ISO 9001:2008 International Standard Certification
LIC No. QACR91/3585
NABL M-0520
Unipath SPECIALTY LABORATORY Ltd.
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TEST REPORT

Reg. No.	: 1044508598	**Reg. Date** : 28-Jul-2021 15:35	**Ref.No** : 2341001 113739	**Collected On**	: 28-Jul-2021 15:35
Name	: Ms. Yukta Yadav			**Reported Date**	: 29-Jul-2021
Age	: 23 Years	**Gender** : Female	**Pass. No. :**	**Dispatch At**	::
Ref. By	:			**Tele No.**	7477743111
Location	: INCLUZN LIFESCIENCE PVT.LTD. @ INDORE				

Test Name	Results	Units	Bio. Ref. Interval

MOLECULAR ANALYSIS FOR QUALITATIVE DETECTION OF SARS-CoV-2.

Type of sample : Nasopharyngeal swab and Oropharyngeal swab.
Methodology : Real time PCR. ICMR NO :UNIPA001

ORF 1ab	Negative
N Gene	Negative
S Gene	Negative
MS2 GENE(Internal Control)	Pass

Interpretation

2019-nCoV	**NEGATIVE**

Note :

For results with S-Gene negative and other two genes positive: These samples may have 69-70del S gene mutation which is usually associated with, but not limited to B.1.1.7 variant (UK VOC-202012/01). Since our assay is designed to detect multiple genetic targets (ORF and N genes along with S gene), the overall test sensitivity is not impacted by this variant. (Ref: https://www.fda.gov/medical-devices/letters-health-care-providers/genetic-variants-sars-cov-2-may-lead-false-negative-results-molecular-tests-detection-sars-cov-2)

1 - Test report should be correlated with the clinical presentation and findings.
2 - The LOD for the three target genes is 10 copies/reaction.
3 - A negative result does not rule out 2019-nCoV and should not be used as the sole basis for treatment or other patient management decisions.
4 - A number of factors could lead to a negative result in an infected individual including 1) Poor quality of the specimen, containing inadequate patient material or non-representative specimen 2) The specimen was collected late or very early in the infection. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple samples from the same patient may be necessary to detect the virus 3) The specimen was not handled and shipped appropriately 4) Technical reasons inherent in the test (like Virus mutation or PCR inhibition) 5) Inadequate numbers of organisms are present in the specimen
5 - Reports will be provided to the treating physician, who is requested to communicate the same to the patient and follow MOHFW policy for isolation, quarantine and treatment of all positive cases along with contact tracing as recommended.
6 - Repeat sampling and testing of lower respiratory specimen is strongly recommended in severe or progressive disease.
7 -The repeat specimens may be considered after a gap of 2-4 days after the collection of the first specimen for additional testing if required.
8 - Categories of viral load is based on Cycle threshold (Ct) detected by RT PCR.

---------- End Of Report ----------

Test done from collected sample.

This is an electronically authenticated report.

Approved by: DR. JIGAR SUTHAR PHD

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