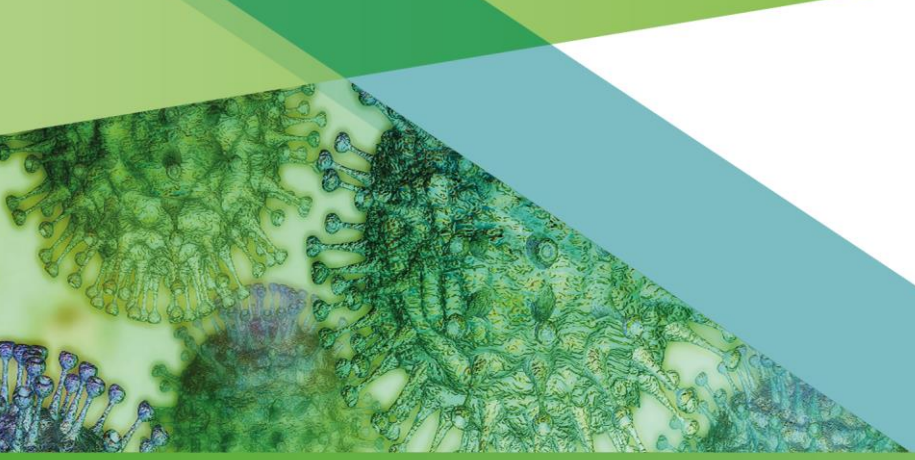

ECDC TECHNICAL REPORT

Considerations for the use of saliva as sample material for COVID-19 testing

3 May 2021

Key messages

- Nasopharyngeal specimens remain the gold standard for COVID-19 testing for use with RT-PCR and rapid antigen diagnostic tests.
- Studies on the performance of RT-PCR tests have variously reported both higher and lower sensitivity for saliva samples compared with nasopharyngeal swabs. However, meta-analyses of such studies suggest an overall similar or non-statistically significant lower sensitivity associated with the use of saliva samples.
- The reported heterogeneity is likely to, in part, reflect differences in sampling techniques, sampling times and the type of population being tested, with evidence that RT-PCR tests with saliva as sample material show similar sensitivity to those using nasopharyngeal swabs for symptomatic patients, if the sample collection is performed within the first five days from onset of symptoms, and when the viral load is high.
- Saliva sample collection is easy, non-invasive, more acceptable for repeat testing and can be performed by non-healthcare professionals or individuals themselves who are properly instructed.
- Evidence supports the conclusion that saliva can be used as an alternative sample material for RT-PCR testing when nasopharyngeal swabs cannot be collected in the following scenarios: in symptomatic patients and for repeated screening of asymptomatic individuals.
- Further clinical studies are warranted on the sensitivity of saliva as sample material for RT-PCR analysis for symptomatic and asymptomatic children, and to standardise the sampling collection methods.
- Current limited evidence does not support the use of saliva as an alternative sample material for rapid antigen or antibody tests. Further clinical validation studies on the different available tests are needed.
- Commercial diagnostic assays for saliva with a CE-marking are available in the European Union/European Economic Area (EU/EEA). None of these assays is included in the Health Security Committee list of mutually recognised tests.

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Stockholm, May 2021

Scope of this document

This document outlines the use of saliva as a diagnostic sample for detecting SARS-CoV-2 infection, considering the advantages, limitations and uncertainties associated with the use of saliva as sample material.

This document is intended to assist European Union/European Economic Area (EU/EEA) Member States in their decision-making by providing a critical evaluation of the current evidence related to salivary diagnostics of SARS-CoV-2 infections. This document should be read in conjunction with the 'Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK' [1] which was published in November 2020 as well as the document, 'COVID-19 testing strategies and objectives 2020' [2].

ECDC has also published a document that outlines public health considerations for the use of self-tests to detect SARS-CoV-2 by public health authorities in the EU/EEA [1].

Target audience

This technical report provides guidelines to laboratories, public health professionals and other relevant stakeholders in the EU/EEA to make decisions on the use of saliva as an alternative sample type for detection of SARS-CoV-2.

Background

Proper sample collection is one of the most important steps in the laboratory diagnosis of SARS-CoV-2. If a specimen is not collected properly, this may cause false negative or inconclusive test results. The detection of viral RNA by real-time reverse transcription polymerase chain reaction (RT-PCR) performed on respiratory specimens, especially nasopharyngeal swabs, is still considered the gold standard for the diagnosis of SARS-CoV-2 infection. However, the collection of nasopharyngeal swabs is invasive, ideally requires experience and clear instruction and has a risk of viral transmission to the sample collector. In view of the potentially easier collection process, the alternative or complementary use of saliva has been considered and investigated since the early stages of the pandemic.

The presence of infectious SARS-CoV-2 virus in saliva in asymptomatic or pre-symptomatic individuals has been demonstrated [3], supporting the applicability of saliva as sample material for COVID-19 testing.

Oral saliva that is produced by the salivary glands, is an 'ultra-filtrate' of white blood cells and contains epithelial cells from which RNA can be extracted. Oral saliva has a different composition than posterior oropharyngeal fluids that are produced when coughing or clearing the throat. It will also contain respiratory secretions from both upper nasopharyngeal and lower airways or from sputum that contains respiratory secretions from the lower respiratory tract [4]. It is important to note that saliva samples may be heterogeneous and a clear distinction between these sample types is difficult, because saliva is also produced when coughing, while respiratory secretions will also be present in oral saliva samples [5].

Methods

Scientific evidence for the applicability of saliva as sample material for COVID-19 testing is available from a wide range of clinical and biomedical studies. This document is based on a non-systematic review of the literature conducted on 25 March 2021 and includes published articles and pre-prints up to this date.

Before publication, the document was shared with the EU/EEA network of national COVID-19 reference laboratories for their written consultation on 7 April 2021. Comments of experts and experiences shared by EU/EEA Member States have been considered.

Scientific evidence: saliva as a diagnostic sample for detecting SARS-CoV-2 infection

Saliva collection

The differences in collection techniques make salivary samples a heterogenous category in terms of composition. Saliva can be collected in many ways including coughing, drooling, or spitting, and from many different locations including the lower throat or oral cavity. Saliva can even be extracted directly from the salivary glands. The different nature of the sample material is due to different collection techniques as well as different collection locations. The different studies included in this report used different saliva collection techniques and often do not differentiate between the different collection techniques or collection locations. Alternative saliva collection techniques that may have an impact on the sensitivity of the method are general spitting technique, early-morning posterior oropharyngeal spitting technique, drooling technique, posterior pharyngeal spitting technique, or saliva collection device (Table 1) [4,5].

Table 1. Description of the different saliva sample collection techniques [5]

Sample type	Description of technique
Early morning posterior oropharyngeal spitting	Coughed up posterior oropharyngeal saliva after clearing the throat and spitting into a sterile collection container, upon waking up, before brushing teeth and eating.
Drooling	Unstimulated whole saliva, asking the subject to let the saliva drop into plastic tubes.
Posterior pharyngeal spitting	The secretion produced after coughing or clearing one's throat, and belongs to the respiratory secretions, a mix of secretions from the upper and lower airways.
Saliva collection device	Oral saliva is collected with the aid of a device according to manufacturer's instructions e.g. swab secretions from cheek, gums, tongue for 20 secs.
General spitting	Accumulation of saliva in the floor of the mouth followed by spitting it into a container.

Sputum is not included in this table as it is a lower respiratory tract specimen that can be collected from patients who develop a productive cough. It is mucous and is coughed up from the lower airways. It can contain saliva but is a different sample type.

Saliva samples may be mucous and viscous and can sometimes be difficult to handle with existing RNA extraction methods and equipment. Despite the fact that heterogeneity of saliva as sample material poses possible limitations to its use as diagnostic material, there are several advantages which are discussed below [6].

It is important to note that there are significant differences in the saliva sample collection and testing protocols. A standard protocol regarding sample collection, including timing and abstention from eating, would decrease the variability in sample quality.

At present, there are several companies that manufacture commercial saliva collection devices for diagnostic and research purposes. As the use of saliva as sample material for clinical molecular diagnostics has a much longer history than the SARS-CoV-2 pandemic [7,8], these methods are well-established. Still, commercial SARS-CoV-2 diagnostic tests that use such devices for saliva collection need to be validated for the intended use.

Advantages of using saliva as diagnostic specimen

The use of saliva samples as specimens for the diagnosis of SARS-CoV-2 has several advantages. Sample collection is non-invasive compared with the collection of nasopharyngeal swabs, which are generally perceived as uncomfortable. When nasopharyngeal swabs are collected by healthcare professionals, protective gear is required, while saliva collection can be easily performed by the individual themselves if they are properly instructed, reducing the risk of transmission to the sample takers. Care should still be taken to decontaminate the tubes in which saliva is collected. Gloves and face masks should always be worn when sampling another person. For self-sampling purposes, it is easier to obtain a reliable saliva sample than a nasopharyngeal sample. Shortages in sampling material (e.g. swabs) and protective gear is not a limiting factor either. Sample collection can be done wherever required at the point of need as, apart from a suitable container, there is no need for additional consumables, such as swabs. The ease of collection increases acceptance among the population to the testing procedure and makes self-sampling a realistic option. The non-invasive nature of the sample collection facilitates sampling of children, disabled or particularly anxious individuals, in addition to helping adhere to routine testing practises performed in repeated intervals.

Although several studies indicate a lower sensitivity of saliva compared with other respiratory samples in RT-PCR analysis, during the period of highest viral load, the sensitivity of the test is sufficient to reliably detect infectious individuals.

Use of saliva in the various diagnostic methods

RT-PCR testing

For the routine laboratory diagnosis of SARS-CoV-2 virus, the gold standard is reverse transcriptase polymerase chain reaction (RT-PCR) performed on nasopharyngeal swab samples [9]. Self-collection of nasopharyngeal swab samples poses a risk of inconclusive or false-negative results, because of the practical difficulty in self-sampling this type of specimen. Saliva sampling is an appealing alternative to nasopharyngeal swabs, since collecting saliva is non-invasive and easy to perform.

Preliminary findings indicate that SARS-CoV-2 can be detected in the saliva of COVID-19 patients .[10]. High SARS-CoV-2 viral load has been detected in saliva samples, particularly in cases with COVID-19 risk factors. A study by Herrera et al. confirms these findings by stating that saliva is effective for the identification of the SARS-CoV-2 and shows higher concentration of RNA viral copies than nasopharyngeal swabs in the same individuals [11,12]. A study by Silva et al., not yet peer-reviewed and published as a preprint, compared the saliva and nasopharyngeal viral load and could show that saliva viral load was significantly higher in cases with COVID-19 risk factors (e.g. male gender, older age, specific respiratory, cardiovascular, oncologic and other systemic and immune-suppressive conditions) [13]. Saliva viral load correlated with a spectrum of disease severity throughout the course of illness and was a predictor of mortality. In addition, saliva viral load correlated with key immunological markers in COVID-19 (including cytokines, chemokines, platelets, and antibody levels over time), and a strong association with the progressive depletion of lymphocytes was noted. Distinct viral shedding dynamics were also shown by Huang et al. when comparing saliva with nasopharyngeal samples, which showed salivary viral burden correlated with COVID-19 symptoms, including taste alterations/loss [3].

Saliva testing has been shown to have a non-significantly lower mean sensitivity to that observed for nasopharyngeal swab tests. A meta-analysis of saliva testing studies found 91% (95%CI = 80%-99%) sensitivity for saliva tests and 98% (95%CI 89%-100%) sensitivity for nasopharyngeal swab tests in previously confirmed COVID-19 infected patients, with moderate heterogeneity among studies [14]. A study on self-sampling showed that saliva was the more sensitive, more reliable and logistically more practical sample type for diagnosis of SARS-CoV-2 compared with nasopharyngeal swabs, and that self-sampling of saliva specimens is characterised by less variability compared with nasopharyngeal swabbing [15]. Another meta-analysis confirmed that saliva diagnostic accuracy is similar to that of nasopharyngeal swabs, especially in the ambulatory setting [16,17]. Self-collected saliva samples were shown to have comparable SARS-CoV-2 detection sensitivity to nasopharyngeal swabs collected by healthcare workers from mild and subclinical COVID-19 cases [18].

Overall, reported studies suggest that the diagnostic sensitivity of RT-PCR on saliva samples is variable, often lower but sometimes higher than that of nasopharyngeal swabs, and sensitivity varies when considering different saliva collection techniques. However, most studies do not specify the sample collection technique used [5]. In one meta-analysis, the highest sensitivity compared with the nasopharyngeal swabs in paired samples was observed in the early morning posterior oropharyngeal spitting (95% CI -42.9 to 73.7), the lowest sensitivity was observed in the general spitting (95% CI -15.3 to -0.9) [5]. Furthermore, sensitivity decreases after the first five days from symptom onset [15,19]. However, saliva should only be used if the manufacturer of the test indicates it as an appropriate sample material. Further research is needed before a conclusion can be made on the performance of the different sampling techniques and sampled population (different age groups, asymptomatic etc.).

As of 14 April 2021, the Joint Research Centre (JRC) listed 298 nucleic acid tests with a CE mark in their COVID-19 in vitro diagnostic medical devices database (https://covid-19-diagnostics.jrc.ec.europa.eu). Among them, there are three that indicate saliva as possible sample material.

RT-LAMP testing

Reverse transcription loop-mediated isothermal amplification (RT-LAMP) is a technique that allows for the rapid and sensitive detection of SARS-CoV-2 [20,21]. The evidence on saliva testing using RT-LAMP is inconclusive. The sensitivity of RT-LAMP for SARS-CoV-2 using upper and lower respiratory tract specimens, including saliva specimens, has been reported to be equivalent to that of RT-PCR, showing a 95% agreement with RT-PCR [22]. However, one study highlighted that the sensitivity of RT-LAMP in detecting SARS-CoV-2 was lower than that of the classic RT-PCR test for COVID-19 with saliva specimens (RT-LAMP: 70.9% vs. RT-PCR: 81.6%) [21].

The clear advantage of using RT-LAMP for diagnosis of SARS-CoV-2 is that the results can be obtained in 30-60 minutes, even at the point of care. A direct colorimetric saliva-based RT-LAMP has a sensitivity of 72.7% when compared with nasopharyngeal laboratory RT-PCR, and when measured on the healthcare worker population, the specificity was 95.7% [23]. Further studies are needed to validate the available RT-LAMP tests with the use of variable respiratory specimens and saliva.

Rapid antigen testing

Sampling for detection of SARS-CoV-2 by rapid antigen test relies mostly on nasopharyngeal or nasal swab specimens, as indicated by the manufacturers. Self-sampling using saliva is not currently clinically validated for rapid antigen tests. Unlike RT-PCR, rapid antigen tests lack controls for confirmation of appropriate sampling; they also lack an amplification step which limits their sensitivity [24].

Theoretically, saliva can serve as sample material for rapid antigen tests based on a lateral flow principle, as has been shown by a few academic groups [21,25]. The nature of the samples, however, can cause difficulties in the processing of the tests, and sensitivity compared to RT-PCR is expected to be further reduced with this sample type. Unpublished data from EU/EEA laboratories have shown reduced sensitivity of rapid antigen tests compared with RT-PCR when saliva is used as sample material (personal communication). Further clinical validation studies are needed to assess the suitability of saliva for the various available rapid antigen tests before this sample type can be used for diagnostic purposes.

As of 14 April 2021, the Joint Research Centre (JRC) listed 385 antigen tests with a CE mark in their COVID-19 in vitro diagnostic medical devices database (https://covid-19-diagnostics.jrc.ec.europa.eu). Among them, 76 tests that indicate saliva as a possible specimen.

Overall, 16 rapid antigen tests are mutually recognised by Member States as agreed in the 'Common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates" as agreed by the Health Security Committee on 17 February 2021' [26]. Among these, there is no test based on saliva as sample material.

Antibody testing

Antibody testing can be done to determine past exposure to the virus and provide insight into the immunological status of an individual [27]. The most common specimen used for antibody detection is blood, but saliva has been used as an alternative type of specimen, especially as is it easy to collect and applied in point-of-care settings. From a methodological point of view, saliva can be used as a sample type in antibody testing devices with lateral flow assay (LFA) technology directly in the field or by enzyme linked immunosorbent assay (ELISA) and/or chemiluminescent assay technologies in a centralised laboratory [4].

A study by Faustini et al, measuring anti-spike IgG, IgA, and IgM antibody responses, among a group of non-hospitalised symptomatic and asymptomatic patients, found that all three antibody types were readily detectable in saliva specimens. Interestingly, antibody responses in the saliva and serum were largely independent of each other and of symptom reporting [27].

In contrast to this study, Pisanic et al. found that SARS-CoV-2 antigen-specific IgG responses in matched serum and saliva samples of 28 study participants who provided saliva and serum samples during the same visit, were significantly correlated, and the kinetics of IgG in the saliva were consistent with those observed in serum [28]. A similar finding was reported from a study by McMullan et al. [29]. The authors attempted to adapt a commercially available serum-based enzyme-linked immunosorbent assay (ELISA) for use with saliva samples, achieving 84.2% sensitivity and 100% specificity in a set of 149 clinical samples. Hettegger et al. reported that in the particular case of IgG, plasma and saliva IgG profiles are highly similar for a large number of antigens [30].

Results from a longitudinal study of COVID-19 patients, looking at the duration of the antibodies in different specimens, reported that IgG antibody levels can remain stable in both blood and saliva for a period up to 105 days post symptoms onset [31].

Saliva can be an appropriate specimen for the detection of IgA antibodies early on during onset of disease, i.e. as early as two days after the onset of symptoms [32] as their concentration appears to be higher in the mucosal secretions, compared with blood. Use of saliva for detection of IgA has been successfully used for many other viral infections including SARS, MERS, HIV, RSV and seasonal influenza [33]. It has also been hypothesised in the past that both salivary IgG and IgM are derived from blood, whereas IgA is mainly produced by the salivary glands. A recent study by Varadhachary et al. reported a positive predictive value (PPV) of 92% and a negative predictive value (NPV) of 97% for a test protocol developed specifically to measure IgA detection in saliva [34].

Preliminary results have shown that saliva can be a potential alternative to blood antibody tests, especially for the detection of IgA. However, for diagnostic purposes, blood samples remain the preferred option and results from antibody tests using saliva as sample material should be confirmed by testing blood samples. Further research is needed on the levels and persistence of the different types of antibodies in saliva over time. Validation of antibody tests using saliva as sample material is strongly recommended.

As of 14 April 2021, the Joint Research Centre (JRC) listed 461 antibody tests with a CE mark in their COVID-19 in vitro diagnostic medical devices database (https://covid-19-diagnostics.jrc.ec.europa.eu). Among them, there is no test that indicates saliva as a possible sample material.

Isolation of viable virus

Studies showing the presence of live virus in the saliva of SARS-CoV-2 infected individuals are limited. Still, in one study, viable virus was isolated from saliva samples obtained from three hospitalised SARS-CoV-2 patients in viral culture [10].

Viable SARS-CoV-2 can be secreted in saliva and contribute to transmission. In a study of five severely ill COVID-19 patients, viable SARS-CoV-2 was demonstrated in saliva samples from two of those individuals on days 11 and 15 of the clinical course, respectively [35]; this finding is in accordance with other observations of prolonged virus isolation from nasopharyngeal samples obtained from severely ill patients [36].

In another study, live virus was successfully isolated during the first week of symptoms from the majority of sputum samples (that contain saliva and lower respiratory tract secretions) (83%), however, no isolates were obtained from samples taken after day eight in spite of ongoing high viral loads detected in other sample types [37]. Similarly, viable virus could not be cultured from saliva samples from asymptomatic or mildly symptomatic COVID-19 patients who had been diagnosed with the disease at least two weeks previously and showed prolonged viral RNA shedding [38].

Taken together, live virus has been successfully isolated from saliva samples from COVID-19 patients during the first week of symptoms. The fact, that virus isolation is laborious and has to be performed in a biosafety level 3 (BSL-3) laboratory makes this method unfeasible for widespread routine diagnostic use.

Applications

Use of saliva in screening symptomatic individuals

For the routine laboratory diagnosis of SARS-CoV-2 virus in symptomatic individuals, the gold standard remains RT-PCR testing on nasopharyngeal swab samples. As self-collection of nasopharyngeal swab samples is practically difficult and poses a risk of inconclusive or false-negative results, saliva sampling is an appealing alternative.

Although sensitivity will differ depending on the different sample collection technique (Table 1) and considering the limitations of this sample type, saliva may be used as an alternative for RT-PCR tests for the detection of infectious patients within the first five days after symptom onset or when practical considerations make nasopharyngeal swabbing difficult [15,19].

Use of saliva in screening asymptomatic individuals

Given the ease of use and the non-invasive nature of saliva collection, it can have great benefits if used for self-collection and repeat testing of individuals in given settings.

Saliva specimen can therefore be considered as an option for the detection of SARS-CoV-2 in asymptomatic individuals who are required to self-test frequently for occupational or other reasons. Even if the tests are less sensitive than swab-based RT-PCR, the sheer number and possible repetitions increase the likelihood of detection in the infected individual [19].

A recent study which performed mass screening by RT-PCR on two cohorts of 1 924 asymptomatic individuals (a contact tracing cohort and an airport quarantine cohort), found 0.998 (90%CI:0.996-0.999) true concordance probability when comparing RT-PCR detection results of SARS-CoV-2 between the nasopharyngeal swabs and self-collected saliva specimens [39]. Another study screened 495 asymptomatic healthcare workers by RT-PCR using both saliva and nasopharyngeal samples, and all 13 asymptomatic cases with positive saliva tests subsequently had COVID-19 confirmed by additional RT-PCR on nasopharyngeal swabs [15].

Screening of asymptomatic individuals using saliva as sample material for RT-PCR analysis can also be considered as an alternative method if nasopharyngeal swabs cannot be obtained, e.g. in case of shortages of swabs, in the very old or disabled individuals, and to increase acceptance for repeated testing. When using saliva as a sample material, its limitations need to be considered.

Nasopharyngeal swabs should be the preferred sample option for persons with high risk of exposure to a positive COVID-19 case; if saliva needs to be collected instead, and the time of exposure is known, testing should be performed as soon as possible after the contacts have been identified. If more than seven days have passed since the exposure, it is recommended that negative tests are repeated.

Use of saliva in testing children

With saliva collection being easy and non-invasive, it should offer a feasible approach for widespread testing of SARS-CoV-2 in children. Unfortunately, data on the use of saliva to detect SARS-CoV-2 in paediatric patients are sparse. The few reports available on the performance of saliva specimens for children showed poor detection of SARS-CoV-2, with sensitivities of 53 to 73%; however, available studies suffer from small sample sizes [40,41].

In a study published in February 2021, the authors concluded that saliva is a reliable diagnostic specimen for the detection of SARS-CoV-2 RNA by RT-PCR, particularly for both symptomatic and asymptomatic children and symptomatic adults. Moreover, testing of saliva was able to identify additional COVID-19 cases that were otherwise missed by nasopharyngeal swabs, possibly due to the particular difficulties in obtaining proper nasopharyngeal swabs from children [42].

Overall, the available limited data do not give a clear picture on whether children can be reliably diagnosed based on saliva samples and more studies are needed.

Limitations

There are some limitations related to the methodological approach used for the literature review, e.g. selection bias, publication bias and citation bias. Other limitations relate to the identified evidence, such as small number of studies addressing the primary review question and large heterogeneity across studies. Some of the studies included did not differentiate saliva from sputum (or lower respiratory tract specimens) or specify the different saliva collection techniques. In addition, methodological differences such as sampling procedures, efficiency of self-testing compared with professional testing, as well as time of sampling were difficult to assess. Clinical validation data were scarce, although interactions with Member States indicated there are unpublished validation data that could further inform this topic. Information on test performance and CE marking is solely based on manufacturer data.

The assessment of the evidence was undertaken based on facts known to ECDC at the time of publication.

Conclusions

Saliva offers many advantages from a public health perspective when used as sample material for COVID-19 testing. The role of saliva as an alternative sample type has been a target for investigation since the beginning of the COVID-19 pandemic, due to the practical difficulties of the collection of nasopharyngeal and oropharyngeal swabs, which remain the gold standard for the detection of SARS-CoV-2.

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. Saliva is an easy to collect, non-invasive, well accepted method of specimen collection for both health and non-healthcare professionals, as well as lay individuals. It does not usually require special equipment for the collection, thus can lead to reduced resources required (laboratory and staff resources, personal protective equipment etc). Self-collection of the sample is possible, also reducing the risk of exposure of healthcare workers.

Overall, study results are variable and often showed that the sensitivity of detection of viral RNA in saliva was lower than that of nasopharyngeal or oropharyngeal swabs performed on the same day of the salivary collection from the same patient, although some studies even showed a slightly higher sensitivity of the saliva samples. However, during the period of highest viral load, the sensitivity is comparable and sufficient to detect infectious individuals reliably. The best performance of saliva-based RT-PCR tests is during the first five days from onset of symptoms and when the viral load is high. It needs, however, to be noted that the composition of saliva samples can be heterogeneous and further studies are needed to assess the performance and standardise the various saliva collection methods.

Although the sensitivity of RT-PCR tests using saliva as a diagnostic specimen for SARS-CoV-2 detection is often lower to nasopharyngeal specimen in several studies, the benefits of saliva testing may outweigh the loss in sensitivity and make it an attractive alternative as a screening tool, especially when nasopharyngeal samples cannot be collected. The collection of nasopharyngeal specimens should always be preferred for patients with a high clinical index of suspicion for SARS-CoV-2 infection, or a high risk of exposure to a COVID-19 case. Overall, the evidence supports the conclusion that saliva can be used as alternative sample material for RT-PCR testing, when nasopharyngeal swabs cannot be collected in the following scenarios: in symptomatic patients and for repeated screening of asymptomatic individuals.

There are very few clinical validation studies on the use of saliva as sample material for rapid antigen tests and data on the sensitivity of the tests are lacking. The majority of available rapid antigen tests recommend the use of nasopharyngeal swabs as sample type. Rapid antigen tests generally have lower sensitivity than RT-PCR and it is expected that using saliva as sample material will reduce sensitivity even further. Further studies are needed to evaluate saliva as a sample material for rapid antigen tests.

There are a variety of studies documenting the use of saliva as sample material for the detection of either SARS-CoV-2 RNA, antigen or antibodies. There are CE-marked commercial test with saliva marked for intended use, in the EU/EEA.

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Disclaimer

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

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