# Rapid antigen test during a COVID-19 outbreak in a private hospital in Hong Kong

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## ABSTRACT

**Introduction:** In response to two nosocomial clusters of coronavirus disease 2019 (COVID-19) in our hospital, we adopted a series of strict infection control measures, including regular rapid antigen test (RAT) screening for high-risk patients, visitors, and healthcare workers. We evaluated the diagnostic performance of a locally developed RAT, the INDICAID COVID-19 Rapid Antigen Test (Phase Scientific, Hong Kong), using respiratory samples from both symptomatic and asymptomatic individuals.

**Methods:** Real-time reverse-transcription polymerase chain reaction (rRT-PCR)–confirmed deep throat saliva (DTS) and pooled nasopharyngeal swab and throat swab (NPS/TS) samples collected from 1 November to 30 November 2020 were tested by INDICAID. Screening RATs were performed on asymptomatic healthcare workers during a 16-week period (1 December 2020 to 22 March 2021).

**Results:** In total, 20 rRT-PCR-confirmed samples (16 DTS, four pooled NPS/TS) were available for RAT. Using the original sample, RAT results were positive in 17/20 samples, indicating 85% sensitivity (95% confidence interval [CI]=62.11%-96.79%). Negative RAT results were associated with higher cycle threshold (Ct) values. For samples with Ct values <25, the sensitivity was 100%. Of the 49 801 RATs collected from healthcare workers, 33 false positives and one rRT-PCR-confirmed case were detected. The overall specificity was 99.93% (95% CI=99.91%-99.95%). The positive and negative predictive values were 2.94% (95% CI=2.11%-4.09%) and 100%, respectively.

**Conclusion:** The INDICAID COVID-19 RAT demonstrated good sensitivity for specimens with high viral loads and satisfactory specificity for low-risk, asymptomatic healthcare workers.


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**New knowledge added by this study**

- Rapid antigen tests (RATs) are simple and rapid; they have high sensitivity for specimens with high viral loads. When RATs were applied as point-of-care tests, using specimens intended analysis by for real-time reverse-transcription polymerase chain reaction (rRT-PCR), infected patients could be identified before molecular results were available.
- The use of RATs to regularly screen asymptomatic high-risk patients, visitors, and healthcare workers during a coronavirus disease 2019 outbreak led to successful control of the nosocomial outbreak and prevented further entry of community-acquired infections into the hospital.
- The use of screening RATs and the establishment of a registration system for patient visitors led to minimal laboratory service disruption; visitation policies were maintained without reducing infection control measures.

**Implications for clinical practice or policy**

- RATs are appropriate for the screening of individuals with recent exposure or early symptoms because of their high sensitivities for specimens with high viral loads.
- RATs can be used in conjunction with rRT-PCR in outbreak situations to allow the rapid triage and isolation of infected individuals before confirmatory rRT-PCR results are available.
- Regular RAT screening for asymptomatic high-risk patients, visitors, and healthcare workers is useful for preventing nosocomial outbreaks while causing minimal disturbances to laboratory services and visitation policies.

 

## 香港私立醫院COVID-19爆發期間的快速抗原測試

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**引言：**針對我院的兩個2019冠狀病毒病（COVID-19）院內感染群組，我們採取了一系列嚴格感染控制措施，包括對高危患者、訪客和醫療保健人員進行定期快速抗原測試篩查。本研究透過有症狀及無症狀患者的呼吸道樣本，評估本地研發的INDICAID COVID-19快速抗原測試的診斷表現。

**方法：**以INDICAID對2020年11月1日至11月30日收集的深喉唾液核酸測試和合併鼻咽拭子和口咽拭子樣本進行測試。在2020年12月1日至2021年3月22 日期間，對無症狀醫護人員進行快速抗原測試篩查。

**結果：**共20個核酸測試樣本（16個深喉唾液及4個鼻咽拭子和口咽拭子）進行快速抗原測試，當中17個樣本呈陽性，表明靈敏度為85%（95%置信區間=62.11%-96.79%）。快速抗原測試陰性結果與較高Ct值相關。Ct值25以下樣本的靈敏度為100%。從醫護人員採集的49 801個樣本中，檢出33例假陽性和1例核酸測試確診。總體特異性為99.93%（95%置信區間=99.91%-99.95%）。陽性和陰性預測值分別為2.94%（95%置信區間=2.11%-4.09%）和100%

**結論：**INDICAID COVID-19快速抗原測試對病毒量高的樣本表現良好靈敏度，對低風險、無症狀醫護人員也有令人滿意的特異度。

## Introduction

Rapid diagnosis of coronavirus disease 2019 (COVID-19) is crucial, particularly during an outbreak situation when the segregation and immediate isolation of infected individuals are critical. This is because up to half of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections are asymptomatic; moreover, infection transmission can be greater during the pre-symptomatic phase than during the symptomatic phase, leading to silent transmission.[1,2] The ideal diagnostic test should be easy to perform and interpret; it should also have a rapid turnaround time. Despite higher costs and greater technical demands, the detection of unique viral sequences (eg, E, RdRP, N, and S genes) by nucleic acid amplification tests such as real-time reverse-transcription polymerase chain reaction (rRT-PCR) remains the 'gold standard' for diagnosis because of superior sensitivity and specificity.[3] Although most contemporary automated PCR platforms are capable of integrated sample preparation, amplification, and software-assisted result interpretation, most such tests require approximately 1 hour to perform; this duration excludes specimen transportation time from the bedside or the field to the laboratory, as well as time for preparation by laboratory personnel. In contrast, rapid antigen tests (RATs; ie, immunochromatographic membrane assays), commonly known as lateral flow assays, are gaining popularity. Rapid antigen tests are rapid, easily deployable in the field without the need for specialised equipment, and relatively inexpensive; they require only minimal training for performance and subsequent interpretation of the results. Despite their lower sensitivities, several antigen-based diagnostic tests have received in vitro diagnostics emergency use authorisations from the United States Food and Drug Administration[4] and are considered valuable for reducing transmission through the early detection of highly infectious cases and facilitation of contact tracing.[5]

Since the first local case of COVID-19 were confirmed on 4 February 2020, Hong Kong has experienced four waves of COVID-19 surges with over 11 000 cases reported. The fourth wave, which began in late October/early November, primarily comprised multiple clusters of locally acquired infections that involved food premises, construction sites, nursing homes, and dancing/singing venues.[6] In November 2020, two clusters of nosocomial transmission of COVID-19 were found in a private ward and the renal dialysis unit of Hong Kong Sanatorium & Hospital. In both clusters, the source of nosocomial infection could be traced back to visitors and relatives of patients who belonged to the largest local COVID-19 cluster—the dancing/singing cluster. As a precautionary measure against future transmission, the hospital subsequently adopted a strict registration policy for patient visitors. Each patient could register a maximum of three visitors; each patient visitor was required to undergo RATs at 3-day intervals. Single RATs were required for other hospital visitors, including technicians and contractors who remained in clinical areas for >1 hour. In addition to the mandatory pre-admission PCR screening for all in-patients, PCR was repeated at 7-day intervals for long-term in-patients. For haemodialysis and oncology patients who required frequent visits, RATs were required at 3-day intervals or before each haemodialysis session, in addition to a weekly PCR test. Single RATs were also required for out-patient visits that involved mask-off procedures, such as dental procedures, rhinoscopy, lung function tests, or gastroscopy. In this study, we evaluated the diagnostic performance of the INDICAID COVID-19 Rapid Antigen Test (Phase Scientific, Hong Kong) using respiratory samples submitted by patients and staff members.

## Methods

### Clinical specimens

The rRT-PCR-confirmed SARS-CoV-2-positive respiratory specimens, including posterior pharyngeal saliva (ie, deep throat saliva; DTS) and pooled nasopharyngeal swab and throat swab

(NPS/TS), submitted to our laboratory during 1 to 30 November 2020 were subjected to additional RATs. Deep throat saliva specimens were self-collected, in accordance with instructions from local health authorities.[7,8] A video with detailed instructions was shown to all patients before the collection of their DTSs in a well-ventilated area with a hand-washing facility. Each DTS was spit into an empty sterile container, which was then double-bagged and submitted to the designated collection point in our hospital. The NPS/TS specimens were collected by healthcare workers in full personal protection equipment using a Dryswab™ PurFlock® (Medical Wire, United Kingdom) for nasal swabbing and a flocked swab (Taizhou Sun Trine Biotechnology Co, Ltd, Taizhou City, China) for throat swabbing. Both swabs were submerged in the same viral transport medium (Biologix, Shandong, China), then double bagged and immediately transferred to the laboratory. Nasal swabs collected for the screening of asymptomatic hospital staff members from 1 December 2020 to 22 March 2021 were included for analysis. Nasal swabs were collected by healthcare workers using swabs provided by the RAT manufacturer. Each swab was inserted 2.5 cm into each nostril, twisted for 5 seconds, and then swirled in buffer solution at least 20 times.

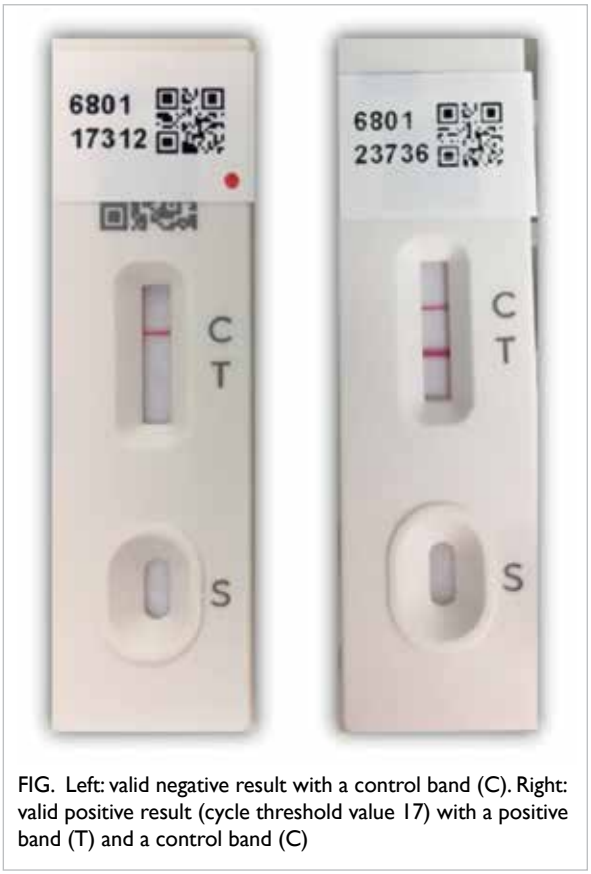


FIG. Left: valid negative result with a control band (C). Right: valid positive result (cycle threshold value 17) with a positive band (T) and a control band (C)

### Severe acute respiratory syndrome coronavirus 2 detection by nucleic acid amplification test

Deep throat saliva specimens (approximately 500 μL) from patients were mixed in a 1:1 (v/v) ratio with Sputasol (Oxoid, England), vortexed for 1 minute to reduce viscosity, and spun for 1 minute. An approximately 300-μL aliquot of the mixture was transferred to the Xpert® Xpress SARS-CoV-2 cartridge. Nucleic acid amplification tests of DTS and pooled NPS/TS were performed in accordance with the manufacturer's protocol.

### Rapid antigen test

The INDICAID COVID-19 Rapid Antigen Test is an immunochromatographic membrane assay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab and NPS samples. The SARS-CoV-2-specific monoclonal antibodies and a control antibody are immobilised at the test line (T) region and control line (C) region of a nitrocellulose membrane in a plastic cassette. Monoclonal anti-SARS-CoV-2 antibodies conjugated with red colloidal gold particles are used to detect the SARS-CoV-2 antigen. In accordance with the test protocol, the collected nasal swab or NPS was swirled 20 times in the buffer solution; three drops of the buffer solution were then applied to the sample well. When the SARS-CoV-2 antigen was present, it bound to the antibody-gold conjugate to form an immunocomplex. The immunocomplex then travelled across the strip via capillary action and bound to the SARS-CoV-2 antibodies at the test line (T), forming a visible red line. The test result was intended to be read between 20 and 25 minutes after sample application to the well. The result was considered invalid if the control line was invisible (Fig). The result was considered false positive if a subsequent PCR result was negative, or the positive band was not reproducible upon repeated assessment with a new INDICAID kit.

For RATs using DTS specimens, a 50-μL aliquot of Sputasol-treated DTS was mixed with 100 μL of INDICAID buffer. An approximately 100-μL aliquot of the mixture was then transferred to the sample well of the INDICAID kit.

For RATs using pooled NPS/TS specimens, a 50-μL aliquot of viral transport medium was added to the INDICAID buffer solution; a 100-μL aliquot of the mixture was then transferred to the sample well of the INDICAID kit.

### Data analysis

To evaluate RAT sensitivity, we calculated the proportion of rRT-PCR-confirmed SARS-CoV-2-positive respiratory specimens that were correctly

identified as positive by the RAT. Nasal swabs from asymptomatic hospital staff were used for evaluation of the RAT false positive rate, specificity, positive predictive value, and negative predictive value. Statistical tests were performed using MedCalc® (https://www.medcalc.org/).

## Results

In total, 20 PCR positive samples (16 DTS, four pooled NPS/TS) were available for further testing by RAT (Table 1). These specimens belonged to 18 symptomatic or asymptomatic patients who attended the hospital's out-patient department and two hospital staff members who had positive screening results during contact tracing of a nosocomial cluster of COVID-19. Using the original sample, RATs yielded positive results in 17 samples, demonstrating 85% sensitivity (95% confidence interval [CI]=62.11%-96.79%). Negative RAT results were associated with higher cycle threshold (Ct) values. For samples with Ct values <25 (Xpert Xpress SARS-CoV-2), the sensitivity was 100%.

In total, 49 801 RAT screenings were performed on asymptomatic healthcare workers during 16 weeks from 1 December 2020 to 22 March 2021 (Table 2). In all, 33 false positives and one PCR-confirmed case were detected during this period. In the first week of hospital-wide staff screening, all specimens with positive RAT results exhibited negative PCR results. Importantly, these false positives were not reproducible by a repeat RAT, and many of them were caused by delays in reading the results (>25 min). Therefore, staff members were subsequently advised to strictly adhere to the manufacturer's instructions; PCR was not performed unless a repeat RAT also yielded positive results. We also ensured that the healthcare workers with positive screening results were asymptomatic and did not have any recent exposure to confirmed cases; otherwise, rRT-PCR was performed. The reported false positive rate greatly decreased in subsequent weeks. The false positive rate of INDICAID was approximately 1/1509 tests in our cohort. The overall specificity was 99.93% (95% CI=99.91%-99.95%). The positive predictive value was 2.94% (95% CI=2.11%-4.09%), while the negative predictive value was 100%.

A staff member from the Engineering and Maintenance Department exhibited positive RAT results during his pre-symptomatic period in March 2021. He subsequently exhibited positive rRT-PCR results (Ct values of approximately 20) and developed mild upper respiratory tract symptoms. This staff member had no known exposure to a confirmed COVID-19 case but had received physiotherapy in the hospital during the incubation period. He did not have any direct patient contact. His close contacts, including co-workers who shared the same workspace and his attending physiotherapist, were offered immediate screening. All of his close contacts were quarantined, but no secondary cases were identified.

TABLE 1. Correlation between INDICAID result and cycle threshold (Ct) value of 20 SARS-CoV-2-positive samples

| Specimen type | Rapid antigen test (INDICAID) | Xpert Xpress SARS-CoV-2 (Ct value) | |
|---|---|---|---|
| | | E gene | N gene |
| NPS/TS | Positive | 22.2 | 24.3 |
| NPS/TS | Positive | 17.5 | 19.6 |
| NPS/TS | Positive | 16.8 | 19.1 |
| NPS/TS | Positive | 17.8 | 20.4 |
| DTS | Positive | 25.8 | 27.2 |
| DTS | Positive | 12.3 | 14 |
| DTS | Positive | 15 | 17.5 |
| DTS | Positive | 18 | 20.6 |
| DTS | Positive | 15.8 | 18.2 |
| DTS | Positive | 22.2 | 24.7 |
| DTS | Positive | 16.1 | 18.4 |
| DTS | Positive | 14.4 | 16.7 |
| DTS | Positive | 20.7 | 23.3 |
| DTS | Positive | 17.3 | 19.9 |
| DTS | Positive | 21.3 | 23.8 |
| DTS | Positive | 21.6 | 28.7 |
| DTS | Positive | 20.3 | 22.5 |
| DTS | Negative | 32.3 | 35.2 |
| DTS | Negative | 39.4 | 40.3 |
| DTS | Negative | 25.9 | 27.5 |

Abbreviations: DTS = deep throat saliva; NPS/TS = nasopharyngeal swab and throat swab

## Discussion

The RAT used in this study was a SARS-CoV-2 antigen lateral flow assay with a reported detection limit of 140 TCID50/swab; it has positive and negative percent agreements of 96% (95% CI=86.3%-99.5%) and 100% (95% CI=92.9%-100%), respectively, when performed on contrived samples near the test's limit of detection (2xLoD) and simulated negative matrix. Although the manufacturer does not specifically recommend the use of DTS and pooled NPS/TS specimens, our evaluation showed a satisfactory sensitivity for these samples, particularly for samples with high viral loads (100% sensitivity for Ct values <25). The INDICAID test specificity was high; however, the positive predictive value was only 2.94% (95% CI=2.11%-4.09%). This finding was presumably caused by low disease prevalence in our cohort because all RATs were performed on asymptomatic healthcare workers without exposure history.

TABLE 2. Number of rapid antigen tests (INDICAID), false positive rate, and specificity when performed on asymptomatic healthcare workers during a 16-week period (1 December 2020 to 22 March 2021)

| Testing period | No. of rapid antigen tests (INDICAID) performed | No. of false positives * | No. of true positives |
|---|---|---|---|
| Hospital-wide weekly screening for in-house staff members | | | |
| 1/12/2020-7/12/2020 | 3159 | 8 | 0 |
| 8/12/2020-14/12/2020 | 3123 | 6 | 0 |
| 15/12/2020-21/12/2020 | 3157 | 2 | 0 |
| 22/12/2020-28/12/2020 | 3112 | 2 | 0 |
| 29/12/2020-4/1/2021 | 3183 | 2 | 0 |
| 5/1/2021-11/1/2021 | 3192 | 1 | 0 |
| 12/1/2021-18/1/2021 | 3202 | 4 | 0 |
| 19/1/2021-25/1/2021 | 3142 | 1 | 0 |
| 26/1/2021-1/2/2021 | 3282 | 1 | 0 |
| 2/2/2021-8/2/2021 | 3258 | 1 | 0 |
| 9/2/2021-15/2/2021 | 2916 | 2 | 0 |
| 16/2/2021-22/2/2021 | 2901 | 1 | 0 |
| 23/2/2021-1/3/2021 | 3068 | 1 | 0 |
| 2/3/2021-8/3/2021 | 3032 | 1 | 0 |
| 9/3/2021-15/3/2021 | 3074 | 0 | 1 |
| 16/3/2021-22/3/2021 | 3000 | 0 | 0 |
| Total | 49801 | 33 | 1 |
| False positive rate: 1/1509 = 0.066% | | | |
| Overall specificity: 99.93% (95% confidence interval=99.91%-99.95%) | | | |

* A test result was considered false positive if a subsequent polymerase chain reaction result was negative, or the positive band was not reproducible upon repeated rapid antigen testing

In a Cochrane review of five studies regarding SARS-CoV-2 RATs, their sensitivities considerably varied (mean, 56.2%; 95% CI=29.5%-79.8%), while their specificities were consistently high (mean, 99.5%; 95% CI=98.1%-99.9%).[9] The World Health Organisation recommends the use of SARS-CoV-2 RATs for screening to support outbreak investigations and contact tracing for rapid isolation of positive cases; they should also be used in communities with widespread transmission where the nucleic acid amplification test capacity is limited, although such tests should meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity. Moreover, a negative RAT result should be considered presumptive and insufficient for removal of a contact from quarantine requirements.[10] The European Centre for Disease Prevention and Control has higher performance requirements of ≥90% sensitivity and ≥97% specificity for SARS-CoV-2 RATs. The positive predictive value of any clinical test could be influenced by the pretest probability. Therefore, both the World Health Organisation and the European Centre for Disease Prevention and Control do not recommend the use of SARS-CoV-2 RATs on asymptomatic individuals without contact history and in low prevalence communities (eg, <10%).[5,10] The United States Centers for Disease Control and Prevention has provided an antigen test algorithm that focuses on pretest probability: a negative RAT result should be confirmed by a nucleic acid amplification test in situations where the pretest probability is high, while a negative antigen test could indicate the absence of SARS-CoV-2 infection in an asymptomatic individual who had no known exposure to a COVID-19 case within the previous 14 days.[11]

Rapid antigen test sensitivity is higher during the early course of infection (5-7 days after symptom onset) when both viral load and infectivity are at their peaks.[9,10,12-14] A negative RAT result is insufficient to rule out infection, although it is associated with lower infectivity. In a field evaluation of the Panbio™ COVID-19 Ag Rapid Test Device for symptomatic patients (n=412) attending primary healthcare centres, SARS-CoV-2 could not be cultured from specimens that yielded rRT-PCR+/RAT– results (n=11); the authors of the study concluded that patients with RT-PCR-proven COVID-19 and negative RAT results were unlikely to be infectious.[15] Because of their timeliness and simplicity, RATs provide added value for contact tracing and patient triage. Considering the limitations of RATs, we used them as screening tools for people who were at highest risk of SARS-CoV-2 transmission, such as immunocompromised oncology and renal failure patients who attended out-patient chemotherapy and haemodialysis treatment centres, as well as out-patients who underwent mask-off procedures. Our frequent screening approach constituted an attempt to compensate for the moderate sensitivity of the RAT. The scale of screening in our hospital was very large and could only be achieved by a point-of-care test that permitted decentralised testing (ie, at the site of clinical encounter); this allowed minimal impact to our daily laboratory operation.

Among the 49 801 RATs performed for weekly staff screening during the 16-week study period, only one PCR-confirmed case was detected. Although the cost-effectiveness has not been determined, the early case detection could have prevented a major nosocomial outbreak and service disruption affecting the Engineering and Maintenance Department and the Physiotherapy Department.

To control the fourth wave of COVID-19 in Hong Kong, authorities repeatedly enforced lockdowns within communities containing multiple cases of COVID-19; this facilitated mandatory testing of all residents in those communities. When respiratory samples were collected for complementary

RAT and PCR assessments, positive results could be obtained before molecular results were available. Rapid antigen tests allowed rapid specimen triage and the preliminary isolation of individuals with presumptive positive results. This type of dual-track testing was also used during screening of a local community outbreak (personal communication). In addition to the screening function, RATs have been utilised by some laboratories for secondary rapid confirmation of positive rRT-PCR results.

Our study had several limitations. First, we could not evaluate the diagnostic sensitivity of the INDICAID test using the recommended types of specimens (ie, nasal swab and NPS) because most of our patient samples were DTS and pooled NPS/TS. Second, asymptomatic infections with viral loads below the INDICAID detection limit could have been missed because no parallel rRT-PCR analyses were conducted. Third, the effects of mutant SARS-CoV-2 strains on the INDICAID detection limit were not evaluated.

In conclusion, RATs are rapid and simple point-of-care tools that can shorten the COVID-19 testing turnaround time; they can be used in many different strategies. Our study showed that the INDICAID COVID-19 RAT has good sensitivity for specimens with high viral loads and satisfactory specificity for low-risk, asymptomatic healthcare workers.

## Author contributions

Concept or design: All authors.
Acquisition of data: All authors.
Analysis or interpretation of data: All authors.
Drafting of the manuscript: JST Zee.
Critical revision of the manuscript for important intellectual content: All authors.

All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

## Conflicts of interest

All authors have disclosed no conflicts of interest.

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## Ethics approval

This study obtained ethics approval (RC-2021-08) from the Research Ethics Committee of the Hong Kong Sanatorium & Hospital Medical Group.

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