

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. Cancer,
6. Tuberculosis,
7. Malaria,
8. Dengue,
9. Chikungunia,
10. Syphilis,
11. Typhoid,
12. Influenza,
13. ToRCH (Toxoplasma gondii, Rubella virus, Cytomegalovirus, Herpes simplex virus)
14. Chlamydia
15. Pneumonia,
16. Methicilline-Resistant Staphylococcus Aureus,
17. Enterovirus,
18. Marker for congenital disorder e.g. Screen test for Down's Syndrome
19. Sexually transmitted agent i.e. Treponema pallidum, Neisseria gonorrhoeae, Human Papilloma Virus, Herpes Virus
20. Other life threatening Infections / agent.

Revised 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 HIV | <ol style="list-style-type: none"> 1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309 2) ICMR-National AIDS Research Institute. (ICMR). 73, 'G'-Block MIDC Bhosari, Pune - 411026, Maharashtra , India 3) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India 4) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 5) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 6) ICMR- National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai, Maharashtra 400012 |
| 2. | In-Vitro Diagnostics for HBV | <ol style="list-style-type: none"> 1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309 2) ICMR-National AIDS Research Institute. (ICMR). 73, 'G'-Block MIDC Bhosari, Pune - 411026, Maharashtra , India 3) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India 4) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 5) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 6) ICMR- National Institute of Immunohaematology, 13th floor, New Multistoreyed Building, KEM Hospital Campus, Parel, Mumbai, Maharashtra 400012 |
| 3. | In-Vitro Diagnostics for HCV | <ol style="list-style-type: none"> 1) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309 2) ICMR-National AIDS Research Institute. (ICMR). 73, 'G'-Block MIDC Bhosari, Pune - 411026, Maharashtra , India 3) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India 4) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 5) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 6) ICMR- National Institute of Eipidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |

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| 4. | 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) ICMR- National Institute of Pathology, Sadarjang Hospital Campus, Ansari Nagar West, New Delhi, Delhi 110029 |
| | | 4) ICMR- National Institute of Immunohaematology, 13th floor, New Multistoreyed Building, KEM Hospital Campus, Parel, Mumbai, Maharashtra 400012 |
| | | 5) ICMR-Regional Medical Research Centre, N.E. Region, P.O.- Lahowal, Dibrugarh - 786 010 Assam, INDIA |
| 5. | Reagents/ Kits for detection of Cancer | 1) ICMR- Institute of Cytology and Preventive Oncology (ICPO), I-7, Sector - 39, Noida 201301 Uttar Pradesh, INDIA |
| | | 2) ICMR- National Institute of Pathology, ICMR- National Institute of Pathology, Sadarjang Hospital Campus, Ansari Nagar West, New Delhi, Delhi 110029 |
| | | 3) ICMR-Regional Medical Research Centre, N.E. Region, P.O.- Lahowal, Dibrugarh - 786 010 Assam, INDIA |
| | | 4) Medical College and Hospital (Department of Oncology/ Medical Oncology), 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073 |
| | | 5) Tata Memorial Hospital, Dr. E Borges Road, Parel, Mumbai - 400 012 India |
| | | 6) Tata Medical Center, 14 MAR (E-W), New Town, Rajarhat, Kolkata 700156 |
| 6. | Reagents/ Kits for Detection of Tuberculosis (TB) | 1) ICMR- National Institute for Research in Tuberculosis, Mayor Sathiyamoorthy Road, Chetpet, Chennai – 600 031, India |
| | | 2) ICMR- National Jalma Institute of Leprosy and other mycobacterial diseases P.O BOX 101, Dr. M. Miyazaki Marg, Tajganj, Agra – 282001 |
| | | 3) ICMR-Regional Medical Research Centre, NALCO Nagar, Chandrasekharpur, Bhubaneswar, Odisha 751023 |
| | | 4) National Institute of Tuberculosis & Respiratory Diseases, Sri Aurobindo Marg, Near Qutub Minar New Delhi- 110030 |
| | | 5) National Tuberculosis Institute, 8, Bellary Road, Bangalore 560 003, India, |
| | | 6) Rajan Babu T.B. Hospital, Kingsway Camp, GTB Nagar, Delhi 110009 |
| | | 7) Shantabai Devarao Shivaram Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Diseases, Someshwara Nagar 1st Main Road, Dharmaram College Post, Bangalore - 560 029 |
| | | 8) Dept. of Microbiology, The Postgraduate Institute of Medical Education and Research, Chandigarh, Sector 12, Chandigarh, 160012 |
| 7. | Reagents/ Kits for Detection of Malaria | 1) ICMR- National Institute of Malaria Research (NIMR), Sector 8, Dwarka, Delhi-110077 (India) |
| | | 2) ICMR- National Institute for Research in Tribal Health, Nagpur Road, Near NSCB Medical College Jabalpur, Madhya Pradesh, 482003. |
| | | 3) ICMR- Vector Control Research Centre, Medical Complex, VCRC Road, Indra Nagar, Priyadarshini Nagar, Puducherry, 605006 |
| | | 4) All India Institute of Medical Sciences, Division of Clinical Microbiology & Molecular Medicine, New Delhi-110029 |

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| 8. | Reagents/ Kits for Detection of Dengue | 1) ICMR- Vector Control Research Centre, Medical Complex, VCRC Road, Indra Nagar, Priyadarshini Nagar, Puducherry, 605006 |
| | | 2) ICMR- National Institute of Malaria Research (NIMR), Sector 8, Dwarka, Delhi-110077 (India) |
| | | 3) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309 |
| | | 4) National Institute of Cholera and Enteric Diseases, P- 33, C.I.T. Road, Scheme XM, Belehata, Kolkata 700010 |
| | | 5) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 |
| | | 6) King Institute, Guindy Flyover, Guindy Institutional Area, SIDCO Industrial Estate, Guindy, Chennai, Tamil Nadu 600032 |
| | | 7) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 |
| 9. | Reagents/ Kits for Detection of Chikungunya | 1) ICMR-National Institute for Research in Tribal Health, Nagpur Road, Near NSCB Medical College Jabalpur, Madhya Pradesh, 482003. |
| | | 2) ICMR- National Institute of Cholera and Enteric Diseases, P- 33, C.I.T. Road, Scheme XM, Belehata, Kolkata 700010 |
| | | 3) ICMR- Vector Control Research Centre, Medical Complex, VCRC Road, Indra Nagar, Priyadarshini Nagar, Puducherry, 605006 |
| | | 4) ICMR- National Institute of Malaria Research (NIMR), Sector 8, Dwarka, Delhi-110077 (India) |
| 10. | 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) ICMR-National AIDS Research Institute. (ICMR). 73, 'G'-Block MIDC Bhosari, Pune - 411026, Maharashtra, India (Including HIV, HBV, HCV & Syphilis in single kit) |
| | | 3) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India (Including HIV, HBV, HCV & Syphilis in single kit) |
| | | 4) ICMR- National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai, Maharashtra 400012 |
| | | 5) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| 11. | Reagents/ Kits for Detection of Typhoid | 1) ICMR-National Institute for Research in Tribal Health, Nagpur Road, Near NSCB Medical College Jabalpur, Madhya Pradesh, 482003. |
| | | 2) ICMR-National Institute of Cholera and Enteric Diseases, P- 33 C.I.T. Road, Kolkata-700010 |
| | | 3) Dept. of Microbiology, The Postgraduate Institute of Medical Education and Research, Chandigarh, Sector 12, Chandigarh, 160012 |

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| 12. | Reagents/ Kits for Detection of Influenza | 1) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| | | 2) ICMR-Regional Medical Research Centre, N.E. Region, P.O.- Lahowal, Dibrugarh - 786 010 Assam, INDIA |
| | | 2) Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Kolkata-700010 |
| | | 3) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 |
| | | 4) Sawai Man Singh Medical College, Jawahar Lal Nehru Marg, Gangawal Park, Adarsh Nagar, Jaipur, Rajasthan 302004 |
| 13. | Reagents/ Kits for Detection of Toxoplasma Gondii | 1) Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Kolkata-700010 |
| | | 2) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| 14. | Reagents/ Kits for Detection of Rubella Virus & Cytomegalovirus | 1) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| | | 2) ICMR- National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai, Maharashtra 400012 |
| | | 3) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| 15. | Reagents/ Kits for Detection of Pneumonia | 1) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| | | 2) ICMR-National Institute for Research in Tuberculosis, Mayor Sathiyamoorthy Road, Chetpet, Chennai – 600 031, India |
| 16. | Reagents/ Kits for Detection of Methicilline-Resistant Staphylococcus Aureus | 1) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| | | 2) ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Kolkata-700010 |
| | | 3) Dept. of microbiology All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar, Odisha 751019 |
| 17. | Regents/Kits for detection of Entero Virus (A/B) | 1) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| | | 2) ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Kolkata-700010 |
| 18. | Reagents/ Kits for Detection of markers for Congenital disorders | 1) ICMR- National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai, Maharashtra 400012 |
| | | 2) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| | | 3) Division of Genetics, Dept. of Paediatrics', All India Institute of Medical Sciences, New Delhi |
| | | 4) Division of Genetics, Dept. of Paediatrics', Maulana Azad Medical College, New Delhi |
| | | 5) Any Central Government or State Government Laboratory of any hospital or of any institute. |

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| 19. | Reagents/ Kits for Detection of Neisseria Gonorrhoeae | 1) ICMR- National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai, Maharashtra 400012 |
| | | 2) ICMR-Regional Medical Research Centre, NALCO Nagar, Chandrasekharapur, Bhubaneswar, Odisha 751023 |
| | | 3) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| 20. | Reagents/ Kits for Detection and typing of Human Papilloma Virus infection | 1) ICMR- National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| | | 2) ICMR- National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai, Maharashtra 400012 |
| | | 3) ICMR-National Institute of Epidemiology, R 127, 3rd Avenue, Second Main Road, Tamil Nadu Housing Board, Ayapakkam, Near Ambattur, Chennai, Tamil Nadu 600077 |
| 21. | Reagents/ Kits for Detection of autoimmune Disorders | Any Central Government or State Government Laboratory of any hospital or of any institute. |
| 22. | Reagents/ Kits for human Genetic testing | Any Central Government or State Government Laboratory of any hospital or of any institute. |

- **Seven ICMR institute included.**



Revised 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) National AIDS Research Institute. (ICMR). 73, 'G'-Block MIDC Bhosari, Pune - 411026, Maharashtra, India |
| | | 3) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| | | 4) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 |
| | | 5) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 |
| 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. | 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 |
| 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, 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) National Institute of Tuberculosis & 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) Rajan Babu T.B. Hospital, Kingsway Camp, GTB Nagar, Delhi 110009 |
| | | 7) Shantabai Devarao Shivaram Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Diseases, Someshwara nagar 1st Main Road, Dharmaram College Post, Bangalore - 560 029 |

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| | | 8) National Institute for Research in Tribble Health, Nagpur Road, Near NSCB Medical College Jabalpur, Madhya Pradesh, 482003. |
| 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 College Jabalpur, Madhya Pradesh, 482003. 3) All India Institute of Medical Sciences, Division of Clinical Microbiology & Molecular Medicine, New Delhi-110029 |
| 7. | Reagents/ Kits for Detection of Dengue | 1) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India 2) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 3) National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, Noida, Uttar Pradesh 201309 4) National Institute for Research in Tribble Health, Nagpur Road, Near NSCB Medical College Jabalpur, Madhya Pradesh, 482003. 5) National Institute of Cholera and Enteric Diseases, P- 33, C.I.T. Road, Scheme XM, Belehata, Kolkata 700010 6) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 |
| 8. | Reagents/ Kits for Detection of Chikungunya | 1) National Institute for Research in Tribble Health, Nagpur Road, Near NSCB Medical College Jabalpur, Madhya Pradesh, 482003. 2) National Institute of Cholera and Enteric Diseases, P- 33, C.I.T. Road, Scheme XM, Belehata, Kolkata 700010 3) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India |
| 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) Sawai Man Singh Medical College, Jawahar Lal Nehru Marg, Gangawal Park, Adarsh Nagar, Jaipur, Rajasthan 302004 3) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India 4) 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. |

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| 13. | Reagents/ Kits for Detection of markers for Congenital disorders | 1) Division of Genetics, Dept. of Paediatrics', Maulana Azad Medical College, New Delhi |
| | | 2) Division of Genetics, Dept. of Paediatrics', All India Institute of Medical Sciences, New Delhi |
| | | 3) 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. |

- 9 New testing lab details included.
- 3 testing lab details excluded.

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) National AIDS Research Institute. (ICMR). 73, 'G'-Block MIDC Bhosari, Pune - 411026, Maharashtra , India 3) National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 11 Pune 411001, India 4) Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004 5) Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70 |
| 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, |

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| | | 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 College 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. |

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| 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 |

Further the services of other laboratories 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. can also be availed subsequently as per MDR-2017 Rules.

