

Guidance on Performance Evaluation of In-vitro Diagnostic Medical Devices

As per the proviso of Clause (h), Paragraph (ii), part II of Fourth Schedule of Medical Devices Rules 2017, where in, it is stated that

“In case of in-vitro diagnostic medical devices, performance evaluation report by the manufacturer shall be submitted by the applicant.

Provided that when the State Licensing Authority specifically requires for Class B or the Central Licence Authority for Class B, Class C and Class D in-vitro diagnostic medical devices, as the case may be, applicant shall submit the report issued by the central medical devices testing laboratory or a medical device testing laboratory registered under rule 83 or by any laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories or by any hospital accredited by National Accreditation Board for Hospitals and Healthcare Providers or by any Central Government or State Government Laboratory of any hospital or of any institute, specified by the concerned State Licensing Authority or the Central Licensing Authority”

In this regard, SLA/ CLA may require the Performance Evaluation Report for the following In-vitro Diagnostics from such laboratories, vide above proviso.

In-vitro Diagnostic Medical Devices intended for :-

1. HIV,
2. HBV,
3. HCV,
4. Blood Grouping reagent,
5. Blood glucose test reagent,
6. Cancer,
7. Tuberculosis,
8. Malaria,
9. Dengue,
10. Chikungunia,
11. Syphilis,
12. Typhoid,
13. Influenza,
14. ToRCH,
15. Chlamydia
16. Pneumonia,
17. Methicillin-Resistant Staphylococcus Aureus,
18. Enterovirus,
19. Marker for congenital disorder e.g. Screen test for Down's Syndrome
20. Sexually transmitted agent i.e. Treponema pallidum, Neisseria gonorrhoeae, Human Papilloma Virus, Herpes Virus
21. Other life threatening Infections / agent.

Guidance list of Laboratories to be considered for conducting Performance Evaluation of In-Vitro Diagnostics is as following

Sr. No.	Category of In vitro Diagnostics Medical Devices	Name of Testing facility
1.	In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus	1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
2.	In vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing	1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309 2) Indian Red Cross Society, 1, Red Cross Road, New Delhi
3.	Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent	1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
4.	Reagents/ Kits for detection of Cancer	1) Institute of Cytology and Preventive Oncology (ICPO), I-7, Sector - 39, Noida 201301 Uttar Pradesh, INDIA 2) Chittaranjan National Cancer Institute, 37, S.P.Mukherjee Road,Kolkata-700 026.INDIA 3) Tata Memorial Hospital, Dr. E Borges Road, Parel, Mumbai - 400 012 India 4) Tata Medical Center, 14 MAR (E-W), New Town, Rajarhat, Kolkata 700156 5) Medical College and Hospital (Department of Oncology/ Medical Oncology), 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073
5.	Reagents/ Kits for Detection of Tuberculosis (TB)	1) National Institute for Research in Tuberculosis, Mayor Sathiyamoorthy Road, Chetpet, Chennai - 600 031, INDIA 2) National Tuberculosis Institute 'AVALON' No.8, Bellary Road, Bangalore 560 003, India, 3) Dept. of Microbiology, The Postgraduate Institute of Medical Education and Research, Chandigarh, , Sector 12, Chandigarh, 160012 4) LRS Institute of TB and Respiratory Diseases, Sri Aurobindo Marg,Near Qutub Minar New Delhi- 110030

		5) National Jalma Institute of Leprosy and other mycobacterial diseases P.O BOX 101, Dr. M. Miyazaki Marg, Tajganj, Agra – 282001
		6) Shantabai Devarao Shivaram Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Diseases, Someshwara nagar 1st Main Road, Dharmaram College Post, Bangalore - 560 029
		7) Rajan Babu T.B. Hospital, Kingsway Camp, GTB Nagar, Delhi 110009
6.	Reagents/ Kits for Detection of Malaria	1) National Institute of Malaria Research (ICMR), Sector 8, Dwarka, Delhi-110077 (India)
		2) National Institute for Research in Tribble Health, Nagpur Road, Near NSCB Medical Cooled Jabalpur, Madhya Pradesh, 482003.
		3) National Institute of Cholera and Enteric Diseases, P-33, C.I.T. Road, Scheme XM, Belegkata, Kolkata 700 010
		4) All India Institute of Medical Sciences, Division of Clinical Microbiology & Molecular Medicine New Delhi-110029
		5) National Institute of Communicable Diseases (NICD) 22, Sham Nath Marg, New Delhi
7.	Reagents/ Kits for Detection of Dengue	1) National Centre for Disease Control 22, Sham Nath Marg, New Delhi-110 054, India
		2) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India
		3) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70
		4) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
		5) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004
8.	Reagents/ Kits for Detection of Chikungunya	Any Central Government or State Government Laboratory of any hospital or of any institute.
9.	Reagents/ Kits for Detection of Treponema pallidum (Syphilis)	1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309
		2) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004

10.	Reagents/ Kits for Detection of Typhoid	1) Dept. of Microbiology, The Postgraduate Institute of Medical Education and Research, Chandigarh, , Sector 12, Chandigarh, 160012
		2) Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Kolkata-700010
11.	Reagents/ Kits for Detection of Influenza	1) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70
		2) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India
		3) Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Kolkata-700010
12.	Reagents/ Kits for Detection of ToRCH	Any Central Government or State Government Laboratory of any hospital or of any institute
13.	Reagents/ Kits for Detection of markers for Congenital disorders	Any Central Government or State Government Laboratory of any hospital or of any institute
14.	Reagents/ Kits for Detection of sexually transmitted Disease	Any Central Government or State Government Laboratory of any hospital or of any institute
15.	Reagents/ Kits for Detection and typing of Human Papilloma Virus infection	Any Central Government or State Government Laboratory of any hospital or of any institute
16.	Reagents/ Kits for Detection of autoimmune disorders	Any Central Government or State Government Laboratory of any hospital or of any institute
17.	Reagents/ Kits for human Genetic testing	Any Central Government or State Government Laboratory of any hospital or of any institute

In case, the above specified Laboratories are not able to test or conduct the Performance Evaluation, It may be evaluated at any laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories or by any hospital accredited, by National Accreditation Board for Hospitals and Healthcare Providers etc. as per MDR-2017 Rules.
