

No. IVD/Misc/133/DCGI/18
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Diagnostic Division)

FDA Bhawan, Kotla Road,
New Delhi-110002, Dated:- 29/10/2019

Sub:- Performance Evaluation of In-vitro Diagnostic Medical Devices, under the provision of Medical Devices Rules, 2017 – Regarding.

Sir/ Madam,


Ministry of Health & Family Welfare, Govt. of India has published New Medical Devices Rules-2017, vide. Notification No. G.S.R 78(E) dated 31st January, 2017 already implemented from 1st January, 2018. In exercise of power conferred by the section 12 and section 33 of the Drugs and Cosmetics Acts, 1940 (23 of 1940), the central government after consultation with Drugs Technical Advisory Board has issued Notification vide G.S.R. 729(E) dated 1st August 2018.

Further, as per the above proviso of Medical Devices Rules 2017, this Directorate has issued Guidance on Performance Evaluation of In-vitro Diagnostic Medical Devices and Reference list of Laboratories to be considered for conducting Performance Evaluation of In-Vitro Diagnostics (IVD) dated 07 Aug 2018 and further revised on 07 Aug 2019, published in the CDSCO website (www.cdsc.gov.in). In this regard, your esteemed laboratory has been included for testing/ evaluation of the specified In-vitro Diagnostic Medical Device mentioned in said guidance document. (Copy of Gazette notification and Guidance document enclosed).

In the public interest, your laboratory may test/ evaluate the In-vitro Diagnostic Medical Device (IVD) mentioned in the list. You are further requested to accept the samples and issue the Performance Evaluation Report (PER) for the purpose of grant of Manufacturing/ Import License as the applicant may approach to your facilities for testing as per Medical devices Rules 2017.

In case of any problem the provision under Medical devices Rules 2017 may be referred and your reply/ action taken in this regard may please be communicated to this office for further necessary action.

Yours faithfully,


(Dr. V. G. Somani)
Drugs Controller General (India)

Enclosures:-

1. Gazette notification G.S.R. 729(E) dated 1st August 2018.
2. Guidance on Performance Evaluation of In-vitro Diagnostic Medical Devices

To,

1. The Director, National AIDS Research Institute (NARI), 73, G-Block, MIDC, Bhosari, Pune-411026
2. The Director, National Institute of Virology, 20/ A, Dr. Ambedkar Road, Post Box No. 1117, Faridkot, Punjab-141001

3. The Director, Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu 632004.
4. The Director, Department of Clinical Virology, Institute of Liver & Biliary Sciences, D-1, Vasant Kunj New Delhi-70.
5. The Director, Indian Red Cross Society, 1, Red Cross Road, New Delhi-110001
6. The Director, Institute of Cytology and Preventive Oncology (ICPO), I-7, Sector - 39, Noida, Uttar Pradesh, INDIA, 201301.
7. The Director, Chittaranjan National Cancer Institute, 37, S.P. Mukherjee Road, Kolkata, INDIA, 700 026.
8. The Director, Tata Memorial Hospital, Dr. E Borges Road, Parel, Mumbai, India, 400 012.
9. The Director, Tata Medical Center, 14 MAR (E-W), New Town, Rajarhat, Kolkata, India 700156.
10. The Director, Medical College and Hospital (Department of Oncology/ Medical Oncology), 88, College St. Calcutta Medical College, College Square, Kolkata, West Bengal, 700073
11. The Director, National Institute for Research in Tuberculosis, Mayor Sathiyamoorthy Road, Chetpet, Chennai, India, 600 031.
12. The Director, National Tuberculosis Institute, 8, Bellary Road, Bangalore, India, 560003.
13. The Director, Dept. of Microbiology, The Postgraduate Institute of Medical Education and Research, Chandigarh, , Sector 12, Chandigarh, India 160012.
14. The Director, Institute of Tuberculosis and Respiratory Diseases, Sri Aurobindo Marg, Near Qutub Minar New Delhi, India-110030.
15. The Director, National Jalma Institute of Leprosy and other mycobacterial diseases P.O BOX 101, Dr. M. Miyazaki Marg, Tajganj, Agra, India – 282001.
16. The Director, Rajan Babu T.B. Hospital, Kingsway Camp, GTB Nagar, Delhi, India 110009.
17. The Director, Shantabai Devarao Shivaram Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Diseases, Someshwara nagar 1st Main Road, Dharmaram College Post, Bangalore, India - 560 029.
18. The Director, National Institute for Research in Tribal Health, Nagpur Road, Near NSCB Medical Cooled Jabalpur, Madhya Pradesh, 482003.
19. The Director, National Institute of Malaria Research (ICMR), Sector 8, Dwarka, Delhi- 110077 (India).
20. The Head of Department, Division of Clinical Microbiology & Molecular Medicine, All India Institute of Medical Sciences, New Delhi-110029.
21. The Director, Division Bacteriology, ICMR-National Institute of Cholera and Enteric Diseases, P-33 C.I.T. Road, Scheme XM, Belegata, Kolkata-700010.
22. The Director, National Institute of Communicable Diseases (NICD) 22, Sham Nath Marg, New Delhi, 110 054, India.
23. The Director, Sawai Man Singh Medical College, Jawahar Lal Nehru Marg, Gangawal Park, Adarsh Nagar, Jaipur, Rajasthan-302004
24. The Head of Dept., Division of Genetics, Dept. of Paediatrics', Maulana Azad Medical College, Balmiki Basti, New Delhi, 110002.
25. The Head of Dept., Division of Genetics, Dept. of Paediatrics', All India Institute of Medical Sciences, New Delhi.

Copy to:- CDSCO website.

परीक्षण और अंशशोधन प्रयोगशालाओं के लिए राष्ट्रीय प्रत्यायन बोर्ड द्वारा प्रत्यायित किसी भी प्रयोगशाला द्वारा अथवा अस्पताल और स्वास्थ्य परिचर्या प्रदाताओं के लिए राष्ट्रीय प्रत्यायन बोर्ड द्वारा प्रत्यायित किसी अस्पताल द्वारा अथवा संबंधित राज्य अनुज्ञापन प्राधिकारी अथवा केन्द्रीय अनुज्ञापन प्राधिकारी द्वारा विनिर्दिष्ट किसी अस्पताल या किसी संस्थान की केन्द्रीय सरकार या किसी राज्य सरकार की प्रयोगशाला द्वारा जारी रिपोर्ट प्रस्तुत करेगा।

[फा. सं. एक्स-11014/5/2018-डीआर]

सुधीर कुमार, संयुक्त सचिव

टिप्पणी : मूल नियम अधिसूचना संख्या सा.का.नि. 78 (अ), तारीख 31 जनवरी, 2017 द्वारा भारत के राजपत्र में प्रकाशित किए गए थे।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st August, 2018

G.S.R. 729(E).—Whereas a draft of certain rules to amend the Medical Device Rules, 2017 was published as required under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R 412(E) dated 27.04.2018 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) by the Central Government, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which copies of the said Official Gazette containing the said notification were made available to the public;

And whereas, copies of the Official Gazette containing the said notification were made available to the public on the 27th April, 2018:

And whereas, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely:-

1. (1) These rules may be called the Medical Devices (Amendment) Rules, 2018.
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Medical Devices Rules, 2017, in the Fourth Schedule, in Part II, in paragraph (ii), for clause (h), the following clause shall be substituted, namely:-

“(h) 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.”

[F. No. X.11014/5/2018-DR]

SUDHIR KUMAR, Jt. Secy.

Note : The principal rules were published in the Gazette of India *vide* notification number G.S.R 78(E), dated the 31st January, 2017.

Dated 07 Aug 2019

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.	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, 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
		8) National Institute for Research in Tribal Health, Nagpur Road, Near NSCB Medical Cooled 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 Cooled 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 Cooled Jabalpur, Madhya Pradesh, 482003.
		5) National Institute of Cholera and Enteric Diseases, P- 33, C.I.T. Road, Scheme XM, Belegghata, 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 Cooled Jabalpur, Madhya Pradesh, 482003.
		2) National Institute of Cholera and Enteric Diseases, P- 33, C.I.T. Road, Scheme XM, Belegghata, 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.

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.

