Simultaneous screening for COVID-19 and tuberculosis, India

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Abstract

Objective To evaluate the implementation of new operational workflows for simultaneous screening of coronavirus disease 2019 (COVID-19) and tuberculosis at four high-volume COVID-19 testing centres located in tertiary hospitals in Mumbai, India.

Methods Each centre already offering antigen-detecting rapid diagnostic tests were equipped with a rapid molecular testing platform for COVID-19 and tuberculosis, sufficient laboratory staff, and reagents and consumables for screening. Using a verbal tuberculosis questionnaire, a patient follow-up agent screened individuals visiting the COVID-19 testing centres. Presumptive tuberculosis patients were asked to provide sputum samples for rapid molecular testing. Subsequently, we reversed our operational workflow to also screen patients visiting tuberculosis outpatient departments for COVID-19, using rapid diagnostic tests.

Results From March to December 2021, we screened 14 588 presumptive COVID-19 patients for tuberculosis, of which 475 (3.3%) were identified as having presumptive tuberculosis. Of these, 288 (60.6%) were tested and 32 individuals (11.1%) were identified as tuberculosis positive (219 cases per 100 000 individuals screened). Of the tuberculosis-positive individuals, three had rifampicin-resistant tuberculosis. Among the remaining 187 presumptive tuberculosis cases not tested, 174 reported no symptoms at follow-up and 13 individuals either refused testing or could not be traced. Of the 671 presumptive tuberculosis cases screened for COVID-19, 17 (2.5%) were positive by antigen rapid diagnostic tests, and five (0.7%) who tested negative, later tested positive on the molecular testing platform (2483 COVID-19 cases per 100 000 individuals screened).

Conclusion Simultaneous screening for COVID-19 and tuberculosis in India is operationally feasible and can improve real time on-site detection of COVID-19 and tuberculosis.
Introduction

The overwhelming need for health care generated by the coronavirus disease 2019 (COVID-19) pandemic had a catastrophic effect on health-care programmes, particularly outpatient tuberculosis screening and detection. Before the COVID-19 pandemic, India already accounted for the highest number of tuberculosis cases in the world, with an estimated 2.95 million people falling ill annually.\(^1\) Because of rapid reductions in screening capacities for tuberculosis during the pandemic, there was an observable drop in the number of global tuberculosis case notifications: India alone contributed an estimated 41% to this decline in 2020.\(^2\) As a result, global tuberculosis-related deaths are expected to increase by about 20% over the next five years.\(^3\) The drop in notifications was linked to the diversion of health-care resources and personnel for COVID-19 response, and restrictions on movement during the pandemic, both of which prevented individuals from seeking regular, day to day preventative and primary health care.

Throughout the pandemic, Indian officials encouraged the use of antigen-detecting rapid diagnostic tests as the diagnostic tool of choice for COVID-19, primarily because of their ease of use and rapid on-site results. As these rapid tests are sensitive but not highly specific, the Indian Council of Medical Research also mandated confirmatory testing using real-time reverse transcription polymerase chain reaction (RT–PCR) for all individuals negative on rapid diagnostic tests but presenting with distinctive COVID-19 symptoms.\(^4\) Under this guidance, health facilities offering COVID-19 confirmatory testing typically referred samples for RT–PCR to off-site council-approved laboratories. In many cases, this workflow led to long turnaround times and delays in the eventual diagnosis, isolation and management of patients.

Given the wide overlap in risk factors and symptoms in COVID-19 and tuberculosis, multiple stakeholders proposed simultaneous screening for COVID-19 and tuberculosis as a way to improve real time detection of these diseases, allowing for optimization of constrained health-care resources.\(^5\) In fact, India’s Ministry of Health and Family Welfare released a rapid response plan in 2020 recommending the simultaneous screening of COVID-19 and tuberculosis in both patient groups – i.e. all COVID-19 patients should be screened for tuberculosis and all tuberculosis patients should be screened for COVID-19.\(^6\) Further, officials from the Brihanmumbai Municipal Corporation in Mumbai issued guidelines reinforcing concurrent screening of patient attendees in outpatient tuberculosis and COVID-19 departments.
In consideration of the above challenges to diagnosis, we launched this study to facilitate a new operational model for the screening of simultaneous COVID-19 and tuberculosis at four high-volume tertiary hospitals in Mumbai, India. In collaboration with the Brihanmumbai Municipal Corporation, FIND and the Indian nongovernmental organization Confluence for Health Action and Transformation Foundation led the project. Here we describe the operational model these groups used to facilitate simultaneous screening programmes in Mumbai and lessons learnt which can be useful for implementation of simultaneous COVID-19 and tuberculosis screening approaches elsewhere, especially settings with a high burden of tuberculosis.

**Methods**

**Study design**

We designed this study as an implementation research study conducted at four high-volume COVID-19 rapid diagnostic testing centres in Mumbai from March to December 2021.

**Setting**

Mumbai is one of the most populous cities in the world with 11.9 million inhabitants\(^7\) The city has been especially hard hit by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), with over 1.1 million COVID-19 cases and 19 500 deaths across Mumbai as of 2 May 2023.\(^8\) As such, officials in Mumbai have remained on high alert throughout the pandemic, focusing their efforts on containment through rapid diagnosis, isolation and appropriate clinical management.

The four tertiary hospitals selected offered walk-in COVID-19 testing using antigen-detecting rapid diagnostic tests, but also sent out samples for confirmatory molecular testing to referral laboratories. These hospitals primarily serve residents of low-income residents of unregulated settlements (60–70%) and other mixed urban residents (30–40%).

**Recruitment of study participants**

We included all people older than 18 years presenting themselves at either the COVID-19 testing centre or the tuberculosis outpatient department. To maintain uniformity in inclusion criteria, we excluded patients visiting other medical and general outpatient departments even if they subsequently tested positive for tuberculosis or COVID-19. All recruited participants were requested to provide verbal consent to participate in this screening.
Study implementation

We set up each study site in close proximity to the hospital’s COVID-19 rapid diagnostic testing centre to minimize potential challenges in sample collection and/or transportation of samples. We provided each centre with a Truenat™ (Molbio Diagnostics Pvt. Ltd, Verna, India) machine – a rapid molecular multidisease testing platform that uses RT–PCR to detect tuberculosis and COVID-19. Truenat™ has been endorsed by the World Health Organization, India’s National Tuberculosis Elimination Programme and the Indian Council of Medical Research for diagnosis of both tuberculosis and COVID-19.9–11 Noteworthy is that the study team allowed clinicians to use the Truenat™ platform to conduct in house screening for COVID-19 on patients outside of the study protocol.

We provided collaborating hospital laboratories with test chips, reagents and consumables for testing as well as one laboratory technician per laboratory. We recruited the laboratory staff using an advertised selection process and a technical interview with a FIND medical officer. A technical support team from Molbio Diagnostics trained all the recruited laboratory technicians and one technician from Brihanmumbai Municipal Corporation in rapid molecular sampling procedures. As required by the Indian government for all tuberculosis screening, the project team prepared a paper-based verbal questionnaire12 to screen for tuberculosis symptoms, in accordance with the National Tuberculosis Elimination Programme guidelines. Brihanmumbai Municipal Corporation subsequently approved the questionnaire.

Each site received a patient follow-up agent, who we trained at the onset of the project, via a 3-hour online orientation, on administering the questionnaire and the workflow of the project. Two months into implementation (May 2021) we provide a 3-hour online refresher training to the agents where they could ask questions regarding any difficulties they had experienced.

Fig. 1 outlines how we screened presumptive COVID-19 cases for tuberculosis. Hospital staff registered individuals presenting at the COVID-19 outpatient department and collected samples for COVID-19 testing before a patient follow-up agent screened them for tuberculosis by using the aforementioned screening questionnaire. Participants identified as presumptive tuberculosis cases on the verbal screening, irrespective of the COVID-19 result, had either their sputum sample collected on-site (one site that had a collection area) or were asked to return the
following day with a sputum sample (three sites did not have a collection area), for testing on the supplied Truenat™ machines. At one site, the National Tuberculosis Elimination Programme’s GeneXpert® machine was also used for tuberculosis testing due to high demand for Truenat™ tests. Presumptive tuberculosis participants unable to produce a sputum sample were referred to a Brihanmumbai Municipal Corporation-run facility for follow-up and linkage to specialized diagnostic and treatment services. The project staff also phoned presumptive tuberculosis patients who had not provided a sputum sample within 14 days to enquire about symptoms and request that individuals with symptoms return to the outpatient departments. All patients testing positive for tuberculosis were linked to Brihanmumbai Municipal Corporation for treatment and follow-up.

Beginning in mid-September 2021, we implemented a reversed operational workflow for simultaneous screening in three out of four sites via the process outlined in Fig. 2, largely in response to a steady decline in demand for COVID-19 rapid testing across all sites. While the earlier workflow screened presumptive COVID-19 cases for tuberculosis, the new workflow screened presumptive tuberculosis patients (walk-ins at the outpatient departments) for COVID-19 using the COVID-19 form and antigen-detecting rapid diagnostic tests. The workflow also included people whose tuberculosis samples were received from outposts linked to the outpatient department. Health workers phoned these patients and requested them to come into the outpatient department for COVID-19 rapid diagnostic testing. We introduced this workflow to reduce the substantial number of presumptive tuberculosis cases not screened for COVID-19 and to use excess Truenat™ capacity to reduce the number of sputum samples being sent outside the hospital for testing.

In this reversed workflow, the patient follow-up agent offered individuals visiting the tuberculosis outpatient departments COVID-19 testing. Subsequently Brihanmumbai Municipal Corporation personnel administered the antigen-detecting rapid diagnostic tests to those who accepted the offer. Consenting individuals who had symptoms of COVID-19 but tested negative by the rapid test had a second sample taken by a health-care worker for confirmatory rapid molecular testing on-site. All rapid molecular diagnostics performed with the Truenat™ platform for SARS-CoV-2 were conducted according to the Indian Council of Medical Research guidelines. Individuals with positive rapid and/or Truenat™ COVID-19 test results were referred to the Brihanmumbai Municipal Corporation programme for confirmation, including
chest radiographs, and treatment. A member of the project team phoned after three days asymptomatic individuals who tested negative on antigen-detecting rapid diagnostic tests to see if symptoms developed and if so, asked them to return for further testing and contact tracing.

This study was regularly monitored via progress review meetings, site visits and joint meetings through a steering committee that consisted of Brihanmumbai Municipal Corporation, the donor Bill & Melinda Gates Foundation, Confluence for Health Action and Transformation Foundation and FIND.

**Cost of intervention**

The project provided one laboratory technician and one patient follow-up agent per site, related stationary, personal protective equipment as well as Truenat™ cartridges. While the patient follow-up agent was dedicated to administering the tuberculosis questionnaire, about 3% of the laboratory technician’s time was allocated to conducting tuberculosis tests at each site for the duration of the study. We used a time estimation analysis to determine the time laboratory technicians required for each task (Table 1). For both personnel, actual salaries were used to determine cost value.

For the reversed screening conducted in tuberculosis outpatient departments, the project only provided a patient follow-up agent to each site, as the Brihanmumbai Municipal Corporation provided the COVID-19 rapid tests as an extension of a larger COVID-19 programme. Hence, the cost of the reversed screening could not be calculated.

**Variables and data sources**

Key variables included in this study are: the total number of participants, the number of participants who tested positive for tuberculosis and/or COVID-19, and the and percentage of participants who tested positive for tuberculosis and/or COVID-19. For tuberculosis positive samples, we also recorded the presence of rifampicin-resistance. The project coordinator digitized the paper-based tuberculosis questionnaire used for screening individuals presenting for COVID-19 testing, in Microsoft Word (Microsoft Co., Redmond, United States of America) before sending the information to the Brihanmumbai Municipal Corporation staff. Using Microsoft Excel, we analysed all tuberculosis testing data, which on-site project personnel had collected using Brihanmumbai Municipal Corporation laboratory registers. Data on COVID-19 screenings
in tuberculosis departments was collected using the Brihanmumbai Municipal Corporation’s COVID-19 tracker form in Excel.

Brihanmumbai Municipal Corporation staff cleaned all study data on-site and de-identified, meaning they only relayed anonymous patient data to the FIND team for final analysis. As the objective of the study was to screen and link patients for further evaluation per Brihanmumbai Municipal Corporation guidelines, de-identified individuals who tested positive under the intervention were reported via their case number to corporation teams at each testing site. Follow-up data on treatment or health outcomes post intervention was beyond the scope of this analysis.

**Ethical considerations**
The study of simultaneous screening for COVID-19 and tuberculosis in Mumbai, India was approved as an intervention under the health department of Mumbai’s Brihanmumbai Municipal Corporation. We only initiated the study after receiving approval for collaboration from the corporation. As simultaneous testing for COVID-19 and tuberculosis was recommended by the Indian Ministry of Health and Family Welfare and the corporation as an intervention in all state hospitals, this study did not require specific ethical approval and was not conducted as a traditional research study, but rather as an evaluation of the implementation experience.

**Results**

**Screening for tuberculosis**
From March to December 2021, we screened a total of 14,588 presumptive COVID-19 patients for tuberculosis and we identified 475 (3.3%) presumptive tuberculosis patients (Table 2). Of the presumptive tuberculosis patients, 286 (60.2%) were male and 188 (39.6%) were female; sex for one individual was unknown. Among the presumptive tuberculosis patients, 288 (60.6%) were tested for tuberculosis and 32 (11.1%) found to be tuberculosis positive (219 cases per 100,000 individuals screened), three of whom were further diagnosed with rifampicin-resistant tuberculosis. As for the 187 identified presumptive tuberculosis cases who were not tested, 174 reported no symptoms at 14 days follow-up and 13 individuals either refused testing or could not be traced.
Among the 14 588 individuals, rapid diagnostic tests were administered to 8118 (55.6%), and 523 (6.4%) were COVID-19 positive. Those not tested by rapid diagnostic tests may have received RT–PCR testing from the Brihanmumbai Municipal Corporation and were not therefore included in participant follow-up exercises.

**Screening for COVID-19**

Between September and December 2021, we offered screening to a total of 886 presumptive tuberculosis cases for COVID-19 (Table 2). Of these, 470 (53.0%) were male and 363 (41.0%) were female; sex was unknown for 53 individuals. Among the individuals screened for COVID-19, 671 (75.7%) were tested for COVID-19 using either antigen-detecting rapid diagnostic tests or Truenat™ machines. Only 17 individuals (2.5%) were identified as COVID-19 positive from the rapid tests. Additionally, 41 symptomatic individuals who tested negative via the rapid test permitted a second sample to be taken for confirmatory testing using rapid molecular methods. From this cohort, a further five individuals (12.2%) were identified as COVID-19 positive using the Truenat™ platform, resulting in average incidence of 2483 cases per 100 000 individuals screened over the project period.

Among the presumptive tuberculosis cases, 843 (95.1%) were tested for tuberculosis, with 175 (20.8%) identified as tuberculosis positive. Three tuberculosis-positive participants were diagnosed with rifampicin-resistant tuberculosis and one participant was infected with both tuberculosis and COVID-19.

**Impact of the simultaneous screening intervention**

In total, this study facilitated 1131 rapid molecular tuberculosis tests among presumptive COVID-19 cases and diagnosed 207 individuals with tuberculosis, six of whom had rifampicin-resistant tuberculosis. The study also facilitated 712 rapid antigen and rapid molecular COVID-19 tests for presumptive tuberculosis patients and subsequently diagnosed 22 presumptive tuberculosis patients with COVID-19.

**Cost**

The total cost of simultaneous screening for COVID-19 and tuberculosis outpatient walk-ins between March and December 2021 was 19 792 United States dollars (US$) or US$ 1.4 per participant screened. This cost includes personnel, printing costs (for tuberculosis questionnaire...
forms), personal protective equipment and Truenat™ tuberculosis cartridges directly attributable to the study.

Discussion
This study of simultaneous COVID-19 and tuberculosis screening in outpatient facilities at tertiary hospitals in India demonstrates that this operational model can be successfully implemented across health facilities using simple verbal screening and inclusion procedures and rapid molecular testing on-site. This study was conducted in close collaboration with the Brihanmumbai Municipal Corporation and the steering committee that closely monitored progress with follow-up visits to implementation sites, made review phone calls and timely course corrections. This approach ensured smooth operations for the duration of the study as well as an effective handover of the study intervention to Brihanmumbai Municipal Corporation after completion.

We observed that although simultaneous screening could be facilitated in either direction, COVID-19 screening in tuberculosis outpatient departments was more streamlined than screening for tuberculosis at COVID-19 testing sites. Reasons include: a verbal questionnaire was not required for tuberculosis patients being screened for COVID-19; tuberculosis clinics were less crowded than COVID-19 testing sites (fewer people walking in per day); and people presenting for tuberculosis testing were more open to being screened for co-morbid illnesses than those presenting for COVID-19 testing alone.

This study also demonstrates that the operational workflows for tuberculosis and COVID-19 screening in India can be harmoniously combined, aided by the fact that the same local government manage the COVID-19 and tuberculosis departments. We also noted that closed rapid molecular testing platforms such as Truenat™ are well suited for deployment in outpatient laboratories as they require minimal infrastructure for set-up and deployment while providing an affordable end-to-end solution for sample collection and results reporting in just a few hours.9

Although the overall study and its implementation were successful, we encountered some barriers along the way. First, availability of sufficient personnel was a challenge, especially during COVID-19 surges, as there were high rates of infection and sick leave across deployed staff, despite staff being vaccinated and following appropriate infection control measures. The reduced number of personnel available potentially affected the number of people that were
recruited for screening. Second, many participants identified as presumptive tuberculosis patients and who were asked to return with their sample at a later date did not return. Additionally, recruited participants were confined to those who self-triaged for COVID-19 and presented at the various tertiary hospitals included in this study, potentially biasing the overall sample.

We designed the project to be sustained beyond the initial implementation, with the project transitioned to Brihanmumbai Municipal Corporation staff after completion. However, we identified several factors as potential limitations towards the ongoing sustainability of the project. First, available personnel cross-trained to collect, analyse and report test results for more than one disease were lacking at the Brihanmumbai Municipal Corporation sites. To overcome this challenge, the study team provided Brihanmumbai Municipal Corporation with additional Truenat™ machines to test concurrently for COVID-19 and tuberculosis on-site. The study also built capacity among laboratory technicians for both testing protocols. A second limitation was the space constraints in hospitals and the fear of patients releasing aerosols containing SARS-CoV-2 during sputum collection, which hindered us from setting up on-site sputum collection areas in three out of four hospitals. The Brihanmumbai municipal corporation and the study hospitals have noted the lessons from these challenges to better respond to future outbreaks.

As the COVID-19 pandemic has now slowed to a near endemic state, the study test sites have now reverted to their original tuberculosis-related testing, with the supplied Truenat™ machines being used by the tuberculosis programme under Brihanmumbai Municipal Corporation supervision.

While this article describes the implementation of simultaneous screening for COVID-19 and tuberculosis in tertiary hospitals in India, a similar approach has been used in several other countries. For example, in Kaduna State, Nigeria, the implementation of integrated community testing for tuberculosis and COVID-19 using a mobile diagnostic facility was found to be feasible and impactful. The Nigerian intervention increased the access of community members to testing for COVID-19, tuberculosis and other diseases, enabled timely turnaround of test results and referral for further management and treatment. Moreover, a report of 12 countries implementing simultaneous testing for COVID-19 and tuberculosis also found that patients seeking COVID-19 testing could also be targeted for tuberculosis screening in areas where there is a known high burden of tuberculosis. This report, although showing successes, also identified several
difficulties related to the facilitation of simultaneous screening, such as a lack of resources for on-site sputum sample collection and loss of participants to follow-up due to off-site sample collection.¹⁴

This study demonstrates that existing rapid molecular testing technology can be leveraged for future outbreak response, such as to provide flexible and temporary testing capacity in the event of an outbreak or pandemic. This study also highlights several measures that can potentially increase the feasibility and yield of future simultaneous screening efforts. These measures include ensuring adequate staffing levels, offering segregated on-site sputum collection areas, and more effective infection prevention and control measures for laboratory staff at sample collection sites. Additionally, simultaneous testing interventions can be streamlined in the laboratory by using a single sample type and test cartridge if possible, and offering dual patient screenings at a single touchpoint, instead of sequentially.

COVID-19 and tuberculosis screening in India is operationally feasible and may improve the detection of COVID-19 and tuberculosis, particularly in settings where is a known high burden of both diseases. The experience gleaned from this study suggests that although operational workflows for tuberculosis and COVID-19 can be combined, COVID-19 screening using antigen-detecting rapid diagnostic tests at tuberculosis outpatient departments may be more practical and better received than attempting to screen for tuberculosis at COVID-19 testing sites.

Acknowledgments
KD and RS contributed equally to this work. We thank Brihanmumbai Municipal Corporation teams on site for their collaboration with the project of the on-ground implementation during the pandemic. Talya Underwood, Anthos Communications Ltd, Northwich United Kingdom of Great Britain and Northern Ireland, provided writing support, which was funded by FIND.

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Competing interests:
KD, RS, SSH, SSC and SSA are employed by FIND and received a grant from the Bill & Melinda Gates Foundation. The other authors declare no competing interests.
References


Table 1. Data used for the time-estimation of simultaneous screening of COVID-19 and tuberculosis, India, 2021

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test performed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>COVID-19</td>
</tr>
<tr>
<td>No. of tests</td>
<td>15 000</td>
</tr>
<tr>
<td>Duration in minutesa</td>
<td>35</td>
</tr>
<tr>
<td>% time of laboratory technician spent</td>
<td>98.1</td>
</tr>
<tr>
<td>% of time considering duration of test</td>
<td>96.8</td>
</tr>
<tr>
<td>% used for calculation of time-estimation</td>
<td>97.0</td>
</tr>
</tbody>
</table>


a Excluding pre-processing time, which we assumed to be equal for both.
Table 2. **Participants screened at either COVID-19 testing sites or at tuberculosis outpatient departments, India, 2021**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No. of participants (%)</th>
<th>Screened at COVID-19 testing sites <em>(n = 14,588)</em></th>
<th>Screened at tuberculosis outpatient departments <em>(n = 886)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants tested for COVID-19&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirmed COVID-19 cases</td>
<td>523 (6.4)</td>
<td>17 (2.5)&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Presumptive tuberculosis patients identified</td>
<td>475 (3.3)</td>
<td>886</td>
<td></td>
</tr>
<tr>
<td>Samples received for tuberculosis testing</td>
<td>288 (60.6)</td>
<td>843 (95.1)</td>
<td></td>
</tr>
<tr>
<td>Tuberculosis detected</td>
<td>32 (11.1)</td>
<td>175 (20.8)</td>
<td></td>
</tr>
<tr>
<td>Rifampicin-resistant. tuberculosis detected</td>
<td>3 (1.0)</td>
<td>3 (0.4)</td>
<td></td>
</tr>
<tr>
<td>COVID-19 and tuberculosis detected</td>
<td>0 (0.0)</td>
<td>1 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Samples not received for tuberculosis testing</td>
<td>187 (39.4)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Symptoms not found on follow up</td>
<td>174 (93.0)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Refused testing and follow up</td>
<td>13 (7.0)</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>


<sup>a</sup> Participants tested with a severe acute respiratory syndrome coronavirus-2 antigen rapid diagnostic test.

<sup>b</sup> Only includes participants whose reports were available.

<sup>c</sup> Not included are five cases that tested positive when using Truenat™ confirmatory testing. A total of 41 negative samples were retested.
Fig. 1. Flow of activities for COVID-19 and tuberculosis testing, India, 2021


Project staff phoned presumptive tuberculosis patients who had not provided a sputum sample within 14 days to enquire about symptoms and request return to the outpatient departments in case of symptoms.

Note: For one site, the national tuberculosis elimination programme provided GeneXpert® for tuberculosis testing. A sample collection agent transported the samples to the laboratory.
Fig. 2. **Flow of activities for COVID-19 and tuberculosis testing, India, 2021**


Note: Samples were transported by a sample collection agent to the laboratory.