A.19-102/2016/NIB
NATIONAL INSTITUTE OF BIOLOGICALS
(MINISTRY OF HEALTH & FAMILY WELFARE)
NOIDA, U.P.
******

Dated: 09-08-2019

OFFICE ORDER: 82/2019-20

Sub: Turnaround Time (TAT) for reporting the results of test or analysis of samples received at NIB - Reg.

It has been decided by the Competent Authority that the Turnaround Time (TAT) for reporting the results of test or analysis of samples received at NIB is as below:

1. The samples received by Government Analyst as per the rule 45 of Drugs and Cosmetics shall be reported within a period of **sixty days** of the receipt of the sample. Provided that where it is not possible to test or analyze the sample within the specified period, the Government Analyst shall seek the extension of time from the Government giving specific reasons for delay in such testing or analysis as specified in rule 45 of Drugs and Cosmetics Rules.

2. The TAT for reporting the results of test or analysis of biological samples other than the samples of drugs mentioned in clause 1 is **42 days** except for the following:

   2.1 The biological samples requiring cell culture based in-vitro testing, the TAT is **60 days**.

   2.2 The biological samples requiring animal based testing (except for abnormal toxicity and pyrogen test, virus inactivation), the TAT is **90-120 days** depending upon the type of biological sample and testing involved e.g. potency & identity.

3. The manufacturer or the importer need to submit all the requirements for the test or analysis e.g. manufacturer's equipment in case of diagnostics, specific cell lines, reagents, controls or reference standards etc.at NIB to initiate the test or analysis depending upon the type of biological sample and testing involved. This date of submission shall be considered as day **ZERO** for calculation of TAT. In case of samples involving manufacturer's equipment for test or analysis at NIB e.g. diagnostic kits, the TAT is applicable only when there is an uninterrupted functioning of the equipment.

4. In case where it is not possible to test or analyze the sample within the specified period mentioned in 2., Head of respective product testing laboratory shall seek the extension of time from the Director NIB giving specific reasons for delay in such testing or analysis.

5. The Sample Receipt & Report Dispatch Unit (SRRDU) will ensure that the manufacturer/ importer submit testing fee to NIB within the TAT as applicable for the type of sample and the test involved. The test report will be released by SRRDU only after the receipt of testing fee except for the samples received from the Central / State Government medical procurement agencies.

All the Laboratories are directed to adhere to the above Turnaround Time:

This issues with the approval of the competent Authority.

(J. P. Pant)
Section Officer

To,

1. All Heads of Labs/ Administration / Finance/ Procurement/ IT / Engineering
2. DDQC I/c (Diagnostic & Vaccine)
3. DDQC I/c (RPL, CDKL & AF)
4. Quality Manager, NIB
5. Head SRRDU
9. PS to Director NIB