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Research Article
Evaluation of the STANDARD™ M10 SARS-CoV-2 Test (SD Biosensor) as a Molecular Diagnostic Tool for COVID-19 in Ouagadougou, Burkina Faso

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Abstract

Background and Objective: Since COVID-19 cases have been low, tools adapted to the rapid diagnosis of SARS-CoV-2 in laboratories receiving low numbers of COVID-19 screenings have proved very necessary. In this context, the objective is to evaluate the performance of the STANDARD™ M10 SARS-CoV-2 test (SD Biosensor) and compare ton RT-PCR as a reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) with a view to its routine use as a molecular diagnostic test for COVID-19. **Materials and Methods:** This was a comparative study carried out between November, 2022 to February, 2023 which included 50 samples from men and women. The samples were nasopharyngeal swabs transported in a viral transport medium. The samples were analyzed by rRT-PCR using the reference method and then tested by STANDARD™ M10 SARS-CoV-2 rRT-PCR (SD Biosensor). Sensitivity, specificity and concordance rates were assessed by statistical analysis using R studio software version 4.1.3. **Results:** A total of 30 positive samples and 20 negative samples (TaqPath™ COVID-19 CE-IVD RT-PCR) were given respectively with the STANDARD™ M10 SARS-CoV-2 (SD Biosensor), 26 true positives with 04 false negatives and 19 true negatives with 01 false positive. The sensitivity of the "STANDARD™ M10 SARS-CoV-2" test was estimated at 86.7% (95% CI; 69.5% to 95.6%, 26/30) while the specificity at 95.0% (95% CI; 74.3% to 100%, 19/20). The test showed moderate concordance (Kappa =0.79) with the reference method (TaqPath™ COVID-19 RT-PCR) and was effective in detecting SARS-CoV-2, even in low viral load samples. **Conclusion:** The "STANDARD™ M10 SARS-CoV-2" test is capable of detecting SARS-CoV-2 in nasopharyngeal samples to the same extent as the TaqPath™ COVID-19 CE-IVD RT-PCR.

Key words: SARS-CoV-2, TaqPath™ COVID-19 CE-IVD RT-PCR, STANDARD™ M10 SARS-CoV-2, acute respiratory disease, Burkina Faso

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

The pathogen responsible for unknown pneumonia was officially identified by a coronavirus study group as "Severe Acute Respiratory Syndrome Coronavirus type 2 (SARS-CoV-2)" and the associated acute respiratory disease epidemic was labeled "Coronavirus Disease 2019" for short COVID-19. On January 30, 2020, the WHO declared COVID-19 to be a "Public Health Emergency of International Concern" and on March 11, 2020, COVID-19 was declared a "pandemic". The disease intensified rapidly, putting hospitals and laboratory services around the world to the test[1]. Due to the efforts of the world's health authorities, the World Health Organization declared on May 03, 2023, that COVID-19 had become an established health problem of a persistent nature and, therefore, no longer constituted a public health emergency of international concern[2].

In Africa, there were an estimated close to seven million COVID-19 cases including 169,608 deaths in 2021[3]. Burkina Faso, whose first cases were reported on March 09, 2020, had recorded a total of 13,588 cases confirmed cases of COVID-19, including 169 deaths the same year[3].

In the fight against the disease, numerous strategies are being implemented, including viral diagnostic techniques. Numerous methods ranging from classical ones such as virus culture and antigenic tests to molecular methods have been used for diagnosis and research on the virus[4]. Among these methods, Reverse Transcription Polymerase Chain Reaction (RT-PCR), targeting regions of the SARS-CoV-2 genome on nasopharyngeal swabs, is the reference method for diagnosing COVID-19[5]. The test procedure involves extraction of viral RNA, reverse transcription of RNA into cDNA, amplification of target genes and detection of fluorescent signals[6] . These tests enable sensitive detection of SARS-CoV-2 even in samples with low viral load. Most of these tests report the viral load of the sample as a "Cycle threshold (Ct)" or estimate it using standard curves. The Ct is the number of PCR cycles at which a fluorescent signal is detected during the reaction. Due to this Ct value, it is possible to establish an inversely proportional relationship with viral load. The lower the Ct value, the earlier the signal appears during the amplification process and the higher the viral load[6]. Several commercial amplification kits have appeared since the start of the pandemic[3]. In Burkina Faso, various SARS-CoV-2 RNA amplification tests are used in the molecular diagnosis of COVID-19[3,7]. Among these tests is the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific), which is used as a reference in the laboratory, given its high detection sensitivity of SARS-CoV-2 nucleic acids[8]. In countries such as Burkina Faso, where the prevalence (22,006 confirmed cases of COVID-19 out of a population of 22,752,315 according to the RGPH 2019) of COVID-19 has been low, tools adapted to the rapid diagnosis of SARS-CoV-2 in laboratories receiving low numbers of COVID-19 screenings have proved very necessary. The purpose of the study is to evaluate the performance of the STANDARD™ M10 SARS-CoV-2 test (SD Biosensor) an automated *in vitro* diagnostic real-time RT-PCR test for qualitative detection of SARS-CoV-2 and compare to RT-PCR as a reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) with a view to its routine use as a molecular diagnostic test for COVID-19.

MATERIALS AND METHODS

Study design: This was a comparative study to evaluate the analytical performance of the STANDARD™ M10 SARS-CoV-2 assay (SD Biosensor) for *in vitro* molecular detection of SARS-CoV-2. The study was conducted between November, 2022 and February, 2023 at the Biomedical Research Laboratory (LaReBio) of the "Health Sciences Research Institute" (IRSS/CNRST) located in Ouagadougou, Burkina Faso.

Samples panel: This study included 50 participants consisting of males and/or females who were suspected cases or contact cases of COVID-19 patients referred for COVID-19 testing. Samples collected consisted of nasopharyngeal swabs transported in viral transport medium (VTM), from sampling sites (airport terminal, medical centers) in Ouagadougou and stored at -80°C until tested. The samples panel was made of thirty TaqPath™ Kit COVID-19 CE-IVD RT-PCR-positive nasopharyngeal samples (Thermo Fisher Scientific, USA) from symptomatic patients, with symptom onset between 0 and 7 days and twenty nasopharyngeal samples negative to the TaqPath™ COVID-19 CE-IVD RT-PCR Kit (Thermo Fisher Scientific, USA) from asymptomatic and non-symptomatic subjects.

Index test/test under evaluation

STANDARD™ M10 SARS-CoV-2 test: The STANDARD™ M10 SARS-CoV-2 test (SD Biosensor, Suwon, South Korea) is an automated *in vitro* diagnostic real-time RT-PCR test based on isothermal amplification. The test is intended for use with the STANDARD™ M10 SARS-CoV-2 system (analyzer) for the qualitative detection of SARS-CoV-2 nucleic acids in nasopharyngeal swabs taken from individuals suspected of having COVID-19. The test detects two specific regions of the SARS-CoV-2 genome, the ORF1ab and E genes, including the detection of fragments of the internal standard gene

Table 1: Interpretation of results with the TaqPath™ kit COVID-19 according to the manufacturer

ORF1ab	Gene N	S gene	MS2	Results	Actions
-	-	-	-	Invalid	Repeat the test, extracting the original sample. If the repeated result remains invalid, collect a new sample
-	-	-	-	-	Render result Negative
At most, one positive target			+ or -	Non-concluding	Repeat the test, extracting the original sample If the result is the same, take another sample
Positive for 2 or more targets			+ or -	+	Making the result positive

+: Positive and -: Negative

Table 2: Interpretation of STANDARD™ (Test Results) M10 SARS-CoV-2 (SD Biosensor) according to the manufacturer

ORF 1ab	Gene E	Internal control	Results
+	+/-	+/-	SARS-CoV-2 positive (+)
-	+	+/-	**SARS-CoV-2 presumed positive (+)
-	-	+	SARS-CoV-2 negative (-)
-	-	-	Invalid/To be retested!

+: Positive and -: Negative, the internal control (IC) can be negative or positive (+/-) in a positive sample and **SARS-CoV-2 presumed positive; sample must be retested. If the result is the same, further confirmatory tests may be carried out and E gene positivity may be caused by other sarbecoviruses

(RNase P). The STANDARD™ M10 SARS-CoV-2 assay is based on an all-in-one cartridge containing nucleic acid extraction and amplification reagents. The cartridge is stored at 2~28°C (36~82°F) and contains primers and probes for each target gene (ORF1ab gene and E gene) and internal control (IC), for *in vitro* qualitative detection of SARS-CoV-2 RNA in 1 hr in nasopharyngeal swab samples[9]. After 40 cycles of amplification, positive results are obtained if the Cycle thresholds (Ct) of the two target genes (ORF1ab gene and E gene) or of the ORF1ab gene are within 38.0 cycles[10]. All experiments are performed in accordance with the manufacturer's instructions.

Reference test: The reference test used in current study was real-time RT-PCR using the TaqPath™ COVID-19 CE-IVD RT-PCR Amplification Kit (Thermo Fisher Scientific, USA); available in the biomedical research laboratory of the "Health Sciences Research Institute" (LaReBio) for routine diagnostics. The RT-PCR was performed on the Applied Biosystems™ Quant Studio 5 thermocycler (Singapore, Singapore) with the TaqPath™ COVID-19 CE-IVD RT-PCR amplification kit (Thermo Fisher Scientific, USA). The latter simultaneously detects three different genes targeting the nucleoprotein (N), spike protein (S) and ORF1ab regions, including detection of fragments of the internal standard gene (MS2) (Table 1).

The QIAamp® Viral RNA Mini Kit (QIAGEN, Germany) was used for manual RNA extraction from nasopharyngeal swabs contained in VTM. The entire procedure followed the instructions provided by the kit manufacturer.

Nasopharyngeal samples were immediately tested with STANDARD™ M10 SARS-CoV-2 assays (SD Biosensor, Suwon, South Korea) using the STANDARD™ M10 SARS-CoV-2 instrument. The system comprises an analytical module known as the STANDARD™ M10 Module, into which the test cartridge is loaded and an M10 console (user interface) with preloaded software for results analysis. It integrates sample preparation, nucleic acid extraction, amplification and target sequence detection. Cross-contamination is minimized by the usage of self-contained single-usage cartridge containing RT-PCR reagents during processing[10]. Amplicons were tested with the fluorochromes FAM, HEX and CY5 corresponding to the ORF1ab, E and internal control genes, respectively (Table 2).

Statistical analysis: Data were entered on Microsoft Excel version 2016 and statistical analysis were carried out using R software with the graphical interface RStudio v. 4.1.3 (R Core Team, Vienna, Austria) version for Windows.

Ethics approval: The Ministry of Health/Burkina Faso approved the evaluation of COVID-19 tests with the letter number N°2020/00004382/MS/SG/DGAP/DLBM/sc dated 28 December, 2020. It was carried out at LaReBio, as recommended by the quality management system to any new method. This technical validation study is a contribution to the improvement of COVID-19 diagnosis in the laboratory. All the samples used were anonymous and the related information was confidential.

RESULTS

In sum, with the STANDARD™ M10 SARS-CoV-2 test (SD Biosensor), of the 30 RT-PCR-positive samples, 26 tested positive (true positives) and 04 negative (false negatives). Concerning the 20 samples negative to the TaqPath™ reference test™ COVID-19 CE-IVD RT-PCR (Thermo Fisher Scientific, USA), 19 were identified as negative (true negative) and : 0.01 alone as positive (false positive) to STANDARD™ M10 SARS-CoV-2 (Table 3).

Table 3: Contingency table of test results for the reference method (Kit TaqPath™ COVID-19 CE-IVD RT-PCR) and the STANDARD™ M10 SARS-CoV-2 test

	Reference method (TaqPath™)		
Nasopharyngeal samples	Positive	Negative	Total
STANDARD™ M10 SD Biosensor SARS-CoV-2			
Positive	26	01	27
Negative	04	19	23
Total	30	20	50

Table 4: Concordance of STANDARD™ M10 SARS-CoV-2 test results with those obtained using the reference method (TaqPath)™

Concordance Reference method (TaqPath)™	Samples	Genes detected	Median	Average, ±SD, IQR	Ct range
STANDARD™ M10 SARS-CoV-2					
Concordant (true positives)	26	ORF1ab	26.64	26.62; ± 4.60 ; 8.30	19.23-35.13
		E	24.31	25.45; ± 4.80 ; 7.61	17.73-34.55
Concordant (true negatives)	19	No	-	-	-
	01	ORF1ab	32.68	32.68	-
Discordant (false positives)		E	34.60	34.60	-
Discordant (false negatives)	04	No	-	-	-

SD: Standard deviation and IQR: Intervalle interquartile

Table 5: Performance indicators for the STANDARD™ M10 SARS-CoV-2 test

Indices	Values (%)	Confidence interval (95%)
Sensitivity	86.7	69.5-95.6
Specific	95.0	74.3-100
Fraction of false positives	0.5	0-13.7
Fraction of false negatives	13.3	1.9-24.8
Positive likelihood ratio	17.3	2.5-117.697
Negative likelihood ratio	0.14	0.056-0.351
Cohen's Kappa (95%)	0.797	0.60-0.80

The median Ct values for the targets detected by the STANDARD™ M10 SARS-CoV-2 test are: 26.64 (IQR 8.30) for the ORF1ab gene and 24.31 (IQR 7.61) for the E gene. The STANDARD™ M10 SARS-CoV-2 test provided 01 false positive results, detecting the 2 genes (ORF1ab and E) with respective Ct values of 32.68 and 34.60. False-negative results provided by the STANDARD™ M10 SARS-CoV-2 test showed no amplification of at least one target (Table 4).

Elsewhere when comparing the results of the STANDARD™ M10 SARS-CoV-2 test with the TaqPath™ COVID-19 CE-IVD RT-PCR reference method (Thermo Fisher Scientific, USA); 2 samples among the reference method negatives gave presumptive positive results (ORF1ab absent and the E gene present with Ct values of 35.70 and 34.74, respectively for the 1er and 2eme sample). These 2 presumptive positive samples had an ORF1ab Ct value by the reference method greater than 37.

For the calculation of sensitivity and specificity, the two negative samples were considered that were identified as presumptive positives of the STANDARD™ M10 SARS-CoV-2 assay as true negatives. The sensitivity of the STANDARD™ M10 SARS-CoV-2 assay compared with the reference method TaqPath™ COVID-19 CE-IVD RT-PCR (Thermo Fisher Scientific, USA) was estimated at 86.7% (95% CI 69.5% to 95.6%; 26/30) and the specificity at 95.0% (95% CI 74.3% to 100%; 19/20) (Table 5). Cohen's kappa coefficient was used to measure the degree of agreement between the two methods (Table 5) and according to Cohen's Kappa interpretation, the STANDARD™ M10 SARS-CoV-2 test has a moderate degree of agreement (Kappa = 0.797) with the reference method.

Statistical parameters for ORF1ab (the only gene common to both methods) and the internal control of each method were measured (Table 6).

In addition, the mean cycle threshold (Ct) values of ORF1ab and the internal control of the Standard™ M10 SARS-CoV-2 tests were compared with those of the reference method using "p-value" probability values (Table 7).

The mean values of Ct<30 on the one hand and Ct$\geq$30 of ORF1ab from the 2 methods were then compared (Table 8).

NB: For the results of the 2 samples presumed positive with STANDARD™ M10 SARS-CoV-2 tests, considered negative.

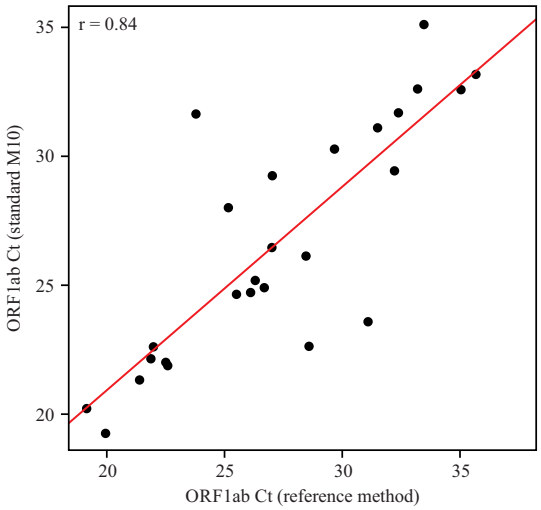

Fig. 1: Pearson rank "rho (r)" correlation between ORF1ab Ct values of the STANDARD™ M10 SARS-CoV-2 assay and the reference method (TaqPath)™

Table 6: Statistical parameter measures of variables

Variable	Sample (n)	1st quartile	Median	Average	3rd quartile	SD
STANDARD™ M10 (ORF1ab)	50	22.60	26.12	26.85	31.36	4.66
Reference method (ORF1ab)	50	24.86	28.54	28.84	33.25	5.50
STANDARD™ M10 (IC)	50	23.56	24.12	23.87	24.49	1.35
Reference method (IC)	50	25.60	26.25	26.44	26.66	1.57

SD: Standard deviation

Table 7: Average Ct threshold values for ORF1ab and internal control according to STANDARD™ M10

Target	STANDARD™ M10 (Means±SD, IQR)	Reference method (TaqPath™) (Means±SD, IQR)	CI (95%)	p-value
ORF1ab	26.85±4.66, 8.76	28.83, ±5.50, 8.39	25.00-28.69	0.144
IC	23.87±3.49, 0.92	26.44, ±1.57, 1.06	23.48-24.25	<0.0001

IC: Internal control, SD: Standard deviation and IQR: Interquartile range

Table 8: Mean values for Ct<30 and Ct≥30 for ORF1ab of samples tested by the 2 methods

Target	STANDARD™ M10 (averages, IQR)	Reference method (TaqPath™) (averages, IQR))	p-value
Ct<30	24.51, 4.21	24.67, 4.80	0.8702
Ct≥30	32.25, 1.31	33.92, 3.36	0.02227

IQR: Interquartile range

The Pearson rank "rho (r) correlation" was calculated to assess the relationship between the ORF1ab Ct values of the STANDARD™ M10 SARS-CoV-2 assay and the reference method (TaqPath™). There was a strong positive correlation between the two variables (r = 0.84, Fig. 1).

Internal control Ct values obtained with the STANDARD™ M10 SARS-CoV-2 assay (median = 24.12, mean = 23.87, IQR = 0.925) were significantly lower than those obtained with the reference method (TaqPath™) (median = 26.25, mean = 26.44, IQR = 1.065, p<0.001, Fig. 2a). The ORF1ab Ct values obtained with the STANDARD™ M10 SARS-CoV-2 assay (median = 26.12, mean = 26.85, IQR = 8.7600) were not significantly different from those obtained with the reference method (TaqPath™) (median = 28.84, mean = 28.84, IQR = 8.3925, p = 0.144, Fig. 2b).

In samples with high viral load (Ct<30), the Ct values of the STANDARD™ M10 SARS-CoV-2 method (median = 24.77; mean = 24.51; IQR = 4.21) did not differ significantly from the reference method (TaqPath™) (median = 25.36, mean = 24.67, IQR = 4.8; p = 0.87; Fig. 3a); this means that there is no difference in Ct values between the 2 methods. In samples with low viral load (Ct≥30), the Ct values of the STANDARD™ M10 SARS-CoV-2 method (median = 32.61, mean = 32.25; IQR = 1.31) were significantly lower than those of the reference method (median = 33.46; mean = 33.92; IQR = 3.36; p = 0.022; Fig. 3b).

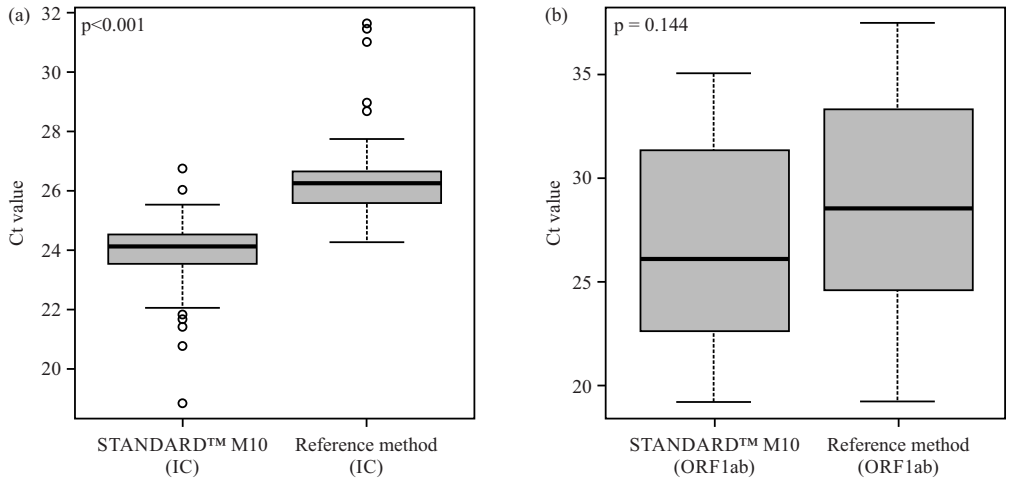

Fig. 2(a-b): Comparison of Ct values between the STANDARD™ M10 SARS-CoV-2 test and the reference method, (a) Ct of internal controls and (b) Ct of ORF1ab, the amplified gene common to both methods

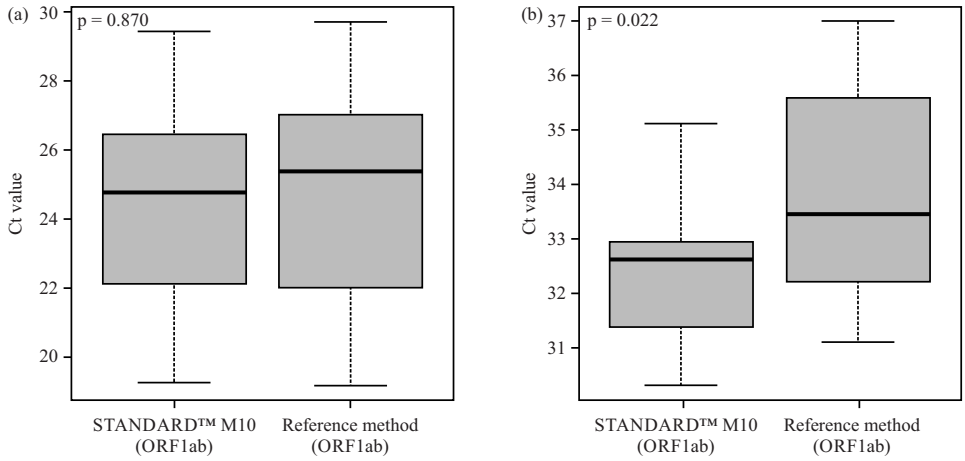

Fig. 3(a-b): Comparison of Ct<30 values on the one hand and Ct≥30 values on the other between the STANDARD™ M10 SARS-CoV-2 test and the reference method, (a) Ct<30 of the ORF1ab gene and (b) Ct≥30 of the ORF1ab gene

DISCUSSION

In the present study, the performance of the STANDARD™ M10 SARS-CoV-2 Test (SD Biosensor) was compared with the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific) as the reference method. Of the 30 positive samples with the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific), the STANDARD™ M10 SARS-CoV-2 test effectively detected 26 concordant positive samples (true positives) on par with the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR (Thermo Fisher Scientific)) (p = 0.144). These samples had successful amplification of the 2 target genes (ORF1ab and the E gene) with mean Ct values of 26.66 and 25.23, respectively and Ct ranges of (19.23-35.13) and (17.73-34.55) respectively. The 04 discordant samples (false negatives), meaning those identified as positive with the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific) and negative with the STANDARD™ M10 SARS-CoV-2, were characterized by a Ct close to the declared threshold (37 Ct) of the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific). A possible explanation for these 04 discordant results could be the low viral load of these samples, which was only identified with the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific). Of the 20 samples negative with the TaqPath™ COVID-19 CE-IVD RT-PCR kit (Thermo Fisher Scientific), 01 false-positive samples

were detected by the STANDARD™ M10 SARS-CoV-2 assay with successful amplification of the target genes (ORF1ab and E) with Ct values of 32.68 and 34.8, respectively. A possible explanation for this false positive result is that this sample, particularly characterized by the exclusive presence of the N gene in the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) with a Ct of 32.02, could therefore be a potential true-positive sample that could not be correctly identified, especially as proceeded manually with certain steps (extraction, preparation and distribution of the master mix, amplicon deposition, etc.). In carrying out tests using the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR). Regarding these discordant results (false negatives and false positives) between the STANDARD™ M10 SARS-CoV-2 test and the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR), it is unable to have the opportunity to repeat the STANDARD™ M10 SARS-CoV-2 tests on these samples. Among those negative to the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR), 02 samples gave presumptively positive results with the STANDARD™ M10 SARS-CoV-2 test (ORF1ab absent and the E gene present with Ct values of 35.70 and 34.74 respectively for the 1er and 2eme sample). These results considered to be negative. This decision was taken on the basis, according to the kit manufacturer's recommendations, that the presence of the E gene alone may be caused by the presence of other sarbecoviruses. In this case, the fact that these 2 "presumed-positive" samples came from our reference-method negative samples (TaqPath™ COVID-19 CE-IVD RT-PCR) was taken into account and was further supported by another study, according to which, of the possible SARS-CoV-2 RT-PCR targets, the E gene is the least specific, as it presents substantial sequence homology with other common or seasonal coronaviruses[11]. However, other authors have suggested that in settings where circulation of other coronaviruses is rare, detection of the E gene alone may be suggestive of SARS-CoV-2 infection, with the caveat that "presumptive positive" samples should be re-tested using alternative assays with different genetic targets[12,13].

The analytical sensitivity and specificity of the STANDARD™ M10 SARS-CoV-2 assay compared with the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) for Target ORF1ab (a target common to both methods) were estimated at 86.7% (95% CI 69.5% to 95.6%, 26/30) and 95.0% (95% CI 74.3% to 100%, 19/20) respectively. There was a qualitative approach that evaluated the STANDARD™ M10 SARS-CoV-2 test and found a 100% for both specificity and sensitivity[9]. Another study evaluated the ORF1ab target sensitivity at 95.5% (95% CI 91.7% to 97.6%) and specificity 100% (95% CI 98.7% to 100%) for the STANDARD™ M10 SARS-CoV-2 test[12]. The sensitivity of the STANDARD™ M10 SARS-CoV-2 test was found to be 98.00% (95% CI 94.96% to 99.45%), while specificity was estimated at 97.50% (95% CI 94.26% to 99.18%) in a different study[14]. The estimate of specificity (95.0%) which was found in the present study is close to the latter 2 studies, but the sensitivity (86.7%) reported here is lower. On the other hand, the first study reporting a sensitivity and specificity of 100% marks a departure from the results found. This could be due to the low ability of the STANDARD™ M10 SARS-CoV-2 assay to detect SARS-CoV-2 in samples with low viral load, as found in some of the positive samples compared to the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) with a Ct value close to 36-37 and 04 false-negative results were obtained. In addition, it is found that in samples with low viral load ($Ct \geq 30$), the mean Ct values of the STANDARD™ M10 SARS-CoV-2 assays were significantly lower than those of the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR kit) ($p = 0.022$) while in high viral load samples ($Ct < 30$), the Ct values of the STANDARD™ M10 SARS-CoV-2 method did not differ significantly from the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) (p-value = 0.870). According to present study hypothesis, it was confirmed in a similar study which demonstrates that STANDARD™ M10 SARS-CoV-2 has high performance except in samples with low viral load[10,14].

The ORF1ab Ct values obtained with the STANDARD™ M10 SARS-CoV-2 assay and the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) were not significantly different (p-value = 0.144). This means that there is no difference in the Ct values of the two methods. Parakatselaki *et al.*[14] in a similar study, also showed that the ORF1ab Ct values of the two methods did not differ significantly especially with high viral load.

The Pearson rank correlation of ORF1ab Ct values from the STANDARD™ M10 SARS-CoV-2 assay and the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) showed a strong positive correlation with a factor $r = 0.84$. Jeong *et al.*[10], in a similar study, proved that there was also a strong correlation ($r > 0.8$) of Ct values of the same gene (ORF1ab) between the STANDARD™ M10 SARS-CoV-2 test and conventional RT-PCR (STANDARD™ M nCoV). The concordance rate between the STANDARD™ M10 SARS-CoV-2 Test and the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR kit) showed a moderate to near-perfect degree of agreement, with a "Cohen's Kappa" precision of 0.797 (95% CI 0.60 to 0.80). This result was similar to other similar results based on the same principle. These are the Cepheid Xpert Xpress SARS-CoV-2 kit (Cepheid, USA), whose overall concordance of Cohen's Kappa coefficient was 0.98 (95% CI: 0.94-1.0) using Panther Fusion (Hologic, USA) as

a reference standard. Another study evaluating STANDARD™ M10 against the NeuMoDx™ test (QIAGEN, Germany) for the molecular diagnosis of SARS CoV-2 reported a Cohen's kappa concordance coefficient of 0.92[15]. A third similar study which also evaluated the performance of two tests (STANDARD™ M10 SARS-CoV-2 and Xpert Xpress SARS-CoV-2) against conventional RT-PCR tests (STANDARD™ M nCoV and Allplex SARS-CoV-2) for detecting SARS-CoV-2 reported that "Cohen's Kappa coefficient" also showed almost perfect agreement between each test and conventional RT-PCR tests[15].

In sum, comparison between the STANDARD™ M10 SD Biosensor SARS-CoV-2 test and the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) showed high specificity, positive predictive values, greater than 96% and negative predictive values of 82.6%. These high values indicate that the positive/negative results of SARS-CoV-2 RNA detection in patient nasopharyngeal samples were reliable and should be considered in patient management. Current study results here corroborated those reported by Meletis *et al.*[15], in a similar study in which they reported positive and negative predictive values of 100 and 90%, respectively. As far as implementation in clinical practice is concerned, the STANDARD™ M10 SARS-CoV-2 test (SD Biosensor) is easy to perform, more economical in time, limits cross-contamination of samples and is suitable for performing a small number of COVID-19 diagnostic samples. However, the study had some limits, mainly due to size of the study sample, making the study difficult to generalize, the non-repeatability of the RT-PCR assays on the tested samples, lack of information and data on the symptoms of the tested subjects. However, the STANDARD™ M10 SD Biosensor SARS-CoV-2 demonstrated performance very close to that of the reference method (TaqPath™ COVID-19 CE-IVD RT-PCR). It's advantage of detecting the SARS-CoV-2 genes (ORF1ab, E) without an external extraction step, nor an external purification process for the virus RNA, makes it a minimal piece of RT-PCR molecular diagnostic equipment required for a medical biology laboratory.

CONCLUSION

It can be established an accurate molecular diagnosis of SARS-CoV-2 in nasopharyngeal samples using the STANDARD™ M10 SD Biosensor SARS-CoV-2, under the same conditions as the reference method. This test is an ideal tool for rapid diagnosis of SARS-CoV-2 infection in countries where the prevalence of COVID-19 is low and especially in situations where quick decision-making is required for treatment follow-up.

SIGNIFICANCE STATEMENT

In countries such as Burkina Faso, where the prevalence of COVID-19 has been low, tools adapted to the rapid diagnosis of SARS-CoV-2 in laboratories receiving low numbers of COVID-19 screenings have proved very necessary. The purpose of the study is to evaluate the performance of the STANDARD™ M10 SARS-CoV-2 test (SD Biosensor) an automated *in vitro* diagnostic real-time RT-PCR test for the qualitative detection of SARS-CoV-2 and compare to RT-PCR as a reference method (TaqPath™ COVID-19 CE-IVD RT-PCR) with a view to its routine use as a molecular diagnostic test for COVID-19. The study shows as a result that the "STANDARD™ M10 SARS-CoV-2" test is capable of detecting SARS-CoV-2 in nasopharyngeal samples to the same extent as a reference method.

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