# Original Article

# Expansion of COVID-19 RT-PCR Diagnostic Laboratories in Private Healthcare Settings through Public-Private Partnership Approaches in Addis Ababa, Ethiopia

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**Abstract**

**Background:** The World Health Organization recommended that expanding COVID-19 laboratory testing is one of the disease mitigation mechanisms. In Ethiopia, even though here are few advanced diagnostic laboratories, most of the COVID-19 RT-PCR based diagnostic laboratory service was provided by public laboratories. This situation creates a major gap in the availability of COVID-19 laboratory testing for the wide public majority, and one of the main challenges in the control and prevention of the disease.

**Objective:** to assess the existing potentials for the expansion of COVID-19 RT-PCR based diagnostic services in private advanced medical laboratories through public-private partnership approaches in Addis Ababa, Ethiopia.

**Methods**: A cross-sectional study was conducted from May to July 2020, among eight private advanced laboratories in Addis Ababa, Ethiopia. A structured questionnaire and on-site observation were made to assess their experiences on molecular laboratory based diagnostic services, perceived challenges, and their readiness to deliver RT-PCR based COVID-19 laboratory services on the level of trained laboratory personnel and molecular laboratory setups. Besides, discussion with government officials on the feasibility of COVID-19 RT-PCR diagnostic services through public-private partnership was made. The collected data were entered and analysed using SPSS version 20 statistical software. The study was approved by the institutional review board of the College of Health Sciences, Addis Ababa University, and Ethiopian Public Health Institute.

**Results:** Among eight advanced private laboratories, five of the laboratories had previous experience in molecular laboratory testing which includes viral load testing for HIV/AIDS (5/8,). Regarding COVID-19 service readiness, one laboratory had excellent grades towards starting COVID-19 testing; four private laboratories graded as very good and had great interest to provide COVID-19 testing with very minimal support and arrangement with government body. Cost of molecular tests (6/8,), lack of reliable suppliers (6/8,), lack of technical advisors (5/8,) and policy related issues (4/8) were the major perceived challenges to arrange molecular laboratory testing. Currently Five out of eight , private laboratories are providing RT-PCR based COVID-19 testing services to the public.

**Conclusion:** In the COVID-19 pandemic era, there is high possibility of expanding COVID-19 diagnostics services in private diagnostic laboratories through mutual benefit and public centred discussion between private laboratories and government bodies through public-private partnership in Ethiopia. This kind of partnership could be a lesson to be considered for any future possible outbreaks, happen to act both public and private Laboratories synergistically. [*Ethiop. J. Health Dev*. 2022; 36(1)]

**Keywords:** RT-PCR, COVID19, Public-Private Partnership, Ethiopia.

## Background

In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) (1). The most recently discovered coronavirus, Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2), causes the associated coronavirus disease (COVID-19) (2). COVID- 19 pandemic is a new incidence that was unknown before the outbreak began in Wuhan, China, in December 2019 (3). Globally, as of 6:22 pm CEST, Since 31 December 2019 and 10 August 2021, there have been 203,295,170 confirmed cases of COVID-19, including 4,303,515 deaths, reported to the World Health Organization (WHO). Globally, the highest number of confirmed cases of 35,081,719 and deaths of 625,363 are reported in the United states of America (4). In Ethiopia, the first COVID-19 case was reported on 13 March 2020 (5). Currently, according to the Ethiopian integrated COVID-19 updated report on August 10, 2021, there were 285,413 confirmed cases, and 4,440 deaths (6).

According to the recommendations of the WHO, one of the important tools to tackle the spread of COVID-19 infection is strengthening and expanding laboratory diagnosis of the disease. Testing for SARS–CoV-2 is becoming increasingly available in Developed nations; meanwhile still limited in resource-limited countries. In most developing countries, the COVID-19 diagnostic laboratories are available in few areas (highly centralized) and limited to government institutions with greater supply chain bottlenecks. According to the WHO guide for Global surveillance for COVID-19 caused by human infection with SARS-CoV-2, there

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are two main factors to consider when screening patients: epidemiological history and clinical manifestations (7). However, among the different diagnostic approaches, currently, the real- time polymerase chain reaction (RT-PCR) method is still the recommended diagnostic test (8).

Public Private Partnership (PPP) is a link between one or more public and private entities with a win-win approach that reflects mutual responsibilities in furtherance of shared interests (9). Among the different health collaborations, the contribution of PPP in laboratory systems strengthening can be exemplary to achieve UNAIDS 90-90-90 (10) and can be adopted for COVID-19 too. In Ethiopia, a study done by Kebede his associates showed that through PPP contributions standardized, streamlined specimen logistics system was established and in Addis Ababa and Amhara region turnaround time (TAT) which is the time from sample collection to delivery of results for ART specimens, reduced in 71% and 50 % respectively (11).

Currently, in Ethiopia, the available advanced molecular laboratories capable of diagnosing COVID-19 are few. Besides, most of these facilities are available in the big cities, and in majority public laboratories and few private advanced laboratories. However, compared to suspected cases and the possible surge of the pandemic, the public laboratories could be overwhelmed and cannot address the question of early testing and case detections.

Therefore, to expand the COVID-19 related laboratory services, which assist in the screening, diagnosis, treatment monitoring, as well as epidemiologic recovery or surveillance, the involvement of private laboratories is crucial and timely. Thus, the PPP implementation approaches may be an insight to expand similar laboratory joint activities between public and private laboratories. Therefore, the present study was aimed to assess how to expand COVID-19 RT-PCR based diagnostic services into private advanced medical laboratories through Public-Private Partnership (PPP) approaches in Addis Ababa, Ethiopia. In this study, the challenges raised by private laboratories and possible solutions to enable these laboratories to deliver COVID-19 laboratory services are also discussed. This in turn may reduce unprecedented stress on the public laboratory system from the SARS-CoV-2 testing. Also, private diagnostic laboratories need to be able to continue in supporting clinical services over the coming period.

## Materials and Methods

**Study Area**: This study was conducted in selected private advanced medical laboratories in Addis Ababa, Ethiopia.

**Study Design and Period:** A cross-sectional study was conducted from May to June 2020 in Addis Ababa; Ethiopia.

**Eligibility Criteria:** Inclusion criteria includes being a privately owned laboratory**, c**urrently have or plan to have a functional molecular laboratory unit**,** located in Addis Ababa, and willing to sign consent.

**Sample Size:** Addis Ababa City has 468 private health facilities with laboratory facilities, and 20 of them are private hospitals" (12). On the present study, among those private laboratories in Addis Ababa (either those imbedded within the hospital or stand-alone laboratories), those which have advanced diagnostic laboratories molecular biology unit (having now or a plan to have) and perform molecular biology-related activities, eight of fifteen laboratories were selected using snowball sampling approach. Then, the selected private laboratories were coded from Laboratory A (Lab A) to Laboratory H (Lab H) sequentially based on the English alphabet order.

**Study Variables:** The readiness of the private diagnostic laboratories for COVID-19 services and perceived challenges experienced for launching molecular biology-based testing services were the dependent variables. While availability of infrastructure, human resources, and policy-related and supply chain factors were the independent variables.

**Data Collection:** After creating a clear clarification of the aim, risk, and confidentiality of the study, participating private laboratories were asked to sign informed consent. A total of eight private laboratories were participated in the study. Firstly, we have assessed first the general set up, whether they do have previous and future molecular biology activities or not, followed by an assessment of the readiness of the laboratories to provide COVID-19 laboratory service. The data collection also included evaluating the molecular biology laboratory set up and equipment availability, and the status of skilled human resource. Accordingly, the molecular biology laboratory and equipment assessment was done by on site evaluation and administration of a standardized questionnaire. The assessment questions include availability and functions of separate molecular biology laboratory, RT-PCR machine, Nested PCR machine, Eppendorf centrifuge machine, Calibrated micropipette with different volumes, bio-safety hood, eye goggle, and special laboratory gown for molecular biology laboratory. On the other hand, molecular biology laboratory staff's skill was assessed by administration of standard questionnaires. Questions that were used to assess laboratory personnel include the presence of human resources that can handle molecular biology activates, molecular laboratory assistants, work experience in RT-PCR, the kind of molecular laboratory works involved in, and how long they work on RT-PCR machine. Finally, we initiated a discussion between government bodies and advanced medical laboratories on how to solve challenges and provide RT-PCR based COVID-19 diagnostic service for the public. This discussion was designed based on public-private partnership principles, and how to expand and sustainably provide quality service for the public in fair conditions.

**Quality Assurance:** We have adopted the WHO molecular biology laboratory setups checklists to

prepare the questionnaires(8). The validity of data collection questionnaire was pretested in one private laboratory (which was not included in this final study). Besides most of the questionnaire, mainly on the molecular biology laboratory set up has been used by the Ethiopian Public Health Institute, to assess and include a public laboratory for COVID-19 RT-PCR based laboratory service.

Then data were collected by well-trained Medical Laboratory personnel where the authors of this manuscript were actively involved in the supervision of the data collection. Adequate time was given for filling the questionnaires and each laboratory was observed during onsite assessment. To maintain data credibility, the questionnaires were filled by senior Medical Laboratory personnel accompanied by the general manager of diagnostic laboratories and/or the owners of the facilities.

**Data analysis and interpretation:** After the data collection, it was checked, cleaned, and entered SPSS 20 software. Then data were analysed descriptively by the statistical software**.** The selected eight private laboratories readiness for the provision of COVID-19 RT-PCR based laboratory service were assessed by analyzing each laboratory response for 27 questions related to a laboratory set up, and 8 questions related with the readiness of skilled professionals. Based on the aggregate scores, criteria have been set to interpret and sought intervention mechanisms, as shown in Table 1.

Table 1. **Criteria set for data assessment, interpretations, and type of intervention required**

| Assessment Score | Interpretation | Intervention Requirement |
|---|---|---|
| **For Laboratory Setup** | | |
| ≥ 25 Points | Excellent, | Easily Fix Intervention |
| 20 – 24 Points | Very Good, | Minimal Intervention |
| 15 – 19 Points | Good | Substantial Intervention |
| Below 15 Points | Limited set up | Comprehensive Intervention |
| **For Skilled Human Resources** | | |
| ≥ 4 Points | Excellent, | Easily Fix Intervention |
| 3 Points | Very Good, | Minimal Intervention |
| 2 Points | Good | Substantial Intervention |
| Below 2 Points | No personnel | Comprehensive Intervention |

**Ethics approval, consent to participate and consent to publish:** Ethical clearance was obtained from Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University research and ethical clearance committee, Institutional Review Board (IRB) of College of Health Sciences, Addis Ababa University and Ethiopian Public Health Institute (EPHI) IRB office. Support letters were collected from the office of the president, AAU, and Minster of Health (MoH) before cascading the project. Data were collected after a written consent was obtained from the study participants. In addition, the study participants consented for publications of the findings by keeping identification of each of them confidentially. In general, to keep confidentiality, non-identifier codes were used, and an unauthorized person could not be able to access the data.

## Results

**Background status of advanced medical laboratories:** In the present study, eight advanced private medical laboratories were involved. Of them (3/8) were established six years ago, (6/8) had more than 11 Medical Laboratory professionals.Majority of staffs (73/ 134), were male and majority of females working in the private laboratories (34/61) were BSc degree qualified on Medical Laboratory Sciences. Additionally, (7/8) private laboratories had previous experience in molecular laboratory service, mainly in HIV/AIDS viral load testing and all eight laboratories have plan to expand molecular laboratory services for the future as summarized in table 2.

Table 2. **Description of private diagnostic laboratories in Addis Ababa, Ethiopia**

| Variable | Category | Frequency |
|---|---|---|
| Year Established | In the last five years | 2 |
| | 6-10 years ago, | 3 |
| | 11 to 20 years ago | 2 |
| | 21 and more years | 1 |
| | 1-5 | 1 |
| Number of total staffs (professionals and assistants) | 6-10 | 1 |
| | 11 and more years | 6 |
| | Diploma | 17 |
| Male professionals (N=73) | BSc | 42 |
| | MSc | 13 |
| | PhD | 1 |
| Female professionals(N=61) | Diploma | 25 |
| | BSc | 34 |
| | MSc | 2 |
| | PhD | 0 |
| Previous Molecular laboratory testing practices (N=7) | HIV Viral Load | 5 |

| | | |
|---|---|---|
| | Hepatitis Viral Load | 4 |
| | Other | 3 |
| Future to start molecular laboratory testing (N=8) | HIV Viral Load | 8 |
| | Hepatitis Viral Load | 8 |
| | SARS-CoV-2 | 8 |
| | Other molecular based tests | 4 |

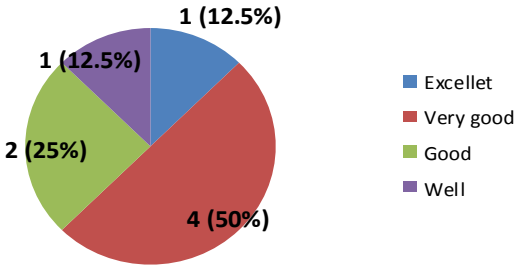
**The readiness assessment of private laboratories for COVID-19 laboratory services:** During the study, the overall readiness of the eight selected laboratories by fulfilling the expected molecular biology setups for COVID-19 services were range from one (12.5%) to eight (100%). On the availability of necessary molecular laboratory materials resource, all eight private advanced medical laboratories had calibrated micropipette, 2-8$^0$ lockable refrigerator, 2-8$^0$c sample transport box, bleach, UPS, Backup generator, adequate water supply, and adequate electric power supply. Regarding the availability of skilled professionals, all private laboratories had a laboratory personnel dedicated for molecular biology services (100%). The overall assessment of eight private advanced medical laboratories on the availability of equipment, supplies, and skill laboratory professionals was shown in table 3.

Table 3. **Readiness of private laboratories and professionals working for the COVID-19 testing, in Addis Ababa, Ethiopia**

| SRN | Readiness Indicators | Response | |
|---|---|---|---|
| | | Yes, | No |
| **Readiness of private laboratories for the COVID-19 testing** | | | |
| 1 | Separate ventilated molecular biology laboratory? | 6 | 2 |
| 2 | Separate molecular biology sample collection room? | 7 | 1 |
| 3 | RT-PCR machine? | 2 | 6 |
| 4 | RT-PCR machine currently functional? | 1 | 7 |
| 5 | Nested PCR machine? | 3 | 5 |
| 6 | Nested-PCR machine currently functional now? | 2 | 6 |
| 7 | Eppendorf centrifuge? | 3 | 5 |
| 8 | Calibrated micropipette of different volume? | 8 | 0 |
| 9 | Sterile micropipette tips of different volume? | 2 | 6 |
| 10 | Master mix solution except primer? | 2 | 6 |
| 11 | Bio-safety hood? | 6 | 2 |
| 12 | Heat block? | 4 | 4 |
| 13 | Eye goggle? | 6 | 2 |
| 14 | Special laboratory gown for molecular laboratory? | 3 | 5 |
| 15 | Water bath? | 7 | 1 |
| 16 | Sample storage 2-8$^O$C degree fridge and is it lockable? | 8 | 0 |
| 17 | Deep freezer (-20$^0$C) for storage and is it lockable? | 7 | 1 |
| 18 | Sample transport box-2-8 $^0$C | 8 | 0 |
| 19 | Vortex mixer? | 5 | 3 |
| 20 | Racks for 1.5 mL micro centrifuge tubes? | 4 | 4 |
| 21 | Molecular grade water, nuclease-free? | 1 | 7 |
| 22 | Bleach commercial (5.25-6.0% hypochlorite bleach)? | 8 | 0 |
| 23 | Disposable powder-free gloves and surgical gowns? | 6 | 2 |
| 24 | Aerosol barrier pipette tips? | 2 | 6 |
| 25 | Face shield? | 6 | 2 |
| 26 | UPS? | 8 | 0 |
| 27 | Backup generator? | 8 | 0 |
| 28 | Adequate water supply? | 8 | 0 |
| 29 | Adequate electric power supply? | 8 | 0 |
| 30 | Laboratory doors have a locker? | 8 | 0 |
| **Readiness of professionals working in Private laboratories** | | | |
| 1 | Trained Personnel dedicated to work in the molecular lab only? | 8 | 0 |
| 2 | Any lab staff attend molecular lab refreshment course in the last one year? | 3 | 5 |
| 3 | Any lab staff experienced in the RT-PCR lab work? | 2 | 6 |
| 4 | Any lab staff experienced in Nested PCR experience? | 2 | 6 |

As a summary of overall assessment of private laboratory in terms of their laboratory set up and available skilled laboratory professionals, only one laboratory was found to be in an excellent status and can readily commence RT-PCR based COVID -19 testing with simple negotiations and arrangements with the government authorities. Four laboratories were in very good status, two laboratories in good status, and one laboratory require tremendous and all-rounded support to commence COVID -19 laboratory testing (figure 1).

Figure 1. **Summery of status of private advanced medical laboratories to start RT-PCR based COVID-19 diagnostic services, in Addis Ababa, Ethiopia**




**Challenges to start molecular laboratory services by private laboratories:** More than half of the laboratories claimed that the costs of molecular-biology tests (6/8), absence of reliable supplies (6/8), and Lack of advisor/s (5/8)were the major challenges to provide and/or expand molecular based testing services for different infectious and non-infectious diseases. Lack of clear policy in Public-Private Partnership was the other major limiting factor for the private diagnostic laboratories to provide a sustainable and affordable molecular biology-based medical laboratory services for the public. Summary of the past and future expected challenges raised by private advanced medical laboratories is shown in table 4.

Table 4. **Previous and Future challenges perceived by private diagnostic laboratories to practice molecular biology services, Addis Ababa, Ethiopia, June 2020**

| Perceived current and future challenges molecular biology diagnostic services | Previous Challenge(N=8) Yes (%) | Expected Challenge(N=8) Yes (%) |
|---|---|---|
| Government policy | 4 | 4 |
| Price of molecular laboratory machine and reagents | 3 | 5 |
| Shortage of human resource | 3 | 4 |
| Expensiveness of molecular laboratory test | 6 | 6 |
| Procurement bureaucracy | 3 | 5 |
| Lack of reliable molecular laboratory test supplies | 6 | 6 |
| Lack of advisor/s | 5 | 4 |
| Shortage of money/finance | 3 | 4 |
| Separate workspace in the laboratory | 2 | 3 |
| Any other, (Specify) | 1 | 1 |

Status of study participants advanced private laboratories

In the present study, among the eight advanced medical laboratories, which were participated in the study, five of them (5/8) provide RT-PCR COVID-19 diagnostic service for the public. Then, gradually the remaining advanced medical laboratories also take a lesson from the first RT-PCR COVID-19 diagnostic service providers, and and currently in general more than ten private advanced medical laboratories provided RT-PCR based COVID-19 diagnostic services for the public. Such an expansion of RT-PCR based COVID-19 services, hopefully contributed a lot to win the COVID-19 pandemic battle in Ethiopia. This PPP based expansion of RT-PCR based COVID-19 services, may also become a good lesson for other countries too.

## Discussion

One of the important strategies to control COVID-19 pandemic is an expansion of laboratory testing services. The WHO recommended that in addition to public laboratory testing diagnostic services, private laboratory services, and academic institutions with standardized laboratories could be additional options,

especially where difficulty in testing exist due to limited facilities (13).

The present study assessed private laboratories readiness to provide RT-PCR COVID-19 laboratory services in Addis Ababa, Ethiopia. Among the selected eight private laboratories, half of them were in a very good status to launch COVID-19 laboratory services. One of the diagnostic laboratories has the necessary RT-PCR machine and accessories and can readily start the service with simple negotiation with the government authorities. This was a golden opportunity where public facilities have very minimal capacity to deliver laboratory-based services particularly during pandemic conditions like COVID-19.

On the other hand, three of the diagnostic laboratories had previous experiences of molecular- based diagnostics such as HIV viral load and Hepatitis B/C viruses. Additionally, two of them had a referral linkage with European laboratories for molecular-based tests. These laboratories were ready to arrange COVID-19 RT-PCR based diagnostic testing as they are in the processes of procurement of the machines and accessories.

The importance of private medical laboratories involvement in the diagnosis of RT-PCR based COVID-19 laboratory diagnostic services was seen in other African countries. In South Africa, the availability of COVID-19 laboratory services in private laboratories provide a choice for those who can afford to check themselves at the private laboratories and reduce the burden of public laboratory workload. This makes South Africa becoming the leading African country to provide many COVID-19 diagnostic services (14).

Similarly in the Republic of Korea, the important strategies implemented enable them to deliver more than 20, 000 COVID-19 laboratory tests per day was due to the establishment of an emergency use authorization (EUA) system, an external quality assessment (EQA), and the collaboration between the public and private sectors (15).

This collaboration between public and private laboratories to expand COVID-19 testing sites should also be encouraged in most developing countries, including Ethiopia. However, the implementation of a sound public- private partnership is not an easy task as almost all the participating diagnostic laboratories perceived different challenges, as indicated in this research. Some of the problems could be a lack of finical incentives from government bodies to expand their infrastructure or policy-related problem. On the other hand, nature of the molecular-based testing as it is expensive, and users may not afford it very easily as any other routine laboratory tests. The absence of reliable supplies for molecular-based tests is another obstacle as this could be exacerbated by a shortage of foreign currency to import the machine and consumables. A study conducted in East African counters showed that most challenges faced in private laboratories in Kenya, Tanzania, Uganda, and Rwanda includes Government mindset, Government bureaucracy, and a Restrictive market environment (16).

Other Far East countries, including Iran, also amend their health polices, on such a way to give more space for the private sectors, to expand COVID-19 diagnostic and treatment services. Such PPP approaches enable both public and private Iranians sectors to fight against the spread of COVID-19 diseases, ad reduce morbidity ad mortality rates (17). Among the developed countries, the usefulness of PPP to expand COVID-19 diagnostic service as an important strategy to combat COVID-19 pandemic was seen in New York, USA. The New York Governor Andrew Cuomo making a deal for the private company Bio-Reference Laboratories to provide testing capacity for the state, which allowed 24–48-hour processing time for all drive-through test sites in NY (18).

In general, as COVID-19 cases are still at a pandemic level, more numbers of morbidity and mortality reports increases so fast every day worldwide. Thus, expanding the laboratory testing for isolation and contact tracing, and treat the infected individuals are so crucial. Governments should consider the roles of private diagnostic laboratories and assist them to increase the availability of test sites. Besides, trust should be developed between public and private sectors and should work hand in hand to improve the quality of public life. Such efforts must be pronounced during the emergency and difficult situations like the case of the COVID-19 pandemic.

**Strength of the study**

The study covers the selected advanced private laboratories in Addis Ababa, Ethiopia. All study participant private laboratories were very cooperative for the study. Knowing their willingness to strengthen PPP with the government to provide quality laboratory service is highly appreciated.

**Limitation of the study**

The study was mainly focused on Addis Ababa, the capital city of Ethiopia. If it covers all over the country, enables assessment countrywide private laboratories status on the readiness of diagnosing COVID-19 by using the RT-PCR method.

**Conclusions**

In general, the present study revealed that through discussion and collaborative actions, COVID-19 diagnostic services can successfully expand further into private medical laboratories, and which could assist a lot in controlling the spreading of the disease. Similar studies are recommended in other parts of the country to make the private laboratories more participatory on the diagnosis of COVID-19.

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**Competing Interest**

The authors declare that they do not have any conflict of interest in publishing this work.

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**Acronyms and Abbreviations**

| | |
|---|---|
| **EPHI:** | Ethiopian Public Health Institute |
| **IRB:** | Institutional Review Board |
| **MoH:** | Ministry of Health |
| **PCR:** | Polymerase Chain Reaction |
| **PPP:** | Public-Private Partnership |
| **RT-PCR:** | Real-Time PCR |
| **SPSS:** | Statistical Package for Social Sciences |
| **WHO:** | World Health Organization |

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