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# External Quality Assessment (EQA) of Laboratory Tuberculosis Diagnosis in Lagos State, Nigeria: A Three-Year Review

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***Abstract***

*The low detection of tuberculosis cases is a big problem in Nigeria. The rate of accurate diagnosis while ensuring the quality of TB treatment monitoring tool – AFB, with a 90% Pass grade system among the testing laboratories requires to be monitored. Therefore, this study evaluated the external quality assessment (EQA) of TB diagnosis to satisfy laboratory quality requirements in Lagos, Nigeria. This study was conducted using data from 132 laboratories in Lagos, examining 3years retrospective EQA reports from 2019 to 2021. A structured data abstraction chart was employed to extract EQA data from the STBLCP database, while a trained supervisor checked for completeness, clarity, and consistency of data. IBM-SPSS version 28.0 was used for data analysis. The external assessment report showed an improved TB Laboratory diagnostic performance in the 2nd quarter of 2019 and 2020, but a decline was noticed in the 3rd and the 4th quarters. There was an increase in the overall laboratory performance from 94.4% in 2019 to 96.1% in 2020. A significant proportion (79.2%) of the slides assessed in 2019 passed external assessment tests (had a concordant score of 90 and above). However, the performance was significantly better in 2020 (84.2%) and 2021 (88.2%). Laboratories should be upgraded to a world-standard level, and staff should be well-trained, with periodic competency assessments to make reliable diagnoses, while ensuring all testing laboratories are enrolled in EQA program for the measure of quality laboratory services and consistency in service delivery.*

***Keywords:*** *Assessment, Diagnosis, External, Laboratory, Tuberculosis, Quality.*

## Introduction

Tuberculosis (TB) is one of the top ten causes of death in all countries and affects all ages [1]. People continue to get infected yearly despite the disease being preventable and curable [2]. The impact of TB on the population has been immense and has one of the most significant consequences on the productive adult population, affecting the economy negatively [3]. TB is an imperative contributor to the global burden of diseases and has received considerable attention over the years [4].

TB is an infectious bacterial disease caused by *Mycobacterium TB* (MTB), transmitted between humans through the respiratory route and typically affects the lungs but can damage

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any tissue [5]. Only about ten percent of people infected with MTB develop active TB disease within their lifetime; the rest successfully contain their infection [6]. One of the problems of TB is that the pathogen can remain latent in many infected people for years before reactivating and causing symptoms [6]. The risk of progression to TB disease is highest shortly after infection and rises significantly in those already infected with HIV/AIDS or other immune-compromising diseases [7]. The weakened immune system has aided the spread of TB due to HIV.

TB has been one of the leading global health challenges, recording less than three million deaths per year [8]. About nine million people worldwide developed TB for the first time in 2004, and the disease recorded almost two million deaths [3]. Aside from AIDS and malaria, TB is responsible for more years of healthy life lost (2.5 percent of all disability-adjusted life years) than any other infectious disease worldwide [3]. Every year records about ten million new cases, four to five million smear-positive, hence highly contagious [9]. The problem is in Europe, North America, Australia, and New Zealand [4]. However, the most significant problem exists in southeast Asia and sub-Saharan Africa [4]. Although the incidence is lower in Latin America than in Africa, it is still five to thirty times more significant than in some countries like Canada [3]. Southeast Asia reported the highest number of new TB cases in 2019, followed by the African region and Western [2].

TB is predominantly a socio-economic issue linked to overcrowding, lousy hygiene, a lack of clean water, and restricted healthcare access [10, 11] The issue of adequate health care infrastructure for case detection and treatment of TB makes disease control in countries more difficult [12] As a result, many cases go unnoticed, are misdiagnosed, or go unreported, especially in developing countries, and available statistical data vastly underestimate the global TB epidemic [12, 13] Only sputum smear-positive cases are detected in these nations because culture facilities are essentially non-existent [13] Diagnosis of TB in children is rare unless a complication occurs [14, 15] Extrapulmonary TB is rarely recognized.

The low detection of TB cases in both adults and children is a big problem in Nigeria [16]. In 2017, Nigeria only identified 104,904 TB cases out of 407,000 suspected TB cases [17]. This finding equates to a treatment coverage of only 25.8%, leaving 302,096 patients with TB who were either unidentified or detected but not notified, particularly in “non-DOTS sites.” [17] A successful TB control programme and a strategy for eliminating TB in countries like Nigeria depend on timely and accurate detection of active TB [18]. Active TB cases are detected, and drug susceptibility testing (DST) is performed in the laboratory, which aids in contact tracing and surveillance, as well as latent TB infection diagnosis [19-21] Treatment regimens and transmission prevention can be significantly improved if drug resistance can be detected.

Laboratories ought to be accredited by the appropriate national organisations in order to assure conformity with the existing international standards for laboratory diagnostics [22]. In order to maintain accreditation, laboratories are supposed to have adequate infrastructure and equipment, well-qualified staff, as well as both Internal and External Quality Assurance procedures, which are significantly lacking in the Nigerian healthcare system. Therefore, this study’s objective is to evaluate the external quality assessment of TB diagnosis in laboratories in Lagos, Nigeria.

## Methods

### Ethical Consideration

Ethical approval for the study was obtained from the ethics and research committee of Lagos State University Teaching Hospital (LASUTH) for the Lagos State Ministry of Health. The ethical approval number is LREC/06/10/1678 and the approval letter was sent to all the

participating laboratories and permission to use their data was obtained. No personal information such as e-mail IDs, institutional names or details of the contributing workers were collected to ensure secrecy. Also, all data were held in an electronic format that was password safe.

## Study Design

This study used retrospective data from external quality assessment (EQA) of TB using the AFB technique. diagnostic laboratories in Lagos state by the State TB, Burruli, and Leprosy Control Program (STBLCP).

## Study Area

This study was conducted in Lagos State, located in the southwestern geopolitical zone of Nigeria. The smallest area of Nigeria's 36 states, with a population of over 15 million. Lagos State is bounded on the north and east by Ogun State. In the west, it shares boundaries with the Republic of Benin. Its southern borders are with the Atlantic Ocean. 22% of its 3,577 $km^2$ are lagoons and creeks. Lagos State is arguably the most economically significant state in the country, containing Lagos, the nation's largest urban area [23]. It is a major financial center and would be the fifth-largest economy in Africa if it were a country [24]. As a result, it has the highest population density of Nigeria's states. However, the actual population total is disputed between the official Nigerian Census of 2006 and a much higher figure claimed by the Lagos State Government.

## Study Population

The study included all 132 laboratories that participated in Acid Fast Bacilli technique - External Quality Assessment (AFB-EQA) from 2019 to 2021 in Lagos State, which was obtained from the Lagos State Ministry of Health, Directorate of Disease Control, STBLCP Unit.

## Sampling Techniques and Sample size

The list of TB testing laboratories in Lagos State was collected from the STBLCP Unit of the Lagos State Ministry of Health, Directorate of Disease Control.

## Data Collection

A structured data abstraction chart was employed to extract external review data from the STBLCP database. Two trained abstractors and one supervisor conducted the data collection and reviews. The supervisors checked for completeness, clarity, and consistency of data and data quality assurance was also carried out. The data abstracted were entered into Microsoft Excel and exported to IBM-SPSS version 28.0 for data analysis.

## Statistical Analysis

The data abstracted were entered into Microsoft Excel and exported to IBM-SPSS version 28.0 for data analysis. Descriptive statistics were performed, presenting outcomes as frequency tables, percentages, pie, and bar charts. Pearson chi-square test was also used to compare variable proportions, setting P-values below 0.05 as significant.

## Inclusion and Exclusion Criteria

Only the TB laboratories that participated in AFB-EQA from 2019 to 2021 as recognised active by the STBLCP within Lagos State were included in the study while laboratories that did not participate and not recognised were excluded.

## On-Site Evaluation

The on-site evaluation included periodic site visits to assess laboratory practices. This method helps you learn where you are and identifies what is good and what areas need improvement.

## Panel Testing

The EQA coordinating organization prepares known sets of stained or unstained sputum smears that are sent out for Acid Fast Bacilli (AFB) and dried, inactivated/non-infectious, Mycobacteria isolates for MTB/RIF detection using Xpert MTB/RIF assay to peripheral laboratories for testing. The Medical Laboratory

Scientist/Technician analyses smears and return results. Results are evaluated by the EQA coordinating organization through a process of comparison of methods/techniques and equipment, and feedback provided to the participating facilities on the outcome using reports.

### Blinded Rechecking

Blinded rechecking is based on Lot Quality Assurance Sampling (LQAS), a random selection of specimens collected from routine workload at the test site and sent to a higher-level laboratory for validation. It is used to confirm that a laboratory meets national performance goals and detects errors.

### Scope of AFB - EQA (rechecking)

Blinded rechecking of smear slides is the only external quality assurance method to provide reliable assurance that a country has an effective AFB microscopy network. Randomly selecting 15 slides at an interval is picked from the routine workload at the different facilities. First, the test slides are sent to higher-level laboratory personnel with vast experience in reading. Then, the facilitators pick on the discordance slides to validate the reports.

The importance of having an EQA done on smear microscopy are but not limited to: it confirms that a laboratory meets its national performance goals, it is used to detect errors, it reflects the reality of routine performance by checking specimen qualities, smear techniques, stains, and reagents potencies, and it gives an accuracy of reading and provides motivation for staff.

## Results

Data from the first quarter of 2019 to the fourth quarter of 2021 TB diagnosis EQA from different laboratories in Lagos state were analysed. In 2019, the state government supported a significant proportion (86.2%) of the laboratories, while the remaining (13.8%) got their EQA support through Shops plus. However, in 2020 – 2021 all the laboratories across Lagos State were supported by the state government (Table 1).

**Table 1.** Laboratory Type and Source of Support

| Parameter | Frequency | Percentage |
|---|---|---|
| **Laboratory type** | | |
| Private | 418 | 55.6 |
| Public | 334 | 44.4 |
| **Source of support (2019)** | | |
| Shops plus | 40 | 13.8 |
| State | 249 | 86.2 |
| **Source of support (2020 – 2021)** | | |
| State | 463 | 100.0 |

A total number of facilities that participated in AFB - EQA for increased considerably from the 1st quarter 2019 (69) to the 3rd quarter of the same year, which was the highest (92). In contrast, there was a decline in the number of participating centres to the lowest (38) in the 2nd quarter of 2020. The number of participants increased to 71 in the 1st quarter of 2021 and 68 in the 4th quarter of 2021. Overall, the highest number of participating centres was recorded in 2019 and the least in 2020 (Figure 1).


**Figure 1.** Number of Health Facilities Enrolled for Lagos AFB - EQA 2019-2021

## EQA of TB Diagnosis Performances of Participating Centres from 2019 - 2021

The external quality assessment report showed an improved TB diagnostic performance of microscopy centres in the 2nd quarter of 2019 and 2020, but a decline was noticed in the 3rd and the 4th quarters. There was a declined percentage performance across the diagnostic centres in the 2nd quarter of 2021. However, there was an upward trend in the 3rd and 4th quarters, as shown in Figure 2 ($p<0.05$). Also, as presented in Figure 3, there was an increase in the overall laboratory performance from 94.7% in 2019 to 95.9% in 2020. The upward trend continues till 2021, when it declined by 0.7% ($p<0.05$).

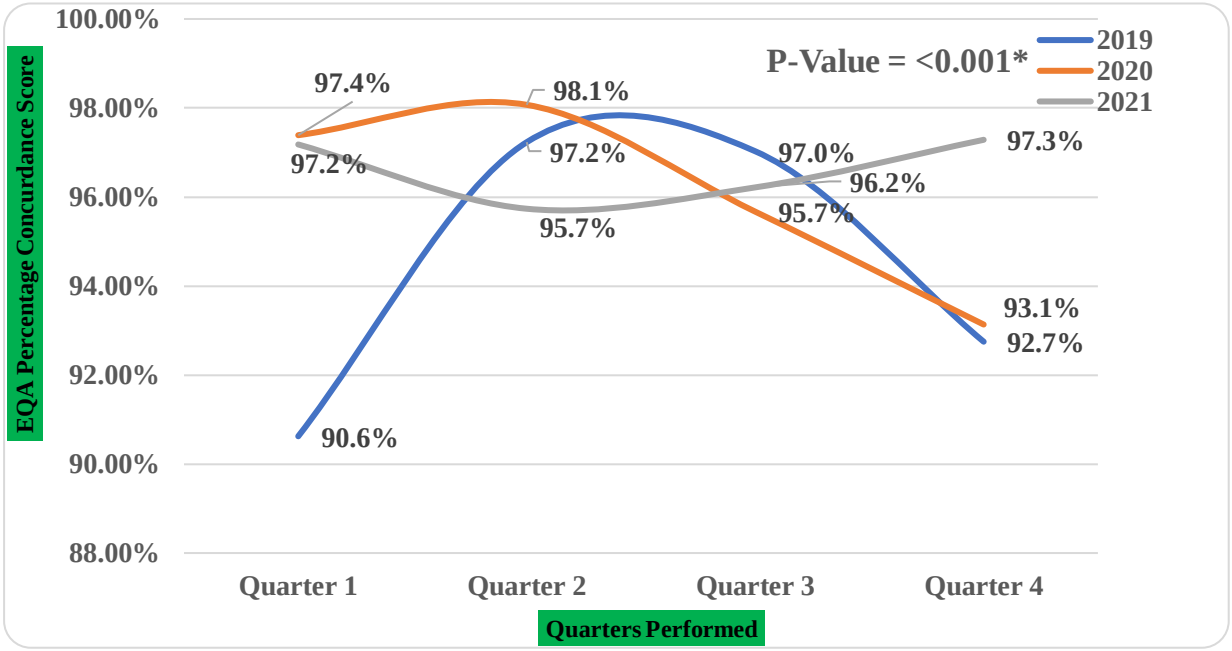


**Figure 2.** Microscopy Centre Quarterly Overall Performance (2019-2021)

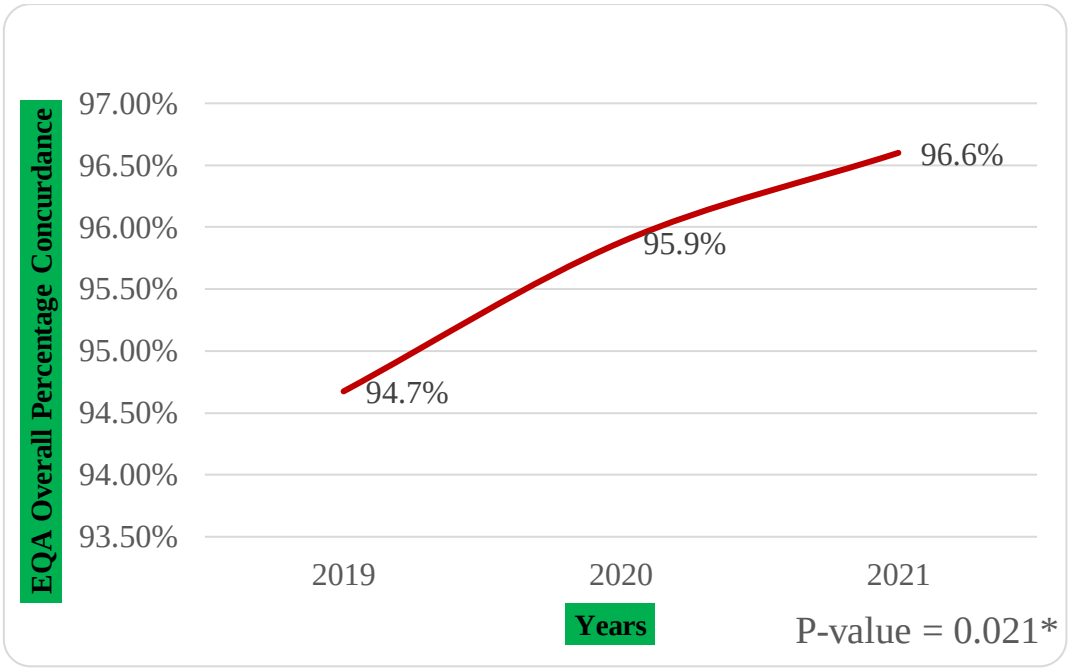


**Figure 3.** Annually Cumulative Laboratory Performance using Concordant

More than half (65.7%) of the slides assessed in 2019 showed good quality laboratory practices (had a concordant score of 100). Likewise, a substantial number (71.7%) of assessed slides in 2020 and 69.9% of the slides assessed in 2021 revealed good quality laboratory practices. Over one-tenth (13.5%) of slides assessed in 2019, 12.5% of 2020 slides, and 18.3% of slides in 2021 passed the assessment (had a concordant score of 90-99%). However, more than one-fourth (20.8%) of assessed slides in 2019, 15.8% of 2020, and 11.8% of assessed slides in 2021 failed the eternal quality assessment (had a concordant score <90%) as shown in Table 2, $p<0.05$.

**Table 2.** AFB - EQA Annual Laboratory Outcome, using Concordant

| Year | EQA Outcome | | | | P-value |
|---|---|---|---|---|---|
| | <90% (Failed) | 90 -99%(Passed) | 100% (GQLP) | Total | |
| | n (%) | n (%) | n (%) | n (%) | |
| **2019** | 60 (20.8) | 39 (13.5) | 190 (65.7) | 289 (38.4) | 0.028* |
| **2020** | 29 (15.8) | 23 (12.5) | 132 (71.7) | 184 (24.5) | |
| **2021** | 33 (11.8) | 51 (18.3) | 195 (69.9) | 279 (37.1) | |

* Significant at $p<0.05$. GQLP = Good Quality Laboratory practice

## Discussion

The study found that a higher percentage of participation was consisted of private laboratories, and the state government supported a significant proportion of the laboratories in participating in AFB-EQA. This result may be due to public laboratories being historically limited to Nigeria's national program to screen and treat TB [25]. Since most Nigerians have increasingly been reported for seeking healthcare from the private sector [26, 27], the WHO's STOP TB strategy recommends linking private facilities to the national TB program. Nigeria's National TB and Leprosy Control Programme (NTBLCP) and its donor partners have recently sought to expand private sector participation in Nigeria's TB. response, which might be a reason for this study's result [28]. Other studies conducted in Plateau, Ogun, Imo

and Lagos state also supported this finding [28-31].

The number of facilities that participated in the AFB-EQA for TB increased considerably from the first quarter of 2019 to the third quarter of the same year, which was the highest. However, a decline was recorded in the second quarter of 2020, which may be due to the COVID-19 pandemic. It is no news that the pandemic affected all aspects of society, and the EQA for TB. was not exempted [32-36]. However, the number of participants increased in the first and third quarters of 2021, which may be due to the realisation of EQA of TB lagging due to the maximum attention given to COVID-19 [37]. Overall, the highest number of participating centres was reported to be higher in 2019 and the lowest in 2020. The external assessment report also showed an improved TB diagnostic performance of microscopy centres in the second quarter of 2019 and 2020 but declined in the third and fourth quarters. There was a declined percentage performance across the diagnostic centres in the second quarter of 2021. However, there was an upward trend in the third quarter. This result shows that the performance is unstable, which may be due to challenges like poor logistics handling that has been reported to be encountered by public and private sectors [38]. [38] further explained that logistical support needed for diagnosis equipment, to track patients lost to follow-up, conduct contact tracing and supervision, collation of data, and report writing were either lacking or grossly insufficient. This result is also similar in other African countries as a finding was reported from Uganda, where there were inadequate resources to support EQA and follow-up TB patients [39]. Funding for health in Nigeria is below par; generally, a Nigerian study demonstrated the government budget for health as a percentage of general government expenditure to be far less than the agreed 15% at the African Union declaration in 2001 [40]. In many high-burden TB countries, gross underfunding may have affected the rate of participation in EQA for TB as found in this study.

## Limitations

The study was conducted in TB laboratories included in STBLCP within Lagos State and not all laboratories, meaning that data was not obtained from all the laboratories. However, it is a decent representation of TB diagnostic monitoring tool status in Nigeria, given that the study was conducted in one of the Nigerian states with the largest number of laboratories.

## Conclusion

The study assessed the quality of TB testing in participating laboratories in Lagos, Nigeria. Figures and tables displayed the trends of laboratories participating in EQA of TB monitoring tool - AFB from 2019 to 2021. For most quarters of the years, the trend was unstable, which could have been due to inadequate funding based on the peculiarity of Lagos State in quality service implementation. Hence, the study found how lacking most medical laboratories are with quality testing, thereby affecting treatment monitoring.

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