Technical paper

COVID 19

SAMPLING – LABORATORIES – TESTING MANAGEMENT

Department of Health & Family Welfare

Government of Kerala

SAMPLING – LABORATORIES - TESTING MANAGEMENT

Steps taken to ensure reporting of results within practically possible timeframe and to avoid any undue delays in the whole process of sample management

1) CAPACITY BUILDING OF LABORATORIES

Capacity building of Labs improved the daily testing capacity so that currently 8 Labs in the state can handle processing and reporting of 1000 samples within 24 hours and 11 other labs can manage around 500 samples in a day . The same has been achieved by providing High End Automated RNA Extraction Machines, Additional technical staff and Data Entry Operators so that labs are fully equipped to function for 24x7. The labs with a testing capacity of ≥1000 are evenly distributed throughout the State. This provided a chance for most Districts to process required number of samples using RT-PCR technique in the nearest lab which reduced the sample transportation time and hence delay in the generation of final results.

Sl.No.	Name of the Laboratories with a testing capacity ≥ 1000	Daily Capacity
1.	NIV, Alappuzha	1000
2.	Govt. Medical College, Trivandrum	1000
3.	Govt.Medical College, Kozhikode	1200
4.	State Public Health Lab, Trivandrum	1000
5.	Rajiv Gandhi Centre for Biotechnology, Kazhakootam	1000
6.	IUCBR & SSH Kottyam	1000
7.	Govt. Medical College, Manjeri	1000
8.	Malabar Cancer Centre, Kannur	1000

2) SAMPLE WAY

The District Sample Management Teams were given guidance for the establishment of a "Sample way" for the collection and transportation of samples to the designated lab within minimum acceptable time. The system includes Walk-In-Sample Collection Kiosks, Collection Centres at designated COVID Out Patient Departments and Mobile sample collection and transportation team which follows a prefixed road route and timings. This has made the process more organised, convenient and time saving which reduced the turnover time of samples from collection to final result.

3) TESTING STRATEGY

Sate has refined the Testing Strategy in such a way that all ICMR recommended categories and high risk and vulnerable population get tested using RT-PCR technique and results are generated within 24 hours. For the same, State has made a shift from the policy of using RT-PCR technique to Rapid-Point-of-care Antigen tests for testing asymptomatic persons belonging to high exposure groups, clusters and containment zones but without compromising quality of care, support and follow up given to each individual tested.

4) STATE HEALTH MONITORING PORTAL FOR DATA MANAGEMENT

Another main factor which contributed to the delay in the reporting of results was the technical issues related to data feeding in ICMR portal and multiple data submission to State and District authorities. In this context State has developed an API with ICMR for the consensual transfer of Data. This has completely revised the lab data management system in the State so that data entry of each sample is shared between Field and Laboratory which avoided the single-handed data entry done at most laboratories. The system also provides a unique feature for real time visualisation of final results for the concerned officials in the District and State level and Superintendents of the COVID Hospitals which fast track the result dissemination to the periphery.

Steps involved and time required for each sample tested using RT-PCR open system

RT-PCR being the gold standard test, involves a series of meticulous and time-consuming steps from the point of sample collection to final result generation which should be considered while waiting for the final result.

Sample Collection and Transportation

Nasopharyngeal/oropharyngeal swab will be collected, labelled and properly packed(Triple layer packing) in thermocol boxes at the designated collection centres in the district. Field data will be entered in the State portal. All such samples collected at a particular collection centre till a particular time will be transported to the designated lab as a single lot along with Sample Referral Form containing SRF ID.

Steps in the laboratory

Step- 1: Sample quality check

Sorting of samples and SRF, checking the quality and adequacy of VTM, Labelling of samples for further processing- Takes about 3 minutes for each sample. This is done inside Biosafety cabinet and takes atleast 3 minutes for each sample. Most of the PCR machines process around 96 samples in a single run. Hence for a single run 96 samples need to be sorted, thus the time taken will be 96x3= 288 minutes, ie about 5 hours.

Step 2: RNA Extraction

Most time-consuming technical procedure which takes around 4-6 hours if done manually, But with Automated Extraction machine 96 samples can be processed in 2 hours.

Step 3:PCR

Running the samples in PCR machine; takes about 2-3 hours. Maximum capacity of the PCR machine in a single run is around 96 samples/ run.

In case of indeterminate results after PCR run, the whole procedure in Step 2 and Step 3 need to be repeated.

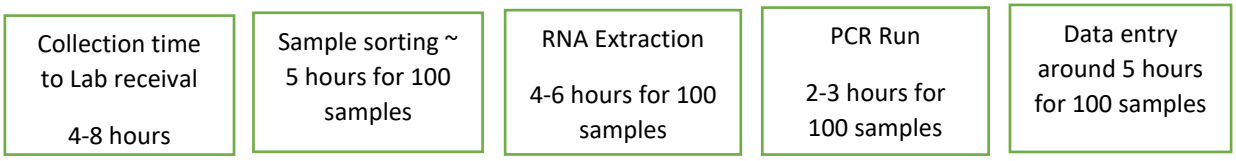
Thus it takes a minimum of 10 – 14 hours, to generate definite results (positive /negative) of 100 samples and if the results turn indeterminate, then in such cases it takes 20-24 hours to generate the final results.

Step 4: Data entry

Decoding the sample ID and data entry in State portal. This can take at least 3 minutes for each sample. I.e., To complete data entry of 100 samples around 5 hours will be needed.

Thus, the turnover time in the laboratory will be 20 hours for samples which got a definite result and 28 hours for a sample which got indeterminate or invalid result in the first run.

In addition, sample transportation (from the time of collection to receival of sample at lab) also shall be considered. Considering a range of 4 hours to 8 hours, total turnaround time will be 24- 28 hours and in case of indeterminate result it will be 32- 46 hours



Situation 1: Lab is located in the same district and is working for 24 hours including Data Entry Operator and received 100 samples

Sample collected at 9 am (Day 0) at periphery of Trivandrum-

Collected by mobile team at 2 pm-

Reaches lab (GMC, Trivandrum) by around 3pm(day 0)

All samples(say 100 samples) will be sorted and labelled by 8 pm (day0)

RNA extraction of 100 samples will be completed by 2 am (day 1)

PCR run will be completed by 5 am (day 1).

Data entry will be completed by 9 am(day 1)

If automated extraction is used the final data can be entered by 5 am in the morning

If result turns indeterminate- 2nd round of extraction will be completed by 11 am and PCR run by 2 pm and data entry of final result will be completed by 6 pm

Situation 2:Lab is located in other district and is working for 24 hours including Data Entry Operators and received 100 samples

-Sample collected at 9 am(day 0) at periphery of Palakkad-

-Collected by mobile team at 2 pm(day 0)-

-Reaches lab (NIV Alappuzha) by around 8 pm(day 0)

-All samples (say 100 samples) will be sorted and labelled by 3 am (day 1)- RNA extraction of 100 samples will be completed by 9 am (day 1)in the morning

- PCR run will be completed by 12 pm (day 1)

- Data entry will be completed by 5 pm (day 1)

-If automated extraction is used the final data can be entered by 1 pm (day 1)

-If result turns indeterminate- 2nd round of extraction will be completed by 6 pm (day 1) and PCR run by 8 pm (day 1) and data entry of final result will be completed by 2 am(day 2)

Discussion

For any new infection the previous infected person is responsible and it can be prevented only by 'breaking the chain' by the person who got infected and the persons who may come in contact with the infected person. This needs a firm resolve by people to bring in behaviour change and take all precautionary measures. People are requested to take all necessary precautions of social distancing of at least 2 meters, wearing mask properly, washing hands frequently, avoid interactions and travel, protect elderly – 'reverse quarantine' and do not neglect even mild symptoms and immediately access health care from Hospitals so as to prevent the infection spread.

The Department of Health and Family Welfare has been taking earnest efforts to ramp up the testing facilities by building capacities of the doctors and technical staff required in the Laboratories, building required Laboratory infrastructure and providing all the facilitatory support. The sample collection, transportation and testing are further facilitated by the District Collectors, District Medical Officers, District Surveillance Officers and the field functionaries. With the hundreds of private laboratories getting approved, the efficiency in testing will go up. At field level very innovative approaches of WISK, Sample route, mobile units to collect the samples etc have been taken. The teams at the field and laboratories are working nonstop from February onward. Out of around 9 lakh samples tested there may be few hundred cases where the results got delayed. If one studies the work load, one will realize the complex activities of planning samples, sample route, doing preparation, going to field by taking all precautionary measures, collecting samples, proper packing, filling of forms and despatch. After reaching to the laboratory unpack, match the SRF and sample and do all the technical processes informed in the paper to complete the test and put up the result and disseminate. In this process there is every possibility of human error. Sometimes forms and samples go to different places, sometimes samples are spilled over. Some of the samples are indeterminate therefore need a fresh sample. These are reasons for the delays for some of the samples. In spite of hectic activities, the Department is taking earnest efforts to study the outliers and take the system performance to the next level.