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Supplementary appendix 2

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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APPENDIX

Integrating tuberculosis and COVID-19 molecular testing in Lima, Peru: A cross-sectional diagnostic accuracy study

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SUPPLEMENTAL METHODS

Study design and population

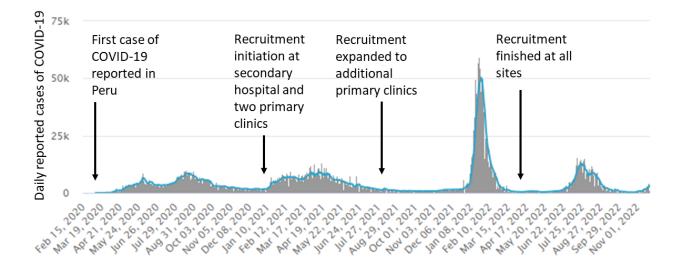


Figure S1: Number of weekly incident COVID-19 cases in Peru between February 15 2021 and 23 November 2022. The blue line represents weekly average. Modified from¹.

Procedures

NPSs were transported via approximately 3 mL of transport media (VTM Swab Kit [Boenmed, China], AB Transport Medium [AB Medical, Korea], or VTM transport medium [Liofilchem, Italy], depending on availability). 300 μ L was used for testing on Xpress as per manufacturer's protocol (LOT numbers: 1000224306, 1000265143). Xpress primers target the nucleocapsid gene N2 and E gene, the envelope protein E.² In the UPCH system, another RT-PCR test using NPS was the standard-of-care for SARS-CoV-2 detection. However, due to its superior analytical sensitivity, we considered a positive result on Xpert Xpress SARS-CoV-2 using NPS to be indicative of SARS-CoV-2 infection.

The 5 mL sputum sample was homogenized using glass beads and split. For TB testing, 1 mL was used for Ultra, while for COVID-19, 300 μ L was run on Xpress. The remaining sputum was decontaminated with the NALC-NaOH method; this sample was used for smear microscopy and bacteriologic culture (BACTEC MGIT, BD, USA), with positive tests undergoing drug-susceptibility testing with DST SIRE (BD).

Participants recruited at primary health clinics received chest X-rays on-site; other individuals were referred to private clinics and given a voucher to recoup costs of the procedure. Chest X-rays were read by a blinded physician experienced in reading radiographic images. Chest X-ray abnormalities were classified as "presence of abnormality" or "no abnormality".

Semi-structured interview questions

Questions regarding feasibility and experience of integrated testing were posed to staff members in informal semistructured interviews.

Questions for discussion with clinical staff involved in recruitment:

- How did you find collecting samples for COVID-19 and TB testing at the same time? What did patients think?

- What did you think about collecting a nasopharyngeal swab from someone seeking TB testing? Would you consider it feasible?
- What did you think about collecting sputum from someone seeking COVID-19 testing? Would you consider it feasible?
- Were any special safety considerations incorporated? Please describe if so

Questions for discussion with laboratory staff involved in running tests:

- How did you find the experience of using GeneXpert for COVID-19 testing as well as TB testing? Was it feasible?
- What was different about sample preparation procedures to perform the integrated testing? Please describe any differences (or not)
- What was the impact on laboratory work flow?
- Were any special safety considerations incorporated? Please describe if so

SUPPLEMENTAL RESULTS

Table S1: Test result patterns among 80 people with culture-confirmed TB. The number of times the test result pattern was observed is indicated in the right-most column. "+" denotes a positive test result and "-" denotes a negative test result. NPS – nasopharyngeal swab; Xpress – Xpert Xpress SARS-CoV-2

Test results			
Culture	Xpress on NPS for SARS-CoV-2	Xpress on sputum for SARS-CoV-2	Observed frequency
+	-	-	67
+	-	+	2
+	+	-	9
+	+	+	1
+	+	NA	1

Table S2: Unavailable results for molecular tests for SARS-CoV-2 detection. NPS – nasopharyngeal swab; Xpress – Xpert Xpress SARS-CoV-2.

	Xpress (NPS)	Xpress (sputum)
Error	0	3
Indeterminate result	0	0
No result	0	1
Missing result	1	10
Total unavailable results	1	14

SUPPLEMENTAL REFERENCES

 Worldometers.info. Worldometer: Peru dashboard. 6 July 2022 2022. <u>https://www.worldometers.info/coronavirus/country/peru/</u> (accessed 6 July 2022).
Cepheid. Instructions for use: Xpert® Xpress SARS-CoV-2. In: Inc. C, editor. Sunnyvale, USA: Cepheid Inc.; 2020.