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LETTER TO THE EDITOR

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Use of a rapid point-of-care molecular test in the triage of suspected COVID-19 cases

During this pandemic period, emergency departments are overwhelmed by patients who present at admission with suspected symptoms of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. These patients are confined into dedicated areas until their polymerase chain reaction (PCR) results are available. Staying in these areas may increase the risk of infection from SARS-CoV-2 positive patients to those who are not infected. Actually, diagnostic platforms take few hours before delivering PCR results slowing down patients flow through clinical wards. Availability of rapid point-of-care (POC) molecular testing may improve patients' management providing results in less than 1 h.[1] Here, we report on the use of a POC test, VitaPCR™ SARS-CoV-2 assay (Menarini Diagnostics), in the triage of suspected patients with COVID-19 admitted to the Emergency Department of the University Hospital Tor Vergata, Rome, Italy. VitaPCR™ SARS-CoV-2 assay detects the presence of SARS-CoV-2 RNA in nasopharyngeal or oropharyngeal swabs collected from patients with signs or symptoms of respiratory infection. The assay contains a specific primers/probe set that targets the N gene of SARS-CoV-2 plus a universal SARS-like primers/probe set. Time to result is 20 min with 1 min hands-on time. Analytical sensitivity is about 90 viral copies/reaction.

From the beginning of September 2020 to the end of November 2020, 1123 nasopharyngeal swabs were processed by VitaPCR™ SARS-CoV-2 assay and the results compared with those obtained by the Allplex™ SARS-CoV-2 assay, which is used with the automated liquid handling workstation NIMBUS (Seegene). This diagnostic platform processes 70 samples in about 5 h and 30 min. The assay targets the common Sarbecovirus E gene and the specific N, RdRp, and S SARS-CoV-2 genes, and has a sensitivity of 50 copies/reaction. Of the 1123 nasopharyngeal swabs tested, VitaPCR™ SARS-CoV-2 assay detected SARS-CoV-2 RNA in 139 samples, while 984 tested negative. Allplex™ SARS-CoV-2 assay detected SARS-CoV-2 RNA in 195 samples and 928 tested negative, Table 1. Fifty-eight samples that were negative by VitaPCR tested positive by Allplex™ PCR as well as two samples positive by VitaPCR™ were negative by Allplex PCR. The sensitivity of VitaPCR™ SARS-CoV-2 assay was 70.3% (95% confidence interval [CI]: 0.675–0.729), specificity 99.9% (95% CI: 0.992–1.000), and accuracy 94.7%. The positive predictive value (PPV) was 98.6% (95% CI: 0.976–0.991) and the negative predictive value (NPV) 94.1% (95% CI: 0.925–0.954). Cohen statistics showed an excellent level of agreement between the two tests, $k = 0.946 > 0.8$.

Rapid diagnosis of SARS-CoV-2 infection is crucial for the proper management of patients with COVID-19. Actually, deterioration of the clinical conditions in COVID-19 patients may occur rapidly, especially in patients with pre-existing comorbidities,[2] and the availability of a sensitive and specific rapid molecular assay allows early intervention. In a recent study, POC testing was associated with an improvement in infection control measures, patients' flow and enrollment into clinical trials. Patients in the POC testing group could be transferred from the assessment area to the definitive appropriate clinical area several hours earlier than the group tested with the routine laboratory PCR. This allowed clinical staff to start directed therapy earlier.[3] Based on this experience, and considering the high number of admissions for suspected COVID-19 in our emergency department, we decided to assess whether a POC molecular assay could speed up the triage of patients with acute respiratory symptoms.

The data generated by the two PCR systems run in parallel showed that the level of agreement between the POC assay and the laboratory PCR was very good as demonstrated by the kappa Cohen's statistics. In addition, the POC assay showed a high PPV and NPV suggesting that it might be reliably used in the emergency department to discriminate COVID-19 positive patients from the negative ones. However, some samples were missed by the POC assay compared with the laboratory PCR calling for a further improvement of the sensitivity of the assay. Based on the results of the POC assay, the triage of the suspected COVID-19 cases admitted at our emergency department was faster, and patients' flow was promptly directed towards the right clinical areas without waiting for the laboratory PCR results.

Given the high sensitivity and specificity of several POC assays currently available in the market (e.g., BIOFIRE® Respiratory panel 2.1, Xpert Xpress SARS-CoV-2, and QIAstat-Dx Respiratory SARS-CoV-2 Panel), it can be envisaged that POC testing could also be used in other settings like schools, nursing homes, and airports where a rapid and accurate response is required as well as easy to use instruments. Overall,

TABLE 1 SARS-CoV-2 RNA detected by the two assays

		Allplex™ SARS-CoV-2 assay	
		Positive	Negative
VitaPCR™ SARS-CoV-2 assay	Positive	137	2
	Negative	58	926

Abbreviation: SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

the data reported in this study support the use of POC testing in the triage of acute suspected COVID-19 cases. Furthermore, they are in line with the results reported by Fournier et al.[4] that support the use of VitaPCR™ SARS-CoV-2 assay for the rapid diagnosis of COVID-19.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Marco Ciotti conception of the work, writing, and final revision. Eleonora Nicolai performed statistical analysis. Fabbio Marcuccilli collected the data. Sergio Bernardini conception of the work and final critical revision.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

1. Ciotti M, Ciccozzi M, Terrinoni A, Jiang W-C, Wan C-B, Bernardini S. The COVID-19 pandemic. *Crit Rev Clin Lab Sci*. 2020;57(6):365-388. https://doi.org/10.1080/10408363.2020.1783198
2. Yi P, Yang X, Ding C, et al. Risk factors and clinical features of deterioration in COVID-19 patients in Zhejiang, China: a single-centre, retrospective study. *BMC Infect Dis*. 2020;20:943.
3. Brendish NJ, Poole S, Naidu VV, et al. Clinical impact of molecular point-of-care testing for suspected COVID-19 in hospital (COV-19POC): a prospective, interventional, non-randomised, controlled study. Lancet. *Respir Med*. 2020;8:1192-1200.
4. Fournier P-E, Zandotti C, Ninove L, et al. Contribution of VitaPCR SARS-CoV-2 to the emergency diagnosis of COVID-19. *J Clin Virol*. 2020;133:104682.