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Short communication

Fast and reliable real life data on COVID-19 triaging with ID NOW

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ABSTRACT

In the context of SARS-CoV-2 pandemic, rapid and easy-to-perform diagnostic methods are essential to limit the spread of the virus and for the clinical management of COVID-19 patients. Although real-time polymerase chain reaction remains the "gold standard" to diagnose acute infections, this technique is expensive, requires trained personnel, well-equipped laboratory and is time-consuming. A prospective evaluation of the Abbott ID NOW COVID-19 point-of-care testing that uses isothermal nucleic acid amplification for the qualitative detection of SARS-CoV-2 RdRp gene was run in the Emergency Department during the third wave of COVID-19 pandemic. ID-NOW significantly simplified SARS-CoV-2 identification and COVID-19 patient triaging, being highly valuable in rapidly locating febrile patients in or out of COVID-19 areas, and can be considered as a first-line diagnostic test in the Emergency Room setting.

In the context of SARS-CoV-2 pandemic, febrile patients admitted to Emergency Departments (ED) require a prompt identification of SARS CoV-2 for immediate entry to care. Polymerase chain reaction (PCR)-based molecular testing is expensive and not feasible without expertise and a well-equipped laboratory, often with considerable turnaround times for final results. Rapid antigen-based tests for SARS-CoV-2 are inexpensive, can return results within 15 min (https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html) and have received Food and Drug Administration (FDA) an CE Emergency Use Authorization (EUA) within the first 5–12 days after symptom onset but test performance have shown poor sensitivity and specificity [1,2]. Therefore new rapid molecular tests are highly desirable and of value for the fast triaging of symptomatic patients during the peak of the pandemic.

ID NOW COVID-19 assay (Abbott Molecular Diagnostics, Des Plaines, IL, USA) has recently proved a simple, rapid, specific and sensitive diagnostic tool for the early detection and identification of SARS-CoV-2 [3–6]. In addition to clinical laboratories, this assay can be performed by trained non-laboratory personnel in patient care settings such ED. The test uses the isothermal nucleic acid amplification technology for qualitative detection of a SARS-CoV-2 unique region of the RdRp gene segment with a manufacturer's claimed lower limit of detection of 125 genome equivalents/ml. Fluorescently labeled molecular beacons are used to specifically identify each of the amplified RNA targets including an internal control. ID NOW COVID-19 test circumvent limitations of the traditional laboratory intensive RT-PCR, producing positive results within 5 to 13 min and negative results within 13–20 min, from dry nasal swabs [7].

In this study, we report the diagnostic performance of ID NOW COVID-19 assay on 148 consecutive patients referring to the Emergency Department of ASL Città di Torino Hospitals, and Santa Croce Hospital, Cuneo, Italy, collected during the peak of March-April 2021 pandemic wave (https://www.worldometers.info/coronavirus/country/italy/, COVID-19 prevalence rate: 20.9%). For each patient with suspicious symptoms (fever, dyspnea, cough, diarrhea, anosmia, dysgeusia), or strict contact with positive person, self-referred positivity for SARS-CoV-2, residency within a high risk setting, at the same time, both nasal (according to ID NOW manifacturer's directions) and nasopharyngeal swabs for conventional RT-PCR as reference standard (Seegene Allplex™ SARS-CoV-2 Assay, Arrow Diagnostics Srl, Genoa, Italy) were collected.

Dry nasal swabs were tested with ID NOW at bed-side in ED, whereas nasopharyngeal swabs (NPS) collected in UTM (Universal Transport Medium) were transported to the laboratory and tested within 3 h. Results of tests performed with ID NOW and RT-PCR are shown in Table 1.

Among 31 RT-PCR positive samples, 26 were correctly detected by ID NOW, whereas 5 false negative results were present, given an overall sensitivity for ID-NOW of 83.9%. All negative samples detected with RT-PCR were negative with ID NOW (100% specificity). Overall concordance between ID-NOW and RT-PCT was 96.6%.

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Table 1
Comparison of Abbott ID NOW COVID-19 and reference method using NPS.

Reference standard (RT-PCR)			
ID Now result	Positive	Negative	Total
Positive	26	0	26
Negative	5	117	122
Total	31	117	148

ID-NOW positive and negative predictive values for the identification of SARS-CoV-2 were 100% and 95.9%, respectively. Discordant ID-NOW-negative/RT-PCR positive samples were resolved with Xpert Xpress SARS-CoV-2 (Cepheid, Sunnyvale, CA, USA) assay, confirming that these were all weak positive, with a mean cycle threshold (C_t) across N and E genes ≥ 35 (C_t range 35–38) suggesting that they had a low SARS-CoV-2 RNA concentration. The rate of invalid ID NOW was 2% (n = 3) at first testing, decreasing to 0% after test repetition, that was done immediately.

In conclusion, the real-life results of this study are in line with others [3] suggesting that ID NOW significantly simplified the diagnostic process of COVID-19 triaging of febrile patients admitted to ED during the pandemic. Patients admission was faster with a more accurate triaging.

Based on our experience, ID NOW is a useful rapid rule-out testing for COVID-19 in patients with acute respiratory symptoms admitted to ED, allowing a sensitive and specific diagnosis of COVID-19 with a fast turn-around-time as required by the pandemic in the emergency setting.

Declaration of Competing Interest

None declared.

CRediT authorship contribution statement

Elisa Burdino: Conceptualization, Visualization, Data curation, Investigation, Formal analysis, Writing – original draft, Writing – review & editing. **Francesco Cerutti:** Conceptualization, Visualization, Data curation, Investigation, Formal analysis, Writing – original draft, Writing – review & editing. **Maria Grazia Milia:** Data curation, Investigation. **Tiziano Allice:** Data curation, Investigation. **Gabriella Gregori:** Data curation, Investigation. **Franco Aprà:** Data curation, Investigation. **Fabio De Iaco:** Data curation, Investigation. **Enzo Aluffi:** Data curation, Investigation. **Gianmatteo Micca:** Data curation, Investigation. **Valeria Ghisetti:** Formal analysis, Writing – original draft, Writing – review & editing.

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