Innovative point-of-care molecular diagnostic test for COVID-19 in India

On Sept 17, 2020, Malick Gibani and colleagues[1] published an Article in *The Lancet Microbe* assessing the diagnostic accuracy of CovidNudge (DnaNudge, UK), a molecular point-of-care test for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). CovidNudge stands out as a reliable point-of-care test, with high sensitivity and specificity, minimal or no laboratory requirements, and a turn-around time of 90 mins per test. Gibani and colleagues[1] highlight the crucial need for rapid and accurate point-of-care tests to increase access to and ease of testing.

A similar approach was used in India to augment testing for COVID-19 in underserved areas and health-care facilities. A combination of different tests and testing platforms has been used to augment capacity to 1·2 million tests per day, as of Sept 25, 2020.[2] Indigenous portable Truelab (Molbio Diagnostics, India) workstations, previously used and recommended by WHO for tuberculosis[3] and also deployed for detection of Nipah virus disease (unpublished) and leptospirosis (unpublished), are now being used for detection of SARS-CoV-2. The Truelab workstation includes sample preparation, an RNA extraction system, an RT-PCR machine, and disposable kit components. The workstation is a chip-based, real-time quantitative PCR system that is portable, battery-operated, and fully automated, and weighs around 3 kg. This laboratory-in-a-suitcase can be used in remote areas and has network data transfer ability and an automated reporting system. Samples are collected in a viral lysis buffer with minimum biosafety and biosecurity requirements. Results from a single test are available in 45 mins. In addition, the quantitative PCR machine is available in three sizes: UnoDx, Duo, and Quattro, with capacity to test one, two, and four samples per run, respectively.

The Truenat Beta CoV E-gene screening assay and Truenat SARS-CoV-2 RdRp gene-confirmatory assay (Molbio Diagnostics, India) were earlier validated as a two-step test.[4] The assays were deployed for COVID-19 testing in various parts of India between April and June, 2020.[4] A multiplex assay combining E-gene screening and Orf1a-gene confirmatory assay has also been validated recently.[5] All three of these assays exhibited 100% sensitivity and specificity, and positive and negative predictive value when compared with the gold-standard RT-PCR test. A total of 2530 Truelab workstations are currently operational at 1008 sites in 530 districts of India. The figure in the appendix depicts the distribution of Truelab workstations in India. Of the total 70·7 million COVID-19 tests done in India up to Sept 25, 2020, 2·7 million (3·8%) have been run on Truelab workstations.

This innovative technology-driven COVID-19 testing platform has been a game changer for testing in underserved areas and quick testing in emergency departments of health-care facilities in India.

The Central Tuberculosis Division of the Indian Ministry of Health and Family Welfare has procured the Truenat machines and provided cartridges for testing all over India. We are not paid by any pharmaceutical company or other agency to write this Correspondence. We declare no competing interests.

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1 Gibani MM, Toumazou C, Sohbati M, et al. Assessing a novel, lab-free, point-of-care test for SARS-CoV-2 (CovidNudge): a diagnostic accuracy study. *Lancet Microbe* 2020; **1:** e300–06.

2 Indian Council of Medical Research. SARS-CoV-2 (COVID-19) testing status. https://www.icmr.gov.in/index.html (accessed Sept 25, 2020).

3 WHO. Rapid communication: molecular assays as initial tests for the diagnosis of tuberculosis and rifampicin resistance. 2020. https://www.who.int/tb/publications/2020/rapid-communications-molecular-assays/en/ (accessed Sept 24, 2020).

4 Basawarajappa SG, Rangaiah A, Padukone S, Yadav PD, Gupta N, Shankar SM. Performance evaluation of Truenat™ Beta CoV and Truenat™ SARS-CoV-2 point of care assays for COVID-19. *Indian J Med Res* (in press).

5 Shantala GB, Ambica R, Sathyanarayan MS, Padukone S. July 29, 2020. Performance evaluation of Truenat™ Covid-19 test on Truelab™ workstation. http://www.molbiodiagnostics.com/uploads/product_evaluation/23_productevaluation_2320200909.124833.pdf (accessed Oct 7, 2020).

For more on the **Truelab workstation** see http://www.molbiodiagnostics.com/products-listing.php

See **Online** for appendix