F.No.CDSCO/IC/2020/(Bione) Ministry of Health and Family Welfare Directorate General of Health Services Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi Dated: 05.04.2020

Public Notice

It has come to the notice that M/s Bione Ventures Private Limited, Bengaluru is offering for sale Rapid single use finger-prick test for CORONAVIRUS which will give result in 5-10 minutes. The product is also widely publicised in the media.

In this regards it is hereby informed that CDSCO, the competent authority for the approval and issuance of license for import/ manufacturer for marketing of Corona virus diagnostic kit has not licensed the aforesaid diagnostic kit by M/s Bione Ventures Private Limited, Bengaluru.

All are advised to follow the guidance issued by ICMR dated 04.04.2020 regarding the use of Rapid Antibody based Blood test for Corona virus.

This is issued in public interest.

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

Copy to:

- 1. All the State/UT Drugs Controllers for necessary action.
- 2. All Stakeholders through CDSCO website.
- 3. PPS to JS(R), MoHFW for information