STUDY TITLE

Analytical Specificity Study Report

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STUDY ARTICLE

MERISCREEN COVID-19 Antigen Detection Test

Report Approvals:
Prepared by:
Name: Ms. Dhanya Menon Signature:  Date:19/04/2021 Designation: Executive-QA
Reviewed by:
Name: Mr. Pradeep Kumar Signature:  Date: 22/04/2021 Designation: DGM- R&D
Approved by:
Name: Mr. Ram Kanoje Signature  Date: 22/04/2021 Designation: Head- QA

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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 Kit	
Measurand: SARS-CoV-2 Antigen	
Title of study: Analytical specificity	
Study site(s) location: In-House **Meril Diagnostics Pvt. Ltd.** Second Floor, D1 – D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191 Gujarat, India.	
Name and contact information of individual responsible for the study:	
Mr. Pradeep Kumar DGM- R&D	Mr. Ram Kanoje Head QA
Study commencement date: 19/04/2021	**Study completion date:** 22/04/2021
Study Objectives: To determine the analytical specificity of MERISCREEN COVID-19 Ag Detection Test kit to be used in determination of SARS-CoV-2 antigen in clinical specimen (i.e. Nasopharyngeal swabs) collected in extraction solution and spiked with interfering pathogens of the same genetic family and circulating area, commensal organisms and interfering endogenous substances by evaluating its performance.	
Study Design: Analytical specificity study/cross reactivity study was performed to demonstrate that the test does not react with related pathogens, high prevalence commensal organisms, and interfering substances that are reasonably likely to be encountered in the clinical specimen (i.e. Nasopharyngeal swabs). The test includes spiking of procured inactivated virus along with interfering pathogens of the same genetic family and circulating area, commensal organisms and interfering endogenous substances into the pooled negative real clinical matrix collected from healthy individual followed by testing with MERISCREEN COVID-19 Ag Detection Test kit to determine the analytical specificity of the kit.	

Statistical methods: Concordance with expected results was evaluated.

2. List of Abbreviation and Definition Terms

- Analytical Specificity: As per PQDx_018 v3 27 August 2014, analytical specificity is defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the specimen.
- COVID-19: Coronavirus-2019
- A **commensal** is an **organism** that uses food supplied in the internal or the external environment of the host, without establishing a close association with the host, for instance by feeding on its tissues.
- Interference occurs when a substance or process falsely alters an assay result. **Endogenous interference** originates from **substances** present in the patient's own specimen.
- SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus

3. Purpose/Scope

The purpose of this study is to determine the analytical specificity of MERISCREEN COVID-19 Ag Detection Test kit to be used in determination of SARS-CoV-2 antigen in clinical specimen (i.e. Nasopharyngeal swabs) collected in extraction solution and spiked with interfering pathogens of the same genetic family and circulating area, commensal organisms and interfering endogenous substances by evaluating its performance.

Scope:

The scope of this report is applicable for MERISCREEN COVID 19 Ag Detection Test Kit assay performance only.

4. References

- BS EN 13612:2002 Performance evaluation of *In-Vitro* Diagnostic medical devices
- 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.

- MM03- Molecular Diagnostic Methods for Infectious Diseases: 3rd Edition
- Food and Drug Administration (FDA) Guidance Document Antigen Template for Test Developers
- EP12 – P, Vol. 20, No. 15 – User protocol for evaluation of qualitative test performance; Approved guideline
- CLSI EP07-A2 Interference Testing in Clinical Chemistry Approved Guideline- Second Edition [2005]
- MERISCREEN COVID-19 Antigen Detection Test Kit Pack Insert : IFU/NCTCAG01/01, Date.25/11/2020

5. Introduction

As per PQDx_018 v3 27 August 2014, analytical specificity is defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the specimen. In this study, the influence of interfering pathogens from the same genetic family and from circulating area, Commensal organisms and interfering endogenous substances that could be expected to be encountered in the setting of intended use shall be addressed and these substances/agents shall be included in this testing to determine analytical specificity of MERISCREEN COVID 19 Ag Detection Test Kit.

6. Intended Use of the Device

COVID-19 Antigen Detection Test is a rapid immunochromatographic assay kit for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal swab from human.

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. Sterilized nasopharyngeal swabs for sample collection
7. Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Medical mask and medical latex gloves
2. Micropipette and disposable pipette tips
3. Watch or timer

7.2 Principle of the method:

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 antibody is coated on the test line region. Antigens of SARS-CoV-2 in the specimens react with the anti-SARS-CoV-2 monoclonal antibody-coupled gold conjugate and form antigen-antibodycomplex followed by reaction with anti-SARS-CoV-2 monoclonal 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 Interference study is mentioned below:

Details of Meril Kit:

- Name of the Kit: MERISCREEN COVID-19 Antigen Detection Test Kit
- Lot #:MI042106
- Expiry Date: 03/2022

Test Samples:

1. Pooled negative Nasopharyngeal swab samples collected individually.

2. Pooled negative nasopharyngeal swab samples collected individually and spiked with interfering pathogens from the same genetic family and from the circulating area.
3. Pooled negative Nasopharyngeal swab sample spiked with inactivated virus.
4. Pooled negative nasopharyngeal swab samples collected individually and spiked with inactivated SARS-CoV-2 virus and also spiked with commensal organisms.
5. Pooled negative nasopharyngeal swab samples collected individually and spiked with inactivated SARS-CoV-2 virus and also spiked with interfering endogenous substances.

9. Operator of assay

Following operator details are mentioned below:

Name of the Operator: Mr. Kardam Dave

Designation: Senior Manager, R&D

10. Study design

Real clinical matrix (i.e. nasopharyngeal swab) were collected from healthy individuals and tested with RT PCR assay for sample status confirmation. After status confirmation (i.e RT PCR result status for the tested swab samples being negative) these individual nasopharyngeal swab samples were pooled together to obtain a common real clinical matrix specimen. Some part of this pooled clinical matrix specimen was utilized to spike with interfering pathogens from the same genetic family and from circulating area in respective testing concentrations listed in below table no.2. The remaining part were distributed equally and to this the procured inactivated virus ("Control 2, MN908947.3, Wuhan - Hu-1" strain) was spiked to obtain a common specimen which mimic natural clinical specimen (i.e swab samples positive for SARS-CoV-2). To this common specimen (i.e pooled nasopharyngeal swab sample spiked with inactivated virus ("Control 2, MN908947.3, Wuhan - Hu-1" strain) following interfering Commensal organisms and interfering endogenous substances in respective testing concentrations listed in below table table no.3 and table no.4 were spiked and later tested with MERISCREEN COVID-19 Antigen Detection Test to determine the Analytical specificity.

a) Testing in presence of Interfering Pathogens from same genetic family and from circulating areas:

In this cross reactivity study, below listed interfering pathogens from the same genetic family and pathogens from the circulating areas were spiked into the pooled nasopharyngeal swab samples .These prepared samples in respective test concentrations were then tested for cross reactivity study with MERISCREEN COVID-19 Antigen Detection Test kit. List of organisms used for this study are mentioned in below table 2. The test concentration of the below listed organisms are mentioned in section 11; table.5 of this report.

Table 2: Recommended Interfering pathogens from the same genetic family and from the circulating area as per Antigen Template for Test Developers:

Sr.No.	List of Organisms
1	Human coronavirus 229E
2	Human coronavirus OC43
3	Human coronavirus NL63
4	Human coronavirus HKU1
5	Adenovirus
6	Human Metapneumovirus (hMPV)
7	Parainfluenza virus-1
8	Parainfluenza virus -4
9	Influenza A
10	Influenza B
11	Enterovirus
12	Respiratory syncytial virus
13	Rhinovirus
14	*Haemophilus influenzae*
15	*Streptococcus pneumoniae*
16	*Streptococcus pyogenes*
17	*Candida albicans*
18	Pooled human nasal wash
19	*Bordetella pertussis*
20	*Mycoplasma pneumoniae*
21	*Chlamydia pneumoniae*
22	*Legionella pneumophila*
23	*Staphylococcus aureus*

24	*Staphylococcus epidermidis*
25	*Mycobacterium tuberculosis*

b) Testing in presence of Interfering commensal Microorganisms:

In this cross reactivity study, below listed interfering commensal microorganisms were spiked into the pooled nasopharyngeal swab samples already spiked with inactivated Control 2, MN908947.3, Wuhan - Hu-1" strain virus. These prepared samples in respective test concentrations were then tested for cross reactivity study with MERISCREEN COVID-19 Antigen Detection Test kit at 3xLoD. List of organisms used for this study are mentioned in below table 3. The test concentration of the below listed organisms are mentioned in section 11; table.6 of this report.

Table 3: List of Common/Commensal organisms

Sr.No.	Name of the organisms
1	*Bordetella pertussis*
2	*Haemophilus influenza*
3	*Mycoplasma pneumonia*
4	*Moraxella catarrhalis*
5	*Staphylococcus aureus*
6	*Streptococcus pneumonia*
7	*Staphylococcus epidermis*
8	*Streptococcus pyogenes*

c) Testing in presence of Endogenous Interfering substances:

In this cross reactivity study, below listed interfering endogenous substances were spiked into the pooled nasopharyngeal swab samples already spiked with inactivated Control 2, MN908947.3, Wuhan - Hu-1" strain virus. These prepared samples in respective test concentrations were then tested for cross reactivity study with MERISCREEN COVID-19 Antigen Detection Test kit at 3xLoD. List of endogenous interfering substances used for this study are mentioned in below table 4. The test concentration of the below listed endogenous substances are mentioned in section 11; table.7 of this report.

Table 4: List of Endogenous Interferring Substances:

Sr.No.	Substance	Concentration
1	Whole Blood	4%
2	Mucin	*0.5%*
3	*Chloracseptic (Menthol/Benzocaine)*	*1.5mg/ml*
4	Naso GEL (NeilMed)	5%v/v
5	CVS Nasal Drops (Phenylephrine)	15%v/v
6	Afrin (Oxymetazoline)	15%v/v
7	CVS Nasal Spray (Cromolyn)	15%v/v
8	Zicam	5%v/v
9	Homeopathic (Alkalol)	1:10 dilution
10	Sore Throat Phenol Spray	15% v/v
11	Tobramycin	4µg/ml
12	Mupirocin	10mg/ml
13	Fluticasone Propionate	5%v/v
14	Tamiflu (Oseltamivir Phosphate)	5mg/ml

11. Test samples

As mentioned in section 10, following test samples were utilized in the study.

1. Pooled negative Nasopharyngeal swab samples collected individually.
2. Pooled negative nasopharyngeal swab samples collected individually and spiked with interfering pathogens from the same genetic family and from the circulating area.
3. Pooled negative Nasopharyngeal swab sample spiked with inactivated virus
4. Pooled negative nasopharyngeal swab samples collected individually and spiked with inactivated SARS-CoV-2 virus and also spiked with commensal organisms.
5. Pooled negative nasopharyngeal swab samples collected individually and spiked with inactivated SARS-CoV-2 virus and also spiked with interfering endogenous substances.

Sample details such as source of procurement, status of the strain and Test Concentration (pfu/ml) and result are mentioned in this section of the report.

Table 5: Sample details of Recommended Interfering pathogens from the same genetic family and from the circulating area as per Antigen Template for Test Developers:

Sr. No.	List of Organisms	Source	Test Titre (Pfu/ml)	Result
1	Human coronavirus 229E	ATCC	1 x $10^{4.5}$ $TCID_{50}$/ml	No cross reactivity
2	Human coronavirus OC43	ATCC	1 x 10^5 $TCID_{50}$/ml	No cross reactivity
3	Human coronavirus NL63	ATCC	1 x 10^4 $TCID_{50}$/ml	No cross reactivity
4	Adenovirus	ATCC	3 x 10^5 $TCID_{50}$/ml	No cross reactivity
5	Human Metapneumovirus (hMPV)	ATCC	1 x 10^5 $TCID_{50}$/ml	No cross reactivity
6	Parainfluenza virus -1	ATCC	1 x 10^5 $TCID_{50}$/ml	No cross reactivity
7	Parainfluenza virus -4	ATCC	1 x 10^5 $TCID_{50}$/ml	No cross reactivity
8	Influenza A	ATCC	3 x 10^5 $TCID_{50}$/ml	No cross reactivity
9	Influenza B	ATCC	3 x 10^5 $TCID_{50}$/ml	No cross reactivity
10	Enterovirus	ATCC	1 x 10^4 $TCID_{50}$/ml	No cross reactivity
11	Respiratory syncytial virus	ATCC	3 x 10^5 $TCID_{50}$/ml	No cross reactivity
12	Rhinovirus	ATCC	1 x 10^5 $TCID_{50}$/ml	No cross reactivity
13	*Haemophilus influenzae*	ATCC	5 x 10^4 cells/ml	No cross reactivity
14	*Streptococcus pneumoniae*	ATCC	5 x 10^4 cells/ml	No cross reactivity
15	*Streptococcus pyogenes*	ATCC	5 x 10^4 cells/ml	No cross reactivity
16	*Candida albicans*	ATCC	5 x 10^4 cells/ml	No cross reactivity
17	Pooled human nasal wash	ATCC	NA	No cross reactivity
18	*Bordetella pertussis*	ATCC	5 x 10^4 cells/ml	No cross reactivity
19	*Mycoplasma pneumoniae*	*ATCC*	5 x 10^4 cells/ml	No cross reactivity
20	*Chlamydia pneumoniae*	*ATCC*	1 x 10cells/ml	No cross reactivity
21	*Legionella pneumophila*	*ATCC*	5 x 10^4 cells/ml	No cross reactivity
22	*Staphylococcus aureus*	*ATCC*	3.3 x 10^9 cells/ml	No cross reactivity
23	*Staphylococcus epidermidis*	*ATCC*	5 x 10^4 cells/ml	No cross reactivity
24	*Mycobacterium tuberculosis*	*ATCC*	5 x 10^4 cells/ml	No cross reactivity

∗ Human coronavirus HKU1 has not been tested. The % identity of the nucleocapsid protein sequence between HKU1 and SARS-CoV-2 is below 35%.

Table 6: List of Common/Commensal organisms

Sr.No.	Name of the organisms	Source	Test Titre (Pfu/ml)	Result
1	*Bordetella pertussis*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*
2	*Haemophilus influenza*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*
3	*Mycoplasma pneumonia*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*
4	*Moraxella catarrhalis*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*
5	*Staphylococcus aureus*	ATCC	3.3 x 10^9 cells/ml	*No cross reactivity*
6	*Streptococcus pneumonia*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*
7	*Staphylococcus epidermis*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*
8	*Streptococcus pyogenes*	ATCC	*5 x 10^4 cells/ml*	*No cross reactivity*

Table 7: List of Endogenous Interferring Substances:

Sr.No.	Substance	Concentration	Result
1	Whole Blood	4%	*No cross reactivity*
2	Mucin	*0.5%*	*No cross reactivity*
3	*Chloracseptic (Menthol/Benzocaine)*	*1.5mg/ml*	*No cross reactivity*
4	Naso GEL (NeilMed)	5%v/v	*No cross reactivity*
5	CVS Nasal Drops (Phenylephrine)	15%v/v	*No cross reactivity*
6	Afrin (Oxymetazoline)	15%v/v	*No cross reactivity*
7	CVS Nasal Spray (Cromolyn)	15%v/v	*No cross reactivity*
8	Zicam	5%v/v	*No cross reactivity*
9	Homeopathic (Alkalol)	1:10 dilution	*No cross reactivity*
10	Sore Throat Phenol Spray	15% v/v	*No cross reactivity*
11	Tobramycin	4µg/ml	*No cross reactivity*
12	Mupirocin	10mg/ml	*No cross reactivity*
13	Fluticasone Propionate	5%v/v	*No cross reactivity*
14	Tamiflu (Oseltamivir Phosphate)	5mg/ml	*No cross reactivity*

Details of Inactivated SARS-CoV-2 virus utilized in this study are mentioned in below table: 8

Also negative Nasopharyngeal samples collected is mentioned in below table no: 9

Table 8: Sample details of SARS-CoV-2 inactivated virus used in the study

Sr. No.	SARS-CoV-2 Strain/Isolate	Source/Sample Type	Concentration (copies/µl)

1.	Control 2, MN908947.3, wuhan-Hu-1	Twist Bioscience/Synthetic RNA genome	1 x 10^6 copies /µl

SARS-CoV-2 negative specimens (i.e Nasopharyngeal swab) were collected from healthy individuals working with Meril Diagnostics Pvt Ltd, Second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191which were confirmed negative for sample status by RT PCR assay.

Table 9: Details of SARS-CoV-2 negative specimens used in this study

Sr. No.	Sample ID	Source/Sample Type	Physiological Condition		Sample Status
			Age	Sex	
1	COVAGN261	Nasopharyngeal swab	30	M	Negative
2	COVAGN262	Nasopharyngeal swab	26	M	Negative
3	COVAGN263	Nasopharyngeal swab	25	F	Negative
4	COVAGN264	Nasopharyngeal swab	34	M	Negative
5	COVAGN265	Nasopharyngeal swab	33	M	Negative
6	COVAGN266	Nasopharyngeal swab	37	M	Negative
7	COVAGN267	Nasopharyngeal swab	25	F	Negative
8	COVAGN268	Nasopharyngeal swab	27	F	Negative
9	COVAGN269	Nasopharyngeal swab	29	F	Negative
10	COVAGN270	Nasopharyngeal swab	28	F	Negative
11	COVAGN271	Nasopharyngeal swab	26	F	Negative
11	COVAGN272	Nasopharyngeal swab	28	M	Negative
12	COVAGN273	Nasopharyngeal swab	28	F	Negative
13	COVAGN274	Nasopharyngeal swab	31	M	Negative
14	COVAGN275	Nasopharyngeal swab	35	M	Negative
15	COVAGN276	Nasopharyngeal swab	33	M	Negative
16	COVAGN277	Nasopharyngeal swab	32	F	Negative
17	COVAGN278	Nasopharyngeal swab	36	M	Negative
18	COVAGN279	Nasopharyngeal swab	38	M	Negative
19	COVAGN280	Nasopharyngeal swab	33	M	Negative
20	COVAGN281	Nasopharyngeal swab	32	M	Negative
21	COVAGN282	Nasopharyngeal swab	31	F	Negative

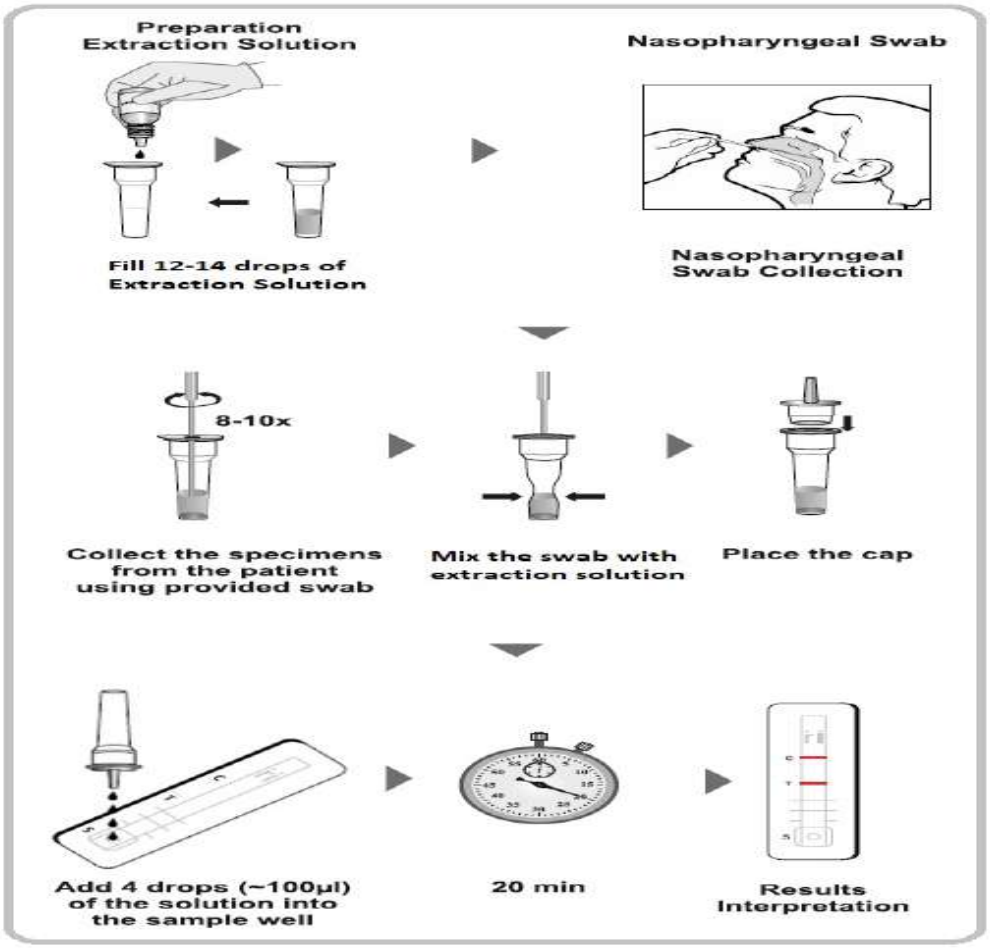
22	COVAGN283	Nasopharyngeal swab	29	F	Negative
23	COVAGN284	Nasopharyngeal swab	28	F	Negative
24	COVAGN285	Nasopharyngeal swab	34	M	Negative
25	COVAGN286	Nasopharyngeal swab	32	F	Negative

12. Test procedure

Testing were performed with MERISCREEN COVID-19 Antigen Detection Test as per the test procedure mentioned in its pack insert and as per the procedure mentioned in Antigen Template for Test Developers.

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, 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.



13. Acceptance criteria

MERISCREEN COVID-19 Antigen Detection Test kit should give accurate results as per the true sample status. Test results of spiked and unspiked samples should be similar for (i.e Pooled negative nasopharyngeal swab samples spiked with interfering pathogens from the same genetic family and from the circulating area) Similarly Test results of spiked and unspiked samples should be similar for (Pooled negative nasopharyngeal swab samples spiked with inactivated SARS-CoV-2 virus and also spiked with commensal organisms, Pooled negative nasopharyngeal swab samples spiked with inactivated SARS-CoV-2 virus and also spiked with interfering endogenous substances).Interference from any potentially interfering pathogens of

the same genetic family and from the circulating area, commensal organisms and interfering endogenous substances should be <5%.

14. Results and data analysis Report

Analytical specificity of MERISCREEN COVID-19 Antigen Detection Test Kit was determined by testing interfering pathogens of the same genetic family and from the circulating area, commensal organisms and interfering endogenous substances that are likely to be present in the real clinical matrix specimen by evaluating its performance. In this testing, test results of spiked samples (i.e pooled negative nasopharyngeal swab samples spiked with interfering pathogens from the same genetic family and from the circulating area, pooled negative nasopharyngeal swab samples spiked with inactivated SARS-CoV-2 virus and with commensal organisms, and pooled negative nasopharyngeal swab samples spiked with inactivated SARS-CoV-2 virus and with interfering endogenous substances) were compared with that of unspiked specimens and it has shown that there is no difference in test results of both spiked and un-spiked specimens. MERISCREEN COVID-19 Antigen Detection Test Kit has given accurate results i.e no cross reactivity observed and have given true sample status when tested with both, spiked and un-spiked specimens. Thus, the test results have met the acceptance criteria of the study. There was no invalid or discrepant results obtained during study.

15. Conclusion

Analytical specificity of MERISCREEN COVID-19 Antigen Detection Test Kit was determined by testing interfering pathogens from the same genetic family and from the circulating area, commensal organisms and interfering endogenous substances present in likely to be present in the real clinical matrix specimen by evaluating performance of MERISCREEN COVID-19 Antigen Detection Test Kit on one lot of the kit. From the results and data analysis, it is concluded that interfering pathogens from the same genetic family and from the circulating areas and interfering commensal organisms such as Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Human Metapneumovirus (hMPV), Parainfluenza virus 1-4, Influenza A & B, Enterovirus, Respiratory syncytial virus, Rhinovirus, *Haemophilus influenza, Streptococcus pneumonia, Streptococcus pyogenes*, *Candida albicans*, Pooled human nasal wash, *Bordetella pertussis*,

Mycoplasma pneumonia, Chlamydia pneumonia, Legionella pneumophila, Staphylococcus aureus, Staphylococcus epidermidis, Mycobacterium tuberculosis, Moraxella catarrhalis, and interfering endogenous substances such as Whole Blood, Mucin, *Chloracseptic (Menthol/Benzocaine),* Naso GEL (NeilMed), CVS Nasal Drops (Phenylephrine), Afrin (Oxymetazoline), CVS Nasal Spray (Cromolyn), Zicam, Homeopathic (Alkalol), Sore Throat Phenol Spray, Tobramycin, Mupirocin, Fluticasone Propionate, Tamiflu (Oseltamivir Phosphate) do not interfere with the performance of MERISCREEN COVID-19 Antigen Detection test Kit. Hence MERISCREEN COVID-19 Antigen Detection Test kit do not show cross reactivity with any of the above listed Inactivated SARS-CoV-2 virus, interfering pathogens of the same genetic family and from the circulating area, Interfering Commensal Organism and with Interfering Endogenous Substances.

15. Enclosures/Annexures

- Enclosure 1: CoA of Inactivated SARS-CoV-2 virus, CoA of interfering pathogens of the same genetic family and from the circulating area & CoA of Interfering Commensal Organism.

16. Amendment history

Table 10: Amendment history

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