872

collector's email 19/1/2021

कार्यालय महानिदेशक, चिकित्सा शिक्षा एवं प्रशिक्षण, उत्तर प्रदेश

संख्याः–एम0ई0 / पर्चेज / कोविड–19 / लखनऊः दिनांकः 19 जनवरी, 2021

सूचना

सर्वसाधारण को सूचित किया जाता है कि True Nat-Real time quantative micro PCR मशीन के मूल निर्माता एम.एस.एम.ई. पंजीकृत (उद्योग आधार नं. GA 02B0000387) M/s Molbio Diagnostics Pvt. Ltd. Verna Goa ने दिनांक 15.01.2021 को शपथ पत्र प्रस्तुत करते हुए घोषित किया है कि ट्रू–नेट मशीन में प्रयोग होने वाला Duplex Kits उनका प्रोपराइटरी प्रोडक्ट है। अतः किसी व्यक्ति / फर्म / निर्माता को M/s Molbio की इस घोषणा व शपथ पत्र के सम्बन्ध में कोई आपत्ति है तो वह इस सूचना के अपलोड होने की तिथि से 07 (सात) दिवसों के अन्दर अपनी आपत्ति dgmededu@gmail.com पर प्रेषित कर सकता है।

(के0के0 गुप्ता)
महानिदेशक।

संख्याः–एम0ई0 / पर्चेज / कोविड–19 / 1928 तद्दिनांक।

प्रतिलिपि निम्नलिखित को इस आशय से प्रेषित कि उक्त सूचना को आज ही अपनी वेबसाइट पर अपलोड कराने का कष्ट करें:–

1. कुलसचिव, समस्त चिकित्सा विश्वविद्यालय।
2. निदेशक, समस्त चिकित्सा संस्थान।
3. प्रधानाचार्य, समस्त राजकीय मेडिकल कालेज।
4. प्रबन्ध निदेशक, उ0प्र0 मेडिकल सप्लाईज कारपोरेशन, सूडा भवन, लखनऊ।

(के0के0 गुप्ता)
महानिदेशक।

HOD Microbiology DMM

21/1/21

APO 22/01

दिनांक 20/1/21 संख्या 17720
डा0 राम मनोहर लोहिया
संस्थान, लखनऊ

Quotation No.N/Lko/150121

Date: 15.01.21

To ,
Director General
Medical Education & Training, U.P.
Lucknow-226001

Sub: Quotation of "TruenatCOVID-19 Duplex test kit"

Ref. No. Letter No. ME/Purchase/1949 dt. 11.01.2021

S.N.	Item	Description	Cost per test
1	Truenat COVID-19 Duplex test	Truenat a single step test that detects the E gene and Orf 1a gene of the SARS CoV-2 virus (with consisting of consumables such as reagents,chips,VTM required to do this test)	Rs 1000 Plus GST @ 12%

TERMS & CONDITIONS

- DELIVERY PERIOD: 4 -6 weeks on confirmation of order from your side.
- PAYMENT: Immediate after receiving part supply materials.
  VALIDITY OF OFFER: 30 Days from the date of quotation.
- TAXES Extra GST @ 12 %
- DELIVERY TERMS : Delivery will be with in 30 days of confirm purchase order.
- SUPPLIES: Will be made through our authorized distributor to M/S Diokronic Medisys Pvt Ltd
- All dispute if any, will only be under the jurisdiction of the courts of Panaji,Goa.
- We look forward to hear from your side & will feel privileged to address any of your concern(s).

Thanking you

MOLBIO DIAGNOSTICS PRIVATE LIMITED LUCKNOW

Sameer Saxena
Deputy Zonal Manager
Molbio Diagnostics Pvt Ltd
Lucknow
7678869500,9415269500
sameersaxena@molbiodiagnostics.com

15/1/2021

(Pages Eleven only)

Dated 15.01.21

To ,
Director General
Medical Education & Training, U.P.
Lucknow-226001

Subject: Declaration regarding Lowest Rate

Reference: Supply of "Truenat COVID-19 Duplex test kit"

We, Molbio Diagnostics Pvt Ltd, Goa, do hereby declare and confirm the following:

That the rate quoted to DGME is the lowest rate quoted to any Government/ non-Government Organization and we shall not quote below this rate to any Government/ non-Government Organization. If found in future after issuance of Purchase Order that we have quoted any lower rate to any Government Organization / non-Government Organization , the double of the difference amount will be deducted from our payment.

1. That the statements made above are true and correct to the best of our knowledge.
2. That the statements if found incorrect, we understand that the department is free to take action against us.

Thanking You.

For Molbio Diagnostics Pvt Ltd.

MOLBIO DIAGNOSTICS (GOA) PRIVATE LIMITED ★ LUCKNOW

Authorized Signatory

Molbio Diagnostics Private Limited
Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722 INDIA
Tel: +91-832-2783267 E mail: admin@molbiodiagnostics.com
Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com
CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP23718296380555T
Certificate Issued Date	:	14-Jan-2021 03:12 PM
Account Reference	:	NEWIMPACC (SV)/ up14243404/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14243404400713718335 20T
Purchased by	:	MOLBIO Diagnostics Pvt Ltd
Description of Document	:	Article 4 Affidavit
Property Description	:	For Govt Affidavit
Consideration Price (Rs.)	:	
First Party	:	MOLBIO Diagnostics Pvt Ltd
Second Party	:	Not Applicable
Stamp Duty Paid By	:	MOLBIO Diagnostics Pvt Ltd
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NOTARY R.C. VERMA NOTARIAL

Please write or type below this line

PROPRIETARY ARTICLE CERTIFICATE

SIGNATTESTED

This is to certify that Molbio Diagnostics (P) Limited, (Factory) Plot No. L 46, Phase II D, Verna Industrial Estate, Goa - 403 722, is the manufacturer and marketer of the Patented "Truelab™ Real Time microPCR/RTPCR system" comprising of the Truelab™ workstation and the Quantrep™ AUTO reagents along with Truenat™ microPCR/RTPCR chips.

INDIA

R.C. VERMA NOTARY

Lucknow

Regd. No. 4/2000

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

(2)

Both the Truelab™ Real Time microPCR Analyzer and the Truenat™ microPCR/RTPCR chips are protected by International Patents & Patent Pending and corresponding claim of any foreign counterpart(s) thereof, and hence the said products are proprietary in nature.

For Molbio Diagnostics Pvt. Ltd.,

MOLBIO DIAGNOSTICS PVT LTD VERNA GOA

Authorized Signatory

MOLBIO DIAGNOSTICS PRIVATE LIMITED LUCKNOW

NOTARY GOVT. OF UTTAR PRADESH

SIGNATURE ATTESTED

NOTARY
Court
India
31/04/2000

INDIAN COUNCIL OF MEDICAL RESEARCH

स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 24/09/2020

Revised Guidelines for TrueNat testing for COVID-19

The TrueNat system is now a comprehensive assay for screening and confirmation of COVID-19 cases.

- Sample is collected in viral lysis buffer and hence biosafety and biosecurity requirements for use of TrueNat are minimal.
- Types of assays:

  There are three different types of TrueNat assays available now:

  1. Assay 1*: TrueNat Beta CoV E gene Screening assay.
  2. Assay 2: TrueNat SARS CoV2 RdRp gene confirmatory assay.

     **Assay 1 needs to be followed by Assay 2 for confirmation of the results.*

  3. Assay 3: TrueNat Covid-19 Multiplex assay.

Detailed guidance on use of the assays is as follows:

1. Two step singleplex assay-

   A) **Step 1:** This is E gene screening assay. All samples of suspect COVID-19 should be first tested by this assay. All negatives are to be considered as **true negatives**. All positive samples should be subjected to confirmation by step 2 assay.

   B) **Step 2:** RdRp gene confirmatory assay. All samples that test positive by this assay must be considered as **true positives.**

2. Multiplex assay-

   TrueNat system is also now a multiplexed point of care test that includes a single assay comprising of both the **screening (E gene)** and **confirmatory (Orf1a)** targets in a single test. All samples of suspected COVID-19 cases can also be tested by this assay. All negatives are to be considered as **true negatives**. All samples that test positive by this assay must be considered as **true positives.**

- No further RT-PCR based confirmation is required for samples that are confirmed as true positives by the TrueNat assays.
- All positive and negative results must be reported to ICMR portal on real time basis.

(AN ENTERPRISE OF GOVT. OF A.P.)
2nd Floor, Plot No 9, Survey No 49, IT Park, Mangalagiri, Guntur -522503

P.O.No:284/437/APMSIDC/EQU/2020-21 Dt:21.09.2020

To
M/s. Molbio Diagnostics Pvt. Ltd.
Plot No. L-46, Phase II D, Verna-
Industrial Estate, Verna – Goa 403 722.

Sir,

Sub: APMSIDC – Equipment Wing – Procurement and supply of Truenat Multiplex Testing Kits including both screening (E gene) & Confirmatory kits to various Govt. Hospitals in Andhra Pradesh for COVID-19 – Purchase Order Issued – Regarding.

Ref: 1. Lr.No.Dr YSRAHCT/COVID-19/Truenat – kits/2020, dt: 15.09.2020 of CEO, Dr YSRAHCT & State Nodal Officer for labs, COVID – 19.
2. Quotation received from M/s. Molbio Diagnostics Pvt. Ltd. Dt:21.09.2020

* * * *

Adverting to the references cited above, you are requested to supply of Truenat Covid-19 (Duplx) Test Kit to various Govt. Hospitals in Andhra Pradesh with a contract value of **Rs.11,20,00,000/-**Including all taxes. The supplier has to abide by the terms and conditions mentioned in Annexure I.

You are requested to supply and install the items and submit 1) Original bills with stock entry, 2)Delivery challans, 3)Installation(if applicable)/ Performance report in original duly certified by the concerned head of the institute/hospital along with recommendations for payment of the bills failing which no payment will be processed.

After the complete execution of PO quantity, the FSD will be released after 3months duration from the date of installation based on the performance report obtained from the Head of the institution or concerned authorities.

It is also informed that, if any instance comes to the notice of the corporation that the above equipment are supplied at a lower price than price quoted now then

shall also entail blacklisting of the firm for a minimum period of three years for a particular product.

Yours faithfully

for Managing Director

Copy to:-

1. The Superintendent of Various Government Hospitals as per Annexure – I: with a request to inform the concerned Authorities to take over the material and issue material received certificate to the suppliers and also submit the Original invoices with endorsement of the stock entries in the prescribed proforma enclosed herewith to the corporation for payment of the bill.
2. The CEO, Dr YSR Aarogyasri Health Care Trust, Guntur for information
3. The Finance Officer, Head office, APMSIDC – for information and necessary action.
4. The Bills Section, Equipment, Head office, APMSIDC – for information and necessary action.

P.O.No:264/437/APMSIDC/EQU/2020-21 Dt:21.09.2020

S. No	Item Description	Unit	Qty	Unit Rate Rs.	GST @ 12%	Total	Amount (Rs)
1	TRUENAT COVID-19 (DUPLEX) {SCREENING & CONFIRAMTION}	Kits	100000	1000	120	1,120	11,20,00,000
	Total Amount:						11,20,00,000

Terms & Conditions:

1)	**Contract Value in Words:**	:	**Rupees Eleven Crores Twenty LakhsOnly**
2)	Total items	:	One Item Only
3)	Unit Rate	:	Inclusive of all Taxes
4)	Installation	:	Not applicable.
5)	Uptime Clause	:	Minimum uptime 95% of 365 working days.
6)	Liquidated Damages	:	LD's will be levied for the delayed goods at 0.5% per week, subject to maximum of 10% of contract value.
7)	Payment terms	:	i). 90% of the contract value of the supply part, after deduction of statutory taxes, will be paid to the supplier on submission of copy of invoice with original Delivery Challan as proof of supply to destinations and provisional stock entry duly certified by the
			ii). The balance 10% of contract value of the supply part to be paid after 3 months from the date of installation (from the date of supply when installation is not applicable) on submission of performance satisfactory report in the proforma given under Annexure-XVI, obtained from the Head of the institute or concerned authorities.
8)	Stock entry, Installation & Performance Certificate	:	To be submitted in the prescribed format enclosed herewith
9)	Delivery Period / Terms	:	Supply & Installation of the items at the final destination within 15 days from the date of receipt of this purchase order

MOLBIO DIAGNOSTICS PRIVATE LIMITED LUCKNOW

for Managing Director

Chip-based Real Time Duplex PCR Test for COVID-19

INTENDED USE

Truenat™ COVID-19 (REF 601430005/601430020/601430050) is a chip-based Real T e duplex Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the semi quantitative detection of SARS CoV-2 RNA in human oropharyngeal and nasopharyngeal swab specimen and aids in detection and confirmation of SARS CoV-2 infection and diagnosis of COVID-19. The test detects the *E* and *Orf1a* genes of the virus.

Truenat™ COVID-19 runs on **Truelab®** Real Time Quantitative micro PCR Analyzers.

INTRODUCTION

SARS CoV 2 is the causative agent for corona virus disease 2019 or COVID-19 in Humans. SARS CoV 2 is a Beta Corona Virus, one of the four genera of Corona Viruses. Coronaviruses are enveloped non-segmented positive sense RNAviruses belonging to the family coronaviridae and the order Nidovirales and broadly distributed in humans and other mammals. The common signs of COVID-19 infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Early and correct identification of infection with SARS CoV-2 is important for effective isolation, treatment and case management of COVID-19. In line with WHO recommendations, molecular diagnostics are currently the method of choice for such virus detection and differentiation. However, molecular tests for COVID-19 have so far been restricted to centralized reference laboratories as they require skilled manpower and elaborate infrastructure. Also the turnaround time for results could take a few days.

The **Truelab®** Real Time micro PCR System enables decentralization and near patient diagnosis of and monitoring of COVID-19. This is enabled by making the real time PCR technology rapid, simple, robust and user friendly, thereby offering "sample to result" capability even at resource limited settings. This is achieved through a combination of lightweight, portable, mains / battery operated **Truelab®** Real Time micro PCR Analyzers and **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device and room temperature stable **Truenat™** micro PCR chips and **Trueprep® AUTO/AUTO v2** Sample Prep kits so that even the peripheral laboratories with minimal infrastructure and minimally trained technician can easily perform these tests routinely in their facilities and report PCR results in less than an hour. Moreover, with these devices PCR testing can also be initiated in the field level, on site.

Truenat™ COVID-19 is a disposable, room temperature stable, chip-based Real Time duplex PCR test with dried $MgCl_2$ in reaction well and freeze dried RT PCR reagents in microtube for performing Real Time RT-PCR test for viral infection and runs on the **Truelab®** Real Time micro PCR Analyzer. It requires only six (6) µL of purified RNA to be added to the reaction well for the analysis. The intelligent chip also carries test and batch related information. The **Truenat™ COVID-19** chip also stores information of used test to prevent any accidental re-use of the chip.

NOTE :Truelab®/ Truenat™ / Trueprep® / Truepet® are all trademarks of Molbio Diagnostics Private Limited.

The Truelab® Real Time micro PCR Analyzer is protected by the following patents and patents granted: IN 2313/CHE/2007 (Patent No. 281573), WO2009/047804 and corresponding claims of any foreign counterpart(s) thereof.

The Truenat™ micro PCR chip is protected by the following patents and patents pending: IN 2312/CHE/2007, WO 2009/047805 and corresponding claims of any foreign counterpart(s) thereof.

PRINCIPLE OF THE TEST

Truenat™ COVID-19 works on the principle of Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) based on Taqman chemistry. The RNA from the patient sample is first extracted using **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Kit. The **Truenat™ COVID-19** chip is placed on the chip tray of the **Truelab®** Real Time micro PCR Analyzer. Six (6) µL of the purified RNA is then dispensed using the provided micropipette and tip into the microtube containing freeze dried PCR reagents, including reverse transcriptase (RT) and allowed to stand for 30-60 seconds to get a clear solution. ⚠ No mixing by tapping shaking or by reverse pipetting should be done. Six (6) µL of this clear solution is then pipetted out using the same pipette and tip and dispensed into the reaction well of the **Truenat™ COVID-19** chip and the test is inserted in the **Truelab®** Real Time Quantitative micro PCR Analyzer where the RNA is first converted into complementary DNA (cDNA) by the RT enzyme and further thermal cycling takes place. A positive amplification causes the dual labeled fluorescent probe in the **Truenat™ COVID-19** chip-based Real Time PCR test to release the fluorophores in nucleic acid in the sample (i.e. the lower the Ct level the greater is the amount of ta nucleic acid in the sample). In the case of negative samples, amplification doe occur and a horizontal amplification curve is displayed on the screen during the run. At the end of the test run, *E* / *Orf1a* gene "DETECTED" or "NOT DETECT result is displayed and in positive cases, semi quantitative result is also displaye the screen. Based on the detection of the internal positive control (IPC), the validi the test run is also displayed. The IPC is a full process control that undergoes al processes the specimen undergoes - from extraction to amplification ther validating the test run from sample to result. Absence of or shift of IPC Ct beyor pre-set range in case of negative samples invalidates the test run. While IPC will amplify in most positive cases also, in some specimen having a high target load, IPC may not amplify, however the test run is still considered valid. The results car printed using the **Truelab®** micro PCR printer or transferred to the lab computer any remote computer via Wifi network or 3G/GPRS network. Upto 20,000 result **Truelab® Uno Dx/Duo/Quattro** can be stored on the analyzer for future recall a reference.

4 TARGET SELECTION

The target sequence for this kit is *E* and *Orf1a* gene and human *RNase P*. Detecti of the human *RNase P* gene serves as a full process internal positive control (IPC) proper swab collection, nucleic acid extraction and PCR.

5 CONTENTS OF THE Truenat™ COVID-19 KIT

A. Individually sealed pouches, each containing a
1. **Truenat™ COVID-19** micro PCR chip.
2. Microtube with freeze dried RT PCR reagents.
3. DNase & RNase free pipette tip.
4. Desiccant pouch.

B. Package Insert.

REF	601430005	601430020	601430050
Σ	5T	20T	50T

6 CONTENTS OF THE Trueprep AUTO Universal Sample Pre-treatment Pack

A. Lysis Buffer (contains lysis cum transport medium).

B. Disposable transfer pipette (graduated).

REF	60205AB05	60205AB20	60205AB50
Σ	5T	20T	50T

7 CONTENTS OF THE Trueprep AUTO Transport Medium for Swab Specime Pack

A. Transport Medium for Swab specimen tubes (contains transport medium).

REF	60206TS05	60206TS20	60206TS50
Σ	5T	20T	50T

8 STORAGE AND STABILITY

Truenat™ COVID-19 is stable for two (2) years from the date of manufacture if store between 2-30°C. It is also stable for upto one (1) month at temperatures up to 45°C Avoid exposure to light or elevated temperatures (above recommended levels). D not freeze.

Trueprep® AUTO Universal Sample Pre-Treatment Pack and **Trueprep® AUT** Transport Medium for Swab Specimen Pack is stable for two (2) years from the da of manufacture if stored between 2-40°C. It is also stable for one (1) month temperatures upto 45°C.

9 MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

Truelab® Real Time micro PCR Workstation (REF 62301001/633010001/ 64301001/653010001) consisting of

1. **Trueprep® AUTO/AUTO v2** Sample Prep Device(REF603041001/603042001
2. **Truelab® Uno Dx/Truelab® Duo/Truelab® Quattro** Real Time micro PCR Analyzer (REF603021001/603022001/603023001).
3. **Truelab®** micro PCR Printer (REF 603050001).
4. **Trueprep®** SPA fixed volume precision micropipette - 6 µl (REF 604070006).
5. **Truelab®** Microtube Stand (REF 603070001).

Also required additionally are: **Trueprep®** AUTO Universal Sample Pre-Treatme Pack (REF60205AB05/REF60205AB20/REF60205AB50), **Trueprep® AUT** Transport Medium for Swab Specimen Pack (REF60206TS05/REF60206TS20/ REF60206TS50), **Trueprep®** AUTO Universal Cartridge Based Sample Prep K (REF60203AR05/REF60203AR25/REF60203AR50) or **Trueprep®** AUTO Universal Cartridge Based Sample Prep Kit (REF60207AR05/REF60207AR25/ REF60207AR50), **Truenat™** Universal Control Kit (REF 601100008), Powder fre disposable gloves, waste disposal container with lid.

specimen into the Transport Medium for Swab Specimen Tube provided and mix well by repeatedly twirling the swab in the buffer solution. Gently break the handle of the nylon swab at the break point, leaving the swab containing the specimen in the Transport Medium for Swab Specimen Tube. Tightly close the cap of the Transport Medium for Swab Specimen Tube (Refer to the package insert of **Trueprep® AUTO** Trans, rt Medium for Swab Specimen Pack for further details). Dispose off the remaining part of the swab after use, as per the section on "Disposal and Destruction" (Section 18).

Sample Storage and Transportation:

Transport Medium for Swab Specimen decontaminates the specimen and makes it ready for storage/ transportation/ extraction. The specimen in this form is stable for up to three (3) days at 40°C and one(1) week at 30°C.

Nucleic acid extraction:

Transfer 500 µL from the Transport Medium for Swab Specimen Tube into the Lysis Buffer Tube for oropharyngeal or nasopharyngeal swabs for further procedure (Refer to the package insert of **Trueprep® AUTO** Universal Sample Pre-treatment pack for further details) with the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit (Refer to the User Manual of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep device and the package insert of **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep kit for details). Dispose off the Transport Medium for Swab Specimen Tube with cap, lysis buffer tube with cap and transfer pipette after use, as per the section on "Disposal and Destruction" (Section 18).

1. SAFETY PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Bring all reagents and specimen to room temperature (20 - 30°C) before use.
3. Do not use kit beyond expiry date.
4. Carefully read the User Manuals and package inserts of all the components of the **Truelab® Real Time micro PCR System** before use.
5. All materials of human origin should be handled as though potentially infectious.
6. Do not pipette any material by mouth.
7. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
8. Use protective clothing and wear disposable gloves when handling samples and while performing sample extraction.

2. PROCEDURAL PRECAUTIONS

1. Check all packages before using the kit. Damage to the packaging does not prevent the contents of the kit from being used. However, if the outer packaging is damaged the user must confirm that individual components of the kit are intact before using them.
2. Do not perform the test in the presence of reactive vapours (e.g. from Sodium hypochlorite, acids, alkalis or aldehydes) or dust.
3. While retrieving the **Truenat™ COVID-19** micro PCR chip, microtube and the DNase & RNase free pipette tip from the pouch, ensure that neither bare hands nor gloves that have been used for previous tests run are used.

3. PROCEDURAL LIMITATIONS

1. Optimal performance of this test requires appropriate specimen collection, handling, storage and transport to the test site.
2. Though very rare, mutations within the highly conserved regions of the target genome where the **Truenat™** assay primers and/or probe bind may result in the under-quantitation of or a failure to detect the presence of the concerned pathogen.
3. The instruments and assay procedures are designed to minimize the risk of contamination by PCR amplification products. However, it is essential to follow good laboratory practices and ensure careful adherence to the procedures specified in this package insert for avoiding nucleic acid contamination from previous amplifications, positive controls or specimens.
4. A specimen for which the **Truenat™** assay reports "Not Detected" cannot be concluded to be negative for the concerned pathogen. As with any diagnostic test, results from the **Truenat™** assay should be interpreted in the context of other clinical and laboratory findings.

4. CLEANING AND DECONTAMINATION

1. Spills of potentially infectious material should be cleaned up immediately with absorbent paper tissue and the contaminated area should be decontaminated with disinfectants such as 0.5% freshly prepared Sodium hypochlorite [10 times dilution of 5% Sodium hypochlorite (household bleach)] before continuing work.
2. Sodium hypochlorite should not be used on an acid-containing spill unless the spill-area is wiped dry first. Materials used to clean spills, including gloves

manual)

1. Switch on the **Truelab®** Analyzer.
2. Select User and enter password.
3. For **Truelab® Uno Dx**, select the test profile for "*E /Orf1a* gene" to be run from Profiles Screen on the Analyzer screen. For **Truelab® Duo/Quattro**, select Bay (Idle1/2) for **Duo** and (Idle1/2/3/4) for **Quattro** from the Status Screen to v the Profiles Screen. Select the test profile for "*E /Orf1a* gene" to be run from Profiles Screen on the Analyzer screen.
4. Enter the patient details as prompted in the **Truelab®** Analyzer screen.
5. Press Start Reaction.
6. For **Truelab® Uno Dx**, Press the eject button to open the chip tray. For **Truel Duo/Quattro**, the chip tray opens automatically on tapping the "Start Reacti button.
7. Open a pouch of **Truenat™ COVID-19** and retrieve the micro PCR chip, microtu and DNase & RNase free pipette tip.
8. Label the chip and the tube with the patient ID using a marker pen at the spa provided on the back side of the chip and the space on the microtube label.
9. Place the **Truenat™ COVID-19** chip on the chip tray without touching the wh reaction well. The reaction well should be facing up and away from the Analyz Gently press the chip to ensure that it has seated in the chip tray properly.
10. Place the microtube containing freeze dried RT PCR reagents in the microtu stand provided along with the **Truelab®** Real Time micro PCR workstation **aft ensuring that white pellet of dried PCR reagents remains at the bottom the microtube.** Remove the microtube cap and dispose it off as per the secti on "Disposal and Destruction" (Section 18). Using the filter barrier tip provided the pouch, pipette out six (6) µL of the purified RNA from the Elute Collected Tul into the microtube. Allow it to stand for 30-60 seconds to get a clear solution. D not mix it by tapping, shaking or by reverse pipetting. Using the same filter barri tip, pipette out six (6) µL of this clear solution and dispense into the centre of th white reaction well of the **Truenat™ COVID-19** chip. Take care not to scratch th internal well surface and not to spill elute on the outside of the well. Dispose c the microtip as per the section on "Disposal and Destruction" (Section 18).
11. For **Truelab® Uno Dx**, slide the chip tray containing the **Truenat™ COVID-1** chip-based Real Time PCR test loaded with the sample into the **Truelat** Analyzer. Press Done on the "Please Load Sample" Alert message. For **Truelat Duo/Quattro**, select "YES" at the Please load Sample prompt. Chip tray w close automatically and the reaction will start.
12. Read the result from the screen.
13. After the reaction is completed, for **Truelab® Uno Dx**, push the Eject button t eject the chip tray. For **Truelab® Duo/Quattro**, tap the "Open/Close Tray" butto to eject the chip tray.
14. Take out the **Truenat™ COVID-19** chip-based Real Time PCR test at end of th test and dispose it off as per the section on "Disposal and Destruction" (Sectio 18).
15. Turn on **Truelab®** micro PCR printer and select print on the screen for printing o hard copy of the results. Test results are automatically stored and can b retrieved any time later. (Refer to the **Truelab®** Analyzer manual).
16. Switch off the **Truelab®** Analyzer.

16. RESULTS & INTERPRETATIONS

Three amplification curves are displayed on the **Truelab® Real Time micro PC Analyzer** screen to indicate the progress of the test. Both the target and the intern positive control (IPC)* curves will take a steep, exponential path when th fluorescence crosses the threshold value in case of positive samples. The time take (Ct) of the specimen will depend on the number of virus copies in the sample. Th curve will remain horizontal throughout the test duration and the IPC curve will take a exponential path in case of negative samples. In case the IPC curve remair horizontal in a negative sample, the test is considered as Invalid. At the end of the te run, the results screen will display "DETECTED" for Positive result or "NO DETECTED" for Negative result. The result screen would also display the viral loa as "HIGH", "MEDIUM" ,"LOW" or " VERY LOW" for positive specimen. The resu screen also displays the validity of the test run as "VALID" or "INVALID". Inval samples have to be repeated with fresh specimen from the sample preparation stag *While IPC will co-amplify in most positive cases also, in some specimen having high target load, the IPC may not amplify, however the test run is still considered vali

Detection Channel			Result Interpretation	ACTION
Orf1a	*E*	*RNase P*		
+	+	+/-	SARS-CoV-2 POSITIVE	Report Positive
-	+	+/-	SARS-CoV-2 PRESUMPTIVE NEG	Repeat after 48 – 72 hours if clinically indicated
+	-	+/-	SARS-CoV-2 PRESUMPTIVE POS	Repeat after 48 – 72 hours Or Conduct follow on test with Truenat™ SARS CoV 2 RdRp gene test
-	-	+	SARS-CoV-2 NEGATIVE	Report Negative
-	-	-	INVALID	Collect new swab and repeat

Whenever a new shipment of test kits is received. • When opening a new test kit lot. • If the temperature of the storage area falls outside of 2-30° C. • By each new user prior to performing testing on clinical specimen.

5. DISPOSAL AND DESTRUCTION

1. Submerge the used content such as Truenat™ **COVID-19** chip, microtube, microtube cap, pipette tips etc. in freshly prepared 0.5% sodium hypochlorite solution for 30 minutes before disposal as per the standard medical waste disposal guidelines.
2. Disinfect the solutions and/or solid waste containing biological samples before discarding them according to local regulations.
3. Samples and reagents of human and animal origin, as well as contaminated materials, disposables, neutralized acids and other waste materials must be discarded according to local regulations after decontamination by immersion in a freshly prepared 0.5% of sodium hypochlorite for 30 minutes (1 volume of 5% sodium hypochlorite for 10 volumes of water).
4. Do not autoclave materials or solutions containing sodium hypochlorite.
5. Chemicals should be handled in accordance with Good Laboratory Practice and disposed off according to the local regulations.

9. SPECIFIC PERFORMANCE CHARACTERISTICS

Performance parameters

1. Analytical Sensitivity:

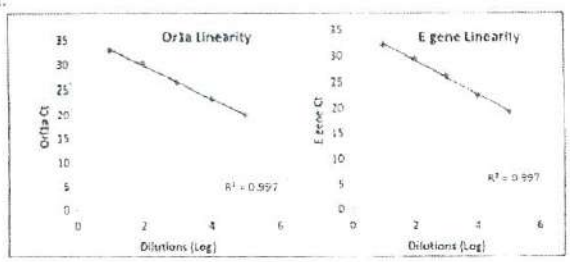
Evaluation of analytical sensitivity of **Truenat™ COVID-19** assay, in comparison to TaqMan SARS CoV-2 qRT-PCR VRDL assay was performed. Sample with low Ct value (ID 54049) was used for this study. An aliquot of VTM of sample ID 54049 was extracted using **Trueprep® AUTO** Sample Prep Device (As per manufacturer protocol). RNA was diluted 10 fold and six dilutions were made from **Trueprep® AUTO** elute. These dilution series were run on **Truenat™ COVID-19** chips as well as Taq Man SARS CoV-2 qRTPCR systems in parallel. Observed Ct values are given in below table.

	Truenat™ COVID-19			Taqman SARS CoV2 [VRDL]		
Sample ID	ORF1a	E Gene	RNAseP	ORF1a	E Gene	RNAseP
54049 D1	19.67	19.17	27.40	28.71	24.12	28.39
54049 D1	20.14	19.11	27.33			
54049 D1	19.60	19.00	27.33			
54049 D2	23.17	22.17	31.29	32.32	28.57	38.47
54049 D2	23.29	22.40	31.14			
54049 D2	23.20	22.33	30.60			
54049 D3	26.29	25.80	33.15	37.29	31.69	ND
54049 D3	26.29	26.50	33.17			
54049 D3	26.00	25.80	33.80			
54049 D4	29.67	29.14	ND	ND	34.06	ND
54049 D4	30.00	29.20	ND			
54049 D4	30.83	29.50	ND			
54049 D5	33.20	31.50	ND	ND	ND	ND
54049 D5	32.28	32.33	ND			
54049 D5	33.00	32.13	ND			
54049 D6	ND	ND	ND	ND	ND	ND
54049 D6	ND	ND	ND			
54049 D6	ND	ND	ND			

Conclusion: Truenat™ assay detected up to dilution 10^{-5}(D5) from undiluted sample, with valid Ct value.

2. Linearity & PCR Efficiency:

Using the dilution series from **Trueprep® AUTO** elutes run on Truenat™ COVID-19, log linear curve was plotted to check the linearity of Ct values on Truenat™ COVID-19 test.



4. Analytical Sensitivity test with samples of low viral load:

Evaluation of analytical sensitivity of **Truenat™ COVID-19** multiplexed PoC te comparison to TaqMan SARS-CoV-2 rRT-PCR VRDL assay was performed. Samples with low viral load (low viral copy number) for Orf1a / E gene was use this study. An aliquot of virus transport medium (VTM) containing sample extracted using **Trueprep® AUTO** and 12 replicates of each sample was rui **Truenat™ COVID-19** and compared against TaqMan SARS CoV-2 qRT-PCR V assay.

Conclusion: All replicates of 5 low viral load samples were detected by **Truen COVID-19**, Orf1a assay.

5. Precision:

To evaluate reproducibility and repeatability of the assay, ten clinical el representing High, Medium and Low Ct values {Sample IDs:54053(Ct:20. 54716(Ct:25.8),54724(Ct:14.71),54745(Ct:29.43),54803(Ct:14.11),54 (Ct:22.83),54918(Ct:24.06),54935(Ct:20.43),55055(Ct:14.60),55113(Ct:24 were run on devices used in this evaluation. Following table depicts the Preci analysis. Ct values for E gene and Orf1a are given, with observed standard devia and % CV.

	ID: 54053		ID: 54716		ID: 54724		ID: 54745		ID: 54803	
Device ID	ORF1a	EGene	ORF1a	EGene	ORF1a	EGene	ORF1a	EGene	ORF1a	E
TLDU1306	27.50	26.33	25.80	24.60	14.71	13.67	29.43	29.00	14.11	1
TLDU0431	28.13	26.43	26.80	25.00	14.30	13.50	30.14	29.17	13.50	1
TLDU0381	28.14	26.22	26.35	24.60	14.50	13.43	31.50	29.33	14.17	1
TLDU0366	26.75	25.80	26.00	24.43	14.17	13.33	28.67	29.00	13.86	1
Mean	27.63	26.20	26.24	24.63	14.42	13.48	29.94	29.13	13.91	1
STDEV	0.659	0.277	0.439	0.255	0.236	0.143	1.204	0.158	0.305	0
%CV	2.38	1.06	1.67	1.03	1.64	1.06	4.02	0.54	2.19	0

	ID: 54887		ID: 54918		ID: 54935		ID: 55055		ID: 5511	
Device ID	ORF1a	EGene	ORF1a	EGene	ORF1a	EGene	ORF1a	EGene	ORF1a	E
TLDU1306	22.83	22.27	24.06	21.29	20.43	19.43	14.60	13.60	24.29	2
TLDU0431	23.13	22.14	22.40	21.00	20.17	19.50	15.00	13.83	24.10	2
TLDU0381	23.00	22.00	23.60	21.00	21.25	19.80	15.14	13.50	24.71	2
TLDU0366	22.71	21.80	23.00	20.80	20.50	19.60	14.67	13.43	24.43	2
Mean	22.92	22.05	23.27	21.02	20.61	19.58	14.85	13.59	24.38	2
STDEV	0.185	0.201	0.722	0.202	0.460	0.161	0.259	0.175	0.257	0
%CV	0.81	0.91	3.10	0.96	2.23	0.82	1.74	1.28	1.05	0

Conclusion: The test was found to be reproducible with percent coefficient variation less than 5% which is well below the accepted 10%, across samples a between devices.

6. Clinical Sensitivity:

Clinical sensitivity was tested by running40 confirmed positives samples of SAF COV-2; representing high [12], medium [13] and low Ct [15] value samples for test and comparison with both the systems using three lots of **Truenat™ COVID-19.** positive samples were detected by all three lots of **Truenat™ COVID-19** assay.

7. Specificity and cross reactivity:

Specificity of the test was evaluated using a panel of clinical samples, includi COVID-19 negatives and other respiratory disease positive ones. The pa included; H1N1 (38samples: 8 positive and 30 Negative), Severe Acute Respirat Illness (SARI) (30 samples), and also blood samples (3 from SARS CoV-2 posit cases and 3 from SARS CoV-2 negative cases) and confirmed COVID-19 negativ (30 swab samples) were used.

E gene and Orf1a was not detected in any of above specimens, indicating specific and no cross reactivity to other common respiratory pathogens.

8. Clinical evaluation:

Clinical evaluation of **Truenat™ COVID-19** was performed at the State VRDL lab Bangalore Medical College. Totally, 45 confirmed SARS CoV-2 positive and confirmed RT-PCR negative samples were tested.

		SARS CoV 2 real-time PCR (n=119)		
		Positive	Negative	Total
Truenat™ COVID-19	Positive	45	0	45
	Negative	0	74	74
	Total	45	74	119

All positive and negatives were correctly detected on **Truenat™ COVID-19** assa indicating 100% sensitivity, specificity and 100% overall concordance to referen gold standard assay.

severe acute respiratory syndrome. N Engl J Med 2003; 348: 1953–66.
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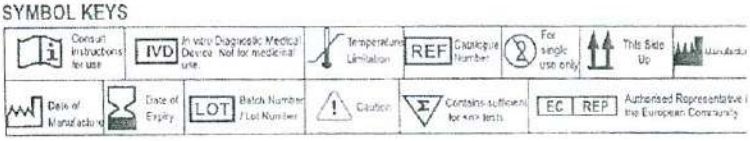
SYMBOL KEYS



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