Validity of A Mobile Phone based Application Tool for COVID-19 Screening Test

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Abstract

Background: The COVID-19 outbreak is proving to be a unique disaster in many countries across the globe. Screening and diagnosis are challenges in resource-limited countries as confirmation with reverse-transcriptase polymerase chain reaction (RT-PCR) is expensive and less accessible. Besides, due to the overlapping manifestations, there are no strongly suggestive symptoms that can be used as a screening tool. The goal of this study was to assess the validity of a newly created mobile phone application tool as a COVID-19 screening approach to the gold standard test (RT-PCR).

Methods: An institution-based cross-sectional study was conducted among 1029 individuals for validity assessment of a newly developed COVID-19 screening tool by having PCR test results as a reference. After obtaining consent, data were collected using a structured questionnaire, maintaining all the COVID 19 prevention protocols. SPSS version 25 was used to analyze the data. The sensitivity and specificity of the tool were determined.

Result: A total of 1005 participants were included in the study, which made the response rate close to 98%. The mean age of the respondents was 50.8 (SD=17.32) years; 574 (57.1%) were males and 108 (10.7%) were in the age category of 41 years and above. The current study identified that the internal consistency of Cronbach's α was 0.769. The validity analysis result of the tool revealed that it has a sensitivity of 77.6% with 31.6% of positive predictive value and specificity of t 46.4% with 86.5% of negative predictive value. This study revealed that 59.4% of the study participants showed COVID-19 related symptoms and classified as tested positive for the infection, based on the newly developed mobile phone COVID-19 screening tool, whereas only 24.4% of them had positive test results for COVID-19 infection.

Conclusion: The sensitivity and specificity of the mobile application tool for symptomatic COVID 19 patients was almost equivalent to the nasal swab RT PCR test. Therefore, we recommend the use of this screening test bot. It is easily accessible and hence an effective way of reaching the population affected by the disease for early detection of symptomatic patients and taking appropriate measures.

Background

In late December of 2019, a cluster of cases of viral pneumonia of unknown aetiology was reported in Wuhan, Hubei Province, which was later identified and referred to as COVID-19Coronavirus Disease 2019) by WHO. It was caused by the novel SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2) that was able to spread rapidly and developed into a global pandemic level within a few months (1–3). Reported symptoms include fever, cough, fatigue, pneumonia, headache, Gastrointestinal (GI) upset (abdominal cramp, nausea/ vomiting or diarrhoea, hemoptysis, and dyspnea which resemble respiratory illnesses caused by other viruses or bacteria (4–5). Masks, hand hygiene procedures, avoidance of public interaction, case identification, contact tracing, and quarantines have all been mentioned as possible ways to scale back transmission(6).

The COVID-19 outbreak is proving to be an exceptional disaster in the most afflicted countries, including the USA, Brazil, Italy, Iran, and China in all aspects, especially the health, social, and economic disasters (7). The current interventions on COVID-19 mainly focused on infection control and the use of effective vaccine (8–9); there is no effective specific antiviral treatment (6). Clinical diagnosis is difficult due to the coinciding symptoms, particularly during the flu season. That is why the confirmation of COVID-19 depends on the detection of SARS-CoV-2 nucleic acid by reverse-transcriptase polymerase chain reaction (RT-PCR) (10).

Infection prevention strategies and patient management depend on the accurate and timely COVID-19 test capacity. This enables or will assist the efforts which are aimed at controlling or slowing down the rapid transmission of the pandemic in the population and at the healthcare facilities (11). According to the recommendation of the World Health Organization (WHO), COVID-19 diagnosis can be made by molecular tests which detect the SARS-CoV-2 virus RNA. However, this test is difficult to perform because it necessitates committed health system with continuous delivery of numerous reagents, expensive laboratory equipment, and trained laboratory technologist. Currently, infrastructure limitations and supply shortages are limiting the testing capacity below the growing request for COVID-19 diagnostics across the world (12).

As a result, having access to consistent rapid diagnostic tests could relieve laboratory pressure and enhance testing capacity to meet the most pressing medical and public health needs (12). Regardless of symptoms, a case of COVID-19 is considered "confirmed" when a positive laboratory test for SARS-Cov-2 virus infection is obtained. Many diagnostic tests are currently available, and more are being accepted for emergency use on a daily basis. The majority of these tests are based on four main procedures: Reverse transcription-polymerase chain reaction (RT-PCR), Loop-mediated isothermal amplification (LAMP), Lateral flow and Enzyme-linked immunosorbent assay (ELISA) (13). These tests are not easily accessible to the low income countries. Therefore, the need for a simple first-line screening tool is a crucial step for lowest-income countries, such as Ethiopia.

In Ethiopia, in particular, the need for proactive population screening for COVID-19 is extremely important as the general public seems to be reluctant to adhere to the preventive measures. Health care workers and community members alike are faced withthe important challenge of quickly identifying symptoms and taking appropriate steps for laboratory investigation in line with the case definition based on surveillance or clinical characterization. Therefore, developing a quick and valid instrument or tool to capture an individual’s COVID-19 like symptoms is important and timely. As a result, the aim of this study was to evaluate the sensitivity and specificity of a newly developed COVID-19 screening test mobile phone based application tool in order to promote its widespread use.

Methods And Materials

Study design, setting, period, and population

A hospital and community-based cross-sectional analysis was designed to determine the validity of a newly developed mobile phone-based screening program. Individuals who came to the COVID-19 testing centers for various purposes were tested for COVID-19 infection symptoms using a standardized questionnaire that was included in the mobile-based screening application. The study participants were those who were suspected as case of COVID-19 by clinicians and isolated in the emergency unit; had contact history with COVID 19 positive individuals; had comorbid illnesses, and required to have preadmission screening or self-interest to be tested for COVID-19. Then, their result was compared with the result of RT PCR performed at St. Paul’s Hospital Millennium Medical College.

Sample Size Determination And Data Collection Methods

The sample size was determined by using PASS software. Considering this study as a screening test, the following assumptions were duly considered: Power of 80%, alpha value of 0.05, a prevalence of 5%, a desired sensitivity of 99%, and 10% of non-response rate. A total of 1029 samples were included. The variables collected include a combination of demographic data such as age, sex, common symptoms of COVID-19, fever, cough, Shortness of breath, sore throat, easy fatigability, headache, anosmia/or Ageusia, GI upset (either vomiting/ nausea/or diarrheal)

travel history, contact history, and the presence and absence of co-morbidities such as diabetes mellitus, cardiovascular, lung, renal and liver diseases.

The researchers have also done a reliability analysis to measure the correctness of the tool that helps to what extent does the current tool would give consistent or dependable results during multiple trials in which a total of eight variables/items were included. The variables were, cough, shortness of breathing (SOB), sore throat, fever, anosmia, headache, easy fatigability, and vomiting are the symptoms that we used to develop the COVID-19 infection screening tool.

Data Presentation:

Result of the screening test is defined into two different categories for validation purposes and further subcategorized into two population groups for recommendation purpose following the screening result.

Category 1: Screening results suggestive of presence COVID 19 in patients who exhibit COVID 19 like symptoms.

Category 2: Screening result Suggestive of absence of COVID 19 disease, in patients who did not exhibit COVID 19 like symptoms.

Data Analysis

The currently used software automatically transfers the data to a database. Data collected were saved on the web and were checked for flaw every day during data collection; completeness was checked, cleaned, and saved in a separate file, while the raw data remained in the main database.

Sensitivity, specificity, positive and negative predictive values of the screening test was compared with the gold standard laboratory PCR test results using two by two tables of measure of diagnostic validity (14).

Result

Socio-demographic characteristics of the respondents

A total of 1005 participants were included in the study which makes the response rate 97.7%. The mean age of the respondents was 37(SD = 15.62) years. Among the respondents, 574 (57.1%) were males and choric medical illness presented in 191(19%) of the participants. Only 238 (23.7%) of them had history of contact with an individual who had confirmed COVID-19 infection (Table 1).

Table 1
-Description of socio demographic and clinical factors among individuals who underwent COVID-19 test, Addis Ababa, Ethiopia, 2020.

Variables		Frequency	Percent (%)
Age	< 29	389	38.7
	30–39	250	24.9
	40–49	147	14.6
	50–59	105	10.4
	> 60	114	11.3
Sex	Female	431	42.9
	Male	574	57.1
Chronic medical illness	present	191	19
	Absent	814	81
Contact History	No	767	76.3
	Yes	238	23.7
Total		1005	100

Mobile screening and RTPCR test results of the study participants

This study revealed that 597 (59.4%) of the study participants showed COVID-19 related symptoms and classified as tested positive for the infection, based on the mobile COVID-19 screening tool. Of those who underwent RTPCR test, only 245 (24.4%) had positive test results for COVID-19 infection (Fig. 1).

Reliability And Validity Of The Tool

The internal consistency of Cronbach's α was 0.769. Principal components factor analysis (PCA) was done to include items that best fit to the data and a total of seven items which had value greater than one were extracted (Table 2). Then, validity analysis was done by including the remaining eight items. Further, item correlation analysis was done and all of the selected items had Cronbach alpha of above 70 (Table 3). Further correlation analysis in between the symptoms was conducted and the result shows a significant correlation among each other at 0.01 level of 2-tailed (Table 4). The current validity analysis result revealed that sensitivity of the tool was 77.6% with 31.6% of positive predictive value. Specificity of the tool was 46.4% with 86.5% negative predictive value (Fig. 2).

Table 2
Extraction Method by using principal components factor analysis result of the mobile phone based application COVID-19 test tool

Total Variance Explained						
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	2.430	14.292	14.292	2.430	14.292	14.292
2	1.570	9.237	23.529	1.570	9.237	23.529
3	1.503	8.841	32.369	1.503	8.841	32.369
4	1.324	7.791	40.160	1.324	7.791	40.160
5	1.255	7.382	47.542	1.255	7.382	47.542
6	1.091	6.417	53.960	1.091	6.417	53.960
7	1.027	6.043	60.003	1.027	6.043	60.003
8	1.019	5.995	65.997	1.019	5.995	65.997
9	.921	5.416	71.413			
10	.858	5.049	76.462			
11	.823	4.840	81.302			
12	.754	4.433	85.735			
13	.632	3.721	89.455			
14	.569	3.349	92.804			
15	.487	2.865	95.669			
16	.437	2.572	98.242			
17	.299	1.758	100.000			

Table 3
Items correlation descriptive analysis of the mobile phone based application of COVID-19 test tool

Item-Total Statistics					
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
COUGH	12.67	2.802	.562	.425	.726
SOB	12.63	2.792	.605	.457	.718
Sore Throat	12.56	3.141	.421	.259	.752
FEVER	12.60	2.852	.602	.430	.720
Anosmia	12.50	3.155	.547	.372	.736
Headache	12.64	3.033	.413	.232	.755
Easy Fatigability	12.63	3.286	.246	.075	.784
Vomiting	12.50	3.272	.410	.203	.754

Table 4
Correlation finding in between symptoms of the mobile phone based application of COVID-19 test tool

Correlations								
		COUGH	SOB	Sore Throat	FEVER	Anosmia	Headache	Easy Fatigability
COUGH	Pearson Correlation	1	.595**	.255**	.532**	.315**	.234**	.237**
	Sig. (2-tailed)		.000	.000	.000	.000	.000	.000
	Sum of Squares and Cross-products	201.546	114.985	43.251	97.424	43.573	45.764	45.206
	Covariance	.201	.115	.043	.097	.043	.046	.045
	N	1005	1005	1005	1005	1005	1005	1005
SOB	Pearson Correlation	.595**	1	.296**	.555**	.341**	.263**	.241**
	Sig. (2-tailed)	.000		.000	.000	.000	.000	.000
	Sum of Squares and Cross-products	114.985	185.274	48.070	97.562	45.159	49.323	44.224
	Covariance	.115	.185	.048	.097	.045	.049	.044
	N	1005	1005	1005	1005	1005	1005	1005
Sore Throat	Pearson Correlation	.255**	.296**	1	.265**	.472**	.236**	.121**
	Sig. (2-tailed)	.000	.000		.000	.000	.000	.000
	Sum of Squares and Cross-products	43.251	48.070	142.563	40.889	54.859	38.700	19.439
	Covariance	.043	.048	.142	.041	.055	.039	.019
	N	1005	1005	1005	1005	1005	1005	1005
FEVER	Pearson Correlation	.532**	.555**	.265**	1	.372**	.382**	.163**
	Sig. (2-tailed)	.000	.000	.000		.000	.000	.000
	Sum of Squares and Cross-products	97.424	97.562	40.889	166.700	46.745	67.883	28.242
	Covariance	.097	.097	.041	.166	.047	.068	.028

	N	1005	1005	1005	1005	1005	1005	1005
Anosmia	Pearson Correlation	.315**	.341**	.472**	.372**	1	.398**	.137**
	Sig. (2-tailed)	.000	.000	.000	.000		.000	.000
	Sum of Squares and Cross-products	43.573	45.159	54.859	46.745	94.820	53.315	18.003
	Covariance	.043	.045	.055	.047	.094	.053	.018
	N	1005	1005	1005	1005	1005	1005	1005
Headache	Pearson Correlation	.234**	.263**	.236**	.382**	.398**	1	.104**
	Sig. (2-tailed)	.000	.000	.000	.000	.000		.001
	Sum of Squares and Cross-products	45.764	49.323	38.700	67.883	53.315	189.309	19.337
	Covariance	.046	.049	.039	.068	.053	.189	.019
	N	1005	1005	1005	1005	1005	1005	1005
Easy Fatigability	Pearson Correlation	.237**	.241**	.121**	.163**	.137**	.104**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.001	
	Sum of Squares and Cross-products	45.206	44.224	19.439	28.242	18.003	19.337	181.110
	Covariance	.045	.044	.019	.028	.018	.019	.180
	N	1005	1005	1005	1005	1005	1005	1005

**. Correlation is significant at the 0.01 level (2-tailed).

Discussion

The new COVID-19 symptom screening test mobile phone based application tool has a high degree of sensitivity and a strong level of specificity. It has also better level of reliability, as demonstrated by the results, which the questions that are included as a screening item can capture and generate significant information regarding COVID – 19 infections. Further, it has also attractive level of ability in detecting true negative and positive results from those who have total negative and positive test results. Therefore, this mobile application was found to perform well in assessing the presence and absence of COVID-19 infection in the general population and an easy to administer as an instrument.

RT-PCR assay is considered as a gold standard technique and still a fundamental method to be applied for the detection of SARS-CoV-2 to date. However, the current pandemic SARS-CoV-2 confuses the scientific and the medical community about which accurate diagnostic tool should be relied on to diagnose COVID-19 because of, the availability of few viewpoints that creates doubts as to underestimating its sensitivity and specificity (15). Therefore, due to its simplicity in utilization, the current application could be used in the screening of SARS-CoV-2. However, it might have some limitations that is usual to other screening methods, because current studies estimating test performance characteristics have imperfect study design and statistical methods for the estimation of test performance characteristics of SARS-CoV-2 tests like rRT-PCR and NAAT (16).

Regarding the percentage of validity, the current study finding is in line with the values obtained through the meta-analysis in its sensitivity, whereas it has lower level of specificity (17). However, even though the previous tests have high value of sensitivity and specificity in terms of detecting COVID-19 infection, it's worth noting that the difficulties and limitations described with respect to pathogen detection through molecular testing (real-time RT-PCR) are for the most part just as relevant to serological detection methods (18). Even though the sensitivity value of our finding is somewhat lower, but it has a higher level of specificity than the other meta-analysis finding report (19). In other words the current study identified high values of specificity than the previous similar attempt. Whereas, the combination of IgM and IgG antibodies, that demonstrated promising results for the parameters, sensitivity and specificity (19).

Different studies revealed that screening for only temperature is not sensitive enough to detect the vast majority of COVID 19 (20, 21, 22). Our study result with respect to sensitivity for COVID 19 is far better than a temperature alone screening. This improved sensitivity is the result of combination of symptoms that led to detect patients who don't exhibit fever or cough.

In conclusion, the worldwide expansion of SARS-CoV-2 infection and the emergence of new strain have led to widespread adoption of symptom and risk screening measures. This mobile phone based application tool has a high level of sensitivity and a good degree of specificity in screening of COVID-19 related symptoms. Besides, the system doesn't have additional cost on anyone and accessible to most people at their convenient place. This screening tool is much better than only temperature screening which is found to be ineffective in most set up. An added benefit is this self-checker mobile application tool is helpful to help patients to sick medical help before they go to serious complication as the application reminds you about new symptom development for 14 days.

Therefore, the development of a friendly screening mobile application tool will definitely help in halting the spread of infection and early detection of disease and look for hospital care. Further, we strongly recommended that this tool can be used by the public to detect COVID 19 like symptoms prevalence in the community. It can also be used by different institutes to guide their staff and visitors to check themselves with this self- checker before they visit the institutions rather than using temperature screening alone.

Abbreviations

COVID-19; Coronavirus disease 2019

FMOH; Federal Ministry of Health

IgG; Immunoglobulin G

IgM; Immunoglobulin M

PCR; polymerase chain reaction

SARS; Severe acute respiratory syndrome

SPHMMC; Saint Paul's Hospital Millennium Medical College

SPSS; Statistical Package for Social Sciences

WHO; World Health Organization

Declarations

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The current manuscript had got ethical approval from St. Paul's Hospital Millennium Medical College (SPHMMC) IRB. In addition, informed consent was obtained from all study participants before they enrolled in the study. They were told that their participation is voluntary, and could withdraw at any time or refuse to answer any question if they wanted to. We used self-administered written questionnaires to maintain privacy. No information concerning the individual was passed to a third party. So, in general, we carried out the current research by fulfilling all the requirements of the institutional (SPHMMC) IRB guidelines and regulations and also it fulfilled the Declaration of Helsinki guidelines and regulations.

Consent for publication

Further, informed consent for publication was also obtained from each study participant under the consent form by mentioned for all of them that the data will be published in international journals. So, this is to confirm that informed consent for publication was obtained from all the study participants. The collected data is kept confidentially under the primary investigator and co-investigators.

Competing interest

All authors read and approved the final manuscript. The authors declare that they have no competing interests.

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Authors' contributions

MB and NT were involved starting from conceiving the idea, developing the proposal, the study design, reviewed the article, analysis, report writing, and drafted and write up of the manuscript; MA, AG and TS involved in developing the proposal, the study design, analysis, report writing and manuscript write up and review AL, TS and AG involved in data collection, data clearing, analysis and review of the manuscript. YB was involved in proposal development, data

analysis, manuscript writing and editing the final manuscript. BT a software engineer involved in developing the mobile phone based screening application (telegram Bot), data cleaning and encoding, data analysis, and revision of the final manuscript.

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Figures

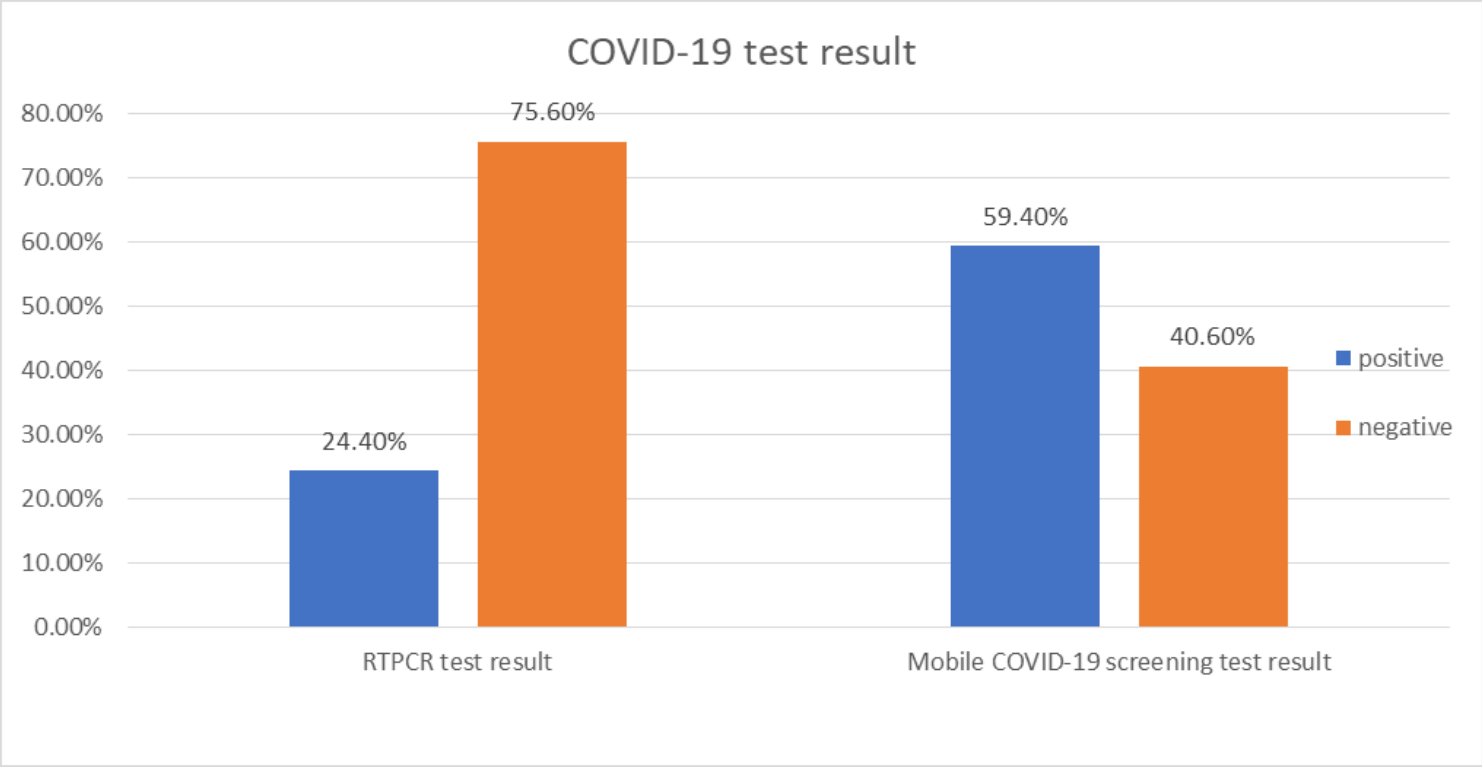

Figure 1

COVID-19 test result of the study participants by using both mobile screening tool and gold standard, Addis Ababa, Ethiopia, 2020

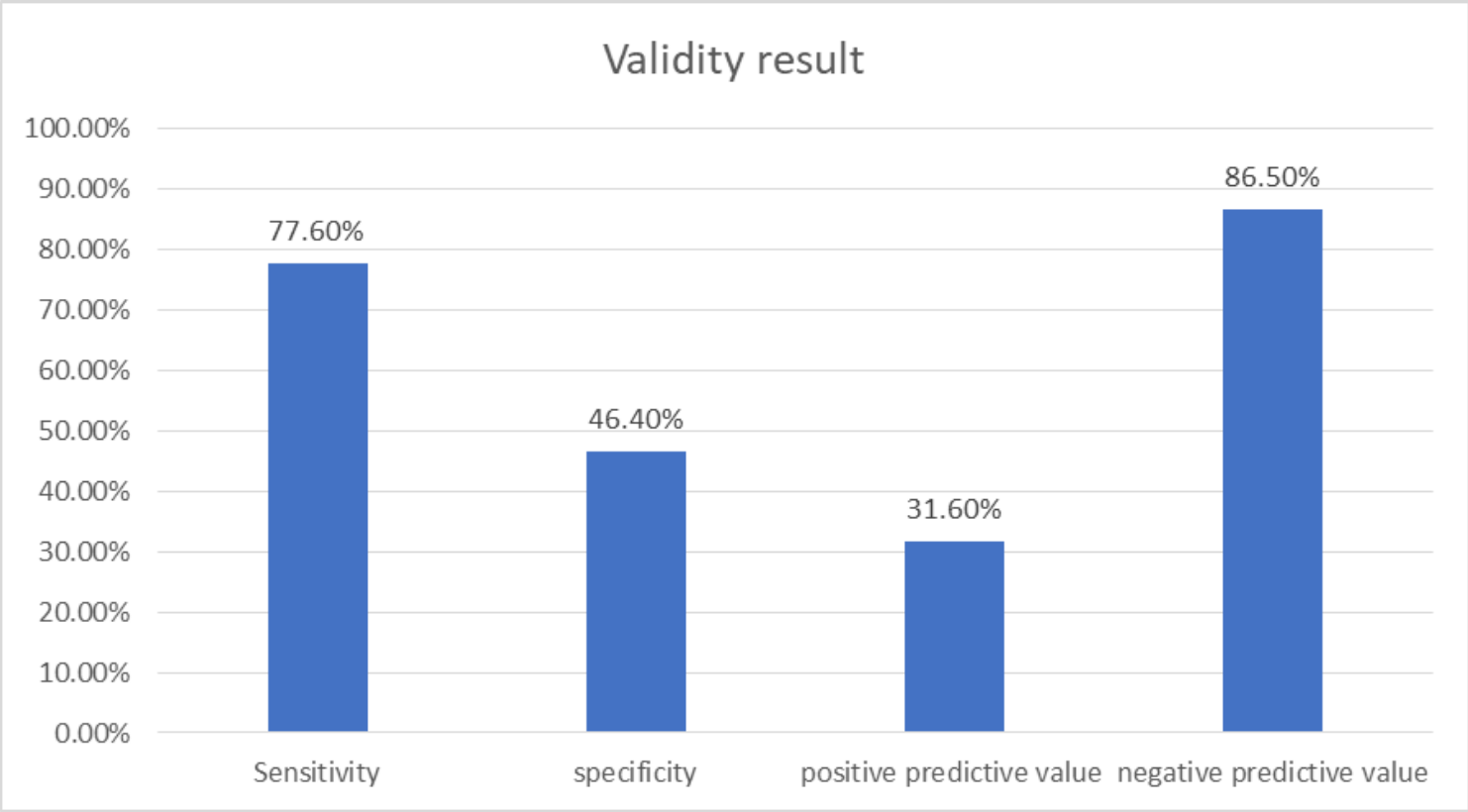

Figure 2

validity result of the mobile phone based application of COVID-19 test tool