Health Technology Review	
Technology Ref.:	HTA22045
Technology Name:	Tata MD Check RT-PCR Fast 3Gene
Approvals by International Bodies:	CE Certified by European Authorized Representative-
Company name:	Tata Medical and Diagnostics Limited,
Agent in UAE:	Manoj V Menon
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Short Description of the Technology:	Tata MD CHECK RT-PCR Fast 3Gene kit is an in-vitro Real time RT-PCR qualitative testing system for the specific detection of SARS-CoV-2 in human respiratory (NP/OP) specimens post RNA extraction. The kit can be used with extracted RNA from specimen collected in compatible transport media. The assay has a ~40 mins fast amplification protocol that is reliable and accurate, and enables quick turnaround time of results

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Tata MD CHECK RT-PCR Fast 3Gene kit uses an in-vitro Real time RT-PCR qualitative assay for the specific detection of SARS-CoV-2 in human respiratory (NP/OP) specimens– it is a multiplex assay kit where four genes (three SARS-CoV-2 and one human internal control) can be detected in a single tube reaction. The Tata MD CHECK RT-PCR Fast 3Gene primer and probe sets are designed for the detection of E-gene, N-gene and RdRP-gene of SARS-CoV-2 along with human internal control RNase P in a single tube assay. The kit is designed for an easy and quick workflow. It is compatible with all Real-Time PCR instruments equipped with minimum of four measurement channels (FAM, HEX/VIC, Texas Red/ROX and CY5).

The test kit has been validated in National Reference Lab for 90 samples and achieved the results with Sensitivity 100 % & Specificity 100%.

Another validation test in October 26, 2022 has been conducted in Union 71 for the purpose of including more samples with high CT value and low viral load, the results for 50 samples was Sensitivity 100 % & Specificity 100%.

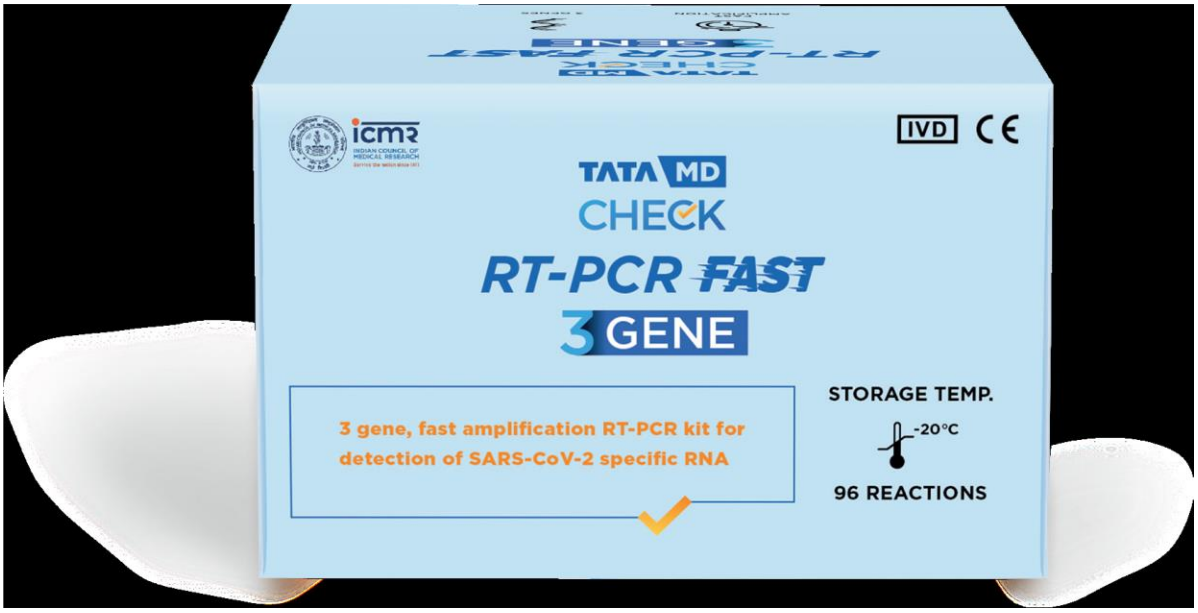
Advantages	Disadvantages
CE marked Test	For professional use only
High Performance (100% sensitivity, 100% specificity)	Exclusion of negative results will be completely dependent on type of infection (acute and chronic), and on appropriate specimen collection time and absence of inhibitors
40 minutes fast amplification	
No risk to healthcare professional	

We recommend an **approval of using this technology** with the following conditions:

1. Using Tata MD Check RT-PCR Fast 3Gene for covid 19 testing at authorized covid19 laboratories.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Use of the product is initially limited under the supervision of authorized COVID-19 laboratory.
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology "Tata MD Check RT-PCR Fast 3Gene"

- **Population/ Intended User**;
  - Using Tata MD Check RT-PCR Fast 3Gene for covid 19 testing.
- **To be performed by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - As per the manufacturer instruction
- **Exclusion criteria:**
  - Other conflicting medical issues