

Biochemical and immuno-hematological test availability during the COVID-19 pandemic: The case of private diagnostic laboratories in Addis Ababa, Ethiopia

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Abstract

Background: Since the emergence of COVID-19 (SARS-CoV-2) in China, in December 2019, the pandemic has continued to be a major public health threat. According to the World Health Organization, on March 02, 2021, there were 113,989,973 confirmed cases of COVID-19 globally, and 2,531,542 reported deaths. In Ethiopia on the same period, there were 159,072 confirmed cases and 2,365 reported deaths. Efforts have been made in Ethiopia to make COVID-19 Biochemical and immuno-hematological tests available; however, the role of private diagnostic laboratories with this perspective has not been assessed. This study aims to address the role of private diagnostic laboratories as service providers of various laboratory tests that can help with the management of COVID-19 patients.

Materials and methods: A cross-sectional survey was carried out with seven standalone laboratories in Addis Ababa. A questionnaire and observation checklists – adopted from the World Health Organization, were used to prepare a structured questionnaire and on-site evaluations of the availability of biochemical and immuno-hematological tests in the city. The data collection tool also assessed whether the diagnostic laboratories had back-up instruments for common biochemical and immuno-hematological tests. The data entry and analysis were conducted using SPSS software version 20.

Results: Among the 7 private diagnostic laboratories participated in this study majority of them have professionals who are males (N=20/33, 60.6%). Most of the laboratory professionals in the private laboratories had Bachelor of Science degrees in medical laboratory sciences (15/33, 45.5%). Almost all of them provide organ function tests including liver and renal functions. However, some important tests like D-dimer were not available. All the laboratories claimed that they had adequate stock for conducting hematological tests, although none had GeneXpert[®] MTB/RIF assays for detection *Mycobacterium tuberculosis* and testing for rifampin resistance.

Conclusions: Private diagnostic laboratories that offer clients most clinical chemistry, hematological and immuno-hematological tests are to be welcomed, particularly during the COVID-19 pandemic, when public health diagnostic laboratories could be overburdened, and the stock of reagents might be low or unavailable. There should be a means to strengthen public-private partnerships and both patients and clinicians could benefit a lot by availing diagnostics as needed. Further detailed study is required to understand the role of private diagnostic laboratories during outbreaks and pandemics situation. [*Ethiop. J. Health Dev.* 2021; 35(1):3-8]

Key words: Private laboratory, biochemical tests, hematological tests, COVID-19

Introduction

The corona virus (COVID-19) pandemic, caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), has been a major public health threat across the world since its emergence in December 2019. According to the World Health Organization (WHO), as of March 02, 2021, 113,989,973 cases and 2,531,542 deaths have been reported across the globe, with Ethiopia reporting 159,072 confirmed cases and 2,365 deaths over the same period (1).

Studies conducted in China and the USA indicate that one third of hospitalized COVID-19 cases have different co-morbidities, including diabetes, hypertension, or cardiovascular diseases. The United States Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* also highlights the roles of underlying disease conditions in COVID-19 cases among US patients (2).

The SARS-CoV-2 virus enters the body cells after attaching to ACE-2 receptors. The ACE-2 receptors are found at the surface of many body cells, including liver, renal, cardiac, as well as alveolar cells in the lungs (3). Therefore, hematological, or biochemical changes observed after SARS-CoV-2 infections could be due either to the direct attack of the different body cells and organs by the virus, or as complications occurred following lung alveolar damage (4).

It is well known that the preferred gold standard for SARS-CoV-2 diagnosis is real-time reverse-transcriptase polymerase chain reaction (RT-PCR), and the focus so far in Ethiopia has been on expanding and strengthening molecular testing facilities (4,5). On the other hand, multiple organ system dysfunctions, hematological abnormalities, including hypercoagulability and thrombotic complications, are commonly observed among hospitalized patients with COVID-19 (4). Thus, besides strengthening molecular

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biology laboratories with RT-PCR and other testing kits, it would be useful to ensure the capacity of laboratories to provide tests required for the diagnosis of the co-morbid conditions of COVID-19 patients, especially for patients admitted in medical wards and intensive care units (ICUs). Specifically, hematological, and biochemical tests should be made available across the country. Like any essential health services, the global corona virus pandemic has affected clinical laboratory services other than COVID-19 testing, particularly in developing nations, where health care systems are highly compromised (5).

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Task Force on COVID-19 and other research groups have shown that abnormalities in routine laboratory tests, particularly hematological tests, biochemical tests for various organ functions, including electrolyte imbalances, have been used as an important laboratory test. These tests can be quickly done, easily available in at least in big hospitals and diagnostic centers and the tests are useful in the diagnostic workup of SARS-CoV-2 infection and the associated co morbid conditions. Importantly these tests can be applied to track the prognosis of the disease and optimization of therapeutic measures (6-8).

According to the Ethiopian Public Health Institute (9), more than 70 laboratories are rendering RT-PCR services across the country. However, prediction models indicate that the transmission rate of COVID-19 is increasing, and more cases could be detected which will result in more hospital admissions of patients. To combat this surge, clinical laboratories, in both the public and private sector, should be ready to make available various metabolic and hematologic laboratory-based evaluation services. Against this backdrop, we assessed the availability of various biochemical, hematological, and basic microbiology laboratory testing facilities in private diagnostic laboratories in Addis Ababa, Ethiopia.

Material and methods

This simple cross-sectional survey was carried out in seven stand-alone laboratories in Addis Ababa, from a total of eight potential candidates, for COVID-19 testing at the time of the study. Addis Ababa is the capital city of Ethiopia, where the majority of private facilities in the country are located.

Data collection: A structured questionnaire and on-site evaluations were employed for data collection. To address the objective of the study, a questionnaire-based approach and on-site observation approach have been followed. Eight laboratories were contacted to participate and seven of them were willing to enroll in the study. Data collection was focused on the available medical laboratory professionals, including their expertise and work experience, available clinical chemistry, and hematology automated machines, including type and capacity, as well as the stock levels of reagents for clinical chemistry and hematological tests. The data collection tool also assessed whether the diagnostic laboratories have back-up instruments for common hematological and biochemical tests. Data quality was assured by using investigators who were actively involved in preparing the data collection tools. The questionnaires and checklists were adopted from WHO and were informed by articles published in 2020 pertaining to laboratory tests for managing COVID-19 cases. After data collection, the data were checked, entered in an Excel spreadsheet, cleaned, and transferred to SPSS software version 20 for analysis. We used simple descriptive statistics to present the study findings.

Results

In the present study, seven of the eight private laboratories were willing to participate, giving a response rate of 87.5%. Figure 1 shows the work force profile of the participating private diagnostic medical laboratories. The majority of private laboratory professionals were males (N=20/33, 60.6%), and most had Bachelor of Science degrees in medical laboratory sciences (15/33, 45.5%).

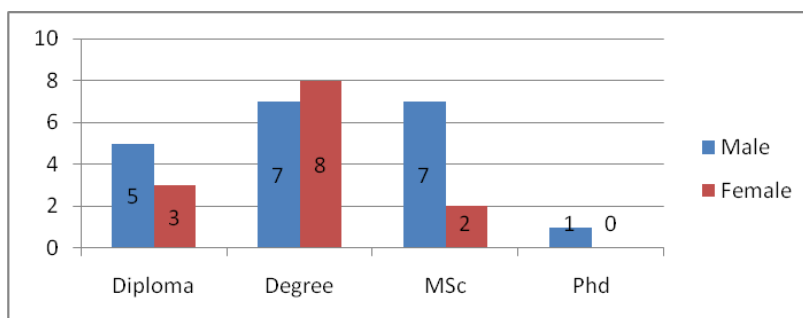


Figure 1: **Workforce profile of participating private diagnostic medical laboratories in Addis Ababa, Ethiopia, June, 2020**

In terms of the availability of clinical chemistry test profile, almost all private laboratories provide liver function tests (LFTs) and renal function test (RFTs). However, some laboratories did not have laboratory tests including electrolyte lithium (3/7, 42.9%), free

prostate-specific antigen (FPSA) (3/7, 42.9%), acid phosphatase (5/7, 71.4%), ferritin, FT3, FT4 each with (1/7, 14.3%). All tests were available in one (14.3%) of the seven laboratories, as shown in Table 1.

Table 1: Availability of common clinical chemistry test panel at selected private diagnostic laboratories during the COVID-19 pandemic, Addis Ababa, Ethiopia, June 2020

Clinical chemistry test panels	Number of labs with all necessary tests (%)
LFT panel ¹	7(100%)
RFT panel ²	7 (100%)
Electrolytes panel ³	6 (85.7%)
Tumour markers panel (TM) ⁴	6 (85.7%)
Hormonal tests panel ⁵	5 (71.4%)
Others ⁶	6 (85.7%)

¹= LFT includes AST, ALT, ALP, TBil, DBil, TPro, Alb, LDH.

²= RFT includes BUN, Cr.

³= Electrolytes include Na, K, Ca, P, Mg.

⁴= Tumor markers include CEA, CA19-9, TPSA, AFP.

⁵= Hormonal tests include TSH, T3, T4, Pro, Est, Test, Prog, LH.

⁶= Others includes Glu, Ferr, HgA1C.

LFT: liver function test; **AST:** aspartate aminotransferases; **ALT:** alanine aminotransferases; **ALP:** alkaline phosphatase; **TBil:** total bilirubin; **DBil:** direct bilirubin; **TPro:** total protein; **Alb:** albumin; **LDH:** lactate dehydrogenase; **RFT:** renal function test; **BUN:** blood urea nitrogen; **Cr:** creatinine; **Na:** sodium; **K:** potassium; **Ca:** calcium; **P:** phosphorous; **Mg:** magnesium; **TM:** tumor marker; **CEA:** carcinoembryonic antigen; **CA19-9:** carbohydrate antigen 19-9; **TPSA:** total prostatic-specific antigen; **AFP:** alpha-fetoprotein; **TSH:** thyroid

stimulating hormone; **T3:** triiodothyronine; **T4:** tetraiodothyronine; **Pro:** prolactin; **Est:** estradiol; **Prog:** progesterone; **LH:** luteinizing hormone; **Glu:** glucose; **Ferr:** ferritin; **HgA1C:** hemoglobin A1C

Among the hematology and immuno-hematology test profile, all seven laboratories had complete blood count (CBC) automations, either with three- or five-part differential counts. However, some laboratories did not perform D-Dimer (4/7, 57.1%) and CD4 T cell count (4/7, 57.1%) during the study period (Table 2).

Table 2: Availability of common hematology and immuno-hematology test panel at selected private diagnostic laboratories during the COVID-19 pandemic, Addis Ababa, Ethiopia, June 2020

Hematology and immuno-hematology tests	Number of labs with all necessary tests (%)
CBC panel ¹¹	7 (100%)
Coagulation test panel ¹²	7 (100%)
Inflammatory marker test panel ¹³	6 (85.7%)
Blood group test panel ¹⁴	7 (100%)
Blood film	6 (85.7%)
CD4 count	3 (42.9%)
HBV and HCV test	7 (100%)

¹¹= CBC includes complete blood count with either three- or five-part differential count.

¹²= Coagulation test includes PT, PTT, INR.

¹³= Inflammatory marker test includes ESR, CRP, ANA, RF.

¹⁴= Blood group test includes ABO and Rh blood type.

CBC: complete blood count; **PT:** prothrombin time; **PTT:** partial thromboplastin time; **INR:** international normalized ratio; **ESR:** erythrocyte sedimentation rate; **CRP:** C reactive protein; **ANA:** antinuclear antibody; **RF:** rheumatoid factor; **CD4:** cluster differentiation 4; **HBV:** hepatitis B virus; **HCV:** hepatitis C virus.

the COVID-19 pandemic. Six of the seven laboratories were doing smear microscopy for tuberculosis (TB). All the assessed private diagnostic laboratories did not have GeneXpert[®] instrumentation, and three out of seven laboratories (42.9%) had culture and drug susceptibility testing (Table 3) for routine bacteriological work up.

We also assessed private laboratories to see if they were performing microbiological-related tests during

Table 3: Availability of common microbiological tests at selected private diagnostic laboratories during the COVID-19 pandemic, Addis Ababa, Ethiopia, June, 2020

Microbiological tests	Number of labs (%)
Smear microscopy	6 (85.7%)
Culture and DST	3 (42.9%)
GeneXpert® MTB/RIF	0 (100%)

DST: drug susceptibility testing; **MTB/RIF:** mycobacterium tuberculosis/resistance to rifampicin

Discussion

Diagnostic laboratories are crucial for screening, diagnosis, prognostic evaluation, and surveillance of infectious and non-infectious diseases (10, 11). Currently, global efforts mainly focus on the availability of testing for COVID-19 and insufficient attention is given to other laboratory tests, especially in resource-constrained settings such as Ethiopia. In this context, the present study indicated that private laboratories in Addis Ababa have enough capacity to support routine clinical chemistry and hematology laboratory services and could relieve the pressure on public laboratories by providing the public with an alternative means of gaining access to diagnostic services.

Private diagnostic laboratories play a pivotal role in supplemental and differential diagnosis of co-morbid conditions linked with COVID-19. A previous study conducted in Jimma Zone, south east Ethiopia, showed that only 23.3% of public health facilities have clinical chemistry tests (12). Unlike these findings, our assessment indicated that all the studied private diagnostic laboratories provide most clinical chemistry tests that can be used for COVID-19 patients in and around Addis Ababa. The private laboratories could serve as a back-up for public-based laboratories, as shortages of reagents and consumables in the latter are a common problem, as reported in previous studies in Ethiopia (13,14).

With regard to the availability of hematology and immunology tests, most laboratories have the basic reagents and consumables, unlike a previous study conducted in Addis Ababa, where only five out of 13 health facilities focused on antenatal care laboratory services (15). In fact, our investigation is more general hematology tests and assessed the private stand-alone diagnostic laboratories. Being profit-based laboratories, they could all have the means of making the various reagents and consumables available to render a range of laboratory tests. In contrast, public health facilities have complex bureaucracy in the purchasing of laboratory commodities in general, and the interruption of testing is quite common (16).

On the other hand, all seven private diagnostic laboratories did not have a GeneXpert® machine. This machine is intended to support TB control programs for the diagnosis of TB. As a platform, this instrument applies the principle of RT-PCR, hence it can be used for the diagnosis of COVID-19 and, as of April 2020, many countries have been using this technology for the diagnosis of COVID 19 (17). On the sharing of COVID-19 and related auxiliary laboratory diagnostic

services, the significant contribution of private laboratories has been clearly shown in some African countries, mainly in South Africa. According to this study, in addition to public laboratories, private laboratories are available, for those who can afford to pay, to provide all-round COVID-19 diagnostic laboratory tests. The presence of such alternative diagnostic approaches makes South Africa the leading country in Africa that is administering large numbers of COVID-19 tests for the public (18). Similarly, such public-private partnerships in providing COVID-19 and supportive laboratory diagnostic services have been practiced in South Korea, making it the leading Asian country in delivering large numbers of COVID-19 tests (19).

Our survey may not be a complete representation of the private laboratories in general, as we mainly focused on stand-alone diagnostic laboratories. Whether the various clinics and private hospitals found in Addis Ababa have adequate biochemical and hematology test services was not ascertained. However, the surveyed private diagnostic laboratories are well known and have large test volumes. From public health perspective, many people could visit private facilities to obtain clinical services, including laboratory diagnostics. Hence, our findings could have implications for intervention measures taken by the government of Ethiopia and other partners. Patients from both public and private health facilities are utilizing these laboratory services. Of note, poor equipment, as well as unavailable / poor-quality reagents, have been reported among the major challenges faced by Ethiopian government hospital laboratories (20), and underscoring the role of such stand-alone private laboratories as options for those patients who is in need and afford the cost is inevitable.

In general, the information generated in this study indicates the test profile of the private laboratories as mentioned by them. Most importantly, all diagnostic laboratories included in this study claimed that they had enough reagents and kits to provide such tests, although they provided no evidence of the extent of their stock.

Conclusions

In general, a private-public partnership in the domain of laboratory services is essential to relieve the high burden on public laboratories. The present study indicates that the studied private diagnostic laboratories have adequate reagents and consumables to render many clinical chemistry and Immuno hematology tests. Therefore, the government and other stakeholders

need to consider these private laboratories as strategic diagnostic service providers especially during COVID-19 emergency and critically support the diagnostic services in general both in the public and private health sectors.

It is imperative that workforce is one of the limiting factors to provide uninterrupted tests for the community in general and assessing the workforce of the private facilities could give us an opportunity for any intervention measures that can be taken by the government in general and the Ministry of Health in particular. Regular discussions and hence developing trust between the government and the private laboratories is needed to strengthen public-private partnerships (PPP) in laboratory services. It will then be a good experience to expand and strengthen the laboratory services by considering public-private partnership approaches in developing countries. Similar studies on PPP related to laboratory services should be conducted in wider scope and methodology in all parts of Ethiopia to deliver high-quality and sustainable laboratory services to the general public.

Ethical approval and consent to participate.

The proposed study was approved by the College of Health Sciences, Institutional Review Board, Addis Ababa University. The study was part of a survey to assess the readiness of stand-alone laboratories to test for COVID-19 in molecular testing facilities in Addis Ababa. Support letter was secured from Addis Ababa University and Federal Ministry of Health. All collected data were coded (Lab A to Lab G) without mentioning the name of the laboratories. The information is kept in password protected computer. Private laboratories were informed that their participation was purely voluntary with no consequences for their business, and that they could withdraw from the study at any time for any reason.

Funding

This research work was financially supported by Addis Ababa University as part of the COVID-19 Emergency Response Fund. The funder had no role in the study design, data collection, data analysis, decision to publish, or preparation of the manuscript.

Authors' contributions

KD, MW, GT and AT were involved during conception, data collection and analysis, and drafting of the manuscript. All authors have read, edited and approved the final manuscript.

Acknowledgement

The authors would like to thank Addis Ababa University for financing this study. We appreciate the active participation of all diagnostic private laboratories in providing information; without them, this study could have not been completed.

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