

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH**

**LOK SABHA
UNSTARRED QUESTION NO. 2267
TO BE ANSWERED ON 23RD SEPTEMBER, 2020**

RT-PCR KITS

2267. SHRIMATI MALA ROY:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether Indian companies are currently manufacturing RTPCR kits;
- (b) if so, the details thereof;
- (c) the percentage of kits that are indigenously manufactured and the percentage of kits being imported; and
- (d) the number of tests per day that can be done using the said kits?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) & (b) The Central Drugs Standard Control Organisation (CDSCO) has informed that it has granted manufacturing licenses to manufacture COVID RTPCR kits to various indigenous companies under Medical Device Rules 2017. A statement containing the details of the indigenous manufacturer for COVID RTPCR kits is laid on the Table of the House is annexed.

(c) CDSCO has informed that it has granted manufacturing licenses for COVID RTPCR kits to 30 companies while Import licenses have been granted to 119 companies.

As per the online survey conducted by ICMR to know the manufacturing capacity of the Indian manufacturers for RT-PCR combo kits, it is learnt that Indian manufacturers have capacity to manufacture around 348.1 lakh test per month of RT-PCR tests based on combo kit in the country. During the month of March to June 2020 around 60% RT-PCR kits procured were from foreign manufacturers and remaining 40% were from Indian manufacturers. However, currently, 100% procurement of RT-PCR combo kits is from Indian manufacturers whereas, the COBAS, CBNAAT etc. kits are still being imported.

(d) ICMR has informed that based on the current manufacturing capacity of the Indian manufacturer around 11.35 Lakh RTPCR tests based on combo kit can be conducted per day in the country.

1. M/s Mylab, Pune
2. M/S Molbio Diag. Pvt Ltd Goa
3. M/S Kilpest India Ltd , Bhopal
4. M/s Medsource Ozone Biomedicals Pvt.Ltd.
5. M/s Cosara Diagnostics Pvt. Ltd. Ahmedabad
6. M/S Huwel Lifesciences Pvt Ltd, Telangana
7. M/S Helini Biomolecules
8. M/S Meril Diagnostics Pvt Ltd
9. M/s Lab care Diagnostics, India Pvt. Ltd
10. M/S BioGenomics Ltd
11. M/S POCT Services Pvt Ltd
12. M/S Angstrom Biotech Pvt Ltd
13. M/S GCC Biotech India Pvt Ltd
14. M/S Oscar Medicare Pvt Ltd
15. M/S Gene Store India Pvt Ltd
16. M/S Trivitron Healthcare Pvt Ltd
17. M/S Genes2Me Pvt Ltd
18. M/S Karwa Enterprises Pvt Ltd
19. M/S Medipol Pharmaceutical India Pvt Ltd
20. M/S Wrig Nanosystems Pvt Ltd
21. M/S Aspen Laboratories Pvt Ltd
22. M/S Bhatt Biotech India PVT Ltd
23. M/S Mylab Discovery Solutions PVT Ltd
24. M/S Achira Labs Pvt Ltd
25. M/s Nucleus Diagnosys
26. M/S Ubio Biotechnology System Pvt Ltd
27. M/S Affigenix Biosolutions Pvt Ltd
28. M/s Biosystems Diag. Pvt Ltd
29. M/s Tata Medical and Diagnostic Ltd
30. M/s Athenes Dx Pvt Ltd