

F.No. IVD/Misc/097/2021
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 29 APR 2021

To,

1. The Association of Diagnostics Manufacturers of India (ADMI)
2. Association of Indian Medical Device Industry (AIMED)
3. Confederation of Indian Industry (CII)
4. Federation of Indian Chambers of Commerce & Industry (FICCI)

Subject: Supply of essential In-Vitro Diagnostic testing reagents/kits for inflammatory markers such as IL-6 (Interleukin 6), D-Dimer and C-reactive protein (CRP) - Regarding.

Sir / Madam,

As you are aware that the import and manufacturing of In-vitro diagnostics reagents/ kits are regulated under the provisions of the Drugs and Cosmetics Act and Medical Devices Rules-2017, thereunder.

Under the COVID-19 pandemic situation, the patients who are COVID-19 positive may require testing for inflammatory markers such as IL-6, D-Dimer and CRP. The results of these important tests directly dictate the management of COVID-19 patients by the physicians to take further timely decisions.

In order to ensure the availability of these reagents/kits in diagnostic laboratories in the country, it is requested that all the manufacturers /importers to increase manufacturing/import of these reagents/kits to maximum capacity and at fast pace in light of increasing cases of COVID-19 positive cases.

Further it is requested to submit the information of these reagents/kits in the proforma enclosed.

Yours faithfully,



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

Copy to :-

- PS to DGHS
- PS to JS (R)
- To upload in website of CDSCO

Proforma

Sr. No.	Name of reagents/kits	Name of the Importer/ Manufacturer	Current Stock	Capacity to manufacture/ import	Proposed capacity
1.	IL-6				
2.	D-Dimer				
3.	CRP				