



Truenat[®]

Beta CoV

Chip-based Real Time PCR Test for Beta Coronavirus

1. INTENDED USE

Truenat[®] Beta CoV (REF 601410005 / 601410020 / 601410025 / 601410050 / 601410100 / 601410200) is a Chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) test for the semi-quantitative detection of Beta Coronavirus (Sarbeco) RNA in human oropharyngeal and nasopharyngeal swab specimen. The test is recommended for use as a first line screening test for **COVID-19**. Samples testing positive by **Truenat[®] Beta CoV** may be confirmed using confirmatory tests for SARS CoV 2. **Truenat[®] Beta CoV** runs on **Truelab[®] Real Time Quantitative micro PCR Analyzers**. **Truenat[®] Beta CoV** is an *in vitro* diagnostics test meant for professional use only.

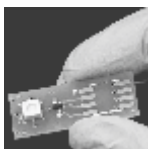
2. INTRODUCTION

Beta coronavirus is the causative agent for SARS and COVID-19 in Humans. Coronaviruses are enveloped non-segmented positive sense RNA viruses belonging to the family coronaviridae and the order Nidovirales and broadly distributed in humans and other mammals. The common signs of 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 the beta coronavirus is important for effective isolation, treatment and case management. In line with WHO recommendations, molecular diagnostics are currently the method of choice for such virus detection and differentiation. However, molecular tests for beta coronavirus 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 and monitoring of Beta Corona virus. 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 Universal Cartridge Based 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[®] Beta CoV is a disposable, room temperature stable, chip-based Real Time PCR test with dried MgCl₂ 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[®] Beta CoV** 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.

3. PRINCIPLE OF THE TEST

Truenat[®] Beta CoV 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[®] Beta CoV** 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[®] Beta CoV** 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[®] Beta CoV** Chip-based

Real Time PCR test to release the fluorophores in an exponential manner which is then captured by the built-in opto-electronic sensor and displayed as amplification curve on the analyzer screen, on a real time basis during the test run. The Cycle threshold (Ct) is defined as the number of amplification cycles required for the fluorescent signal to cross the threshold (i.e. exceed the background signal). Ct levels are inversely proportional to the amount of target nucleic acid in the sample (i.e. the lower the Ct level the greater is the amount of target nucleic acid in the sample). In the case of negative samples, amplification does not occur and a horizontal amplification curve is displayed on the screen during the test run. At the end of the test run, Beta CoV "DETECTED" or "NOT DETECTED" result is displayed and in positive cases, semi-quantitative result is also displayed on the screen. Based on the detection of the internal positive control (IPC), the validity of the test run is also displayed. The IPC is a full process control that undergoes all the processes the specimen undergoes - from extraction to amplification thereby validating the test run from sample to result. Absence of or shift of IPC Ct beyond a pre-set range in case of negative samples invalidates the test run. While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid. The results can be printed using the **Truelab[®] micro PCR printer** or transferred to the lab computer/or any remote computer via Wifi network or 3G/GPRS network. Upto 20,000 results in **Truelab[®] Uno Dx/Duo/Quattro** can be stored on the analyzer for future recall and reference.

4. TARGET SELECTION

The target sequence for this kit has been taken from the *E gene* of Sarbeco virus and human *RNase P*. Detection of the human *RNase P* gene serves as a full process internal positive control (IPC) for proper swab collection, nucleic acid extraction and PCR.

5. CONTENTS OF THE Truenat[®] Beta CoV KIT

- Individually sealed pouches, each containing a
 - Truenat[®] Beta CoV** micro PCR chip
 - Microtube with freeze dried RT-PCR reagents
 - DNase & RNase free pipette tip
 - Desiccant pouch
- Package Insert

REF	601410005	601410020	601410025	601410050	601410100	601410200
▽	5T	20T	25T	50T	100T	200T

6. CONTENTS OF THE Trueprep[®] AUTO Universal Sample Pre-treatment Pack

- Lysis Buffer (contains lysis cum transport medium)
- Disposable transfer pipette (graduated)
- Package Insert

REF	60205AB05	60205AB20	60205AB25	60205AB50	60205AB100	60205AB200
▽	5T	20T	25T	50T	100T	200T

7. CONTENTS OF THE Trueprep[®] AUTO Transport Medium for Swab Specimen Pack

- Transport Medium for Swab specimen tubes (contains transport medium)
- Package Insert.

REF	60206TS05	60206TS20	60206TS25	60206TS50	60206TS100	60206TS200
▽	5T	20T	25T	50T	100T	200T

8. STORAGE AND STABILITY

Truenat[®] Beta CoV is stable for two (2) years from the date of manufacture if stored 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). Do not freeze.

Trueprep[®] AUTO Universal Sample Pre-treatment Pack and **Trueprep[®] AUTO Transport Medium for Swab Specimen Pack** is stable for two (2) years from the date of manufacture if stored between 2-40°C. It is also stable for one (1) month at temperatures upto 45°C. Do not freeze.

9. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

Truelab[®] Real Time micro PCR Workstation (REF 623010001 / 633010001 / 643010001 / 653010001) consisting of

- Trueprep[®] AUTO/AUTO v2 Universal Cartridge Based Sample Prep Device** (REF603041001/603042001).
- Truelab[®] Uno Dx / Truelab[®] Duo / Truelab[®] Quattro** Real Time micro PCR Analyzer (REF603021001/603022001/603023001).
- Truelab[®] micro PCR Printer** (REF 603050001).
- Truepet[®] SPA** fixed volume precision micropipette - 6 µl (REF 604070006).
- Truelab[®] Microtube Stand** (REF 603070001).

Also required additionally are: **Trueprep[®] AUTO Universal Sample Pre-treatment Pack** (REF60205AB05 / REF60205AB20 / REF60205AB25 / REF60205AB50 / REF60205AB100 / REF60205AB200), **Trueprep[®] AUTO Transport Medium for Swab Specimen Pack** (REF60206TS05 / REF60206TS20 / REF60206TS25 /

REF60206TS50 / REF60206TS100 / REF60206TS200), **Trueprep**[®] **AUTO** Universal Cartridge Based Sample Prep Kit (REF60203AR05 / REF60203AR25 / REF60203AR50 / REF60203AR100) or **Trueprep**[®] **AUTO v2** Universal Cartridge Based Sample Prep Kit (REF60207AR05 / REF60207AR25 / REF60207AR50 / REF60207AR100), **Truenat**[®] Positive Control Kit - Panel I (REF 801010008), Powder free disposable gloves, waste disposal container with lid.

10. SPECIMEN PREPARATION FOR EXTRACTION WITH **Trueprep**[®] **AUTO/AUTO v2**

Swab specimen:

Oropharyngeal or nasopharyngeal swab specimen must be collected as per standard procedures using a standard nylon flocked swab. Insert the swab with 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** Transport 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).

11. 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.

12. 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**[®] **Beta CoV** 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.

13. 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.

14. 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 should be disposed off as potentially bio-hazardous waste e.g. in a biohazard waste container.

15. TEST PROCEDURE

(Please also refer the **Truelab**[®] Real Time Quantitative micro PCR Analyzer user manual)

1. Switch on the **Truelab**[®] Analyzer.
2. Select User and enter password.
3. For **Truelab**[®] **Uno Dx**, select the test profile for "Beta CoV" to be run from the Profiles Screen on the Analyzer screen. For **Truelab**[®] **Duo/Quattro**, select the Bay (Idle1/2) for **Duo** and (Idle1/2/3/4) for **Quattro** from the Status Screen to view the Profiles Screen. Select the test profile for "Beta CoV" to be run from the 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 **Truelab**[®] **Duo/Quattro**, the chip tray opens automatically on tapping the "Start Reaction" button.
7. Open a pouch of **Truenat**[®] **Beta CoV** and retrieve the micro PCR chip, microtube and DNase & RNase free pipette tip.
8. Place the **Truenat**[®] **Beta CoV** chip on the chip tray without touching the white reaction well. The reaction well should be facing up and away from the Analyzer. Gently press the chip to ensure that it has seated in the chip tray properly.
9. Place the microtube containing freeze dried RT PCR reagents in the microtube stand provided along with the **Truelab**[®] Real Time micro PCR workstation **after ensuring that white pellet of dried PCR reagents remains at the bottom of the microtube**. Remove the microtube cap and dispose it off as per the section on "Disposal and Destruction" (Section 18). Using the filter barrier tip provided in the pouch, pipette out six (6) µL of the purified RNA from the Elute Collection Tube into the microtube. Allow it to stand for 30-60 seconds to get a clear solution. **⚠ Do not mix it by tapping, shaking or by reverse pipetting**. Using the same filter barrier tip, pipette out six (6) µL of this clear solution and dispense into the centre of the white reaction well of the **Truenat**[®] **Beta CoV** chip. Take care not to scratch the internal well surface and not to spill elute on the outside of the well. Dispose off the microtip as per the section on "Disposal and Destruction" (Section 18).
10. For **Truelab**[®] **Uno Dx**, slide the chip tray containing the **Truenat**[®] **Beta CoV** Chip-based Real Time PCR test loaded with the sample into the **Truelab**[®] Analyzer. Press Done on the "Please Load Sample" Alert message. For **Truelab**[®] **Duo/Quattro**, select "YES" at the Please load Sample prompt. Chip tray will close automatically and the reaction will start.
11. Read the result from the screen.
12. After the reaction is completed, for **Truelab**[®] **Uno Dx**, push the Eject button to eject the chip tray. For **Truelab**[®] **Duo/Quattro**, tap the "Open/Close Tray" button to eject the chip tray.
13. Take out the **Truenat**[®] **Beta CoV** Chip-based Real Time PCR test at end of the test and dispose it off as per the section on "Disposal and Destruction" (Section 18).
14. Turn on **Truelab**[®] micro PCR printer and select print on the screen for printing out hard copy of the results. Test results are automatically stored and can be retrieved any time later. (Refer to the **Truelab**[®] Analyzer manual).
15. Switch off the **Truelab**[®] Analyzer.

16. RESULTS & INTERPRETATIONS

Two amplification curves are displayed on the **Truelab**[®] **Real Time micro PCR Analyzer** screen to indicate the progress of the test. Both the target and the internal positive control (IPC)* curves will take a steep, exponential path when the fluorescence crosses the threshold value in case of positive samples. The Cycle threshold (Ct) will depend on the number of target nucleic acids in the sample. The curve will remain horizontal throughout the test duration and the IPC curve will take an exponential path in case of negative samples. In case the IPC curve remains horizontal in a negative sample, the test is considered as Invalid. At the end of the test run, the results screen will display "DETECTED" for Positive result or "NOT DETECTED" for Negative result. The result screen would also display the viral load as "HIGH (Ct<20)", "MEDIUM (20≤Ct<25)", "LOW (25≤Ct<30)" or "VERY LOW (Ct ≥ 30)" for positive specimen. The result screen also displays the validity of the test run as "VALID" or "INVALID". Invalid samples have to be repeated with fresh specimen from the sample preparation stage. *While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid.

17. QUALITY CONTROL PROCEDURES

To ensure that the **Truelab**[®] Real Time micro PCR Analyzer is working accurately, run positive and negative controls from time to time. **Truenat**[®] Positive Control Kit - Panel I (REF 801010008), The containing Positive Control and Negative Control must be

ordered separately. It is advisable to run controls under the following circumstances:

- 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.

18. DISPOSAL AND DESTRUCTION

1. Submerge the used content such as **Truenat® Beta CoV** chip, microtube, microtube cap, pipette tips, nylon flocked swab, Transport Medium for Swab Specimen Tube, lysis buffer tube, 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.

19. SPECIFIC PERFORMANCE CHARACTERISTICS:

Analytical Inclusivity:

Analytical inclusivity of the primer/probe used is verified using recent 1048 genomes of SARS CoV-2, obtained from GISAID database. This included 2 sequences reported from India. Primer and probe binding region was mapped onto this database to verify alignment and to check for any mutations in these region. Alignment studies showed that the primer and probe binding region is well conserved in reported genomes. NCBI primer blast was also performed against beta coronavirus database and results shows conserved 113 bp amplicon, without any mutations in binding regions.

Analytical sensitivity:

To evaluate comparative limit of detection, RNA from a high titre positive sample (ID 613) was serially diluted, to create 6 dilutions. These were run in parallel on **Truenat® Beta CoV** and also the reference test SARS CoV-2. Below table shows the Ct values for COVID 19 target (E gene) obtained on both systems. It was observed that **Truenat® Beta CoV** could detect 2 more dilutions below the limit of reference real time assay. This was further verified using dilutions of IVT RNA and same result was obtained.

	Truenat® Beta CoV	SARS CoV 2 real-time PCR
Dilutions	E gene (Ct)	E gene (Ct)
613	15.4	21.45
613 D1	18.8	22.91
613 D2	21.8	26.63
613 D3	25.75	36.39
613 D4	29.33	ND
613 D5	31.33	ND
613 D6	ND	ND

Linearity & PCR efficiency

Using the dilution series from **Trueprep® AUTO** elute run on **Truenat® Beta CoV**, log linear curve was plotted to check the linearity of Ct values on **Truenat® Beta CoV** test.

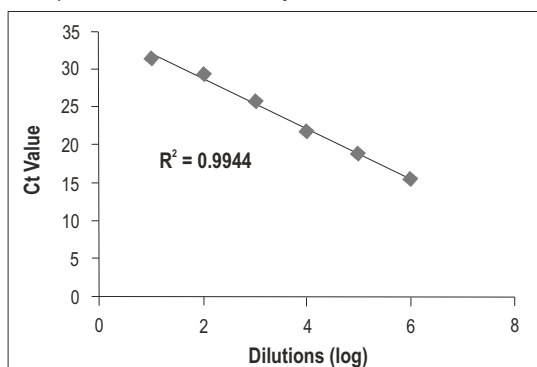
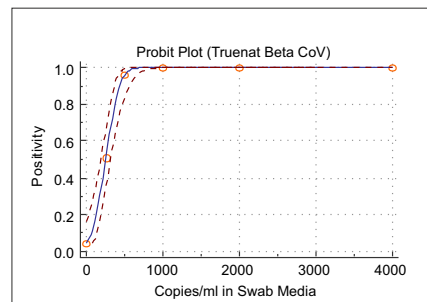


Figure 1: Linearity and PCR efficiency on **Truenat® Beta CoV**. Y axis indicate Ct values and X axis is arbitrary log numbers indicating dilutions.

Conclusion: Slope of the curve was -3.298. Assay was observed to be linear over the range of dilutions tested and PCR efficiency was found to be 101.3%.

Limit of Detection (LoD):

The limit of detection (LoD) was estimated using AccuPlex™ SARS-CoV-2 Verification Panel (Seracare, 0505-0129), as per CLSI EP-17A guidelines. Briefly, six dilutions of quantified material was done in **Trueprep® AUTO** Transport Medium for Swab Specimen Pack. Each dilution was extracted 24 times using **Trueprep® AUTO** Universal Cartridge based Sample Prep Device and tested on the **Truenat® Beta CoV** chip. Probit regression was used to estimate LoD at 95% positivity, as indicated below.



LoD was estimated to be 486 genome copies/ml in transport medium for swab specimen, with 95% CI interval of 405 - 640.

Precision:

Repeatability of PCR test is essential to ensure assay reproducibility & reliability. Three clinical elutes representing High (522), Medium (1304) and Low (1342) Ct as per reference assay were run on all 4 PCR devices used in this evaluation. Following table depicts the Precision analysis. Ct values for E gene are given in table below, with observed standard deviation and % CV.

Device ID	Truenat® Beta CoV		
	(E gene Ct values)		
	Sample 522	Sample 1304	Sample 1342
TLDU 431	15.5	20.83	22.43
TLDU 404	15.33	20.6	22.33
TLDU 381	15.6	21.17	22.6
TLQU 001	16.4	22	22.43
Mean	15.71	21.15	22.45
STDEV	0.47	0.61	0.11
% CV	3.00%	2.90%	0.50%

Conclusion: Observed coefficient of variation in **Truenat® Beta CoV** was within generally accepted value of 10%.

Analytical exclusivity:

In silico analysis was performed to check potential cross reactivity of *E gene* primers and probe to other pathogen genome and human genome. No specific PCR products were observed in NCBI primer blast against other viruses, bacteria and parasites. There are no specific hits to human genome as well. This indicate the primers and probes are specific to sarbeco virus category.

Specificity and cross reactivity:

In vitro specificity studies were done using swabs collected from healthy volunteers (26 nos), as well as elutes positive for Influenza A (3), Influenza B (1) & H1N1 Suspected and positives (25), Tuberculosis (3), Atypical pneumonia (1) and Severe Acute Respiratory Illness – SARI cases (4). None of these runs showed amplification *E gene* target and all gave valid internal control Cts. This indicates no cross reactivity to common respiratory pathogens in **Truenat® Beta CoV**.

Extraction efficiency of Trueprep® AUTO for swab samples:

Five positive and negative throat swab samples in VTM were extracted using **Trueprep® AUTO** system and run on **Truenat® Beta CoV**. Same samples were also extracted using Qiagen mini kit in parallel and run on SARS CoV-2 real-time assay. Ct values obtained on **Truelab®** real time micro PCR workstation was earlier (by average 2 ct) than the reference assay and also all negatives were detected as negative on **Truenat® Beta CoV**. Combined with **Trueprep® AUTO** extraction, **Truenat® Beta CoV** thus showed equivalent/better sensitivity, and the differences were within 0.5 log copies.

Clinical evaluation:

Clinical evaluation of **Truenat® Beta CoV** was performed at the State VRDL lab at Bangalore Medical College. Totally, 18 clinical positives spanning high, medium and low viral load and 46 confirmed negatives were included as a blinded panel.

		SARS CoV 2 real-time PCR		
		Positive	Negative	Total
Truenat® Beta CoV	Positive	18	0	18
	Negative	0	46	46
	Total	18	46	64

All positive and negatives were correctly detected on **Truenat® Beta CoV** assay, indicating 100% sensitivity, specificity and concordance to reference gold standard assay.

20. REFERENCES

1. Richman DD, Whitley RJ, Hayden FG, eds. Clinical virology, 4th edn. Washington: ASM Press, 2016.
2. Ksiazek TG, Erdman D, Goldsmith CS, et al. A novel coronavirus associated with severe acute respiratory syndrome. N Engl J Med 2003; 348: 1953–66.
3. WHO. Middle East respiratory syndrome coronavirus (MERS-CoV). November, 2019. <http://www.who.int/emergencies/mers-cov/en/> (accessed Jan 19, 2020).
4. WHO. Novel coronavirus – China. Jan 12, 2020. <http://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/> (accessed Jan 19, 2020).
5. WHO. Novel coronavirus – Thailand (ex-China). Jan 14, 2020. <http://www.who.int/csr/don/14-january-2020-novel-coronavirusthailand/en/> (accessed Jan 19, 2020).

SYMBOL KEYS

Consult instructions for use	In vitro Diagnostic Medical Device. Not for medicinal use.	Temperature Limitation	Catalogue Number	For single use only	This Way Up	Manufacturer	Unique Device Identifier
Date of Manufacture	Date of Expiry	Batch Number / Lot Number	Caution	Contains sufficient for $n-1$ tests	Keep dry	Keep away from sunlight	Authorised Representative in European Community


Molbio Diagnostics Private Limited

Registered Office & Manufacturing Unit:

Plot No. L-46, Phase II D,
Verna Industrial Estate, Verna,
Goa - 403 722, INDIA
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