



#### **GOVERNMENT OF KERALA**

#### **Abstract**

Health & Family Welfare Department – COVID-19 Instructions for using GeneXpert / TrueNAT-beta- CoV in the private sector in Kerala - Revised guidelines for Truenat testing for COVID-19 - Modified Orders Issued.

# HEALTH AND FAMILY WELFARE (M) DEPARTMENT

G.O.(Rt)No.939/2020/H&FWD Dated, Thiruvananthapuram, 26/05/2020

Read: 1) G.O.(Rt) No. 726/2020/H&FWD dated 16/04/2020.

2) Revised guidelines issued by the ICMR for TrueNAT testing for COVID-19 dated 19/05/2020.

#### **ORDER**

As per the Government Order read as above, instructions were issued for testing COVID-19 using GeneXpert / TrueNAT-beta-CoV in the private sector in Kerala. ICMR vide Reference 1 has stated that biosafety and biosecurity requirements for use of TrueNAT machines are minimal, as the sample is collected in viral lysis buffer. ICMR advisory also stated that the TrueNAT system is now a comprehensive two step assay. Step I is E gene screening assay that is to be followed by step 2 that is a RdRp gene confirmatory for all samples that are tested as positive by E gene assay'.

- 2) In the above circumstance, Government are pleased to modify the Government Order read above as follows.
- I) Clause 2 under the heading 'DESIGNATED TESTING FACILITY for doing TrueNAT/ GeneXpert tests ' is replaced as 'Private labs who would like to use TrueNAT system may contact NABL (venkat@nabl.qcin.org or ceo@nabl.qcin.org) for accreditation for this test. Test shall be performed in laboratories with NABL

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### accreditation for TrueNAT test.'

II) Clause 4 under the heading 'DESIGNATED TESTING FACILITY for doing TrueNAT/ GeneXpert tests' is replaced as 'For all positive tests obtained in assay with E gene in TrueNAT, laboratory need to perform confirmatory assay using RdRp gene in TrueNAT or any other confirmatory RTPCR test. If that is positive, the test may be declared as positive. It is the responsibility of the laboratory to perform confirmatory test and report the results. Laboratories must ensure confirmation of tests in case of positive results in Step 1 assey of TrueNAT- beta -CoV.'

III) The following is included as last paragraph under the heading 'RATE OF TEST' as

'ICMR has fixed maximum cost of RTPCR test as Rs. 4500/- and of a Screening test as Rs. 1500/-. Hence, the maximum cost of Step I TrueNAT assay will be Rs. 1500/- and of Step II confirmatory assay will be Rs. 3000/-.'

3) The Government Order read above is modified to the above extent.

(By order of the Governor)
RAJAN NAMDEV KHOBRAGADE
PRINCIPAL SECRETARY

To

The Director of Medical Education, Thiruvananthapuram.

The Director of Health Services Thiruvananthapuram

All District Collectors

All District Medical Officers (through DHS)

The Director, IT Mission

The Managing Director, KMSCL, Thiruvananthapuram

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The Drugs Controller, Thiruvananthapuram
Information and Public Relations (Web & New Media) Department.
Stock File/Office Copy.

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Section Officer

### Copy to:

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PS to Minister Health & Social Justice

Special Secretary to Chief Secretary

PA to Additional Chief Secretary Home & Vigilance

PA to Principal Secretary Planning and Economic Affairs

PA to Principal Secretary Health &Family Welfare

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