No. IVD/Misc/115/18
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Diagnostics Division)

FDA Bhawan, Kotla Road,
New Delhi, Dated 17 OCT 2019

To,

All State Drugs Controller
All Zonal/ Sub Zonal/ Port Offices of CDSCO

Sub: - Expansion of Testing of IVDs (In vitro Diagnostics) for Clinical Chemistry Reagents/Kits at NIB, Noida under the provision of the Medical Device Rules 2017 - reg.

Sir,

Please find the enclosed copy of letter no. 1/Dir.off/2018/NIB/1478 dated 24.08.2018 received from National Institute of Biological, Noida, on the above mentioned subject, which is self explanatory.

In this connection, you are requested to forward sample of Clinical Chemistry Reagents/Kits mentioned in NIB letter no. 1/Dir.off/2018/NIB/1478 dated 24.08.2018 to the Biochemistry kit laboratory of NIB, Noida for validation of various quality Control parameters followed by their Quality Evaluation and testing for issuing Certificate of Analysis as an ongoing activity.

Yours faithfully,

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

Enclosure:-

1. NIB letter no. 1/Dir.off/2018/NIB/1478 dated 24.08.2018

Copy to:-

1. The Director, National Institute of Biological, A-32, Sector-62 (Industrial Area), Noida.
2. CDSCO website.
3. O/o DCGI secretariat.

राष्ट्रीय जैविक संस्थान
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare, Government of India

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Sr. no - 3

No.1/Dir.off/2018/NIB/1478

Dated : 24.08.2018

10 36163/DCG(I)/2018/10

To

Drugs Controller General (India)
CDSCO
FDA Bhavan, ITO, Kotla Road,
New Delhi-110002

Subject: **Expansion of Testing of *IVDs (In Vitro Diagnostics)* at NIB under the Provisions of sub-rule (2) rule 4 of the Medical Devices Rules 2017.**

Sir,

It may please be stated that National Institute of Biologicals was notified as CDL wide notification G.S.R.908 (E) dated 22nd Dec'2014 for the following six IVDs:

(i) Diagnostics Kits for Human Immunodeficiency Virus
(ii) Hepatitis B Surface Antigen
(iii) Hepatitis C Virus
(iv) Blood grouping reagents
(v) Glucose Test Strips Fully Automated Analyser Based Glucose Reagents

[All the notified products in this category are being tested regularly in this laboratory]

Biochemical Kit testing Laboratory started functioning at NIB since 2004 after receiving instruction from the office of DCG(I) and finally notified as CDL for two products i.e. Glucose Test Strips and Fully Automated Analyser Based Glucose Reagents.

Under new Medical Devices Rules 2017 (which is effective from 1st January'2018), **247** *In Vitro Diagnostics (IVDs)* under provisions of sub-rule (2) rule 4 of the Medical Devices Rules 2017 have been notified. NIB proposes to expand the Biochemical Kit Laboratory activity by taking up the QC testing of the following products from the list of 42 newly notified Clinical Chemistry Reagents /Kits :

S.No.	Name of the Test reagents/kits	S.No	Name of the Test reagents/kits
1.	Albumin	10.	Potassium
2.	Bicarbonate/ Carbon dioxide	11.	Aspartate Amino Transferase (AST/SGOT)
3.	Bilirubin (total and direct)	12.	Alanine Amino Transferase (ALT/SGPT)
4	Calcium	13.	Sodium
5.	Cholesterol (total)	14	Total Protein
6.	HDL Cholesterol	15.	Triglycerides
7.	LDL Cholesterol	16	Urea (BUN)
8.	Creatinine	17.	Uric Acid
9.	Glycosylated Hemoglobin		

In view of above, if you kindly concur with the NIB's proposal you may take necessary steps so that Clinical Chemistry Reagents/Kits as proposed above are sent to the Biochemical Kit Laboratory of NIB for validation of various Quality Control parameters followed by their Quality Evaluation and testing for issuing Certificate of Analysis as an ongoing activity.

Yours sincerely,

(Dr. Surinder Singh)
Director

Copy to:

Joint Secretary (R), Ministry of Health & Family Welfare, Govt. of India, Nirman Bhawan, New Delhi

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 22nd December, 2014

G.S.R. 908 (E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with section 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. 312(E), dated the 5th May, 2014, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 5th May, 2014, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 12th May, 2014;

And whereas, no objections and suggestions were received from the public on the said rules;

Now, therefore, in exercise of the powers conferred under section 12 read with 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 further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (7th Amendment) Rules, 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in rule 3A, for sub-rule (8), the following sub-rule shall be substituted, namely:—

"(8) (a) The functions of the Laboratory in respect of the following kits or class of drugs shall be carried out at the National Institute of Biologicals, Noida and the functions of the Director in respect of the said drugs or class of drugs shall be exercised by the Director of the said institute.

(b) The kits or class of drugs referred to in clause (a) are-

(1) Blood grouping reagents.
(2) Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus.
(3) Blood products-
  (a) Human Albumin;
  (b) Human Normal Immunoglobulin (intramuscular and intravenous);
  (c) Human Coagulation Factor VIII;
  (d) Human Coagulation Factor IX;
  (e) Plasma Protein Fractionation;
  (f) Fibrin Sealant Kit;
  (g) Anti Inhibitor Coagulation complex.
(4) Recombinant products such as-
  (a) Recombinant Insulin and Insulin analogues;
  (b) r-erythropoietin (EPO);
  (c) r-Granulocyte Colony Stimulating Factor (G-CSF).
(5) Biochemical kits-
  (a) Glucose Test Strips;
  (b) Fully automated analyser based glucose reagents.".

[F. No. A.11018/6/2011-DFQC]

K. L. SHARMA, Jt. Secy.

Note.—The principal rules were published in the Gazette of India, vide notification No. F.28-10/45-H (1) dated the 21st December, 1945 and last amended vide notification number G.S.R. (E), dated the 12th December, 2014

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