



Clinical evaluation of single-swab sampling for rapid COVID-19 detection in outbreak settings in Dutch nursing homes

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Key summary points

Aim To assess whether in the nursing home (NH) setting a single-swab sampling method, in which one swab can be used to perform both the Ag-RDT and RT-PCR, can be used for rapid COVID-19 detection during an outbreak.

Findings In the NH setting, the single-swab method had a sensitivity of 51% and a specificity of 89% compared to RT-PCR, which was lower than in the laboratory setting (69% and 100%, respectively). During focus groups, both advantages and disadvantages of the single-swab method emerged.

Message For the vulnerable NH residents, it is important to find the right balance between effective testing policy and the burden this imposes.

Abstract

Purpose To assess whether one swab can be used to perform both the antigen-detection rapid diagnostic test (Ag-RDT) and reverse transcriptase polymerase chain reaction (RT-PCR) for COVID-19 detection during an outbreak in the nursing home (NH) setting.

Methods The single-swab method (SSM), where the Ag-RDT is performed with the transport medium used for RT-PCR, was evaluated in three Dutch NHs and compared to the laboratory setting. We collected Ag-RDT and RT-PCR results, NH resident characteristics and symptomatology. In addition, two focus groups were held with the involved care professionals to gain insight into the feasibility of the SSM in the NH setting.

Results In the NH setting, the SSM had a sensitivity of 51% and a specificity of 89% compared to RT-PCR. These were lower than in the laboratory setting (69% and 100% respectively). Yet, when stratified for cycle threshold values, the sensitivity became comparable between the settings. Symptoms occurred more frequent in the Ag-RDT+ group than Ag-RDT– group. Resident characteristics did not differ between these groups. Based on the focus groups, the SSM was feasible to perform if certain requirements, such as availability of staff, equipment and proper training, were met. However, the rapid availability of the test results were perceived as a dilemma.

Conclusion The advantages and disadvantages need to be considered before implementation of the SSM can be recommended in the NH setting. For the vulnerable NH residents, it is important to find the right balance between effective testing policy and the burden this imposes.

Keywords Long-term care facility · Coronavirus · Testing · SARS-CoV-2 · Older adults · CT value

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Introduction

The WHO officially declared the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as a worldwide pandemic on March 11, 2020. The current average (up to January 26, 2021) of the share of all COVID-19 deaths who were nursing home (NH) residents is 41% (based on 22 countries) [1]. Testing for SARS-CoV-2 is crucial in containing COVID-19 outbreaks. To date, Dutch NHs are advised to test their residents and healthcare workers (HCW) for SARS-CoV-2 via nucleic acid amplification tests (NAAT) on nasopharyngeal swabs, with reverse transcriptase polymerase chain reaction (RT-PCR) being the gold standard. However, this gold standard has several limitations, such as the requirement for specialized laboratories [2]. Moreover, test results are not always available within 24 h, and sometimes takes up to 48 h. Yet, as many NH residents have cognitive impairment or dementia, they do not understand the measures and freedom restriction is often needed to hold them in isolation. The use of antigen-detection rapid diagnostic tests (Ag-RDTs) could offer a solution to this. Ag-RDTs results are available within 15 min. As a result, adequate measures can be taken more rapidly and the spread of SARS-CoV-2 may be further contained. In addition, there is no need for specialized equipment, they are easy-to-use, of low cost and could thus be implemented in the NH setting.

However, a systematic review of 64 studies on the accuracy and validity of different Ag-RDTs shows a considerable variation in sensitivity and there were differences in sensitivity between symptomatic (72.0%) and asymptomatic participants (58.1%). The differences in specificity were, 99.5% in symptomatic participants and 98.9% in asymptomatic participants [3].

In NH residents, a COVID-19 infection is often poorly recognized [4, 5]. This can be partly explained by the large proportion of all NH residents that has cognitive impairment and impaired ability to communicate, making it difficult to accurately observe and interpret symptoms. A greater proportion of asymptomatic infections has also been reported among residents [6–9].

Given these results, the current policy in the Dutch NH setting is to follow up a negative Ag-RDT test with an RT-PCR to confirm the negative test result. This implies in most cases sampling of two nasopharyngeal swabs: one for the Ag-RDT test and—if negative—one for the RT-PCR. Moreover during an outbreak, weekly testing is recommended, resulting in short interval recurrent testing of individual residents. As most residents are vulnerable and many are not able to understand what happens when being sampled, it is considered to be especially invasive in this population. We received signals from clinicians that sometimes even sedation was necessary to perform the swab collection or isolation. Therefore, to reduce the number of swabs, a

single-swab method was tested in which one swab can be used to perform both the Ag-RDT and RT-PCR in the NH setting.

In the single-swab method, the Ag-RDT (Roche/SD Biosensor lateral flow antigen rapid test) is performed with the transport medium used for RT-PCR. The throat–nose swab is placed in the tube with the transport medium. A small amount of the medium is then pipetted into the extraction buffer of the Ag-RDT and mixed together. This mix is then applied on the cassette of the Ag-RDT. This method was based on the two pilot studies that ran simultaneously with our study. The data of one of these studies are reported in the supplementary material. These results demonstrated that sensitivity was not significantly different between using the Ag-RDT (65.5%) according to the manufacturer's instructions, and using transport medium for RT-PCR instead of the swab (66.7%) (see Supplementary Material Tables S1 and S2). Moreover, in the laboratory setting no difference in sensitivity was observed when the Ag-RDT was performed with a double swab versus the single-swab method. However, these pilot studies were performed in a laboratory setting, a professional COVID-19 test location with trained personnel using micropipettes, and the tested population consisted of HCWs.

Therefore, we assessed whether an adjusted single-swab method can be applied in the NH setting in an outbreak situation. Apart from the Ag-RDT test and RT-PCR test results, we collected data on resident characteristics and symptomatology. In addition, to gain insight into the feasibility of the single-swab method in the NH setting, two focus groups were held with the involved care professionals.

Methods

Study design, population and setting

This was a mixed-methods study, performed from December 1, 2020 up to March 31, 2021 in three NH organizations in The Netherlands (NH-A, NH-B, and NH-C). We collected data on NH resident characteristics, symptomatology and the Ag-RDT test and NAAT test results during SARS-CoV-2 outbreaks. An outbreak was defined as at least one SARS-CoV-2-positive resident. At the time of study conduction, the NHs implemented a policy of weekly testing after a SARS-CoV-2 introduction of all residents and HCWs regardless of symptoms at the ward or smallest lockable unit where the outbreak occurred. Only NH-B had experience using Ag-RDT tests. To assess the feasibility of the single-swab method in the NH setting, two online focus groups were held with the HCWs involved in the single-swab method in NH-A and NH-B. NH-C only agreed to participate in the

first part of the study. This is why NH-C is not included in the focus groups.

Single-swab method

To make the single-swab method feasible in the NH setting, we instructed the participating NHs to not alter their method and policy of nasopharyngeal swab collection for the RT-PCR. This implied that in NH-A, there was a mobile test team, consisting of two medical students that assisted on site when an outbreak occurred, whereas in NH-B and NH-C the healthcare professionals on site performed the swab collection. Prior to the start of the study, they were instructed via online training and instruction cards and videos that showed each step of the procedure in detail.

In line with standard procedure, both residents and healthcare professionals working on the ward underwent testing. The obtained material (e.g., nasopharyngeal swab) was placed in the tube with a transport medium of RT-PCR. The transport medium for NH-A was glucose lactalbumin yeast medium (GLY) whereas NH-B and NH-C used universal transport medium (UTM) or viral transport medium (VTM). After vortexing briefly, 0.5 ml of the transport medium was pipetted with a Pasteur pipette from the nucleic acid amplification tests (NAAT) tube and mixed in with the extraction buffer of Ag-RDT (see Fig. 1). Specificity according to the manufacturer was 99.2% and sensitivity 96.52% (CT value ≤ 30) in symptomatic patients [10]. Sensitivity and specificity in asymptomatic patients were evaluated at the time the study started. The Ag-RDT was executed as usual and the NAAT tube including the swab was sent to the laboratory for RT-PCR. As the nursing homes collaborate with different laboratories, different NAATs were used; NH-A

and NH-C used Aptima® SARS-CoV-2 Assay from Hologic and NH-B used the LightCycler 480 from Roche Diagnostics or the Applied Biosystems QuantStudio 5 Real-Time PCR System from Thermo Fisher Scientific. Corman's RT-PCR was used to obtain the C_t values [11]. We labeled the Ag-RDT test result as 'positive' when a strong visible test line appeared and 'negative' when no line appeared. A very light test line, considered a positive test result according to the Roche guidelines, was referred to as 'weak positive'. For an extensive description of the single-swab method, see supplementary material.

Assessment of characteristics and COVID-related symptoms

Healthcare professionals of the NH wards completed the questionnaire on the characteristics and COVID-related symptoms. From NH residents, data about gender, date of birth, type of ward, any previous positive COVID-19 test and comorbidity were assessed. In addition, COVID-19-related symptoms and the start date of the symptoms were queried at the time of the test administration on both residents and healthcare workers who underwent testing.

Data collection focus groups

Participants of the online focus groups were invited via email. Various disciplines were invited that were closely involved in the implementation of the single-swab method. Eleven healthcare professionals (one certified health assistant, two nurses, one medical manager, two location managers, two elderly care physicians, one elderly care physician in

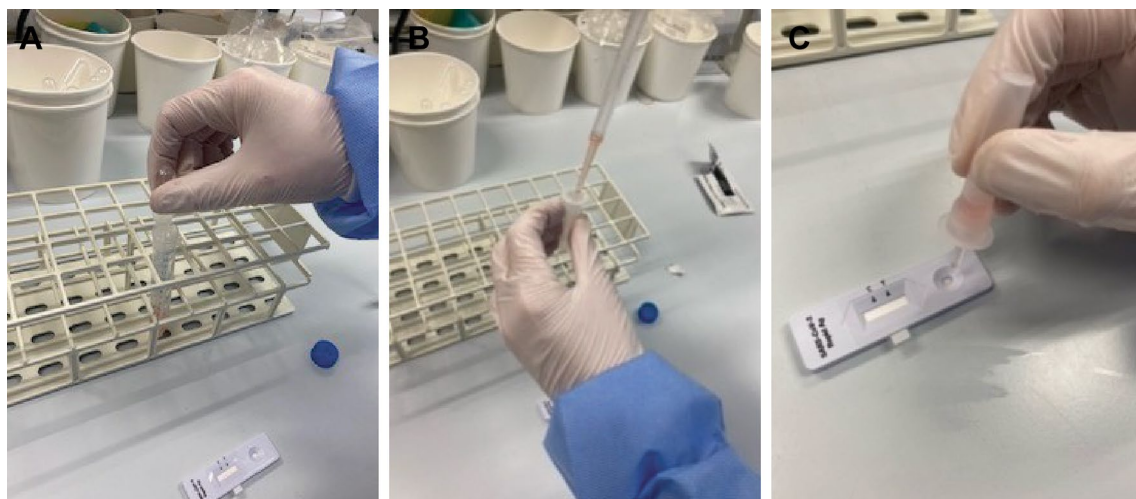


Fig. 1 **A** Pipetting 0.5 ml with the Pasteur pipette and **B** adding and mixing of the transport medium with the extraction buffer of the Ag-RDT. **C** Three drops of mixed liquid were applied on the test surface of the Ag-RDT cassette

training and two medical students (test team) participated in the first focus group (NH-A) and eight healthcare professionals (three nurses, two quality nurses, one nursing student, one location manager and one elderly care physician) in the second focus group (NH-B). The focus groups had a duration of ~90 min each for meeting held via Microsoft teams in the period February–March 2021. The focus group meetings were video recorded. Each focus groups was facilitated by a moderator (CH for focus group NH-A; KP for focus group NH-B). An observer was present (focus group NH-A: LB; focus group NH-B: AL) who also took notes.

Three topics to evaluate the single-swab method were presented using PowerPoint during the focus group meetings: (1) What went well in using the single-swab method? (2) What was difficult or inconvenient in using the single-swab method? (3) What is required to successfully use the single-swab method in the NH?

Data analysis

The results of the Ag-RDT, RT-PCR and questionnaire data were entered in Microsoft Excel, and data analysis was performed using SPSS statistical package, version 26.0 (SPSS, Armonk, NY: IBM Corp). Sensitivity and specificity of Ag-RDT were calculated in relation to the RT-PCR results as the gold standard. Chi-square was used to compare the differences in characteristics and symptomatology between the groups (RT-PCR+/Ag-RDT– and RT-PCR+/Ag-RDT+).

For the analyses of the focus groups, a summary was made by KP based on the video recordings and combined with the notes from the observer that were made during the focus groups. Next, a thematic analyses was performed on this summary (KP), followed by an ordering (KP, AL and LB) of the findings on the advantages and disadvantages of the single-swab method as well requirements and recommendations to perform the single-swab method. Next, a search was made for possible coherence and/or connections and differences between the themes and the focus groups.

Ethics

The Medical Ethics Committee of the Academic Medical Centre in Amsterdam, The Netherlands, reviewed the study protocol and stated that the study did not fall under the scope of the Medical Research Involving Human Subjects Act. Residents, or their representatives in case of legal incapacity, were informed about the study and given the opportunity to opt out of using their data in the study. Each focus group participant provided written informed consent prior to participating in the focus groups.

Results

NAAT

Between December 1th and March 31th, 2021, 461 residents underwent an Ag-RDT single-swab test for SARS-CoV-2. Covid-19 was confirmed by RT-PCR test in 53 (11%) of the residents and ruled out in 408 (89%) residents (see Table 1). Of these 53 COVID-19 confirmed residents, 26 residents tested negative on Ag-RDT and 27 tested positive on Ag-RDT, a combination of the positive and weakly positive. The single-swab method had a sensitivity of 50.9% and a specificity of 89.0%. This was lower than the 69% sensitivity and 100% specificity observed in the laboratory setting (see Supplementary Table S3). In total, we found 45 false positive Ag-RDT results in 408 RT-PCR negative results. Of these 45 false positives, 44 were observed in RT-PCR-negative samples where GLY medium was used ($N=290$), whereas in 118 RT-PCR negative samples using UTM only 1 false positive Ag-RDT result emerged (see Supplementary Table S4).

Sensitivity increased with lower CT values (see Table 2), but we missed 11.3% (6/53) of the CT values. These results were very similar to that observed in the laboratory setting (see Supplementary Table S5).

Characteristics of RT-PCR-confirmed residents

Characteristics of residents with a positive RT-PCR did not significantly differ between residents with Ag-RDT+ and Ag-RDT– (all Chi values < 2.848 , all p values > 0.091), except for ward type (see Supplementary Table S6). Residents with Ag-RDT+ resided more often on psychogeriatric wards and less on somatic or short-term care wards compared to residents with Ag-RDT– ($\chi^2(2, N=51)=7.428$, $p=0.024$).

Signs and symptoms of RT-PCR-confirmed residents

Symptoms were rarely reported; more than half (56.9% (29/51)) were asymptomatic, see Supplementary Table S7). Fever and fatigue were the most common reported symptom

Table 1 Distribution of the test results in the NH setting

Ag-RDT	RT-PCR (throat–nose swab)		
	Positive (+)	Negative(–)	
Positive (+)	27	25	52
Weakly positive(+)	0	20	20
Negative (–)	26	363	389
	53	408	461

Table 2 Results stratified to RT-PCR CT values in the NH setting

CT value	Ag-RDT		Sensitivity (%)
	Positive (+)	Negative (–)	
< 20	14	0	100
20–25	9	1	90.0
25–30	2	7	22.2
> 30	2	12	14.3
Total	27	20	

on the day of testing (20%). Generally, symptoms occurred less frequently in the group with Ag-RDT– than in the Ag-RDT+ group, and this was the case for 12 out of the 16 symptoms (75%). However, none of these differences were significant ($X^2(1, N=51) < 3.315$, all p values > 0.069).

Focus groups

In both focus groups, the same advantages and disadvantages were indicated. The requirement of only one swab instead of two and only the small adjustment of an additional pipetting step compared to conventional Ag-RDT test were mentioned as advantages (see Table 3). In addition, multiple dilemmas related to the application of the Ag-RDT test results emerged. On the one hand, the rapid availability of

the test results was perceived as an advantage and very helpful to contain an outbreak, since preventive measures could be taken more swiftly. On the other hand, participants indicated that quickly available test results also caused unrest, since it required immediate adjustment of organizational procedures such as the replacement of COVID-19-positive healthcare workers, informing the family of positive residents and immediate need of relocating and isolating COVID-19-positive residents. Thus, the quickly available test results are accompanied by disadvantages as well. Furthermore, the additional pipetting and pipetting the right amount of extraction buffer on the Ag-RDT cassette surface were perceived as quite difficult to perform. This additional pipetting step might also have caused unreliability of the Ag-RDT test outcome and that also caused unrest. Another disadvantage was that the execution of the Ag-RDT, irrespective of the single-swab method, was experienced as time consuming and required the availability of trained staff.

Availability of staff was mentioned in both focus groups as a requirement, as well as the availability of a proper testing room and clear work instructions and responsibility (see Table 4). Both focus groups valued the online training, video and instructions card as very clear and helpful and mentioned this as an important requirement for the successful implementation of the single-swab method. Focus group B participants suggested to train the healthcare workers to train their colleagues and to repeat the training to maintain the testing skills.

Table 3 Advantages and disadvantages for use of the single-swab method in NHs

Advantages	<p>Only one swab was required instead of two swabs in case of a negative Ag-RDT test result “Especially for people with dementia, it is not so pleasant to perform multiple swabs, you are already happy if you are able to collect one of them, just one is a lot friendlier for the resident”</p> <p>Quick to perform, compared to the conventional Ag-RDT test “it doesn’t take much time, a big plus”</p> <p>Quickly available test results allow for a fast response in terms of taking adequate measures “Because of the quick results I can better explain why I take certain measures and I can act more quickly in accordance with the guidelines, this gives a safe feeling for the resident, co-resident but also for myself”</p>
Disadvantages	<p>Quickly available test results cause unrest and limit the time for the organization to prepare for consequences of positive test results During an outbreak around Christmas, the test team in NH-A was not available for support and the single-swab method was not performed “Otherwise we might not have had employees all Christmas, we had some delay in the results which allowed us to celebrate another Christmas dinner without knowing there were so many positives”</p> <p>The test results were unreliable “On one ward the Ag-RDT test result was positive in 3 out of 7 residents and we placed them in isolation. But, based on the PCR results we received the next day, 6 out of 7 residents were positive thus the whole ward should have been placed in a cohort.”</p> <p>and caused uncertainty “the time advantage only applies for positive Ag-RDT test results, since according to the current policy, in case of a negative Ag-RDT test, the PCR test result must still give the final outcome”</p> <p>Pipetting was difficult to perform Performance of the Ag-RDT test requires availability of trained staff “If there would not have been a test team, the employees at the ward would have to carry out the performance of the Ag-RDT single-swab method themselves, which would lead to a higher workload, in an already stressful situation of an outbreak and regular health care also continues”</p>

Discussion

We investigated the single-swab method to test for a COVID-19 infection in an outbreak situation in the NH setting. The single-swab method had a sensitivity of 51% and a specificity of 89% compared to RT-PCR. Both sensitivity and specificity were lower in the NH setting than seen in the laboratory setting (69.0% and 100% respectively). Yet, when stratified for CT values, the sensitivity was comparable to the sensitivity in the laboratory setting. Residents characteristics did not differ between Ag-RDT+PCR+ and Ag-RDT-PCR+, and symptoms occurred less frequent in the group Ag-RDT-PCR+ than Ag-RDT+PCR+ group. Based on the focus groups, the single-swab method was feasible to perform if certain requirements, such as availability of staff and proper training, were met. Yet, the reported advantages, disadvantages and dilemmas need to be considered and require further research before implementation of the single-swab method can be recommended in the NH setting.

First, sensitivity was very low when using the single-swab method (51%). However, sensitivity increased with lower CT values up to 100%. Therefore, the method is capable of identifying the most infectious persons with the highest viral load. These findings and the increase in sensitivity with lower CT values are in line with previous studies that compared the Ag-RDT with PCR performances [3, 11–13]. In addition, the low sensitivity observed in our study could potentially be attributed to lack of symptoms, as more than half of the NH residents were asymptomatic. Sensitivity has been reported to be higher in symptomatic than asymptomatic patients [3] and depends on symptom onset [12, 14]. This is in concordance with that observed previously in the NH setting [4, 5]. However, one has to bear in mind that symptoms may be difficult to recognize, which may lead to an overestimation of the number of asymptomatic residents

[15]. Daily measurements of oxygen saturation or body temperature might offer a solution to this issue [16]. In addition, symptoms occurred less frequently in the Ag-RDT-PCR+ group than in the Ag-RDT-PCR+ group.

Next, due to the high prevalence of false positives, the specificity (89%) in our study was much lower compared to the specificity (100%) observed in the laboratory setting, and also compared to other studies that did not use the single-swab method [3]. It seems probable to attribute this to the adjusted single-swab method in the NH setting. For one, the GLY transport medium, when applied to the cassette of the Ag-RDT test without patient material, sometimes resulted in a weak positive test result (data not published, $N = 1/60$). In NH-A where most false weak positives were observed, the GLY medium was used, whereas in the other NHs, using UTM, only one false positive was observed. Thus, the required step of mixing the transport medium of the RT-PCR with the extraction buffer of the Ag-RDT test for the single-swab method might prove to be problematic in the NH setting, especially when using GLY medium. This means that, in accordance with the guidelines of the Ag-RDT manufacturer, when using the single-swab method the routinely used transport medium might need to be adapted. For feasibility, Pasteur pipettes were used. Possibly, too much transport medium was used: 0.5 ml compared to 0.375 ml pipetted using micropipettes in the laboratory setting for the single-swab method. This could lead to false negative results by extra dilution or false positive results, due to too much GLY medium. Whether this was indeed the reason for the high prevalence of false positives requires further investigation, for example, by comparing the single-swab method using different amounts of medium and different types of transport media. Furthermore, it could be that a specific binding of GLY substances like the yeast extract or the gelatin components could have caused the false positive test results. Another reason for the false positive test results seemed to

Table 4 Requirements and recommendations for use of the single-swab method in NHs

Requirements and recommendations	<p>Availability of staff, ideally a separate mobile test team or healthcare workers not directly involved with patient care, is needed to perform the single-swab method</p> <p>Availability of all adequate and necessary materials for performance of the single-swab method</p> <p>Available test room with adequate properties (a quiet, sterile, well-ventilated and well-lit room, with an easy to disinfect table), preferably determined in advance, before an outbreak</p> <p>Training and instruction of the method, the online training, video and instruction card were very helpful</p> <p>Clear work instructions and responsibilities, especially for smaller locations where support from experienced nursing staff or physicians is not always available</p> <p>Short communication lines between management, those involved in performing the single-swab method and healthcare workers directly involved with patient care</p> <p>Evaluate test results in pairs ('four-eye principle') to prevent errors</p> <p>Maintaining testing skills, for example by watching back instructions and by ensuring regular practice with single-swab method, especially the use of the Pasteur pipette and pipetting the right amount of extraction buffer on the Ag-RDT test surface</p>
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be a possible learning effect in performing the tests. The NHs, where less false positive test results occurred, had been using the Ag-RDT test for a few months already. A third source of error for false positive test results is explained by the fact that weak bands were assessed as positive to avoid incorrectly assessing patients as RAT negative and to prevent further spread of the infection.

Residents with positive RT-PCR and positive Ag-RDT frequently stayed in a psychogeriatric ward. It is unclear whether these residents also had a higher viral load. The incidence of these psychogeriatric residents is expected to be higher, since this population is difficult or impossible to instruct. Another study indicated that the virus spreads rapidly within this population because people with cognitive impairment wander a lot [9].

An unexpected effect of the implementation of Ag-RDT was that the (unreliable) results of the Ag-RDT caused uncertainty at the wards according to the focus group participants. If an infrastructure for a fast PCR result, within 24 h is put in place, the advantages of a quick, but potentially unreliable Ag-RDT test result diminishes. Moreover, the rapidness of the results when using an Ag-RDT test appeared a double-edged sword. On one side, the rapid test results can be very helpful to contain the outbreak faster because preventive measures could be taken more swiftly. On the other side, the speed of the test result requires adjustment of organizational procedures and could also cause unrest. For example, in the case of many positive Ag-RDT results among care professionals, this could also lead to sudden large dropouts because positively tested professionals were instructed to go home immediately. The 24-h RT-PCR test makes one anticipate what is to come, while the Ag-RDT does not take this time, the result is known within 15 min and immediate action may be taken. In the end the same actions are performed, but with the Ag-RDT this will happen much faster. If the organization around this is not adjusted, this (the faster result) can lead to a lot of unrest. This dilemma not only applies to the single-swab method, but also to the use of Ag-RDT testing in the NH setting, since the single-swab method for the largest part consists of performing the Ag-RDT test. Similarly, the availability of staff and a properly equipped test room to perform Ag-RDT tests, as well as short communication lines, were important requirements for successful implementation of the single-swab method. Performing the single-swab method with two people was recommended, since the execution of multiple Ag-RDT tests during a large outbreak can be quite time consuming and evaluation of test results can then also occur in pairs ('four-eye principle') to prevent errors. The use of a separate mobile test team to perform the Ag-RDT was recommended to support the staff and perceived as very valuable. The training and instruction of the single-swab method were evaluated as positive and important factors for successful implementation. It was

suggested to regularly practice or use a trainer to maintain the testing skills. Buckle et al. [17] also report that implementation of Ag-RDT test can be complex. They state that it is important to require staffing preparation and take into account the (financial) impact of false positives (e.g., staff absences, additional staffing requirements associated with quarantine) and false negatives (e.g., infection days) results [17]. True certainty about the test result is only received with the RT-PCR or the single swab in a laboratory setting. The strength of this study is that we compared the single-swab method in the NH setting to the laboratory setting. Second, most of the recommendations and requirements reported in this study can be generalized to the deployment of Ag-RDT testing in the NH setting. The participating NHs were instructed not to alter their current clinical and care practice and COVID-19 policies; therefore, our study was performed in a realistic NH setting. The number of PCR-positive tests in the NH setting was relatively low ($N=53$), and this can be a limitation of our study. However, during the time of the study, the COVID-19 prevalence was declining, vaccination of residents started and due to the following shortages of staff some of the outbreaks were missed and the single-swab method could not be performed. Yet, the single-swab method was still performed 461 times in the NH setting. Since the RT-PCR positive cases were only retested in the preliminary studies, the specificity of the Ag-RDT test in comparison with the RT-PCR test was unknown in the laboratory setting.

Conclusions and implications

Given the low sensitivity and specificity of the single-swab method, the reliability and advantages of this method in the NH setting became questionable. Yet, sensitivity increased when considering the lower CT values, similar to a laboratory setting, indicating a higher viral load and thereby identifying the most infectious persons. Specificity was much higher when the single-swab method was performed in a laboratory setting. Moreover, the number of false positive was especially high when the GLY medium was used. Whether the low sensitivity and specificity could be attributed to the adapted procedure during the single-swab method in the NH setting or the transport medium itself needs to be addressed. Further research is especially important since the importance of testing for SARS-CoV-2 remains. Even with the introduction of vaccination, variants will still pose risk, and also the level of protection and duration of immunity are currently unknown in this vulnerable population. The proposed requirements, such as having enough trained staff and clear working instructions, also apply for a successful implementation of Ag-RDT testing in the NH setting in itself and these should be considered, as well as the dilemma that arises with acquiring faster test results. For the vulnerable population in the NH setting, it is important to find the right

balance between effective testing policy and the burden this imposes on the residents and the HCWs.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s41999-021-00584-3>.

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Author contributions KP and AL were responsible for acquisition of data, data analysis and interpretation of data and writing the manuscript. All authors substantially contributed to the study concept and design, analysis and interpretation of data, and revised the article critically and approved it for final publication.

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Data availability The datasets used and analyzed during the study are available from the corresponding author on reasonable request.

Code availability Not applicable.

Declarations

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Consent to participate Residents, or their representatives in case of legal incapacity, were informed about the study and given the opportunity to opt out for using their data in the study. Each focus group participant provided written informed consent prior to participating in the focus groups.

Consent for publication Not applicable.

Ethical approval The Medical Ethics Committee of the Academic Medical Centre in Amsterdam, The Netherlands, reviewed the study protocol and stated that the study does not fall under the scope of the Medical Research Involving Human Subjects Act.

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