

STUDY TITLE

Clinical Performance Study Report

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STUDY ARTICLE

MERISCREEN COVID-19 Antigen Detection Test

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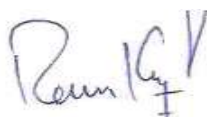
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Date: 08/06/2021

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1. Report synopsis

Table 1: Report synopsis

Name of sponsor/company: Meril Diagnostics Pvt. Ltd. Second Floor, D1 – D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191 Gujarat, India.	
Trade name of device: MERISCREEN COVID-19 Antigen Detection Test	
Measurand: SARS-CoV-2 Antigen	
Title of study: Clinical Performance Study	
Study site(s) location: Gagan Pathology Centre, F-26/22, Near Ayodhya Chowk, Pocket 26, Sector 7, Rohini, Delhi, 110085	
Name and contact information of individual responsible for the study:	
Name and Designation: Mr. Pradeep Kumar DGM , R&D	Name and Designation: Mr. Ram Kanoje Head QA
Study commencement date: 03/05/2021	Study completion date: 29/05/2021
Study objective: To establish clinical performance by prospectively evaluating diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test kit to be used for qualitative detection of SARS-CoV-2 Antigen in the specified clinical matrix (e.g. Nasopharyngeal swab)	
Study design: A total of 255 nasopharyngeal swab specimens were collected sequentially are tested in a blinded fashion to determine the diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test with RT-PCR kit. These tests are carried out in a blinded fashion with respect to operators handling the tests at the testing site.	
Statistical methods: Diagnostic sensitivity and specificity was calculated using MedCalc statistical software.	

2. List of abbreviation and Definitions of terms

- Diagnostic sensitivity: As per Common Technical Specification (CTS), 27th November 2009, Diagnostic Sensitivity is defined as the probability that the device gives a positive result in the presence of the target marker.
- Diagnostic specificity: As per Common Technical Specification (CTS), 27th November 2009, Diagnostic Specificity is defined as the probability that the device gives a negative result in the absence of the target marker.
- True Positive: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be positive for the target marker and correctly classified by the device
- False Negative: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be positive for the target marker and misclassified by the device
- False Positive: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be negative for the target marker and misclassified by the device
- True Negative: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be negative for the target marker and correctly classified by the device
- COVID-19: Coronavirus-2019
- SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus
- PPA: Positive predictive value
- NPV: Negative predictive value

3. Purpose/Objective & Scope

Purpose / Objective:

The purpose of this study is to establish the clinical performance by evaluating diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test Kit to be used for qualitative detection of infection with SARS-CoV-2 Antigen in Specified clinical matrix (e.g. Nasopharyngeal swab).

Scope:

The scope of this report is applicable for MERISCREEN COVID-19 Antigen Detection Test performance only.

4. References

- EN 13612:2002 Performance evaluation of In-Vitro diagnostic medical devices
- Common Technical Specification (CTS), 27th November 2009 - COMMON TECHNICAL SPECIFICATION (CTS) as defined in EUROPEAN COMMISSION DECISION 2009/886 amending decision 2002/364/EC
- GHTF/SG1/N063:2011 Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of In-Vitro diagnostics medical devices
- EP12 – P, Vol. 20, No. 15 – User protocol for evaluation of qualitative test performance; Approved guideline
- Clinical Performance Protocol – Independent Study for MERISCREEN COVID-19 Antigen Detection Test Kit (Document No.: CPP-01/IM/GRA/017)
- MERISCREEN COVID-19 Antigen Detection Test Kit Pack Insert: IFU/NCTCAG01/04, Date: 19/05/2021

5. Introduction

As per Common Technical Specification (CTS), 27th November 2009, Diagnostic Sensitivity is defined as the probability that the device gives a positive result in the presence of the target marker. Diagnostic Specificity is defined as the probability that the device gives a negative result in the absence of the target marker.

This study is performed to find out the diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test Kit using specimens collected from suspected symptomatic/asymptomatic population collected in specified clinical matrix (i.e Nasopharyngeal swab).

Results of tested samples are presented in the below table format and diagnostic sensitivity & specificity along with positive predictive value (PPV) and negative predictive value (NPV) are found out.

Table 2: Reference table for result presentation

		True Disease Status		
		Positive	Negative	
Results of assay under evaluation	Positive	A True Positives	b False Positives	a+b
	Negative	C False Negatives	d True Negatives	c+d
		a+c	b+d	

- Sensitivity: The sensitivity is the number of true positive sera identified by the assay under evaluation as positive (a), divided by the number of sera identified by the reference assays as positive (a+c), expressed as a percentage.
- Positive Predictive Value (PPV): The probability that when the test is reactive, the specimen does contain SARS-Cov-2 antigens. This may be calculated using the simple formula $a/(a+b)$ which will give an approximate value.
- Positive predictive value = $a/(a+b)$
- Specificity: The specificity is the number of true negative sera identified by the assay under evaluation as negative (d), divided by the number of sera identified by the reference assays as negative (b+d), expressed as a percentage.
- Negative Predictive Value (NPV): The probability that when the test is negative, the specimen does not have SARS-Cov-2 antigens. This may be calculated using the simple formula $d/(c+d)$ which will give an approximate value.
- Negative predictive value = $d/(c+d)$

6. Intended use of the device

MERISCREEN COVID-19 Antigen Detection Test is a lateral flow immunochromatographic rapid assay kit for the qualitative detection of SARS-CoV-2 specific antigen (viral nucleocapsid protein) in nasopharyngeal swab from human. This test is designed for use in laboratory and point of care (POCT) environment by healthcare professional that meets the requirements specified in the instruction for use and local regulation. This test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. Negative results must be combined with clinical observations, patient history and epidemiological information.

7. Device description and principle of the method

7.1 Device Description:

KIT COMPONENTS:

1. Individually packed test devices with desiccant
2. Extraction solution
3. Extraction tube
4. Extraction Tube Stand
5. Disposable dropper cap
6. Disposable nasopharyngeal swabs for sample collection
7. Package Insert

7.2 Principle of the method:

MERISCREEN COVID-19 Antigen Detection Test is an immunoassay kit for rapid and qualitative determination of SARS-CoV-2 infection from swab specimens. Monoclonal anti-SARS-CoV-2 nucleocapsid antibody is coated on the test line region. Antigens of SARS-CoV-2 in the specimens react with the anti-SARS-CoV-2 monoclonal nucleocapsid antibody coupled with gold conjugate, and form an antigen-antibody complex followed by reaction with anti-SARS-CoV-2 monoclonal nucleocapsid antibodies immobilized in the test line. This complex migrates on the membrane, where it will be captured by the monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no line appears in the test line. The control band is used for procedural control and should always appear if the test procedure is performed correctly.

8. Equipment and Materials

The detail of materials used in the study is mentioned below:

- **Study performed by testing MERISCREEN COVID-19 Antigen Detection Test**
 - **Details of Meril Kit:** Three lots of MERISCREEN COVID-19 Antigen Detection Test kit are utilized in the study. Details of the lots are mentioned below:
 - **Name of the Kit: MERISCREEN COVID-19 Antigen Detection Test kit**
 - Lot 1:** MI042105, **Expiry Date:** 2023/03
 - Lot 2:** MI042106, **Expiry Date:** 2023/03

Lot 3: MI042107, **Expiry Date:** 2023/03

▪ **FDA EUA approved RT PCR Assay kit**

Name of the Kit: TRUPCR® SARS-CoV-2 RT qPCR Kit (V-3.2)

Lot #: COV-19/V3.2/2021/10

Expiry Date: 2022/04

▪ **Test sample**

105 positive and 150 negative nasopharyngeal swab samples were collected prospectively from suspected symptomatic/asymptomatic population enrolled sequentially at the test site for MERISCREEN COVID-19 Antigen Detection Test and Sample status was confirmed by FDA EUA approved RT PCR assay.

9. Operator of assay

The study was performed at the site mentioned below

Site Address: Gagan Pathology Centre, F-26/22, Near Ayodhya Chowk, Pocket 26, Sector 7, Rohini, Delhi, 110085

Detail of operators at Site:

Three lots of MERISCREEN COVID-19 Antigen Detection Test were tested with EUA FDA approved RT-PCR assay by trained operators.

Details of operators are given below:

Operator 1: Pooja

Operator 2: Khushboo

Operator 3: Kirti

Operator 4: Samiksha

10. Study design

Clinical Performance characteristics of MERISCREEN COVID-19 Antigen Detection Test for rapid detection of SARS-CoV-2 was established in prospective, blinded study in which Nasopharyngeal swabs from patients sequentially enrolled are collected and tested on three different lots of MERISCREEN COVID-19 Antigen Detection Test by different operators. Status confirmation of the specimens was done by testing the nasopharyngeal and oropharyngeal

specimens from the same individuals with FDA EUA approved RT-PCR kit. Total 105 confirmed SARS-CoV-2 positive specimens and 150 confirmed SARS-CoV-2 Negative specimens enrolled sequentially are tested in a blinded fashion to determine the diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test with RT-PCR kit.

11. Test samples:

As mentioned in section 10, 105 SARS-CoV-2 positive and 150 SARS-CoV-2 negative from suspected symptomatic/asymptomatic population were collected in the specified clinical matrix (e.g. Nasopharyngeal swabs) and were utilized in this study.

Inclusion Criteria:

Suspected Symptomatic/Asymptomatic patients positive to SARS-CoV-2 infection.

Exclusion Criteria:

Specimen positive to virus infections other than SARS CoV-2

Testing were performed with MERISCREEN COVID-19 Antigen Detection Test and FDA EUA approved TRUPCR[®] SARS-CoV-2 RT qPCR Kit (V-3.2) in a blinded fashion to get the Ct value and test line band intensity which confirms status of the specimens tested.

The of details of specimens utilized for determining diagnostic sensitivity and diagnostic specificity using FDA EUA approved TRUPCR[®] SARS-CoV-2 RT qPCR Kit (V-3.2) assay with MERISCREEN COVID-19 Antigen Detection Test and the Ct value and test line band intensity obtained is mentioned in below Table no:3

Table 3: Details of specimens tested with TRUPCR[®] SARS-CoV-2 RT qPCR Kit (V-3.2) and MERISCREEN COVID-19 Antigen Detection Test at test site:

Sr. No.	Source Patient ID	Physiological Condition	Sample Type	RT PCR Ct Value	Sample Status	Sample type	MERISCR EEN COVID-19 Antigen Detection Test		Sample Status
		(Age/Sex)					Band Intensity		
							C	C	
1	135869	15 Yrs/Male	NS + O	RdRp+N-31, E-32	Positive	NS	4+	1+	Positive
2	135872	29Yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
3	135875	34 Yrs/Male	NS + O	RdRp+N-24, E-23	Positive	NS	4+	0	Positive
4	135879	30yrs/Female	NS + O	RdRp+N -27, E-26	Positive	NS	4+	2+	Positive
5	135880	26yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
6	136583	13 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
7	136585	42 Yrs/Male	NS + O	RdRp+N -31, E-32	Positive	NS	4+	1+	Positive
8	136587	44 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
9	136589	32 yrs/Female	NS + O	RdRp+N -21, E-22	Positive	NS	4+	3+	Positive
10	136590	45 yrs/Female	NS + O	RdRp+N-19, E-18	Positive	NS	4+	0	Negative
11	136592	44 yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
12	136595	14 yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
13	136596	29 yrs/Female	NS + O	RdRp+N -25, E-24	Positive	NS	4+	2+	Positive
14	136598	21 yrs/Female	NS + O	RdRp+N -24, E-23	Positive	NS	4+	2+	Positive
15	136599	57 Yrs/Male	NS + O	RdRp+N -15, E-16	Positive	NS	4+	4+	Positive
16	136603	15 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
17	136609	21 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
18	136611	6 Yrs/Male	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
19	136616	31 yrs/Female	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
20	136618	24 Yrs/Male	NS + O	RdRp+N-14, E-15	Positive	NS	4+	0	Positive
21	136620	67 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
22	136622	45 yrs/Female	NS + O	RdRp+N -28, E-27	Positive	NS	4+	2+	Positive

23	136623	61 Yrs/Male	NS + O	RdRp+N-21, E-20	Positive	NS	4+	0	Positive
24	136624	61 yrs/Female	NS + O	RdRp+N -25, E-24	Positive	NS	4+	2+	Positive
25	136625	38 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
26	136627	41 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
27	136629	51 Yrs/Male	NS + O	RdRp+N -25, E-24	Positive	NS	4+	2+	Positive
28	136630	58 Yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	3+	Positive
29	136632	32 Yrs/Male	NS + O	RdRp+N -32, E-31	Positive	NS	4+	1+	Positive
30	136633	70 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
31	136635	73 Yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
32	136637	68 Yrs/Male	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
33	136640	49 yrs/Female	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
34	136641	24 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
35	136642	36 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
36	136646	56 Yrs/Male	NS + O	RdRp+N -17, E -16	Positive	NS	4+	4+	Positive
37	136647	48 yrs/Female	NS + O	RdRp+N -20, E-21	Positive	NS	4+	3+	Positive
38	136651	68 yrs/Female	NS + O	RdRp+N -16, E-17	Positive	NS	4+	4+	Positive
39	136653	73 yrs/Female	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
40	136655	58 Yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
41	136657	32 Yrs/Male	NS + O	RdRp+N -17, E-18	Positive	NS	4+	4+	Positive
42	136659	46 Yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
43	136661	19 yrs/Female	NS + O	RdRp+N -17, E-18	Positive	NS	4+	4+	Positive
44	136663	44 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
45	136667	24 yrs/Female	NS + O	RdRp+N -31, E-32	Positive	NS	4+	1+	Positive
46	136668	56 Yrs/Male	NS + O	RdRp+N -30, E-31	Positive	NS	4+	2+	Positive
47	136671	56 Yrs/Male	NS + O	RdRp+N -32, E-33	Positive	NS	4+	0	Negative
48	136674	57 yrs/Female	NS + O	RdRp+N -15, E-13	Positive	NS	4+	4+	Positive

49	136675	81 yrs/Female	NS + O	RdRp+N - 16, E-15	Positive	NS	4+	4+	Positive
50	136677	59 yrs/Female	NS + O	RdRp+N - 19, E-20	Positive	NS	4+	4+	Positive
51	136679	26 Yrs/Male	NS + O	RdRp+N - 18, E-17	Positive	NS	4+	4+	Positive
52	136682	23 Yrs/Male	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
53	136685	31yrs/Female	NS + O	RdRp+N - 17, E-16	Positive	NS	4+	4+	Positive
54	136687	21 Yrs/Male	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
55	136688	49 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
56	136691	60 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
57	136694	24 Yrs/Male	NS + O	RdRp+N - 20, E-19	Positive	NS	4+	4+	Positive
58	136697	43yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
59	136699	08yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
60	136702	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
61	136705	32 Yrs/Male	NS + O	RdRp+N - 22, E-23	Positive	NS	4+	4+	Positive
62	136709	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
63	136711	17 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
64	136713	55yrs/Female	NS + O	RdRp+N - 16, E-15	Positive	NS	4+	4+	Positive
65	136715	32 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
66	136718	54yrs/Female	NS + O	RdRp+N - 16, E-15	Positive	NS	4+	4+	Positive
67	136720	35yrs/Male	NS + O	RdRp+N - 17, E-18	Positive	NS	4+	4+	Positive
68	136723	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
69	136725	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
70	136729	57yrs/Male	NS + O	RdRp+N - 17, E-16	Positive	NS	4+	4+	Positive
71	136732	49yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
72	136739	44yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
73	136742	55yrs/Female	NS + O	RdRp+N - 18, E-19	Positive	NS	4+	3+	Positive
74	136746	65yrs/Male	NS + O	0	Negative	NS	4+	0	Negative

75	136749	44yrs/Female	NS + O	RdRp+N - 17, E-16	Positive	NS	4+	4+	Positive
76	136753	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
77	136756	23yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
78	136757	36yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
79	136760	34yrs/Male	NS + O	RdRp+N - 16, E-15	Positive	NS	4+	4+	Positive
80	136762	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
81	136764	42yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
82	136766	45yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
83	136767	54yrs/Male	NS + O	RdRp+N - 22, E-23	Positive	NS	4+	3+	Positive
84	136769	42yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
85	136770	44yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
86	136772	22yrs/Female	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
87	136773	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
88	136775	48yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
89	136778	33yrs/Male	NS + O	RdRp+N - 20, E-19	Positive	NS	4+	3+	Positive
90	136780	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
91	136784	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
92	136788	29Yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
93	136791	24yrs/Female	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
94	136793	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
95	136796	28yrs/Female	NS + O	RdRp+N - 16, E-15	Positive	NS	4+	4+	Positive
96	136799	34yrs/Male	NS + O	RdRp+N - 32, E-33	Positive	NS	4+	0	Negative
97	136801	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
98	136805	32yrs/Female	NS + O	RdRp+N - 32, E-33	Positive	NS	4+	0	Negative
99	136808	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
100	136811	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

101	136814	24yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
102	136816	19yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
103	136820	21yrs/Female	NS + O	RdRp+N - 27, E-28	Positive	NS	4+	3+	Positive
104	136823	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
105	136828	27yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
106	136833	35yrs/Male	NS + O	RdRp+N - 18, E-19	Positive	NS	4+	3+	Positive
107	136837	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
108	136840	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
109	136843	44yrs/Female	NS + O	RdRp+N - 32, E-31	Negative	NS	4+	4+	Positive
110	136849	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
111	136853	26yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
112	136857	38yrs/Male	NS + O	RdRp+N - 20, E-21	Positive	NS	4+	3+	Positive
113	136859	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
114	136861	49yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
115	136863	23yrs/Male	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
116	136865	44yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
117	136868	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
118	136873	55yrs/Male	NS + O	RdRp+N - 23, E-24	Positive	NS	4+	3+	Positive
119	136877	41yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
120	136879	21yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
121	136886	23yrs/Male	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
122	136890	18yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
123	136892	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
124	136895	40yrs/Male	NS + O	RdRp+N - 18, E-17	Positive	NS	4+	4+	Positive
125	136899	43yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
126	136901	26yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

127	136903	21yrs/Male	NS + O	RdRp+N - 22, E-23	Positive	NS	4+	4+	Positive
128	136907	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
129	136910	31yrs/Female	NS + O	RdRp+N - 24, E-25	Positive	NS	4+	3+	Positive
130	136912	28yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
131	136915	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
132	136919	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
133	136921	48yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
134	136924	51yrs/Male	NS + O	RdRp+N - 32, E-31	Positive	NS	4+	4+	Positive
135	136926	30yrs/Female	NS + O	RdRp+N - 31, E-30	Positive	NS	4+	3+	Positive
136	136929	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
137	136933	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
138	136935	39yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
139	136940	22yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
140	136942	27yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
141	136959	30yrs/Female	NS + O	RdRp+N - 24, E-23	Positive	NS	4+	3+	Positive
142	136961	32yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
143	136964	45yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
144	136967	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
145	136970	35yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
146	136972	42yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
147	136975	49yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
148	136979	32yrs/Male	NS + O	RdRp+N - 20, E-19	Positive	NS	4+	4+	Positive
149	136981	51yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
150	136984	22yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
151	136987	18yrs/Male	NS + O	RdRp+N - 19, E-18	Positive	NS	4+	4+	Positive
152	136991	28yrs/Male	NS + O	0	Negative	NS	4+	0	Negative

153	136996	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
154	136999	35yrs/Male	NS + O	RdRp+N - 26, E-27	Positive	NS	4+	3+	Positive
155	137002	25yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
156	137013	19yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
157	137017	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
158	137020	29yrs/Male	NS + O	RdRp+N - 29, E-30	Positive	NS	4+	4+	Positive
159	137033	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
160	137037	36yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
161	137038	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
162	137041	31yrs/Male	NS + O	RdRp+N - 26, E-27	Positive	NS	4+	2+	Positive
163	137043	34yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
164	137048	52yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
165	137050	34yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
166	137053	25yrs/Male	NS + O	RdRp+N - 16, E-17	Positive	NS	4+	4+	Positive
167	137056	29yrs/Female	NS + O	RdRp+N - 20, E-21	Positive	NS	4+	3+	Positive
168	137059	32yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
169	137063	21yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
170	137067	24yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
171	137069	35yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
172	137072	39yrs/Male	NS + O	RdRp+N - 21, E-22	Positive	NS	4+	3+	Positive
173	137075	41yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
174	137079	48yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
175	137081	32yrs/Female	NS + O	RdRp+N - 20, E-21	Positive	NS	4+	4+	Positive
176	137083	45yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
177	137085	45yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
178	137088	32yrs/Male	NS + O	RdRp+N - 19, E-20	Positive	NS	4+	4+	Positive

179	137092	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
180	137102	24yrs/Female	NS + O	RdRp+N - 17, E-16	Positive	NS	4+	3+	Positive
181	137107	29yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
182	137111	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
183	137115	28yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
184	137118	46yrs/Female	NS + O	RdRp+N - 17, E-16	Positive	NS	4+	4+	Positive
185	137121	42yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
186	137125	56yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
187	137127	47yrs/Male	NS + O	RdRp+N - 23, E-24	Positive	NS	4+	2+	Positive
188	137129	24yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
189	137132	39yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
190	137133	42yrs/Female	NS + O	RdRp+N - 20, E-19	Positive	NS	4+	3+	Positive
191	137135	22yrs/Male	NS + O	RdRp+N - 15, E-14	Positive	NS	4+	3+	Positive
192	137137	35yrs/Female	NS + O	RdRp+N - 22, E-23	Positive	NS	4+	4+	Positive
193	137139	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
194	137141	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
195	137143	32yrs/Male	NS + O	RdRp+N - 26, E-27	Positive	NS	4+	4+	Positive
196	137146	37yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
197	137148	53yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
198	137149	23yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
199	137152	27yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
200	137155	32yrs/Male	NS + O	RdRp+N - 21, E-22	Positive	NS	4+	2+	Positive
201	137158	45yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
202	137162	41yrs/Male	NS + O	RdRp+N - 28, E-29	Positive	NS	4+	3+	Positive
203	137164	58yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
204	137167	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

205	137169	42yrs/Female	NS + O	RdRp+N - 26, E-25	Positive	NS	4+	3+	Positive
206	137172	52yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
207	137175	43yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
208	137177	23yrs/Male	NS + O	RdRp+N - 24, E-25	Positive	NS	4+	4+	Positive
209	137179	25yrs/Male	NS + O	RdRp+N - 22, E-23	Negative	NS	4+	0	Negative
210	137181	22yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
211	137184	32yrs/Female	NS + O	RdRp+N - 28, E-29	Positive	NS	4+	4+	Positive
212	137185	41yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
213	137187	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
214	137190	23yrs/Male	NS + O	RdRp+N - 14, E-15	Positive	NS	4+	3+	Positive
215	137194	27yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
216	137196	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
217	137199	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
218	137202	42yrs/Female	NS + O	RdRp+N - 16, E-17	Positive	NS	4+	3+	Positive
219	137205	22yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
220	137207	24yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
221	137210	36yrs/Female	NS + O	RdRp+N - 28, E-29	Positive	NS	4+	4+	Positive
222	137213	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
223	137215	34yrs/Female	NS + O	RdRp+N - 24, E-23	Positive	NS	4+	4+	Positive
224	137218	43yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
225	137220	34yrs/Male	NS + O	RdRp+N - 28, E-27	Positive	NS	4+	3+	Positive
226	137223	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
227	137228	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
228	137231	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
229	137234	46yrs/Female	NS + O	RdRp+N - 17, E-18	Positive	NS	4+	2+	Positive
230	137238	43yrs/Male	NS + O	0	Negative	NS	4+	0	Negative

231	137240	21yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
232	137241	25yrs/Male	NS + O	RdRp+N - 21, E-20	Positive	NS	4+	4+	Positive
233	137247	27yrs/Male	NS + O	RdRp+N - 16, E-17	Positive	NS	4+	4+	Positive
234	137250	29yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
235	137252	31yrs/Male	NS + O	RdRp+N - 22, E-23	Positive	NS	4+	3+	Positive
236	137255	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
237	137256	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
238	137258	44yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
239	137261	49yrs/Female	NS + O	RdRp+N - 17, E-18	Positive	NS	4+	4+	Positive
240	137263	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
241	137267	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
242	137269	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
243	137271	30yrs/Male	NS + O	RdRp+N - 24, E-25	Positive	NS	4+	3+	Positive
244	137274	21yrs/Female	NS + O	RdRp+N - 21, E-22	Positive	NS	4+	4+	Positive
245	137279	49yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
246	137281	20yrs/Male	NS + O	RdRp+N - 26, E-27	Positive	NS	4+	4+	Positive
247	137284	26yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
248	137287	40yrs/Male	NS + O	RdRp+N - 22, E-23	Positive	NS	4+	4+	Positive
249	137289	35yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
250	137291	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
251	137293	21yrs/Female	NS + O	RdRp+N - 27, E-28	Positive	NS	4+	4+	Positive
252	137295	18yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
253	137299	20yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
254	137301	40yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
255	137312	33yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

12. Test procedure

For Test procedure of TRUPCR[®] SARS-CoV-2 RT qPCR Kit (V-3.2) kit, refer pack insert

Test procedure of MERISCREEN COVID-19 Antigen Detection Test kit as per the pack insert:

Test Procedure:

1. Bring the specimen and test components to room temperature if refrigerated or frozen.
2. Place the device on a clean, flat surface.
3. Fill the extraction tube by adding 12-14 drops of Extraction solution.
4. Insert the nasopharyngeal swab sample into the extraction solution, and then mix the swab for 8 to 10 times.
5. Remove the swab while pressing against the solution tube in order to extract most of the specimen.
6. Place the dropper cap tightly onto the tube and add 4 drops (100uL) into the sample well.
7. Interpret the test results at the end of 20 minutes. Do not read the results after 30 minutes.

INTERPRETATION OF THE RESULTS:

- Positive result: If Control (C) and Test (T) bands are developed, the test indicates for the Presence of antigens to SARS-CoV-2 in the sample. The result is positive.
- Negative result: If only the Control (C) band is developed, the test indicates that the result is negative.
- Invalid result: If no Control(C) band is developed, then the assay is invalid regardless of colour development on Test (T) band. Repeat the assay with a new device.

13. Acceptance criteria

The diagnostic sensitivity should be equal to or greater than 90% at the lower limit of the 95% confidence interval for each specimen type.

The diagnostic specificity should be equal to or greater than 95% at the lower limit of the 95% confidence interval for each specimen type.

14. Results and data analysis

At **Site**, from total of the sequentially enrolled symptomatic/asymptomatic patients, 105 positive and 150 negative Nasopharyngeal swab samples were utilized for deriving the diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test. Three lots of MERISCREEN COVID-19 Antigen Detection Test were evaluated for diagnostic sensitivity and diagnostic specificity with FDA EUA approved TRUPCR[®] SARS-CoV-2 RT qPCR Kit (V-3.2) assay by different operators at the testing site.

Site: Gagan Pathology Centre, F-26/22, Near Ayodhya Chowk, Pocket 26, Sector 7, Rohini, Delhi, 110085 were chosen to perform clinical performance of MERISCREEN COVID-19 Antigen Detection Test.

There were no any discrepant results or invalid results obtained during study.

Evaluation plan with respect to the planned numbers of samples, tested samples, invalid or rejected results, and acceptance conditions is summarized below in Table 5:

Table 5: Summary of Evaluation

#	Planned Number of Samples to be tested	Acceptance conditions of the samples	No. of Samples Tested	No. of tested samples for which the output received	Acceptance Criteria of the study	No. of False Results Obtained	Invalid Results	Discrepant Results
Study performed by testing MERISCREEN COVID-19 Antigen Detection Test								
1	105 Positive specimens	Please refer Section 11 Test	105	102	Diagnostic sensitivity $\geq 90\%$ at the lower limit of	03	None	None

2	150 Negative specimens	Samples for inclusion and exclusion criteria of specimens	150	150	the 95% confidence interval for each specimen type Diagnostic specificity ≥95% at the lower limit of the 95% confidence interval for each specimen type	None	None	None
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Diagnostic sensitivity and Diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test is calculated using MedCalc Software.

Summary & Calculation of diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection test in comparison to FDA EUA Approved RT PCR assay at test site is mentioned below in table format:

Table 6: Diagnostic sensitivity and Diagnostic specificity results of specimens tested with MERISCREEN COVID-19 Antigen Detection Test

		TRUPCR® SARS-CoV-2 RT qPCR Kit (V-3.2)		
		Positive	Negative	Total
MERISCREEN COVID-19 Antigen Detection Test	Positive	102	00	102
	Negative	003	150	153
	Total	105	150	255
Diagnostic Sensitivity		97.14% (95% CI: 91.88% to 99.41%)		
Diagnostic Specificity		100.00% (95% CI: 97.57% to 100.00%)		
Positive Predictive Value		100.00%		

15. Conclusion

Clinical performance study was performed to determine diagnostic sensitivity and specificity of MERISCREEN COVID-19 Antigen Detection Test kit. A total of 105 positive and 150 negative SARS-CoV-2 specimens from population were tested at site using different operators and different lots of MERISCREEN COVID-19 Antigen Detection Test Kit. Sample status was confirmed using FDA EUA approved RT PCR Assay kit.

Out of 105 positive samples confirmed by RT-PCR, 03 samples detected to be false negative in MERISCREEN COVID-19 Antigen Detection Test Kit. There was no any discrepant or invalid result obtained during testing. Diagnostic sensitivity of MERISCREEN COVID-19 Antigen Detection Test Kit is calculated as 97.14% (95% CI: 91.88% to 99.41%) using MedCalc software when tested with specimens positive for SARS-CoV-2 infections. Diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test Kit is calculated as 100.00% (95% CI: 97.57% to 100.00%) when tested with SARS-CoV-2 negative specimens.

16. Enclosures

- Enclosure- Site-1 Study Data: Raw Data sheet for Diagnostic Sensitivity and Diagnostic Specificity Study of MERISCREEN COVID-19 Antigen Detection Test Kit (Document no.: RD-01//IM/GRA/017)

17. Amendment history

Table 7: Amendment history

Revision No.	Date	Amendment Description
00	As on approval date	Initial Issue

Enclosure-1

**Raw Data Form for Diagnostic Sensitivity
and Specificity Study of MERISCREEN
COVID-19 Antigen Detection Test**

RD-01//IM/GRA/017
Reference Protocol: CPP-01/IM/GRA/017

**1.0 Raw Data Form for Diagnostic Sensitivity and Specificity Study of MERISCREEN COVID-19
Antigen Detection Test**

The purpose of this study is to establish the clinical performance by evaluating diagnostic sensitivity and diagnostic specificity of MERISCREEN COVID-19 Antigen Detection Test kit to be used for qualitative detection of SARS-CoV-2 Antigen in the specified clinical matrix (e.g. Nasopharyngeal swab)





Scope:

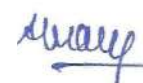
The scope of this protocol is applicable for MERISCREEN COVID-19 Antigen Detection Test kit (NCTCAG-01, 25T) assay kit performance only.

2.0 Name and Address of Study Site:

Gagan Pathology & Imaging Pvt Ltd
F-26/22, Near Ayodhya Chowk,
Pocket 26, Sector 7,
Rohini,
Delhi, 110085

3.0 Details of Operators:

Sr. No.	Name of the Operator	Designation	Signature
1	Pooja	Lab Technician	
2	Khushboo	Lab Tech.	
3	Kirti	Lab Tech.	
4	Samiksha	Lab Technician	



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On Panel : CGHS, D.G.E.H.S., DJB, NDPL, ECHS, DDA, ITPO, NDMC, MCD, LIC (TPA), ESI, DELHI UNIVERSITY

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MRI CT ULTRASOUND ECHO TMT EEG EMG
MAMMOGRAPHY NCV DEXA SCAN OPG ECG
PFT BERA VEP DIGITAL & PORTABLE X-RAYS

Lab Report

**Raw Data Form for Diagnostic Sensitivity
and Specificity Study of MERISCREEN
COVID-19 Antigen Detection Test**

RD-01//IM/GRA/017
Reference Protocol: CPP-01/IM/GRA/017

4.0 Dates of Testing:

Study Commencement Date: 03/05/2021

Study Completion Date: 10/05/2021

5.0 Details of Materials Used:

5.1 Details of Kits used


Sr. No.	Name of the Kit	Make	Purpose of the Kit	Lot No.	Exp. Date
1	MERISCREEN COVID-19 Antigen Detection Test kit	Meril	Kit under evaluation	MI042105	2023/03
2				MI042106	2023/03
3				MI042107	2023/03

5.2 Details of the FDA EUA approved RT-PCR Assay Kit

Sr. No.	Name of the Kit	Make	Purpose of the Kit	Lot No.	Exp. Date
1	TRUPCR® SARS-CoV-2 RT qPCR Kit (V-3.2)	Black Bio	Specimen status confirmation	Cov- 19/V3.2/2021/1 0	April-2022

5.3 Details of the RT-PCR instrument used

Sr. No.	Name of the Kit	Make	Purpose of the Kit	Serial No. of instrument
1	BIORAD CFX96	BIORAD	To run the specimen for status confirmation	785BR16842


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Raw Data Form for Diagnostic Sensitivity
and Specificity Study of MERISCREEN
COVID-19 Antigen Detection Test

RD-01//IM/GRA/017
Reference Protocol: CPP-01/IM/GRA/017

6.0 Details of Samples Used:

Details of SARS CoV-2 positive & SARS CoV-2 negative specimens:

Sr. No.	Source Patient ID	Physiological Condition	Sample Type	RT PCR Ct Value	Sample Status	Sample type	MERISCRE EN COVID-19 Antigen Detection Test		Sample Status
		(Age/Sex)					Band Intensity		
							C	C	
1	135869	15 Yrs/Male	NS + O	RdRp+N-31, E-32	Positive	NS	4+	1+	Positive
2	135872	29Yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
3	135875	34 Yrs/Male	NS + O	RdRp+N-24, E-23	Positive	NS	4+	0	Positive
4	135879	30yrs/Female	NS + O	RdRp+N-27, E-26	Positive	NS	4+	2+	Positive
5	135880	26yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
6	136583	13 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
7	136585	42 Yrs/Male	NS + O	RdRp+N-31, E-32	Positive	NS	4+	1+	Positive
8	136587	44 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
9	136589	32 yrs/Female	NS + O	RdRp+N-21, E-22	Positive	NS	4+	3+	Positive

Ankur

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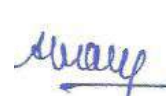
Lab Report

Raw Data Form for Diagnostic Sensitivity and Specificity Study of MERISCREEN COVID-19 Antigen Detection Test

RD-01//IM/GRA/017
Reference Protocol: CPP-01/IM/GRA/017

10	136590	45 yrs/Female	NS + O	RdRp+N- 19, E-18	Positive	NS	4+	0	Negative
11	136592	44 yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
12	136595	14 yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
13	136596	29 yrs/Female	NS + O	RdRp+N -25, E-24	Positive	NS	4+	2+	Positive
14	136598	21 yrs/Female	NS + O	RdRp+N -24, E-23	Positive	NS	4+	2+	Positive
15	136599	57 Yrs/Male	NS + O	RdRp+N -15, E-16	Positive	NS	4+	4+	Positive
16	136603	15 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
17	136609	21 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
18	136611	6 Yrs/Male	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
19	136616	31 yrs/Female	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
20	136618	24 Yrs/Male	NS + O	RdRp+N- 14, E-15	Positive	NS	4+	0	Positive
21	136620	67 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
22	136622	45 yrs/Female	NS + O	RdRp+N -28, E-27	Positive	NS	4+	2+	Positive
23	136623	61 Yrs/Male	NS + O	RdRp+N- 21, E-20	Positive	NS	4+	0	Positive

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Lab Report

**Raw Data Form for Diagnostic Sensitivity
and Specificity Study of MERISCREEN
COVID-19 Antigen Detection Test**

RD-01//IM/GRA/017
Reference Protocol: CPP-01/IM/GRA/017

24	136624	61yrs/Female	NS + O	RdRp+N -25, E-24	Positive	NS	4+	2+	Positive
25	136625	38 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
26	136627	41 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
27	136629	51 Yrs/Male	NS + O	RdRp+N -25, E-24	Positive	NS	4+	2+	Positive
28	136630	58 Yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	3+	Positive
29	136632	32 Yrs/Male	NS + O	RdRp+N -32, E-31	Positive	NS	4+	1+	Positive
30	136633	70 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
31	136635	73 Yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
32	136637	68 Yrs/Male	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
33	136640	49 yrs/Female	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
34	136641	24 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
35	136642	36 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
36	136646	56 Yrs/Male	NS + O	RdRp+N -17, E - 16	Positive	NS	4+	4+	Positive
37	136647	48	NS + O	RdRp+N	Positive	NS	4+	3+	Positive

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		yrs/Female		-20, E-21					
38	136651	68 yrs/Female	NS + O	RdRp+N -16, E-17	Positive	NS	4+	4+	Positive
39	136653	73 yrs/Female	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
40	136655	58 Yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
41	136657	32 Yrs/Male	NS + O	RdRp+N -17, E-18	Positive	NS	4+	4+	Positive
42	136659	46 Yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
43	136661	19 yrs/Female	NS + O	RdRp+N -17, E-18	Positive	NS	4+	4+	Positive
44	136663	44 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
45	136667	24 yrs/Female	NS + O	RdRp+N -31, E-32	Positive	NS	4+	1+	Positive
46	136668	56 Yrs/Male	NS + O	RdRp+N -30, E-31	Positive	NS	4+	2+	Positive
47	136671	56 Yrs/Male	NS + O	RdRp+N -32, E-33	Positive	NS	4+	0	Negative
48	136674	57 yrs/Female	NS + O	RdRp+N -15, E-13	Positive	NS	4+	4+	Positive
49	136675	81 yrs/Female	NS + O	RdRp+N -16, E-15	Positive	NS	4+	4+	Positive
50	136677	59 yrs/Female	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive

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51	136679	26 Yrs/Male	NS + O	RdRp+N -18, E-17	Positive	NS	4+	4+	Positive
52	136682	23 Yrs/Male	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
53	136685	31yrs/Female	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
54	136687	21 Yrs/Male	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
55	136688	49 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
56	136691	60 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
57	136694	24 Yrs/Male	NS + O	RdRp+N -20, E-19	Positive	NS	4+	4+	Positive
58	136697	43yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
59	136699	08yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
60	136702	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
61	136705	32 Yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	4+	Positive
62	136709	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
63	136711	17 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
64	136713	55yrs/Female	NS + O	RdRp+N -16, E-15	Positive	NS	4+	4+	Positive

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65	136715	32 Yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
66	136718	54yrs/Female	NS + O	RdRp+N -16, E-15	Positive	NS	4+	4+	Positive
67	136720	35yrs/Male	NS + O	RdRp+N -17, E-18	Positive	NS	4+	4+	Positive
68	136723	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
69	136725	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
70	136729	57yrs/Male	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
71	136732	49yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
72	136739	44yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
73	136742	55yrs/Female	NS + O	RdRp+N -18, E-19	Positive	NS	4+	3+	Positive
74	136746	65yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
75	136749	44yrs/Female	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
76	136753	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
77	136756	23yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
78	136757	36yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

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79	136760	34yrs/Male	NS + O	RdRp+N -16, E-15	Positive	NS	4+	4+	Positive
80	136762	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
81	136764	42yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
82	136766	45yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
83	136767	54yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	3+	Positive
84	136769	42yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
85	136770	44yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
86	136772	22yrs/Female	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
87	136773	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
88	136775	48yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
89	136778	33yrs/Male	NS + O	RdRp+N -20, E-19	Positive	NS	4+	3+	Positive
90	136780	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
91	136784	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
92	136788	29Yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

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93	136791	24yrs/Female	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
94	136793	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
95	136796	28yrs/Female	NS + O	RdRp+N -16, E-15	Positive	NS	4+	4+	Positive
96	136799	34yrs/Male	NS + O	RdRp+N -32, E-33	Positive	NS	4+	0	Negative
97	136801	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
98	136805	32yrs/Female	NS + O	RdRp+N -32, E-33	Positive	NS	4+	0	Negative
99	136808	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
100	136811	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
101	136814	24yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
102	136816	19yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
103	136820	21yrs/Female	NS + O	RdRp+N -27, E-28	Positive	NS	4+	3+	Positive
104	136823	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
105	136828	27yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
106	136833	35yrs/Male	NS + O	RdRp+N -18, E-19	Positive	NS	4+	3+	Positive

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107	136837	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
108	136840	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
109	136843	44yrs/Female	NS + O	RdRp+N -32, E-31	Negative	NS	4+	4+	Positive
110	136849	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
111	136853	26yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
112	136857	38yrs/Male	NS + O	RdRp+N -20, E-21	Positive	NS	4+	3+	Positive
113	136859	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
114	136861	49yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
115	136863	23yrs/Male	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
116	136865	44yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
117	136868	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
118	136873	55yrs/Male	NS + O	RdRp+N -23, E-24	Positive	NS	4+	3+	Positive
119	136877	41yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
120	136879	21yrs/Male	NS + O	0	Negative	NS	4+	0	Negative

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121	136886	23yrs/Male	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
122	136890	18yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
123	136892	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
124	136895	40yrs/Male	NS + O	RdRp+N -18, E-17	Positive	NS	4+	4+	Positive
125	136899	43yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
126	136901	26yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
127	136903	21yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	4+	Positive
128	136907	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
129	136910	31yrs/Female	NS + O	RdRp+N -24, E-25	Positive	NS	4+	3+	Positive
130	136912	28yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
131	136915	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
132	136919	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
133	136921	48yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
134	136924	51yrs/Male	NS + O	RdRp+N -32, E-31	Positive	NS	4+	4+	Positive

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135	136926	30yrs/Female	NS + O	RdRp+N -31, E-30	Positive	NS	4+	3+	Positive
136	136929	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
137	136933	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
138	136935	39yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
139	136940	22yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
140	136942	27yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
141	136959	30yrs/Female	NS + O	RdRp+N -24, E-23	Positive	NS	4+	3+	Positive
142	136961	32yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
143	136964	45yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
144	136967	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
145	136970	35yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
146	136972	42yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
147	136975	49yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
148	136979	32yrs/Male	NS + O	RdRp+N -20, E-19	Positive	NS	4+	4+	Positive

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149	136981	51yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
150	136984	22yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
151	136987	18yrs/Male	NS + O	RdRp+N -19, E-18	Positive	NS	4+	4+	Positive
152	136991	28yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
153	136996	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
154	136999	35yrs/Male	NS + O	RdRp+N -26, E-27	Positive	NS	4+	3+	Positive
155	137002	25yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
156	137013	19yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
157	137017	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
158	137020	29yrs/Male	NS + O	RdRp+N -29, E-30	Positive	NS	4+	4+	Positive
159	137033	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
160	137037	36yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
161	137038	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
162	137041	31yrs/Male	NS + O	RdRp+N -26, E-27	Positive	NS	4+	2+	Positive

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On Panel : CGHS, D.G.E.H.S., DJB, NDPL, ECHS, DDA, ITPO, NDMC, MCD, LIC (TPA), ESI, DELHI UNIVERSITY

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and Specificity Study of MERISCREEN
COVID-19 Antigen Detection Test**

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Reference Protocol: CPP-01/IM/GRA/017**

163	137043	34yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
164	137048	52yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
165	137050	34yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
166	137053	25yrs/Male	NS + O	RdRp+N -16, E-17	Positive	NS	4+	4+	Positive
167	137056	29yrs/Female	NS + O	RdRp+N -20, E-21	Positive	NS	4+	3+	Positive
168	137059	32yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
169	137063	21yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
170	137067	24yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
171	137069	35yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
172	137072	39yrs/Male	NS + O	RdRp+N -21, E-22	Positive	NS	4+	3+	Positive
173	137075	41yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
174	137079	48yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
175	137081	32yrs/Female	NS + O	RdRp+N -20, E-21	Positive	NS	4+	4+	Positive
176	137083	45yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

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177	137085	45yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
178	137088	32yrs/Male	NS + O	RdRp+N -19, E-20	Positive	NS	4+	4+	Positive
179	137092	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
180	137102	24yrs/Female	NS + O	RdRp+N -17, E-16	Positive	NS	4+	3+	Positive
181	137107	29yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
182	137111	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
183	137115	28yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
184	137118	46yrs/Female	NS + O	RdRp+N -17, E-16	Positive	NS	4+	4+	Positive
185	137121	42yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
186	137125	56yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
187	137127	47yrs/Male	NS + O	RdRp+N -23, E-24	Positive	NS	4+	2+	Positive
188	137129	24yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
189	137132	39yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
190	137133	42yrs/Female	NS + O	RdRp+N -20, E-19	Positive	NS	4+	3+	Positive

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191	137135	22yrs/Male	NS + O	RdRp+N -15, E-14	Positive	NS	4+	3+	Positive
192	137137	35yrs/Female	NS + O	RdRp+N -22, E-23	Positive	NS	4+	4+	Positive
193	137139	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
194	137141	21yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
195	137143	32yrs/Male	NS + O	RdRp+N -26, E-27	Positive	NS	4+	4+	Positive
196	137146	37yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
197	137148	53yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
198	137149	23yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
199	137152	27yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
200	137155	32yrs/Male	NS + O	RdRp+N -21, E-22	Positive	NS	4+	2+	Positive
201	137158	45yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
202	137162	41yrs/Male	NS + O	RdRp+N -28, E-29	Positive	NS	4+	3+	Positive
203	137164	58yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
204	137167	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

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205	137169	42yrs/Female	NS + O	RdRp+N -26, E-25	Positive	NS	4+	3+	Positive
206	137172	52yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
207	137175	43yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
208	137177	23yrs/Male	NS + O	RdRp+N -24, E-25	Positive	NS	4+	4+	Positive
209	137179	25yrs/Male	NS + O	RdRp+N -22, E-23	Negative	NS	4+	0	Negative
210	137181	22yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
211	137184	32yrs/Female	NS + O	RdRp+N -28, E-29	Positive	NS	4+	4+	Positive
212	137185	41yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
213	137187	46yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
214	137190	23yrs/Male	NS + O	RdRp+N -14, E-15	Positive	NS	4+	3+	Positive
215	137194	27yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
216	137196	33yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
217	137199	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
218	137202	42yrs/Female	NS + O	RdRp+N -16, E-17	Positive	NS	4+	3+	Positive

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219	137205	22yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
220	137207	24yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
221	137210	36yrs/Female	NS + O	RdRp+N -28, E-29	Positive	NS	4+	4+	Positive
222	137213	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
223	137215	34yrs/Female	NS + O	RdRp+N -24, E-23	Positive	NS	4+	4+	Positive
224	137218	43yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
225	137220	34yrs/Male	NS + O	RdRp+N -28, E-27	Positive	NS	4+	3+	Positive
226	137223	37yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
227	137228	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
228	137231	31yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
229	137234	46yrs/Female	NS + O	RdRp+N -17, E-18	Positive	NS	4+	2+	Positive
230	137238	43yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
231	137240	21yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
232	137241	25yrs/Male	NS + O	RdRp+N -21, E-20	Positive	NS	4+	4+	Positive

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233	137247	27yrs/Male	NS + O	RdRp+N -16, E-17	Positive	NS	4+	4+	Positive
234	137250	29yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
235	137252	31yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	3+	Positive
236	137255	23yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
237	137256	32yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
238	137258	44yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
239	137261	49yrs/Female	NS + O	RdRp+N -17, E-18	Positive	NS	4+	4+	Positive
240	137263	31yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
241	137267	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
242	137269	38yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
243	137271	30yrs/Male	NS + O	RdRp+N -24, E-25	Positive	NS	4+	3+	Positive
244	137274	21yrs/Female	NS + O	RdRp+N -21, E-22	Positive	NS	4+	4+	Positive
245	137279	49yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
246	137281	20yrs/Male	NS + O	RdRp+N -26, E-27	Positive	NS	4+	4+	Positive

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247	137284	26yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
248	137287	40yrs/Male	NS + O	RdRp+N -22, E-23	Positive	NS	4+	4+	Positive
249	137289	35yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
250	137291	25yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
251	137293	21yrs/Female	NS + O	RdRp+N -27, E-28	Positive	NS	4+	4+	Positive
252	137295	18yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
253	137299	20yrs/Male	NS + O	0	Negative	NS	4+	0	Negative
254	137301	40yrs/Female	NS + O	0	Negative	NS	4+	0	Negative
255	137312	33yrs/Female	NS + O	0	Negative	NS	4+	0	Negative

Foot Note: NS = Nasopharyngeal swab & O= Oropharyngeal swab

Note: Sample status was confirmed for their true status by RT PCR method.



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