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Comparison of diagnostic efficacy of the Abbott RealTime SARS-CoV-2 Assay and the BGI Real-Time Fluorescent RT-PCR Kit for the RT-PCR-based detection of Severe Acute Respiratory Syndrome Coronavirus-2

Поређење дијагностичке ефикасности *Abbott RealTime SARS-CoV-2* и *BGI Real-Time Fluorescent RT-PCR* теста за *RT-PCR* детекцију тешког акутног респираторног синдрома коронавирус-2

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SUMMARY

Introduction/Objective Based on the World Health Organization guidelines, the current "gold standard" to diagnose Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) is reverse transcription-quantitative real-time polymerase chain reaction (RT-qPCR).

The objective of this study was to compare and analyze the detection performance of two different authorized SARS-CoV-2 nucleic acid detection assays: the Abbott RealTime SARS-CoV-2 (ACOV) assay and the BGI Real-Time Fluorescent RT-PCR (BGI) kit.

Methods Our study included 384 randomly selected nasopharyngeal and oropharyngeal swabs previously tested by the ACOV and subsequently tested by the BGI kit for detecting SARS-CoV-2. All patients were adult individuals with symptoms or suspected of Coronavirus disease 2019 (COVID-19).

Results We found that the ACOV assay detected more cases of COVID-19 infection than the BGI assay. The positive percent agreement was 98.3% (95% confidence intervals (95% CI): 95.7–99.3%), while Cohen's Kappa coefficient (Kappa) was 0.86 (95% CI: 0.80–0.91), indicating a strong level of agreement between these two tests. The negative percent agreement was 85.1% (95% CI: 78.3–90%), while 5.47% of cases were false negative using the BGI test to detect SARS-CoV-2. The sensitivity of the BGI test compared to Abbott was 91.73% (95% CI: 87.64–94.81%), and the specificity of the BGI test was 96.77% (95% CI: 91.95–99.11%).

Conclusion The Abbott kit showed a bit better diagnostic performance, and due to possible false negative results using the BGI test, we recommend complete testing with the ACOV test.

Keywords: COVID-19; diagnostic efficacy; PCR kits; real-time PCR; RNA isolation; SARS-CoV-2

САЖЕТАК

Увод/Циљ На основу смерница Светске здравствене организације, тренутни „златни стандард" за дијагнозу тешког акутног респираторног синдрома коронавирус-2 (*SARS-CoV-2* је квантитативна реакција ланчане полимеразе реверзне транскрипције у реалном времену (*RT-qPCR*).

Циљ ове студије био је да упореди и анализира учинак детекције два различита овлашћена теста за детекцију нуклеинске киселине *SARS-CoV-2*: *Abbott RealTime SARS-CoV-2* (*ACOV*) и *BGI Real-Time Fluorescent RT-PCR* (*BGI*) теста.

Методе Наша студија је укључивала 384 насумично одабрана назофарингеална и орофарингеална бриса која су претходно тестирана од стране *ACOV* теста, а затим тестирана помоћу *BGI* теста за откривање *SARS-CoV-2*. Сви пацијенти су одрасле особе са симптомима или сумњама на болест корона вируса 2019 (ковид 19).

Резултати Открили смо да је *ACOV* тест детектовао више случајева ковид 19 инфекције него *BGI* тест. Позитиван проценат слагања био је 98,3% [95% интервали поузданости (95% *CI*): 95,7–99,3%], док је Коенов капа коефицијент био 0,86 (95% *CI*: 0,80–0,91), што указује на чврст ниво сагласности између ова два теста. Негативан проценат слагања био је 85,1% (95% *CI*: 78,3–90%), док је 5,47% случајева било лажно негативно коришћењем *BGI* теста за откривање *SARS-CoV*-2. Осетљивост *BGI* теста у поређењу са *ACOV* била је 91,73% (95% *CI*: 87,64–94,81%), а специфичност *BGI* теста била је 96,77% (95% *CI*: 91,95–99,11%).

Закључак Аботов тест је показао нешто боље дијагностичке перформансе, а због могућих лажно негативних резултата коришћењем *BGI* теста, препоручујемо комплетно тестирање са *ACOV* тестом.

Кључне речи: ковид 19; дијагностичка ефикасност; *PCR* тестови; real-time PCR; РНК изолација; SARS-CoV-2

INTRODUCTION

The first cases of pneumonia with an unknown etiology were recorded in Wuhan, the

capital of China's Hubei Province, at the beginning of December 2019. The cause of severe acute respiratory syndrome (SARS), a newly discovered ribonucleic acid (RNA) beta-coronavirus linked to the present severe acute respiratory syndrome Coronavirus (SARS-CoV), was given the name SARS-CoV-2 [1]. As of January 21, 2023, there were 673,035,039 confirmed cases of SARS-CoV-2 infection worldwide, resulting in 6,744,203 deaths [2].

The Republic of Serbia reported its first COVID-19 case on March 6, 2020, and the epidemic is still going on. The epidemiological situation is favorable right now, with illness incidence on the decline globally. The Ministry of Health of the Republic of Serbia reports that as of January 21, 2023, 12,065,603 people had been tested in Serbia, of whom 2,464,509 had confirmed cases, resulting in 17,647 deaths and a mortality rate of 0.72 percent [2].

All data from this rapidly spreading COVID-19 pandemic points to the significance of an accurate molecular diagnosis of coronavirus infection due to the prevalence of coronavirus infection in the Republic of Serbia as well as the worldwide epidemic. For the epidemiology and illness features of an evolvable infectious virus like SARS-CoV-2, as well as for monitoring its transmission, laboratory research is crucial.

The molecular diagnosis of COVID-19 is based on the specific and sensitive detection of viral RNA. RT-qPCR is considered the gold standard in the detection of the SARS-CoV-2 virus, and is based on the fact that genetic material is first extracted from patient samples, and then reverse transcriptase is used to create a complementary deoxyribonucleic acid (DNA) strand from the viral RNA [1, 3]. RT-qPCR can detect several specific genes that encode viral structural proteins, including the spike (S), envelope (E), membrane (M), and nucleocapsid (N), plus eight accessory proteins, as well as open reading frame-1 antibodies (ORF1ab), which encode non-structural proteins — enzymes [4, 5, 6]. Orf1ab polygen is a polyprotein region encoding 16 non-structural proteins (NSPs), NSP1–NSP16, among which are RNA-dependent RNA polymerase (RdRp, NSP12) and 2'-O-ribose–methyltransferase (2'-

O-Mtase, NSP16) [5-8].

Usually, 5 to 6 days after the beginning of symptoms, COVID-19 patients had increased viral loads in both their upper and lower respiratory tracts [9, 10]. Researchers are now attempting to build new methods for identifying novel coronaviruses all around the world [11]. Currently, there are roughly 400 commercially accessible genetic tests [12].

Guidelines regarding target genes for SARS-CoV-2 detection vary worldwide. With the emergence of the SARS-CoV-2 virus, the WHO recommended protocols targeting the E gene for screening and the RdRp gene for confirmatory testing. As per the Centers for Disease Control and Prevention (CDC) recommendation, among the target genes of the developed SARS-CoV-2 RT-qPCR test, the N gene is the most frequently selected target gene except for ORF1a/b, while the S gene is the least frequently selected target gene [13].

This investigation compared the results of the ACOV and the BGI RT-PCR kit, two approved commercial SARS-CoV-2 RNA virus detection assays, at various viral loads to see if the choice of targeted genes affected the test's specificity. At that time, the reason for comparing two different authorized tests for SARS-CoV-2 nucleic acid detection was that the BGI test was more affordable than the ACOV test.

METHODS

Study design and data analysis

We conducted a prospective study at the tertiary inpatient healthcare facility in Novi Sad (the University Clinical Center of Vojvodina — UCCV). The Department for Infectious Diseases, and the hospital units of UCCV all enrolled patients as inpatients from October 17th, 2022, through October 22nd, 2022. All of the physicians and nurses engaged in the trial had ten days of training on appropriate sample handling and sampling techniques before the study's start [14].

During this time, 384 randomly selected specimens were collected sequentially from adult participants in this study with suspected COVID-19. From each patient, one nasopharyngeal swab and one oropharyngeal swab were collected and put into the same tube with 3 ml of the viral transport medium (VTM) (SANLI Medical Technology Development Co., Liuyang, Hunan, China) with antifungal and antibiotic supplements. Each patient provided one nasopharyngeal and oropharyngeal swabs (NOS) sample. Transport of clinical samples from the sampling site to the UCCV Virology The laboratory was carried out in a manual refrigerator (from +2 to +8°C).

For RT-qPCR SARS-CoV-2 laboratory confirmation, samples were kept refrigerated at 4°C and tested with ACOV and BGI tests within twelve hours of collection. The NOS 384 samples were heat inactivated in a water bath at 56°C for 30 minutes before testing to lower the possibility of accidental SARS-CoV-2 transmission to lab personnel [14]. Each NOS specimen was utilized for both the ACOV reference assay, which was performed first, and the BGI test, which was performed second, for comparison. The handling of biological samples suspected of containing COVID-19 where the laboratory procedure has the potential to produce aerosols or droplets as a result of vortexing was done according to WHO standards, utilizing a Class II biological cabinet (BSC) [14].

On September 30, 2022, the UCCV Ethics Committee approved the study (Decision No. 00-166).

Test descriptions

Abbott Molecular RealTime SARS-CoV-2 assay

On the Abbott m2000 System (Abbott Molecular Inc., North Chicago, IL, USA), which consists of amplification and detection equipment called the Abbott m2000rt and a sample preparation unit called the Abbott m2000sp, ACOV testing was performed according to the

manufacturer's instructions. On Abbott m2000sp equipment, viral RNA was isolated utilizing the Abbott mSample Preparation Systems DNA kit (Abbott Molecular Inc., North Chicago, IL). Automated extraction was done using a specimen with an input volume of 500 µl VTM, and then extracts and reagents from the amplification package (40 µl of each) were added automatically for RT-qPCR amplification and detection. The structural N and the non-structural RdRp gene within the Orf1ab domain (RdRp/Orf1ab) (NSP12) gene of the SARS-CoV-2 genome are the targets of the ACOV assay. (Table 1) [15]. To show that the sample preparation method was correctly used with each specimen and control, every sample receives internal control (IC) at the start of the process. Because the two SARS-CoV-2-specific probes are marked with the same fluorophore, fluorescein (FAM), and the IC-specific probe is marked with another fluorophore, 2′-chloro-7′-phenyl-1,4-dichloro-6-carboxyfluorescein (VIC), it is possible to detect SARS-CoV-2 as well as IC-amplified products within the same reaction (Table 1). The m2000rt system software analyzed the amplification curve and the result was reported as detected or not detected. The sample was deemed positive if a signal was observed at the cycle threshold (Ct) ≤ 37 for any gene. A sample was deemed negative if the viral genes were not amplified but the internal control was. A specimen was considered invalid if the internal control was not amplified.

BGI Real-Time Fluorescent RT-PCR Kit

The BGI testing was performed as per the manufacturer’s instructions. Viral RNA was isolated utilizing the Viral DNA and RNA Extraction Kit (Xi'an Tianlong Science and Technology Co., Ltd., Xi'an, China) for the Rotary Nucleic Acid Extraction System (GeneRotex 96L) (Xi'an Tianlong Science and Technology Co., Ltd., Xi'an, China). As per the manufacturer's recommendations, isolated RNA extracts (10 µl) have been aliquoted and put into an aliquoted RT-PCR master mix (20 µl), along with the relevant controls. According

to the manufacturer's instructions, amplification was carried out utilizing the Gentier 96E quantitative RT-PCR system (Xi'an Tianlong Science and Technology Co., Ltd., Xi'an, China). To identify SARS-CoV-2 RNA in the FAM channel (Orf1ab gene) as well as a human specimen adequate control in the HEX (hexachlorofluorescein channel) channel (IC), the BGI kit uses multiplex RT-qPCR. Each PCR run included an internal control (human actin), a positive control, and a negative control. Internal control was put in place to keep an eye on the laboratory's processes, which included the isolation of nucleic acids, reverse transcription, and amplifying each reaction. The specimen was deemed to be SARS-CoV-2 positive if the FAM channel showed a sigmoidal amplification curve with Ct values ≤ 38. (Table 1). All samples should have positive ICs and Ct values no greater than 35. The specimen was considered negative if the IC was amplified but did not replicate the viral genes. A valid no template (negative) control should have a Ct value of "0" in the FAM channel and no sigmoidal amplification curve. A specimen was found invalid if the IC was not amplified.

Statistical analysis

For statistical analysis, data were collected and analyzed using the IBM® SPSS Version 23.0 software (IBM, Armonk, NY, USA). 254 positive samples were chosen to represent the whole range of observed Ct values on the Abbott assay, spanning from 3-29 cycles, to assess assay efficiency at different virus concentrations.

Using ACOV as the reference test, the BGI assay's positive percent agreement and 95% CI 95% were computed. To assess the negative agreement, 124 additional negative specimens were chosen. A 95% CI was also obtained for Cohen's Kappa of qualitative findings (identified or not identified) between the BGI and ACOV tests. A moderate level of agreement was characterized as values of Cohen's Kappa greater than 0.600, while values of

0.80–0.90 were interpreted as a strong agreement between the two assays [16].

RESULTS

In our investigation, 384 NOS samples – 254 (66.15%) positive, 124 (32.29%) negative, and 6 (1.56%) invalid – were initially tested with the ACOV for SARS-CoV-2 and then again using the BGI RT-PCR kit. All of the patients, who ranged in age from 17 to 93, were adults with symptoms or suspected COVID-19. For positive samples, the average age was 64.58 years old, whereas, for negative samples, it was 55.36 years old. In general, male samples produced the majority of positive findings (55.9%), while female samples produced the majority of negative results (61.3%). (Table 2).

Table 3 shows the results of RT-PCR SARS-CoV-2 tests provided by BGI and ACOV. Both tests identified the SARS-CoV-2 gene sequences in 233 (60.68%) specimens; however, neither test found SARS-CoV-2 RNA in 120 (31.25%) of those specimens. Compared to ACOV, the BGI test correctly identified 233/254 specimens that were positive with SARS-CoV-2 target sequences and 120/124 negative samples, yielding a 93.4% (95% CI: 90.4–95.5%) total percent concordance (Table 3). The Cohen's Kappa value was 0.86 (95% CI: 0.80-0.91), and the positive percentage concordance was 98.3% (95% CI: 95.7-99.3%) (Table 3), indicating a strong level of agreement between these two tests. The negative percentage concordance was 85.1% (95% CI: 78.3–90%).

The ACOV assay produced 254 (66.15%) positive results (Table 3). The median Ct value of concordantly positive specimens tested on the ACOV assay was 10.75 (95% CI: 9.65–11.32), ranging from 3.31 to 27.30 with a standard deviation of 5.73. According to the BGI test, the median Ct value of the concordant specimens was 23.56 (95% CI: 21.79 to 24.22), ranging from 11.96 to 37.19, with a standard deviation of 5.81.

Discordant findings were found in 27 (7.03%) of the samples when tested with both

tests (Table 3). Twenty-one individuals (5.47%) that tested positive on ACOV but negative on the BGI test had a mean Ct value of 24.47 (95% CI: 24.22–24.74), ranging from 22.48 to 26.60, with a standard deviation of 0.04. Five samples (2.15%) that tested positive on the ACOV test, and had a Ct value ranging from 22.48 to 26.60 were positive on the BGI test with a median Ct value of 35.05 (95% CI: 34.16–35.94), ranging from 33.91 to 36.87, with a standard deviation of 1.27. Our study found 6 cases (1.56%), including 2 invalid samples, in which samples examined using ACOV were negative despite being positive obtained using the BGI test, having a mean Ct of 32.65 (95% CI: 29.50–36.83), ranging from 29.50 to 36.83, and a standard deviation of 0.07. Four (1.04%) samples were invalid on both the ACOV and the BGI kits. In total, 27 samples that yielded discordant SARS-CoV-2 results were retested with ACOV and BGI tests within 24 hours of collection. The same results were obtained. ACOV test results were provided to patients as valid.

In comparison to the Abbott test, the BGI test has a sensitivity of 91.73% (95% CI: 87.64–94.81%) and a specificity of 96.77% (95% CI: 91.95–99.11%).

The Ct values obtained from the ACOV assay and those obtained from the BGI kit were compared using a T-test. The ACOV assay Ct values were significantly lower ($p < 0.001$).

The values of Ct between samples detected by the ACOV and BGI assays are shown in Figure 1 alongside the Ct values between samples detected exclusively using the ACOV test. To compare median Ct value differences, the Mann-Whitney U-test was used. The Mann-Whitney U-test was utilized to compare differences in median Ct values. The Ct values detected only from the ACOV assay were significantly higher ($p < 0.001$). Overall, the BGI assay compared to the ACOV test demonstrated no significantly different performance characteristics.

DISCUSSION

The global epidemic is still ongoing. To rapidly test, care for, and trace patients' contacts for medical care, reliable, precise, and prompt laboratory-supported pandemic screening, and management are essential.

Nucleic acid amplified assays (NAATs) on airway samples are the primary laboratory methods for detecting SARS-CoV-2 infections [9]. A large number of NAATs for SARS-CoV-2 are available because of the global need for COVID-19 testing. The gold standard for SARS-CoV-2 molecular diagnostics is nucleic acid RT-qPCR [12]. The target gene and the Ct threshold used to identify a positive sample are two differences in SARS-CoV-2 detection that are widely recognized and published in the literature. Some techniques reach beyond 39 Ct, which indicates a very low viral burden. In this study, the ACOV assay and the BGI RT-PCR kit were compared for clinical performance [17].

We discovered that the ACOV test identifies more cases of COVID-19 infection compared to the BGI test in our comparative analysis. Additionally, we discovered that there was a strong level of agreement between the ACOV kit and the BGI assay [16]. Our results, which compare the ACOV and BGI tests, are in agreement with the findings reported by Harrington et al., which found that ACOV was more effective in identifying RNA gene sequences for SARS-CoV-2 than the ID Now COVID-19 (IDNCOV) test (Abbott). Between ACOV and IDNCOV, there was a 75% positive agreement (95% CI: 67.74-80.67%) and a 99% negative agreement (95% CI: 97.64-99.89%) [15]. According to Moore et al.'s study, ACOV was more effective in detecting RNA gene sequences for SARS-CoV-2 than IDNCOV and a laboratory-developed CDC 2019-nCOV RT-PCR (CDC COV) test [18]. Positive agreement varied from 75.2% to 100%, with the ACOV and IDNCOV tests showing the lowest positive agreement and the ACOV and CDC COV tests showing the highest positive agreement. From 92.4% (ACOV/CDC COV) to 100% (ACOV/IDNCOV), there was

negative agreement. Our results, which compare the ACOV and BGI tests, differ from those of Abay Sisay et al., who found that BGI performed less well at identifying SARS-CoV-2 RNA gene sequences than the TIB and DaAn assays. Using 279 COVID-19 suspicious people, there was a significant agreement between the TIB and BGI tests, resulting in a Kappa of 0.61 (95% CI: 0.49–0.72), and a moderate agreement between the DaAn and BGI tests, yielding a Kappa coefficient of 0.55 (95% CI: 0.44-0.67) [19].

In contrast with our findings, Altamimi et al. show a greater agreement of 0.97 (0.93–1) between BGI and the commercial assays used in the research [20]. With a positive percentage agreement of 88.89% (95% CI: 83.4%-94.3%), Alcoba et al. and their concordance results with the positive case of BGI of SARS-CoV-2 in Australia have shown significant diagnostic power in identifying SARS-CoV-2. The primary distinction can be the length of the study and the sampling of the presumptive cases [21].

When compared to Abbott, the BGI test's sensitivity and specificity are marginally lower than those of a study employing the BGI kit conducted by Altamimi AM et al., who reported sensitivity ranges of 100% (94%–100%) and specificity of 97% (83%–99%) [20]. The amount of viral analytes varies greatly depending on anatomical location and infection stage. As the illness progresses, the viral load of SARS-CoV-2 fluctuates significantly. Therefore, the biology of the virus ultimately shapes our capacity to identify SARS-CoV-2. The sensitivity of tests for identifying SARS-CoV-2 might depend on the time and location of the sample as well as the assay's technical performance [22]. Furthermore, the performance of our assays was very good. The IC is a powerful element of both of our assays. The hydroxypyruvate reductase gene of the pumpkin plant, *Cucurbita pepo*, provides the IC for the Abbott assay and is given in an Armored RNA® particle dissolved with negative human blood plasma. The identification of IC is important in demonstrating the reliability of the sampling procedure. The IC gene for the BGI assay has been selected to be the human

housekeeping gene — β-actin. To assess the effectiveness of the extraction of RNA as well as identify possible inhibitors of PCR that will be added to the samples prior to the extraction of RNA. Furthermore, it has been demonstrated that inadequate nasopharyngeal sample collection is one of the most frequent and likely sources of false negative results and, consequently, of a late diagnosis. This is an important aspect of the preanalytical phase that significantly impacts NAAT findings [12]

Twenty-one samples (5.47%) that tested and retested positive on ACOV but negative on the BGI test showed a mean Ct of 24.47 (95% CI: 24.22–24.74), ranging from 22.48 to 26.60, with a standard deviation of 0.04, and were consistent with lower viral loads. All samples were a follow-up/control NOS of a patient that tested SARS-CoV-2 positive fourteen days earlier. A Ct indicates the number of replicating cycles necessary to generate a fluorescent signal. Lower values for Ct indicate larger viral RNA concentrations. A lower Ct value indicates a more favorable result with a quick turnaround time (TAT) and a PCR cycle that may be more successful than all of the others, whereas a greater Ct value suggests a requirement for more time and resources. Eight discordant samples (of a total of 200 tested on COVID-19) were not identified or yielded unclear findings on the CDC COV test, yet they were found on the ACOV test in a study by Moore and colleagues. According to the ACOV test, the mean Ct value of these samples was 27.73 (95% CI: 27.37-28.40). Almost all of the discrepant results were found in specimens that had greater Ct values, that is, that had lower virus quantities. [17, 18]. These results indicate that the lower limit of detection (LOD) of the tests varied. The official instructions to utilize ACOV specify a LOD of 100 copies/ml for the ACOV test and 100 copies/ml for the BGI assay.

According to literature data, the N gene being targeted may be the most sensitive to SARS-CoV-2 identification because it produces fewer sub-genomic N gene RNA messengers compared to other targets [21, 22]. The N gene is known to have a broader detection window

than other gene targets. In addition to the findings of our investigation, those hypotheses were highly confirmed in a previously published study, which discovered that the N gene targeted could increase the SARS-CoV-2 detection's sensitivity. This might be the reason why samples examined with the BGI assay yielded fewer positive findings more frequently False-negative results on the BGI test are most likely because the ORF1ab gene is the target of the primers and probe sequences used in this test. Our results imply that the need for improvement should concentrate on the quick adjustment of primer sets, the selection of cut-off Ct values, and the emergence of novel variations. But a "positive" PCR test does not always indicate the existence of a living virus; rather, it only indicates the detection of RNA from the virus.

The reduced input volumes utilized for the extraction (200 µl) and amplification (10 µl) in comparison to the extraction volumes of 500 µl and the amplification volumes of 40 µl in the ACOV test might help to explain the negative results acquired utilizing the BGI assay. The ACOV assay's targets of amplification and detection are simpler to attain; however, the ACOV yielded more positive SARS-CoV-2 results, indicating that the same samples were misclassified as false negatives when tested with the BGI kit [15].

CONCLUSION

In conclusion, we discovered that the ACOV test identifies more cases of COVID-19 infection compared to the BGI test. There was strong agreement between both the ACOV and the BGI tests, with just 5.47% of SARS-CoV-2 detection cases producing false-negative results with the BGI assay. We suggest complete testing using the ACOV kit because the Abbott kit showed slightly better diagnostic performance and because employing the BGI assay may produce false-negative results.

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Conflict of interest: None declared.

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Table 1. Description of the SARS-CoV-2 identification tests included in this research

Name of the commercial kit	Gene target	Fluorophore	RNA (template) volume per each reaction tube (μl)	Reaction volume (μl)	Cycling time	Analytical sensitivity (LOD)	Positivity cut-off (Ct value)
ACOV	N RdRP/Orf1ab	FAM	40	40	3h:5 min	100 copies per ml	≤37
BGI	Orf1ab	FAM	10	20	1h:38 min	100 copies per ml	≤38

RNA – ribonucleic acid; LOD – limit of detection; Ct – the cycle threshold; ACOV – Abbott real-time of SARS-CoV-2; BGI RT-PCR Kit – BGI Real-TIme Fluorescent RT-PCR Kit

Table 2. Patients demographics who were engaged

Abbott C_t Category	Average Age (years)	Male (%)	Female (%)	Total n of patients
Positive	64.6	142 (55.9%)	112 (44.1%)	254
Negative	55.4	48 (38.7%)	76 (61.3%)	124
Invalid	67.2	2 (33.3%)	4 (66.7%)	6
Total no. of patients		192	192	384

Ct – the cycle threshold
[a]The data is presented as an absolute number (percentage) or mean

Table 3. Proving SARS-CoV-2 RNA by the ACOV and the BGI RT-PCR assays

ACOV	BGI			Total no. of samples tested	% of agreement	Value of Kappa (95% CI)
	Detected	Not detected	Invalid			
Detected	233 (60.68%)	21 (5.47%)	0 (0%)	254 (66.15%)	93.4	0.86 (0.80–0.91)
Not detected	4 (1.04%)	120 (31.25%)	0 (0%)	124 (32.29%)		
Invalid	2 (0.52%)	0 (0%)	4 (1.04%)	6 (1.56%)		
Total no. of samples tested	239 (62.24%)	141 (36.72%)	4 (1.04%)	384 (100%)		

ACOV – Abbott real-time of SARS-CoV-2; BGI RT-PCR Kit – BGI Real-TIme Fluorescent RT-PCR Kit; CI – confidence intervals

[a]The data is presented as an absolute number (percentage)

[b]Invalid defined as a sample that gave neither a positive nor a negative result

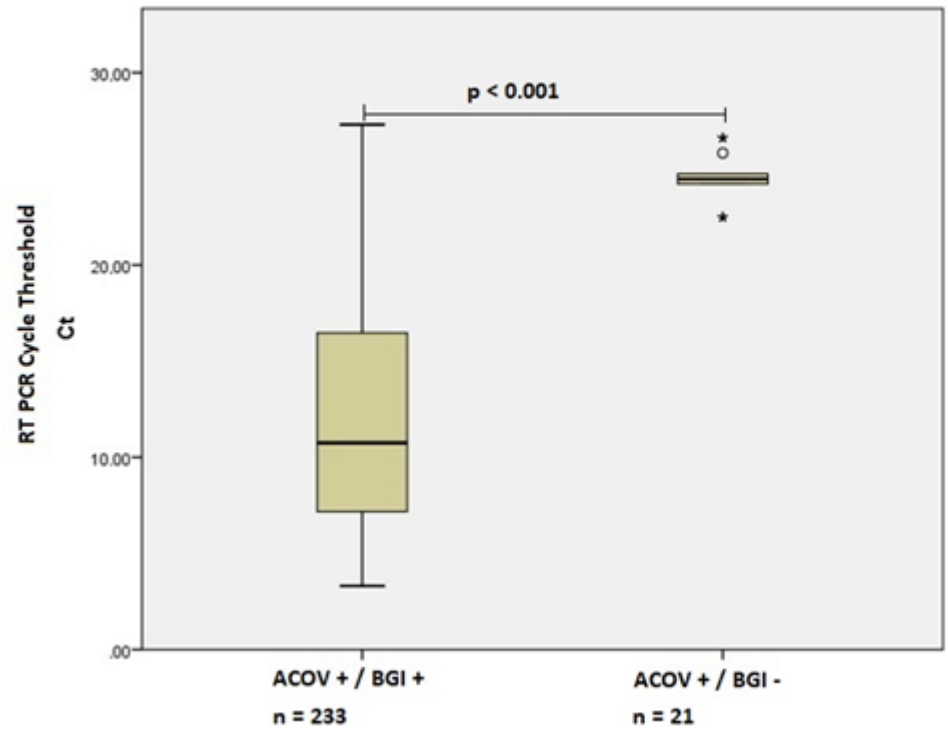

Figure 1. Comparison of Ct values between specimens obtained using both assays (ACOV and BGI) with Ct values between specimens identified with the ACOV assay only.

