No. IVD/Clarification/247/19
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,
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Circular

Subject: External Performance evaluation of IVD's under MDR – further guidance

With reference to subject cited above, it is clarified that as per the Guidance on Performance Evaluation, SLA / CLA may require the Performance Evaluation Report from the external lab for three batches for the purpose of grant of Import/ Manufacturing license only for the following In-vitro Diagnostics;

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. Syphlis, 11. Typhoid, 12. Influenza, 13. ToRCH (Toxoplasma gondii, Rubella virus, Cytomegalovirus, Herpes simplex virus) 14. Chlamydia 15. Pneumonia, 16. Methioilline-Resistant Staphylococcus Aureus, 17. Entero virus. 18. Marker for congenital disorder e.g. Screen test for Down's Syndrome 19. Sexually transmitted agent i.e. Treponema pallidurn, Neisseria gonorrhoeae, Human Paoliloma Virus, Herpes Virus 20. Other life threatening Infections / agent.

In case of In-vitro Diagnostics mentioned at s.no 13 to 20 which are licensed and available in the Indian market for long time and manufactured in lesser number of batches per year, SLA / CLA may initially require the Performance Evaluation Report from the external lab for one batch for the purpose of grant of license, however, the subsequent two consecutive batches satisfactory PER shall be submitted by the manufacturer to the concerned authority as an when it is manufactured.

Further, with respect to the question that, where performance evaluation by External lab can be carried out for the consideration of grant of license for IVDs specified above, it is to clarify that it may be carried out at place as per the rule and it is generally expected that testing is performed at laboratory indicated in the guidance document on PER and If there is any problems including inability of lab or longer testing time etc., other options for testing like any Central Government or State Government Laboratory of any hospital or of any institute laboratory accredited by NABL or by any hospital accredited by NABH are also available as provided in the Medical Device Rules.

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