



ICMR invites suggestions for revision of National Essential Diagnostics List

Since 2018, the WHO recommends the development and implementation of National Essential Diagnostics List (NEDL) to facilitate availability of In-Vitro Diagnostics (IVDs) across the various tiers of the healthcare pyramid, facilities with or without a laboratory on-site.¹ The Indian Council of Medical Research released the first National Essential Diagnostics List (NEDL) in 2019 to make the availability of diagnostics an essential component of the health care system. The link to the existing NEDL can be seen here https://main.icmr.nic.in/sites/default/files/guidelines/NEDL_2019.pdf. India is the first country to release the NEDL. The list enumerates minimum number of tests that should be available at various levels of healthcare facilities, including – village level, Sub Health Centre/Health & Wellness Centres (HWCs), Primary Health Centres (PHC)/HWCs, Community Health Centres (CHC), Sub-District Hospital (SDH), and District Hospital (DH). The inclusion of diagnostic tests in the NEDL was based on careful consideration of the disease burden data across different states of India, alignment with National programs and adherence to Indian public health standards. The required manpower, infrastructure and logistical support required at each health facility to carry out the tests were also recommended in line with the IPHS (2012) guidelines. In a positive outcome following development of NEDL, the list has been adopted by the Free Diagnostic Service Initiative (FDSI)² of the National Health Mission (NHM) in 2019. This adoption has ensured that the diagnostic services provided under the FDSI align well with the essential diagnostic tests outlined in the NEDL.

Since considerable time has elapsed following the release of the first NEDL in 2019, ICMR invites suggestions for revision of the existing list i.e. addition or deletion of diagnostic tests, from all the relevant stakeholders. The stakeholders should consider the following criteria before proposing any additional tests to the existing list:

¹ World Health Organization Model List of Essential In Vitro Diagnostics First edition (2018). https://cdn.who.int/media/docs/default-source/in-vitro-diagnostics/edl/first-meeting/edlexecutive-summary_nov2018.pdf?sfvrsn=eee95e46_5

² National Health Mission. Free Diagnostics service Initiative. Guidance Document for Implementing Laboratory Services in States, 2019. https://nhsrcindia.org/sites/default/files/2021-07/Guidance_document_for_Free_Laboratory_Services.pdf

- a. Essentiality of the test:** Essential diagnostic tests are defined as those "that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy, and comparative cost-effectiveness."³
- b. Disease burden:** The test should focus on conditions with a high disease burden or having significant public health relevance, where introduction of diagnostic test will have a clear impact on disease diagnosis and management.
- c. Alignment with Indian Public Health Standards (IPHS) 2022:** The proposed test should have documented utility and necessity at the level for which it is suggested and the proposed addition should be in alignment with the availability of equipment, infrastructure and manpower, as per the Indian Public Health Standards (IPHS) 2022.⁴
- d.** Suggestions for inclusion of point of care tests are encouraged.
- e.** The diagnostics suggested for addition should have obtained necessary regulatory approvals

The applicant should submit suggestions on addition or deletion of diagnostics tests to the current list using the Google form <https://forms.gle/93Rn586J3PkSV9Wc6> latest by February 29, 2024.

³ Moussy FG, Berumen AV, Pai M. The WHO list of essential in vitro diagnostics: Development and next steps. *EBioMedicine*. 2018 Nov; 37:1-2. doi: 10.1016/j.ebiom.2018.10.070. Epub 2018 Oct 30. PMID: 30389503; PMCID: PMC6286302.

⁴ Indian Public Health Standards (IPHS) 2022 guidelines. <https://nhsrcindia.org/IPHS2022/iphs-2022-guidelines>