity of 0.8 and a specificity of 0.98 the NPV will be 1.000 and PPV will be 0.020. With a sensitivity of 0.98 and specificity of 0.999 the NPV and PPV are 1.000 and 0.329, respectively. For more conceptual examples with different prevalence see Table 2 in [4].

In summary, based on the above and what is presented in Table 1:

- **In a high COVID-19 prevalence setting**: the use of RADTs and self-test RADTs can be useful for identification of individuals infected with SARS-CoV-2, especially in early stages of the infection when the virus load is high, as individuals testing positive can be considered true positives. This will allow rapid isolation of test-positive cases and follow up with public health action. However, individuals testing negative might be false negatives. Continued strong compliance with occupational safety and health measures and all other non-pharmaceutical interventions (NPIs) and public health recommendations continues to be crucial.
- **In a low prevalence setting**: the use of RADTs and self-test RADTs can be useful for rapid identification of highly infectious individuals. However, they will be less useful than in a high prevalence setting for identification of SARS-CoV-2 infected individuals, as many individuals testing positive will be false positives.

This could lead to unnecessary public health responses to isolate cases and follow-up with public health action; efforts and resources which could be used elsewhere. Contrarily, individuals testing negative can more confidently be considered truly negative. Continued strong compliance with all other NPIs and public health recommendations are crucial.

As will be described in the next section, the use of RADTs and self-test RADTs should be regarded in the overall context of the occupational setting, and within a defined framework/public health strategy for the prevention and control of SARS-CoV-2 in the workplace.

### Considerations when introducing RADTs and/or self-test RADTs in the occupational setting

The key public health objective for providing RADTs and/or self-test RADTs in the occupational setting will be to prevent the introduction and spread of SARS-CoV-2-infection in the workplace itself. It is again crucial to underline that such an approach must only complement, and not replace, existing occupational safety and health measures, workplace NPIs and practices for preventing the introduction and spread of SARS-CoV-2 in the workplace.

In an occupational setting, access to testing with RADTs and/or self-test RADTs could be provided in two ways:

- As screening of employees at the workplace (or before arriving to the workplace): this approach will commonly fall under employers' responsibilities, likely be carried out by occupational health services, and therefore need to be in alignment with the existing occupational health regulations and procedures.
- As part of the local public health prevention and control programme for the identification of cases and for outbreak investigations/contact tracing efforts: this approach will involve public health authorities and require a close link between the companies' occupational health services and public health services.

Regardless of which approach is taken, it is essential that the existing national occupational safety and health regulations and legal frameworks for the provision of health services at the workplace are abided by, as well as the local, regional and/or national public health regulations and recommendations for the prevention and control of SARS-CoV-2.

Discussions on appropriate testing approaches should be initiated between relevant stakeholders (e.g. employers, occupational safety and health authorities, and public health authorities) before their implementation. When considering the use of RADTs and/or self-test RADTs in an occupational setting to support the public health objective of preventing the introduction and spread of SARS-CoV-2-infection in the workplace, the following should be established and considered [2,4,5]:

- **Testing strategy**: A clear testing strategy and plan will be of support to the setting itself, to ensure both the occupational safety and health and the public health objectives of testing are met. Such a strategy could be designed at the national level or cover specific sectors or occupations. It could also be set out by employers, for example based on workplace risk assessment. Any strategy should take into consideration the national testing and surveillance strategy for COVID-19 as well as the potential occupational safety and health regulations in place. The public health objective(s) should be clearly stated, as well as a description on who to test (and why). Furthermore, a step-by-step description of the actions to be taken, whether the test is negative or positive, is essential.
  - From a public health perspective this should include information on the isolation of positive cases and reporting to public health authorities, who will in turn coordinate confirmatory testing, contact tracing and quarantining of close contacts [2,4,5].
  - From an occupational safety and health perspective this should include clear procedures that would be consulted with workers or their representatives, if at the enterprise level, with the health and safety committee, if in place, and with occupational physicians or health services, and address how sensitive medical data are handled at the workplace level. Where a regular preventive testing programme is set up, clear indications should be given on when to do a RADT, who should undergo tests, the intervals for testing, how and where tests are carried out, and how information is processed/shared. Furthermore it should be set out clearly what information for workers on testing will be provided, and how they will be informed on the results, as well as what to do when there is a positive RADT, including occupational safety and health measures. The rationale for the programme should be explained, including how it fits in the overall occupational safety and health strategy of the company. Employers may need to adapt their workplace risk assessment and revise the occupational safety and health measures. Testing of workers should ideally be voluntary and carried out within working time.
- **Test performance**: Only high-performance tests according to the internationally recognised standards, should be selected for use. Again, it is advisable that the relevant public health or occupational safety and health authority is consulted to identify the tests that are recommended for use [4].
- **COVID-19 prevalence in the target setting**: please see section above.
- **Transmission dynamics in the target setting**: As described earlier, in certain occupational settings there might be a higher risk for SARS-CoV-2 transmission, e.g. it may be difficult to maintain physical distancing and/or climatic conditions may not be optimal (working at low temperature).

To ensure the above, establishing a close cross-sectoral collaboration with local public health and occupational safety and health authorities will be essential, whether the testing is being offered as part of the occupational health services or as part of the public health prevention and control programme.

### **RADTs versus self-test RADTs in the occupational setting**

From a public health perspective, self-test RADTs in general (i.e. not only specifically to the occupational setting), can offer advantages when used to complement professionally administered RADTs or RT-PCR tests. They can improve the accessibility to testing, which could support the early detection of infectious cases and reduce further community transmission [5]. However, there is a risk of underreporting of test results when the responsibility is shifted from health professionals and laboratories to individuals. There can also be different policies regarding whether confirmatory testing is recommended. This change in responsibility for reporting would also make response measures such as contact tracing and quarantine of contacts even more challenging. Current indicators for monitoring the intensity and spread of the COVID-19 pandemic (testing rates, test positivity rates, and case notification rates) could be affected, and it could be difficult to monitor disease trends over time. An additional challenge is that samples from self-testing would not be available for sequencing and monitoring variants of concern [5].

Differently from RADTs, self-test RADTs can be performed in any setting without specialised laboratory equipment and training. In occupational settings, the self-test RADTs could thus allow an even more rapid identification of infectious individuals as compared to RADTs, allowing rapid isolation of cases, quarantine of their contacts and prevention of further transmission in the targeted setting provided results are communicated properly and in a timely fashion to public health authorities [5]. The reliability of the self-test RADTs depends on the ability of the person taking the sample, how good the instructions are, how well the individual can follow instructions, the viral load at the time of the sample collection and the disease prevalence at the time the test is performed [5]. This in turn needs to be considered together with any occupational health regulations there may be for the use of selftests in the workplace. For more information please refer to the ECDC dedicated document on consideration for the use of self-test RADTs [5].

The aforementioned EU-OSHA survey indicated that the use of self-test RADTs in most EU/EEA countries was limited in the occupational settings. Sharing of confidential medical data could be an issue here, as communication via occupational physicians or services was reported to be the preferred option. Furthermore, in some countries, collective results of tests were communicated to employers by preventive services and these could lead to revision of the workplace risk assessment and the measures at workplaces. At the time of the EU-OSHA survey, self-test RADTs had largely been used in occupational settings where there was a high risk of exposure (e.g. healthcare settings) or where there were a large number of individuals mixing (e.g. educational facilities).

As mentioned in the previous section, it will be essential to ensure a close link with local public health and occupational safety and health authorities when considering the introduction of self-test RADTs in an occupational setting in order to ensure all approaches are supportive of the public health objectives and respect the legal frame provided by occupational safety and health legislation. Please refer to the previous section for the considerations needed.

### **Additional considerations**

Most available RADTs recommend the use of nasopharyngeal swabs as sample type. Self-sampling using saliva is not currently clinically validated for RADTs. Unlike RT-PCR, RADTs lack controls for confirmation of appropriate sampling; they also lack an amplification step, which limits their sensitivity [4].

When implementing a testing strategy in an occupational setting, testing should be made available to all employees without discrimination and/or additional cost. The entire testing process should be clearly explained to all individuals in advance, particularly if testing is a requirement to enter the workplace (e.g. due to a higher risk of exposure to SAR-CoV-2 for vulnerable individuals or because NPI measures cannot be implemented).

The epidemiological situation in the EU/EEA is continuously evolving and new types of tests are becoming available.

The use of saliva as sample material [31] for molecular diagnostics has a much longer history than the SARS-CoV-2 pandemic [32,33]. Saliva sample collection is easy, non-invasive, and more acceptable for repeat testing and can be performed by non-healthcare professionals or individuals themselves who are properly instructed. Although nasopharyngeal swabs remain the gold standard for diagnostic testing of SARS-CoV-2, saliva sampling can contribute to timely identification of infectious individuals in the community with RT-PCR when used at the right time, i.e. when viral loads are the highest, and when sampling is performed properly. However, there are very few clinical validation studies on the use of saliva as sample material for RADTs and data on the sensitivity of the tests are lacking.

In addition, there are ongoing COVID-19 vaccination campaigns in all EU/EEA countries, meaning that occupational settings will soon increasingly have staff who have been vaccinated against COVID-19, which will in time result in adaptations/changes in the testing, occupational safety, and health and NPI requirements in the workplace. Public health authorities may consider exempting fully vaccinated individuals from repeat testing in occupational and other community settings. However, caution is warranted for e.g. healthcare workers and long-term care facility

staff because of the higher risk of onward transmission to vulnerable, high-risk individuals [34]. ECDC continues to monitor the situation and to assess the impact of vaccination on preventing not only severe disease but also transmission.

It should also be taken into account that with the evolving epidemiological situation, changes in testing strategies (including occupational settings) and the increasing number of people being vaccinated may all have an impact on surveillance. Additional information on the possible impact on surveillance on a population-based level for self-test RADTs can be found in Annex 3 of ECDC's *Considerations on the use of self-tests for COVID-19 in the EU/EEA* [5].

## Conclusions

In summary, RADTs are available in EU/EEA countries; the EU-OSHA survey showed that these test were available to employers in all 19 countries that replied to the EU-OSHA survey; these were reported as being made available through different approaches and/or under specific national legal framework. The survey further showed that employers in both the public and private sectors were introducing the use of RADTs in different sectors, depending on the country. However, the use of self-test RADTs was reported as being used to a very limited extent in the responding countries. Testing was reported to usually be voluntary for workers, with a few exceptions reported by the countries. Twelve countries reported regulatory measures on the use of RADTs, of which half fell under the occupational safety and health approach and half under the public health approach. Ten countries reported that guidance had been issued for rapid antigen testing in a workplace context (Annex 1).

RADTs and self-test RADTs can support efforts to prevent the introduction and spread of SARS-CoV-2 in the workplace, as a complement to existing NPIs.

The use of RADTs is appropriate in high prevalence settings when a positive result is likely to indicate true infection, as well as in low prevalence settings for rapid identification of highly infectious individuals.

When looking to introduce testing in the workplace, as for any setting, a clear strategy will be of support to the setting. It is important that it is in line with existing national, regional, and local public health and occupational health regulations and recommendations. Furthermore, the strategy needs to take into account what is known about the test performance (ensuring only those with recognised performance are used), as well as considering the COVID-19 prevalence and transmission dynamics in the setting.

Establishing a close link with local public health and occupational safety and health authorities will be essential, whether the testing is being offered as part of the occupational health services or as part of the public health prevention and control programme.

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## Annex 1

## Table 2. Summary of the EU-OSHA survey, replies to selected questions from the questionnaire (Annex 2)

Question	Options	Number countries (tota 19 replying)
Rapid antigen test available only to some sectors?		
	Yes	4
	No	0
Rapid antigen tests distributed to enterprises free of charge?		
-	Yes, to all	1
	Yes, to some	8
	No	8
Are there any regulatory measures on the use of apid antigen tests in the workplace context?		
	Yes	3
	Yes, under OSH regulatory approach	6
	Yes, under public health	6
	No	5
Do regulations require employers to offer rapid antigen testing for workers?		
	Yes, all workplace	2
	Yes, some sectors/workplaces only	6
	No	11
Are there any social partner agreements on the use of rapid antigen tests at workplaces?		
	Yes	2
	No	17
s there guidance on the use of rapid antigen tests or screening at workplaces?		
	Yes	10
	No	5
What are the areas where RADTs are used?		
	Schools and kindergartens	6
	Universities	1
	Shops, retail	3
	Hairdressers, beauty salons	2
	Gyms	2
	Restaurants and hotels	3
	Cleaning services	2
	Delivery services	1
	Public transport	3
	Taxi	1
	Healthcare (incl. private practice)	9
S	Social care (care homes and imilar services)	9
	Manufacturing	2
	Energy sector	3

ECDC TECHNICAL REPORT Considerations on the use of rapid antigen (including self-) tests for SARS-CoV-2 in occupational settings

Question	Options	Number countries (total 19 replying)
	Police	5
	Prisons	3
	Agriculture	1
	Seasonal work	1
	Food preparation and processing	2
	Meat sector	1
	Other reported sectors	Oil industry, construction sector, entertainment sector

## Annex 2

### FOP survey on Member State regulations or guidance regarding the use of rapid antigen tests in a workplace context

#### Introduction

The European Commission has made a formal request to EU-OSHA and ECDC to prepare a joint report on the use of rapid antigen tests<sup>1</sup> in a workplace context for the detection of COVID-19 among workers.

Such rapid antigen tests include those that are self-administered, those that are directly administered by the employer (e.g. by their onsite occupational health service), or those administered via a third party (either a public body or a private service provider).

The Commission is seeking an overview of the current state of play in workplaces – including in the public sector (e.g. education). Specifically, they wish to ascertain whether criteria exist where rapid antigen tests should be or are recommended for use, and where such tests are used, how the data is used and handled. This includes what happens to workers (e.g. seasonal workers) with a positive test result.

The outcome of this survey will be the basis of EU-OSHA's contribution to this report. The Agency will provide a summary to focal points following the completion of the survey.

#### Availability of rapid antigen tests

#### Do employers have access to rapid antigen tests?

Access may be direct (e.g. tests purchased directly), or indirect (e.g. tests accessed via a third party)

If only some employers have access, click yes and this will be clarified in a later question.

- Yes
- No

If yes, what type of rapid antigen tests are available?

If yes, are rapid antigen tests available (directly or indirectly) for all employers?

- All employers
- Only for some (e.g. only those in certain sectors (e.g. healthcare) or with particular worker types (e.g. seasonal workers or workers from abroad).

If only for some, please provide more information on those who have access. In particular, please tell us about access depending on sector (e.g. food production), employer type (public or private), and size of employer (e.g. for SMEs).

#### Are rapid antigen tests distributed free of charge to enterprises?

- Yes, to all
- Yes, to some (please specify which)
- No

#### If no, are they available at reduced cost with support by public authorities?

- Yes
  - (If yes, distributed by whom?)
- No

<sup>&</sup>lt;sup>1</sup>Rapid antigen detection tests (RADTs) have been developed as both laboratory-based tests (requiring specialised equipment for analysis) as well as for "near-patient" or "point-of-care" use, for which the analysis is performed on a handheld cartridge with a visual readout. RADT results are usually generated 10 to 30 minutes after the start of the analysis.

#### Use of rapid antigen tests in a workplace context

#### Are rapid antigen tests used in a workplace context?

Workplace context includes tests conducted outside of the workplace but for work reasons

- Yes in all types of workplace
- Yes in some workplaces
- No

#### If yes in some workplaces, what are the areas where they are used?

- Schools and kindergartens
- Universities
- Shops, retail
- Hairdressers, beauty salons
- Gyms
- Restaurants and hotels
- Cleaning services
- Delivery services
- Public transport
- Taxi
- Healthcare (incl. private practice)
- Social care (care homes and other similar services)
- Manufacturing (explain which sectors)
- Energy sector
- Police
- Prisons
- Agriculture
- Seasonal work
- Food preparation and processing
- Meat sector
- Other (please explain).

#### Are there criteria other than sector that lead to the use of rapid antigen tests?

Such criteria could include the number of workers, a specific feature of the workplace (e.g. refrigerated workplaces), types of worker (e.g. seasonal workers), or particular arrangements for sectors that mainly offer home-office (e.g. staff can only come to the office if they show a negative antigen test).

- Yes If yes, box text
- Please give further information
- No

#### Do rapid antigen tests have to fulfil any requirements if they are to be used at workplaces

#### For example, do they have to meet any specific certification requirements?

- Yes Please explain
- No

#### Where workers undergo rapid antigen tests, by whom can they be administered?

Please tick all that apply

- Self-administered
- By health professionals
- By occupational health professionals
- Others (e.g. volunteers)
- More information.

#### Where are rapid antigen tests for workers being undertaken?

Please tick all that apply

- At work
- In the worker's home
- At a service provider (e.g. OSH service, private clinic)
- At a public testing location
- Other
- More information.

#### Legal requirements for the use of rapid antigen tests at workplaces

#### Are there any regulatory measures on the use of rapid antigen tests in the workplace context?

This may include specific sectoral requirements. Note however, there is a later question on social partner agreements.

- Yes
- No

#### If yes, are these regulations under the occupational safety and health regulatory approach?

- Yes
- No If no, under which policy area do these regulatory measures fall? (e.g. public health, education<sup>2</sup>)

#### Please explain what regulatory measures are in place

Please provide a reference of the national/regional regulation on the use of rapid antigen tests at workplaces (title, internet link).

#### Do regulations require employers to offer rapid antigen testing for workers?

For example, where workers have to come to the workplace to carry out their work.

- Yes
- Yes, some sectors/workplaces only (see next question)
- No

### If yes, some sectors, where requirements exist for only some sectors/workplaces, which sectors/workplaces are concerned?

Please tick all relevant

- Private sector
- Public sector
- Education (e.g. kindergarten, schools, universities)
- Retail (e.g. shop, markets)
- Personal care (e.g. Hairdressers, beauty salons)
- Cleaning services
- Delivery services
- Hotels, catering and restaurants (HORECA)
- Healthcare (e.g. hospitals, clinics, incl. private practice)
- Social care (e.g. care homes)
- Food preparation and manufacture
- Meat processing
- Agriculture (e.g. seasonal workers)
- Transport (e.g. airlines, railways, taxi, bus and coach services)
- Public and emergency services (e.g. police, fire brigade, prisons)
- Energy sector
- Non-food manufacturing
- Workplaces employing seasonal or migrant workers
- Other.

At what intervals do the workers (have to) undergo a rapid antigen test? (please in particular clarify where different intervals apply in different workplaces or sectors)

#### Is rapid antigen testing voluntary for workers?

- Yes
- Some workers are obliged to undergo rapid antigen tests If yes box text to provide more information
- No

#### What are the consequences if the worker declines a rapid antigen test?

Please tick all relevant

- Reassignment to other tasks
- Workers cannot attend the workplace

<sup>&</sup>lt;sup>2</sup> It may be that there are sectoral requirements or recommendations, e.g. for schoolteachers

- Telework
- Dismissal
- Other Please explain

#### What are the potential consequences of a positive rapid antigen test in a worker?

Please tick all appropriate

- Dismissal
- Worker is required to self-isolate
- Worker undergoes re-testing
- Worker undergoes PCR test and screening of contacts
- The workers is granted leave in case of a positive PCR test
- Revision of workplace risk assessment and preventive measures
- Visit by labour inspectorate
- Other.

#### Please provide further information if available

For example, if there are differences between sectors, please clarify here

## Do the regulations include what information has to be provided to workers about the rapid antigen test?

For example, information about testing, the outcome of the test, the consequences of failing or refusing a test

- Yes, please provide further information
- No

#### Social partner views and agreements

## What are the views of social partners on the use of rapid antigen tests for COVID-19 at the workplace?

#### Workers:

#### **Employers:**

#### Are there any social partner agreements on the use of rapid antigen tests at workplaces?

- Yes
- No

If yes, please provide further information and any references to the agreements or statements from social partners (title, internet links)

#### Guidance on the use of rapid antigen tests

#### Is there guidance on the use of rapid antigen tests for screening at workplaces?

- Yes
- No

#### Is this guidance issued in the occupational safety and health policy context?

- Yes
- No If no, please tell us which policy context (e.g. public health, education).

#### Which type of guidance?

Please tick all relevant types

- National
- Regional
- Sectoral
- Other.

#### Please provide further information

For example, if there is regional guidance, please explain the differences between them, or if there is specific sectoral guidance then please identify which sectors.

#### For whom is the guidance intended?

Please tick all relevant

- Employers
- Workers or their representatives
- Those who will administer the testing (e.g. occupational health services)
- Other (Please explain).

#### Please indicate for which sector the guidance is intended

Please tick all relevant

- Private sector
- Public sector
- Education (e.g. kindergarten, schools, universities)
- Retail (e.g. shop, markets)
- Personal care (e.g. Hairdressers, beauty salons)
- Cleaning services
- Delivery services
- Hotels, catering and restaurants (HORECA)
- Healthcare (e.g. hospitals, clinics, incl. private practice)
- Social care (e.g. care homes)
- Food preparation and manufacture
- Meat processing
- Agriculture (e.g. seasonal workers)
- Transport (e.g. airlines, railways, taxi, bus and coach services)
- Public and emergency services (e.g. police, fire brigade, prisons)
- Energy sector
- Non-food manufacturing
- Workplaces employing seasonal or migrant workers
- Other.

#### What does the guidance cover?

Please tick all relevant

- When to do a rapid antigen test
- How information is processed/shared
- Information for workers on testing
- Information for workers on the results
- Test intervals
- What to do when there is a positive antigen test
- Occupational safety and health measures
- Other Please explain.

#### Please provide references and any further relevant information regarding the guidance

Please give title and where possible link to online

#### Management of data generated by rapid antigen testing

### Is there specific legislation or guidance for employers on the management of the sensitive health data generated by the performance of rapid antigen tests?

- Yes
- No
- Please provide more information if available.

#### Who receives information on the results of rapid antigen testing?

Please tick as appropriate

- Workers who underwent testing
- Occupational health services
- Employers
- Other Please explain.

### When employers organise rapid antigen testing for workers, are there reporting obligations or are data shared with external bodies?

For example, is the data provided to the national institutes coordinating COVID response, or to insurance services?

• Yes - Please tell to whom

No No

## What type of information does the employer receive regarding the outcome of rapid antigen testing for workers?

Please tick all relevant answers

- Individual result (positive or negative)
- Collective results
- Information on the measures taken (isolation, collective PCR testing, adaptation of workplace measures)
- Other
- Please provide any information or details.

#### **Good practice examples**

#### Do you have any good practice examples on the use of rapid antigen tests in the workplace?

- Yes Please provide information
- No

#### Use of rapid antigen tests by users seeking services (to protect workers)

#### Are rapid antigen tests available to the general public?

- Yes If yes, how?
- No

## Are there settings where clients, customers, patients or pupils are required to show a negative rapid antigen test or PCR to access services?

- Yes
- No

#### Where there are such requirements, in which type of workplace?

Please tick all that apply

- Education (kindergartens, schools, universities)
- Shops, retail
- Hairdressers and beauty salons
- Gyms
- Restaurants and hotels
- Health care (e.g. hospitals)
- Care homes and similar social services
- Transport (e.g. airports, bus and rail services)
- Industry
- Other workplace types please explain.