Data in Brief

Dataset from the comparative evaluation of the STANDARD M10 point-of-care analyzer versus the NeuMoDx assay for the molecular diagnosis of SARS-CoV-2

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ABSTRACT

The STANDARD M10 is a novel cartridge-based real time RT-PCR point of care platform that provides significant advantages regarding SARS-CoV-2 detection including fast turnaround times and no need for specialized personnel and facilities. This assay was recently evaluated in our hospital as a rapid alternative to the already present NeuMoDx assay that is used in everyday practice. For this purpose, 30 nasopharyngeal samples by patients admitted to our hospital were used, regardless of clinical suspicion of COVID-19. In our evaluation, the sensitivity of STANDARD M10 was 95%, the specificity was 100%, the positive predictive value was 100%, the negative predictive value was 90% and the kappa coefficient of agreement was 0.927 (p < 0.001).

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Specifications Table

| Subject | Health and medical sciences: Infectious Diseases & Laboratory medicine |
|---------|-----------------------------------------------------------------------|
| Specific subject area | Evaluation of the new STANDARD M10 assay for SARS-CoV-2 detection |
| Type of data | Table |
| How the data were acquired | Patient samples were analyzed by both STANDARD M10 and NeuMoDx real time RT-PCR assays. The STANDARD M10 analyzer targets the Open Reading Frame 1ab gene (ORF1ab) and the Envelope gene (E) of SARS-CoV-2. NeuMoDx detects the Nucleocapsid gene (N) and the Non structural protein 2 gene (Nsp2). |
| Data format | Raw Analyzed |
| Description of data collection | Nasopharyngeal samples by patients admitted to the hospital regardless of clinical suspicion of COVID-19 were used. Results were expressed as rt RT-PCR cycle threshold values for each gene detected by the assays |
| Data source location | Institution: AHEPA University Hospital, City/Region: Thessaloniki/Central Macedonia, Country: Greece |
| Latitude: 40° 38′ 21.66″ N; Longitude: 22° 56′ 40.59″ E |
| Data accessibility | 1. With the article 2. Repository name: Mendeley Data Data identification number: 10.17632/v4dby8sfbj.1 Direct URL to data: https://data.mendeley.com/datasets/v4dby8sfbj/2 |
| Related research article | N.A. |

Value of the Data

- Point-of-care platforms present significant advantages regarding SARS-CoV-2 detection.
- Since many techniques have been rapidly implemented for the detection of SARS-CoV-2 in a short time, not enough independent data on the performance of each one are available.
- Reporting real-world evidence on the performance of diagnostic tools for SARS-CoV-2 has become increasingly important.
- Medical laboratory professionals can benefit from evaluation data of the new STANDARD M10 analyzer.
- These data can be useful for the implementation of STANDARD M10 as an alternative for reducing the turnaround time and the increased needs in personnel and facilities.

1. Objective

Real-time reverse transcription polymerase chain reaction (RT-PCR) of nasopharyngeal samples is the gold standard for the detection of severe acute respiratory coronavirus 2 (SARS-CoV-2) [1]. Nevertheless, the aforementioned assay has long turnaround times and requires trained personnel and specific facilities [2]. On the other hand, molecular point of care testing (POC) platforms provide alternatives that overcome the need for specialized personnel and improve significantly the time to result [3]. Moreover, they can be implemented almost anywhere including laboratories, emergency departments, clinics and when rapid and/or massive screening is needed, even outside the hospital environment [4]. Their cost per sample is higher than that of conventional real time RT-PCR and each one has its unique characteristics. Because of the aforementioned features, the STANDARD M10 assay was recently evaluated in our hospital as a rapid alternative to the already present real time RT-PCR based technique (NeuMoDx) that is in use in everyday practice.
2. Data Description

The NeuMoDx assay targets the N and Nsp2 genes whereas STANDARD M10 targets the ORF1ab and the E gene of SARS-CoV-2. In real time PCR assays, positive reactions are detected by accumulation of fluorescent signals. The cycle threshold (Ct) of positive samples is the number of cycles required for the fluorescent signal to exceed the background level (threshold) [5]. In our evaluation, we had one case (case 9, Table 1) that was positive with high Ct values (30.97/31.67) by the NeuMoDx and negative by the STANDARD M10. All other cases presented identical outcomes. Compared to the NeuMoDx SARS-CoV-2 assay, the sensitivity of STANDARD M10 was 95%, the specificity was 100%, the positive predictive value was 100%, the negative predictive value was 90% and the kappa coefficient of agreement was 0.927 (p < 0.001). The Ct value is inversely proportional to the amount of the target nucleic acid present in each sample. Therefore, high Cts generally indicate low viral loads and low Cts indicate high viral loads. Taking into consideration that low viral load samples are commonly unable for viral growth in cell cultures [6], especially in terms of clinical significance of the outcome, the evaluation of the STANDARD M10 assay was successful.

Table 1

| Test No | Test ID   | NeuMoDx  (N Ct / Nsp2 Ct) | STANDARD M10 (ORF1aband E Ct) |
|---------|-----------|---------------------------|-------------------------------|
| 1       | 128206    | POS (- /30.92)            | POS (33.56/-)                 |
| 2       | 128400    | NEG                       | NEG                           |
| 3       | 128928    | POS (28.65/28.64)         | POS (30.34/-)                 |
| 4       | 129005    | POS (16.47/17.04)         | POS (18.32/17.28)             |
| 5       | 129099    | POS (27.73/28.39)         | POS (28.73/25.75)             |
| 6       | 129095    | POS (16.54/17.00)         | POS (18.21/17.32)             |
| 7       | 129195    | POS (29.50/29.12)         | POS (30.62/-)                 |
| 8       | 129324    | POS (22.34/22.54)         | POS (23.23/22.25)             |
| 9       | 129617    | POS (30.97/31.67)         | NEG                           |
| 10      | 129525    | POS (14.40/15.50)         | POS (14.08/12.85)             |
| 11      | 130294    | NEG                       | NEG                           |
| 12      | 130387    | NEG                       | NEG                           |
| 13      | 132054    | POS (14.08/14.47)         | POS (14.23/13.15)             |
| 14      | 131536    | POS (12.68/13.20)         | POS (14.09/12.99)             |
| 15      | 131539    | POS (17.52/19.45)         | POS (21.27/20.29)             |
| 16      | 131593    | POS (9.81/11.90)          | POS (15.46/14.48)             |
| 17      | 131591    | POS (17.66/18.23)         | POS (19.62/18.81)             |
| 18      | 131928    | POS (30.57/29.76)         | POS (33.66/-)                 |
| 19      | 131889    | POS (27.95/28.65)         | POS (29.29/28.13)             |
| 20      | 135240    | NEG                       | NEG                           |
| 21      | 131694    | POS (15.82/16.14)         | POS (16.52/15.00)             |
| 22      | 131768    | POS (13.06/13.99)         | POS (14.29/13.00)             |
| 23      | 135566    | POS (13.44/13.95)         | POS (15.32/14.37)             |
| 24      | 135313    | NEG                       | NEG                           |
| 25      | 135301    | NEG                       | NEG                           |
| 26      | 135302    | NEG                       | NEG                           |
| 27      | 135371    | NEG                       | NEG                           |
| 28      | 135317    | NEG                       | NEG                           |
| 29      | 135392    | NEG                       | NEG                           |
| 30      | 163513    | POS (18.85/19.04)         | POS (18.37/17.55)             |
3. Experimental Design, Materials and Methods

The STANDARD M10 assay (SD Biosensor, Seoul, Korea) is a cartridge-based multiplex RT-PCR for the qualitative detection of SARS-CoV-2. The molecular detection is performed on the STANDARD M10 analyzer that can include up to 8 modules. The assay targets the Open Reading Frame 1ab gene (ORF1ab) and the Envelope gene (E) and the turnaround time is 60 minutes. For this evaluation, we used 30 nasopharyngeal samples by patients admitted to AHEPA University hospital of Thessaloniki in Greece, regardless of clinical suspicion of coronavirus disease 19 (COVID-19), as testing all new admissions for COVID-19 by NeuMoDx assay is standard practice in the hospital. The samples were tested in parallel with the STANDARD M10 and the NeuMoDx SARS-CoV-2 assay according to the appropriate manufacturer’s instructions for each assay. The reagents used for the RT-PCR reactions of the NeuMoDx assay described in this dataset were NeuMoDx SARS-CoV-2 Test strips 114714 and 114722, NeuMoDx Extraction Plates 107874 and 113630, NeuMoDx Lysis Buffer 2 113023 and 110755, NeuMoDx Cartridges 116619 and 111912, Wash 106696 and Release 117898. The Lot Number of the STANDARD M10 cartridges used was MNCO0322084. The kappa coefficient of agreement was calculated using SPSS Statistics version 28.

Ethics Statements

No case details or other personal information or images of patients or any other individuals are included in this article. The publication of the RT-PCR results was approved by the AHEPA University Hospital bioethics committee (protocol number: 29694-3/6/22). Patient consent was waived in the context of emerging infectious diseases according to the guidelines regarding data processing in scientific research in the context of the COVID-19 outbreak by the European Data Protection Board (page 16, paragraph 7, available at: https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_el_0.pdf) and the article 49 of the GDPR (point d, available at: https://www.privacy-regulation.eu/el/49.htm).

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability

STANDARD M10 Evaluation vs NeuMoDx (Original data) (Mendeley Data).

CRediT Author Statement

Georgios Meletis: Conceptualization, Methodology, Software, Writing – original draft; Areti Tychala: Data curation, Investigation; Ioanna Gkeka: Data curation, Investigation; Efthymia Protonotariou: Methodology, Validation, Supervision; Lemony Skoura: Validation, Supervision, Writing – review & editing.

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Supplementary Materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.dib.2022.108690.

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