

भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research

Department of Health Research, Ministry of Health

and Family Welfare, Government of India

Date: 06.07.2023

Latent TB diagnostic test kits prospectively validated & approved by ICMR

Please Note:

- Below listed kits are validated with the mentioned lot/batch numbers only as per specified scope of the test kit.
- Responsibility for use and batch to batch consistency does not lie with ICMR.
- ICMR validation is not a pre-requisite for DCGI approval.
- ICMR validation does not guarantee that the kit will be included in ICMR tenders.

<u>Till date, one latent TB diagnostic test kit has been validated by ICMR and found to be satisfactory for diagnosis of latent TB</u>

S.	Name of the company	Name of the kit	Lot / Batch	Test principle	Scope of the Test kit
No			No.	validated	validated
1.	Serum Institute of India Pvt. Ltd. (SIIPL), Pune, India	Cy-Tb test* "rdESAT-6 & rCFP-10"	3880Н002	Intra-dermal skin test	For diagnosis of latent TB in people who are 18 years or above

^{*} Cy-Tb skin test is marketed by M/s Mylab Discovery Solutions Pvt. Ltd. Pune, as an authorized distributor partner of Serum Institute of India Pvt. Ltd. (SIIPL), Pune, India as on 06.07.2023.