STUDY TITLE

Analytical Specificity Study Report

DOCUMENT NUMBER

APR-08/IM/GRA/014

Revision No. 00

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

Table of Contents

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/NCTCAG01/02, Apr'2021

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 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) environments by healthcare professional that meets the requirements specified in the Instructions 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. 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

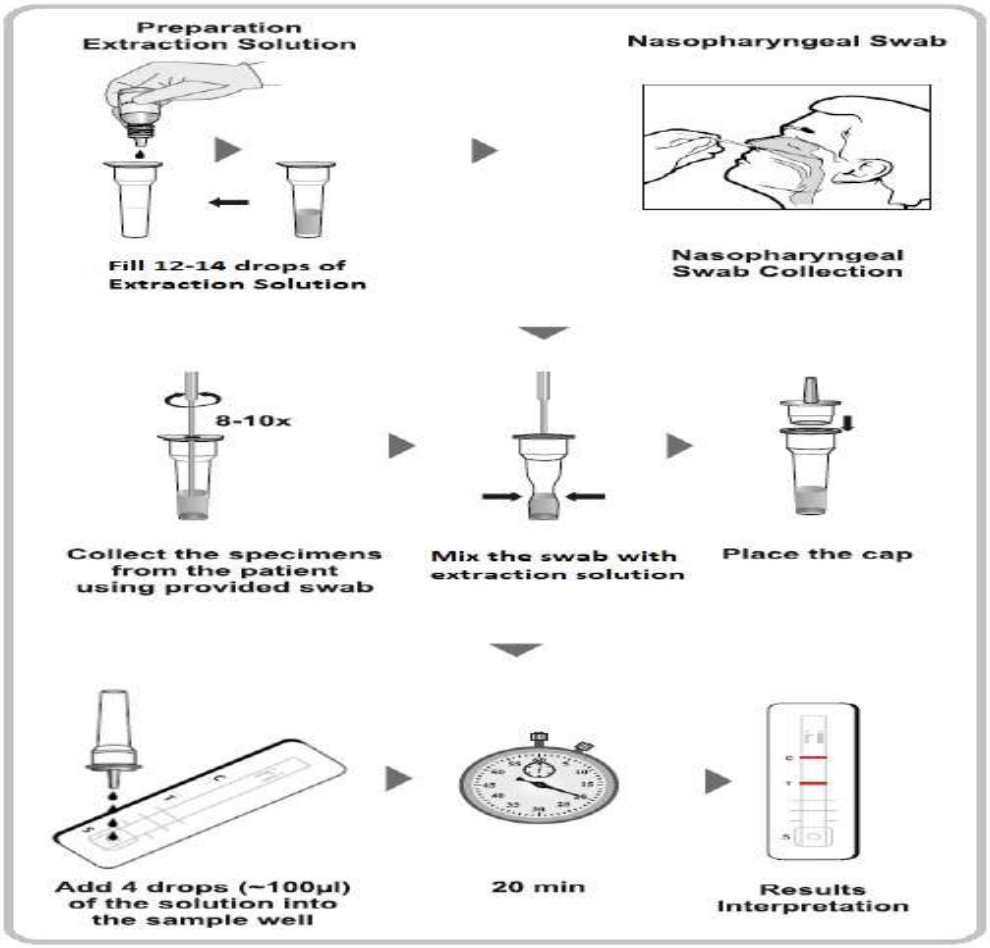
15	COVAGN276	Nasopharyngeal swab	33	M	Negative
16	COVAGN277	Nasopharyngeal swab	32	F	Negative
17	COVAGN278	Nasopharyngeal swab	36	M	Negative
18	COVAGN279	Nasopharyngeal swab	38	M	Negative
19	COVAGN280	Nasopharyngeal swab	33	M	Negative
20	COVAGN281	Nasopharyngeal swab	32	M	Negative
21	COVAGN282	Nasopharyngeal 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.



INTERPRETATION OF THE RESULTS:

1. 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.
2. Negative result: If only the Control (C) band is developed, the test indicates that the result is negative.
3. 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

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.
- Enclosure 2: Raw data sheet of Analytical Specificity Study (RD-08/1M/GRA/014-a, RD-08/1M/GRA/014-b, RD-08/1M/GRA/014-c)

16. Amendment history

Table 10: Amendment history

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

Merit Diagnostics	**AnalyticalSpecificity Study (Cross Reactivity) MERISCREEN COVID-19 Antigen Detection Test**	**RD-08/1M/GRA/014-a**

Results and Data Analysis

Product Name:	MERISCREEN COVID-19 Ag Detection test		
Date of testing:	19-04-2021	Date of Completion:	22-04-2021
Lot No:	MI042106		
Mfg. Date:	2021/04		
Exp. Date:	2023/03		
1 **Tested at:**	Merit Diagnostics Pvt. Ltd., Chala, Vapi, Gujarat, India.		

2	**Sample ID:**	Pooled Nasopharyngeal swab samples confirmed negative for SARS-CoV-2 by RT PCR method Inactivated synthetic SARS-CoV-2 procured from twist bioscience (positive control) Control 2, MN908947.3, wuhan-Hu-1

3 Acceptance Criteria:

COVID-19 Ag Rapid Test should give accurate result as per true sample status.The color development on control (C) and test (T) bands indicates for the presence of antigens to SARS-CoV-2 in the sample, whereas the development of color only on Control(C) band indicates the test result is negative. If no control band is developed, then the assay is invalid regardless of colour development on test (T) band.

4 Introduction:

Analytical Specificity/ Cross reactivity 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. The influence of substances or agents 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.

Table 1: Analytical Specificity

Analytical specificity of MERISCREEN COVID 19 Ag Detection Test shall be determined by testing interfering and/or cross reacting pathogens from same genetic family which shall be wet tested in negative real clinical matrix (i.e human nasopharyngeal swab sample). These negative real clinical matrix were collected from healthy individuals and confirmed negative for sample status by RT PCR assay, later pooled and spiked with inactivated SARS-CoV-2 virus ("Control 2, MN908947.3, Wuhan - Hu-1" strain). To this, a virus concentration of 10^5 copies/µl from the same genetic family is spiked. Test results of un-spiked specimens shall be compared with that of the spiked specimens to determine whether below mentioned interfering and/or cross reacting pathogens affect the performance of the kit or not.

1. Testing Results of Interfering pathogens from the same genetic family and from circulating area:

Sr.No.:	Sample ID	Interference		Testing with MERISCREEN COVID-19 Ag Detection Test kit			
				Band Intensity			Result
		Interfering pathogens from the same genetic family and from circulating area	Spiked/ Unspiked	C	T	Results	Background clearance time (In Minutes)
1	COVAGN261	Human coronavirus 229E 1 x $10^{4.5}$ $TCID_{50}$/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	12min
2	COVAGN261	Human coronavirus OC43 1 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	14min
			Spiked	4+	0	-ve	12min
3	COVAGN261	Human coronavirus NL63 1 x 10^4 $TCID_{50}$/ml	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	12min
4	COVAGN261	Adenovirus 1 x 10^4 $TCID_{50}$/ml	Unspiked	4+	0	-ve	15min
			Spiked	4+	0	-ve	13min
5	COVAGN262	Human Metapneumovirus (hMPV) 1 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	14min
6	COVAGN262	Parainfluenza virus -1 1 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	13min
7	COVAGN262	Parainfluenza virus -4 1 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	14min
			Spiked	4+	0	-ve	14min
8	COVAGN262	Influenza A 3 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	13min
9	COVAGN263	Influenza B 3 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	14min
10	COVAGN263	Enterovirus 1 x 10^4 $TCID_{50}$/ml	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	14min
11	COVAGN263	Respiratory syncytial virus 3 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	15min
			Spiked	4+	0	-ve	14min
12	COVAGN263	Rhinovirus 1 x 10^5 $TCID_{50}$/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	13min
13	COVAGN264	Haemophilus influenzae 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	12min
14	COVAGN264	Streptococcus pneumoniae 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	14min
15	COVAGN264	Streptococcus pyogenes 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	15min
16	COVAGN264	Candida albicans 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	12min
17	COVAGN265 COVAGN266	Pooled human nasal wash	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	15min
18	COVAGN267	Bordetella pertussis 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	14min
			Spiked	4+	0	-ve	12min
19	COVAGN267	Mycoplasma pneumoniae 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	14min
			Spiked	4+	0	-ve	15min
20	COVAGN267	Chlamydia pneumoniae 1 x 10 cells/ml	Unspiked	4+	0	-ve	14min
			Spiked	4+	0	-ve	12min
21	COVAGN267	Legionella pneumophila 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	14min
22	COVAGN268	Staphylococcus aureus 3.3 x 10^5 cells/ml	Unspiked	4+	0	-ve	14min
			Spiked	4+	0	-ve	12min
23	COVAGN268	Staphylococcus epidermidis 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	13min
			Spiked	4+	0	-ve	13min
24	COVAGN268	Mycobacterium tuberculosis 5 x 10^4 cells/ml	Unspiked	4+	0	-ve	12min
			Spiked	4+	0	-ve	12min
Footnotes :		0, 1+, 2+, 3+ & 4+ = Color band intensity by using WHO color chart Prototype: A -Ve : Negative, +Ve : Positive, C :Control Band , T: SARS-CoV-2 Ag					

Tested By:	**Reviewed By:**
Date: 22-04-2021	**Date:** 22-04-2021

Meril Diagnostics	AnalyticalSpecificity Study (Cross Reactivity) MERISCREEN COVID-19 Antigen Detection test	RD-08/IM/GRA/014-b

Results and Data Analysis

Product Name:	MERISCREEN COVID-19 Ag Detection test		
Date of testing:	19-04-2021	Date of Completion:	22-04-2021
Lot No:	MI042106		
Mfg. Date:	2021/04		
Exp. Date:	2022/03		
1	**Tested at:**	Meril Diagnostics Pvt. Ltd., Chala, Vapi, Gujarat, India.	

2	**Sample ID:**	Pooled Nasopharyngeal swab samples confirmed negative for SARS-CoV-2 by RT PCR method Inactivated synthetic SARS-CoV-2 procured from twist bioscience (positive control)

3	**Acceptance Criteria:**
	COVID-19 Ag Rapid Test should give accurate result as per true sample status.The color development on control (C) and test (T) bands indicates for the presence of antigens to SARS-CoV-2 in the sample, whereas the development of color only on Control(C) band indicates the test result is negative. If no control band is developed, then the assay is invalid regardless of colour development on test (T) band.

4	**Introduction:**
	Analytical Specificity/ Cross reactivity 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. The influence of substances or agents 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.

Table 1: Analytical Specificity

Analytical specificity of MERISCREEN COVID 19 Ag Detection Test shall be determined by testing interfering and/or cross reacting commensal organisms which shall be wet tested in negative real clinical matrix (i.e human nasopharyngeal swab sample). These negative real clinical matrix were collected from healthy individuals and confirmed negative for sample status by RT PCR assay, later pooled and spiked with inactivated SARS-CoV-2 virus ("Control 2, MN908947.3, Wuhan - Hu-1" strain). To this, a virus concentration of 10^5 pfu/ml from commensal organisms is spiked. Test results of un-spiked specimens shall be compared with that of the spiked specimens to determine whether below mentioned interfering and/or cross reacting pathogens affect the performance of the kit or not.

The Potential cross-reactivity of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using MERISCREEN COVID-19 Antigen Detecton test. Potential microbial interference was evaluated with samples containing heat inactivated SARS-CoV-2 isolate Control 2, MN908947.3 Wuhan-Hu-1 at approximately 3xLoD

2. Testing Results of Interfering Commensal Organisms :

Sr.No .:	Sample ID	Interference			Testing with MERISCREEN COVID-19 Ag Detection Test kit			
					Band Intensity			Result
		Interfering Commensal Organisms	Spiked/ Unspiked	Replicates	C	T	Results	Background clearance time (In Minutes)
1	COVAGN269	Bordetella pertussis 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	14min
			Unspiked	2	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	12min
			Unspiked	3	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	12min
2	COVAGN269	Haemophilus influenza 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	13min
			Spiked		4+	4+	+ve	13min
			Unspiked	2	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	14min
			Unspiked	3	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	12min
3	COVAGN270	Mycoplasma pneumonia 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	15min
			Unspiked	2	4+	4+	+ve	15min
			Spiked		4+	4+	+ve	12min
			Unspiked	3	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	14min
4	COVAGN270	Moraxella catarrhalis 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	13min
			Unspiked	2	4+	4+	+ve	13min
			Spiked		4+	4+	+ve	12min
			Unspiked	3	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	12min
5	COVAGN271	Staphylococcus aureus 3.3 x 10^5 cells/ml	Unspiked	1	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	14min
			Unspiked	2	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	15min
			Unspiked	3	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	14min
6	COVAGN271	Streptococcus pneumonia 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	12min
			Unspiked	2	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	14min
			Unspiked	3	4+	4+	+ve	13min
			Spiked		4+	4+	+ve	13min
7	COVAGN272	Staphylococcus epidermis 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	12min
			Unspiked	2	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	14min
			Unspiked	3	4+	4+	+ve	13min
			Spiked		4+	4+	+ve	13min
8	COVAGN272	Streptococcus pyogenes 5 x 10^4 cells/ml	Unspiked	1	4+	4+	+ve	12min
			Spiked		4+	4+	+ve	12min
			Unspiked	2	4+	4+	+ve	14min
			Spiked		4+	4+	+ve	14min
			Unspiked	3	4+	4+	+ve	13min
			Spiked		4+	4+	+ve	12min
Footnotes :		0, 1+, 2+, 3+ & 4+ = Color band intensity by using WHO color chart Prototype: A -Ve : Negative, +Ve : Positive, C :Control Band , T: SARS-CoV-2 Ag						

Tested By:	**Reviewed By:**
Date: 22-04-2021	**Date:** 22-04-2021

Meril Diagnostics	**Analytical Specificity Study (Cross Reactivity) MERISCREEN COVID-19 Antigen Detection test**	**RD-08/IM/GRA/014-c**

Results and Data Analysis

Product Name:	MERISCREEN COVID-19 Ag Detection test		
Date of testing:	19-04-2021	Date of Completion	22-04-2021
Lot No:	MI042106		
Mfg. Date:	2021/04		
Exp. Date:	2022/03		
1 **Tested at:**	Meril Diagnostics Pvt. Ltd., Chala, Vapi, Gujarat, India.		

2	**Sample ID:**	Pooled Nasopharyngeal swab samples confirmed negative for SARS-CoV-2 by RT PCR method
		Inactivated synthetic SARS-CoV-2 procured from twist bioscience (positive control)

3 **Acceptance Criteria:**

COVID-19 Ag Rapid Test should give accurate result as per true sample status.The color development on control (C) and test (T) bands indicates for the presence of antigens to SARS-CoV-2 in the sample, whereas the development of color only on Control(C) band indicates the test result is negative. If no control band is developed, then the assay is invalid regardless of colour development on test (T) band.

4 **Introduction:**

Analytical Specificity/ Cross reactivity 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. The influence of substances or agents 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.

Table 1: Analytical Specificity

Analytical specificity of MERISCREEN COVID 19 Ag Detection Test shall be determined by testing interfering and/or cross reacting pathogens from same genetic family which shall be wet tested in negative real clinical matrix (i.e human nasopharyngeal swab sample). These negative real clinical matrix were collected from healthy individuals and confirmed negative for sample status by RT PCR, later pooled and spiked with inactivated SARS-CoV-2 virus ("Control 2, MN908947.3, Wuhan - Hu-1" strain). To this, a virus concentration of 10^5 pfu/ml from the same genetic family is spiked. Test results of un-spiked specimens shall be compared with that of the spiked specimens to determine whether below mentioned interfering and/or cross reacting pathogens affect the performance of the kit or not.

3. Testing Results of Endogenous substances:

Sr.No.:	Sample ID	Interference		Testing with MERISCREEN COVID-19 Ag Detection Test kit			
				Band Intensity			Result
		Interfering Endogenous substances	Spiked/ Unspiked	C	T	Results	Background clearance time (In Minutes)
1	COVAGN273	Whole Blood 4%	Unspiked	4+	4+	+ve	14min
			Spiked	4+	4+	+ve	14min
2	COVAGN274	Mucin 0.5%	Unspiked	4+	4+	+ve	12min
			Spiked	4+	4+	+ve	12min
3	COVAGN275	Chloracseptic (Menthol/Benzocaine)	Unspiked	4+	4+	+ve	12min
			Spiked	4+	4+	+ve	13min
4	COVAGN276	Naso GEL (NeilMed) 5%v/v	Unspiked	4+	4+	+ve	13min
			Spiked	4+	4+	+ve	15min
5	COVAGN277	CVS Nasal Drops (Phenylephrine)	Unspiked	4+	4+	+ve	15min
			Spiked	4+	4+	+ve	12min
6	COVAGN278	Afrin (Oxymetazoline) 15%v/v	Unspiked	4+	4+	+ve	13min
			Spiked	4+	4+	+ve	14min
7	COVAGN279	CVS Nasal Spray (Cromolyn)	Unspiked	4+	4+	+ve	12min
			Spiked	4+	4+	+ve	14min
8	COVAGN280	Zicam 5%v/v	Unspiked	4+	4+	+ve	14min
			Spiked	4+	4+	+ve	12min
9	COVAGN281	Homeopathic (Alkalol) 1:10 dilution	Unspiked	4+	4+	+ve	13min
			Spiked	4+	4+	+ve	13min
10	COVAGN282	Sore Throat Phenol Spray	Unspiked	4+	4+	+ve	12min
			Spiked	4+	4+	+ve	12min
11	COVAGN283	Tobramycin 4µg/ml	Unspiked	4+	4+	+ve	14min
			Spiked	4+	4+	+ve	15min
12	COVAGN284	Mupirocin 10mg/ml	Unspiked	4+	4+	+ve	14min
			Spiked	4+	4+	+ve	14min
13	COVAGN285	Fluticasone Propionate 5%v/v	Unspiked	4+	4+	+ve	12min
			Spiked	4+	4+	+ve	13min
14	COVAGN286	Tamiflu (Oseltamivir Phosphate)	Unspiked	4+	4+	+ve	13min
			Spiked	4+	4+	+ve	12min
Footnotes :		0, 1+, 2+, 3+ & 4+ = Color band intensity by using WHO color chart Prototype: A -Ve : Negative, +Ve : Positive, C :Control Band T: SARS-CoV-2 Ag					

Tested By:	**Reviewed By:**
Date: 22-04-2021	**Date:** 22-04-2021

Certificate of Analysis

ATCC® Number: VR-825™
Lot Number: 58923546 (Reference Lot 9W)

Description: Pooled allantoic fluid from inoculated eggs
Classification: Orthomyxoviridae, Influenzavirus A
Agent: Influenza A virus (H1N1)
Strain: A/WS/33
Storage: - 60°C or colder

Test	Specifications	Results
Viability (Infectivity)*	$TCID_{50}$ or $CEID_{50} \geq 10^{3.0}$ per 0.2 ml	Pass
Authentication**	Virus identity verified by CPE, FA, HA, ELISA, Serum Neutralization, PCR and/or sequencing	Pass
Test for Mycoplasma Contamination		
Broth and agar culture (direct method)	No growth	No growth
DNA detection by PCR of test article nucleic acid	None detected	None detected
Sterility test (BacT/ALERT 3D)		
iAST bottle (aerobic) at 32°C, 14-day incubation	No growth	No growth
iNST bottle (anaerobic) at 32°C, 14-day incubation	No growth	No growth

***Titer notes:** $10^{6.5}$ $CEID_{50}$/0.2 mL in 2 days on 10-day-old SPF CE (intra-allantoic inoculation) at 33°C with humidity as determined by HA using 0.5% CRBC in DPBS at room temperature for 30 minutes.

****Authentication notes:** Molecular authentication was performed by the generation of a 900bp amplicon by RT-PCR. A portion of the amplicon was sequenced and shown to have 99% homology to NCBI number CY009604.1 [Influenza A virus, strain A/Wilson-Smith/33 (H1N1)].

Kim Ellis

Digitally signed by Kim Ellis
DN: cn=Kim Ellis, o=ATCC, ou=QC Manager - Quality, Compliance and Biosafety, email=kellis@atcc.org, c=US
Date: 2010.05.11 15:18:24 -04'00'

Quality Control Manager; Quality, Compliance and Biosafety

ATCC hereby represents and warrants that the material provided under this certificate has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

The ATCC trademark and trade name and any and all ATCC catalog numbers are trademarks of the American Type Culture Collection.

ATCC (American Type Culture Collection)
P.O. Box 1549
Manassas, VA 20108 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-1D™

Lot Number: 70023022

Product Name: Genomic DNA from Human adenovirus 1 Strain: Adenoid 71

Classification: *Adenoviridae, Mastadenovirus,* Human adenovirus C

Volume: 102 µL in TE, pH 8.0

Product Format: Total genomic material from a preparation of cell lysate and supernatant from infected cells

Expiration Date: Not applicable

Storage Conditions: - 70°C or colder

Test / Method	Specification	Result
DNA concentration by PicoGreen® measurement (viral and cellular) Tested on bulk material prior to vialing	Report results	431 ng/102 µL = 4.22 ng/µL
DNA integrity by PCR and gel electrophoresis	≥ 500 bp DNA amplicon with no degradation and single band present at expected size (RNA may be present)	Pass
Functional activity by PCR and gel electrophoresis	Material that is diluted ≥ 1:10 can be successfully amplified by PCR	Pass
Authentication*	Sequence is consistent with that of infecting agent	Pass
Viral inactivation: ≥ 10% of input seed is incubated with host cells under appropriate growth conditions	No viable infecting agent detected by visual observation	Pass

***Authentication notes:** Molecular authentication was performed by PCR. An amplicon of approximately 979 bp was generated. A portion of the amplicon was sequenced and shown to have 99% homology to NCBI number AB330082.1 (Human adenovirus 1 gene for hexon, complete cds, strain: Adenoid 71).

Jo Salisbury

Digitally signed by Jo Salisbury
DN: cn=Jo Salisbury, o=ATCC, ou=Quality Assurance, email=jsalisbury@atcc.org, c=US
Date: 2019.03.08 08:12:02 -05'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **VR-1D™**

Lot Number: **70023022**

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-2282™

Lot Number: 70025701

Classification: *Chlamydiaceae, Chlamydophila*

Agent: *Chlamydophila pneumoniae*

Strain: TW-183

Passage History: Submission laboratories: Unknown

ATCC: Hep-2 (ATCC® CCL-23™) (4)

Fill Volume: 1.0 mL

Product Format: Fluid and cell lysate from infected cultures

Expiration Date: Not applicable

Storage Conditions: -70°C or colder

Test / Method	Specification	Result
Viability (Infectivity)*	PFU, IFU, $TCID_{50}$ or $CEID_{50}$ ≥ 5 x 10^3 per mL	Pass
Authentication**	Virus identity verified by Immunofluorescence, ELISA, and/or sequencing	Pass
Test for Mycoplasma Contamination		
Broth and agar culture (direct method)	Report results	***Mycoplasma detected***
DNA detection by PCR of test article nucleic acid	Report results	***Mycoplasma detected***
Sterility test (BacT/ALERT 3D)		
iAST bottle (aerobic) at 32.5°C, 14-day incubation	No growth	No growth
iNST bottle (anaerobic) at 32.5°C, 14-day incubation	No growth	No growth

***Titer notes:** 9.1 x 10^7 IFU/mL in 36.5 hours on Hep-2 cells (ATCC® CCL-23™) at 35°C with 5% CO_2, using Pathfinder® Chlamydia Culture Confirmation System (Bio-Rad catalog # 30701). Tested on 08Aug2019.

****Authentication notes:** Genomic authentication was performed by Next Generation Sequencing (NGS) and results meet requirements of ≥ 1000 bp with ≥ 98% homology to NCBI number AE009440.1 (*Chlamydophila pneumoniae* TW-183, complete genome).

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2019.08.15 09:42:04 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **VR-2282™**

Lot Number: **70025701**

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-1803D™

Lot Number: 62038845

Product Name: Genomic RNA from Human respiratory syncytial virus, Strain: ATCC-2012-11

Classification: *Paramyxoviridae, Pneumovirinae, Pneumovirus*

Volume: 100 µL in TE, pH 7.4

Product Format: Total genomic material from a preparation of cell lysate and supernatant from infected cells

Expiration Date: Not applicable

Storage Conditions: -70°C or colder

Test / Method	Specification	Result
RNA concentration by RiboGreen® measurement (viral and cellular)	Report results	2.16 ng/µL
RNA integrity by RT-PCR and gel electrophoresis	≥ 500 bp RNA amplicon with no degradation and single band present at expected size	Pass
Functional activity by RT-PCR and gel electrophoresis	Material that is diluted ≥ 1:10 can be successfully amplified by RT-PCR	Pass
Authentication*	Sequence is consistent with that of infecting agent	Pass
Viral inactivation: ≥ 10% of input seed is incubated with host cells under appropriate growth conditions	No viable infecting agent detected by visual observation	Pass

***Authentication notes:** Molecular authentication was performed by RT-PCR. An amplicon of approximately 700 bp was generated. A portion of the amplicon was sequenced and shown to have 99% homology to Human respiratory syncytial virus B.

Kim Ellis

Digitally signed by Kim Ellis
DN: cn=Kim Ellis, o=ATCC, ou=Quality Assurance, email=kellis@atcc.org, c=US
Date: 2014.11.19 09:32:09 -05'00'

Manager of Material Release; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC (American Type Culture Collection)
P.O. Box 1549
Manassas, VA 20108 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **VR-1803D™**

Lot Number: **62038845**

ATCC (American Type Culture Collection)
P.O. Box 1549
Manassas, VA 20108 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 14053D-5™

Lot Number: 70027300

Designation: *Candida albicans* genomic DNA

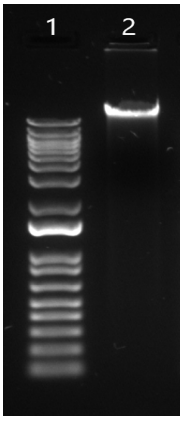
Fill Volume Prior to Drying: 75 µL

Product Format: Dried microbial DNA

Expiration Date: Not applicable

Storage Conditions: 2°C to 8°C”

Test / Method	Specification	Result
OD_{260}/OD_{280} ratio (Spectrophotometer method)	1.6 to 2.1	2.0
Total amount of DNA (PicoGreen® measurement)	≥ 5 µg per vial	8 µg/vial
Agarose gel electrophoresis	High molecular weight chromosomal DNA	High molecular weight chromosomal DNA See photograph below
PCR Functionality	Successful PCR amplification of selected gene(s)	Successful PCR amplification of selected gene(s)
Sequencing of selected gene(s)	Consistent with source organism	Consistent with source organism



Lane 1: Invitrogen™ TrackIt™ 1 Kb Plus DNA Ladder
Lane 2: 14053D-5

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2019.08.23 09:49:34 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **14053D-5™**

Lot Number: **70027300**

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 25177D-5™

Lot Number: 70035501

Designation: *Mycobacterium tuberculosis* genomic DNA

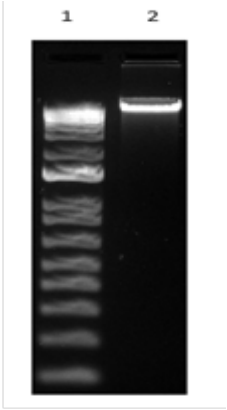
Fill Volume Prior to Drying: 85 µL

Product Format: Dried microbial DNA

Expiration Date: Not applicable

Storage Conditions: 2°C to 8°C

Test / Method	Specification	Result
OD_{260}/OD_{280} ratio (Spectrophotometer method)	1.6 to 2.1	1.7
Total amount of DNA (PicoGreen® measurement)	≥ 5 µg per vial	7 µg/vial
Agarose gel electrophoresis	High molecular weight chromosomal DNA	High molecular weight chromosomal DNA See photograph below
PCR Functionality	Successful PCR amplification of selected gene(s)	Successful PCR amplification of selected gene(s)
Sequencing of selected gene(s)	Consistent with source organism	Consistent with source organism
Inactivation of source organism (BSL 2 or higher) (Visual observation method)	No viable source organism detected	No viable source organism detected



Lane 1: Invitrogen™ TrackIt™ 1 Kb Plus DNA Ladder
Lane 2: 25177D-5

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2020.09.15 08:08:40 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **25177D-5™**

Lot Number: **70035501**

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 29342D™

Lot Number: 70028211

Designation: *Mycoplasma pneumoniae* genomic DNA

Fill Volume: 60 µL

Product Format: Frozen microbial DNA

Expiration Date: Not applicable

Storage Conditions: - 20°C or colder

Test / Method	Specification	Result
OD_{260}/OD_{280} ratio (Spectrophotometer method)	1.6 to 2.1	1.8 Tested on bulk prior to dilution and vialing
Total amount of DNA (PicoGreen® measurement)	≥ 50 ng per vial	108 ng/vial
Concentration of DNA (PicoGreen® measurement)	Report results	1.8 ng/µL
Agarose gel electrophoresis	High molecular weight chromosomal DNA	High molecular weight chromosomal DNA See photograph below Tested on bulk prior to dilution and vialing
PCR Functionality	Successful PCR amplification of selected gene(s)	Successful PCR amplification of selected gene(s)
Sequencing of selected gene(s)	Consistent with source organism	Consistent with source organism
Inactivation of source organism (BSL 2 or higher) (Visual observation method)	No viable source organism detected	No viable source organism detected

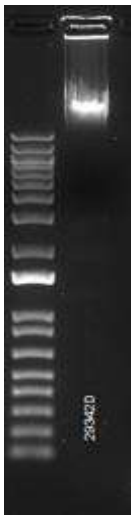
ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **29342D™**

Lot Number: **70028211**



Lane 1: Invitrogen™ TrackIt™ 1 Kb Plus DNA Ladder
Lane 2: 29342D

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2019.10.31 10:34:25 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **700110™**

Lot Number: **70023759**

Organism: ***Neisseria meningitidis* serogroup b**

Fill Volume: **0.25 mL**

Note: If material is in lyophilized format, the fill volume denotes the volume filling into the vial prior to drying.

Product Format: **Bacterial cells suspended in an appropriate cryoprotectant**

Expiration Date: **Not applicable**

Storage Conditions: **2°C to 8°C for freeze-dried cultures; - 80°C or colder for frozen cultures**

Note: Do not store frozen vials in freezers with a defrost cycle, as this will expose the vials to increased temperatures.

Test / Method	Specification	Result
Gram stain and cell morphology (Visual observation method)	Gram stain (when applicable) and cell morphology are consistent with the organism being tested.	Gram negative, non-motile, coccobacilli with a few diplococci present in singles and pairs
Colony description (Visual observation method)	Colony description is consistent with the organism being tested.	Tan, circular, convex, entire and smooth
Purity (Visual observation method)	Sample material is inoculated onto non-selective media. Cultures are examined macroscopically and microscopically after incubation. Cultures show no evidence of aberrant growth.	No evidence of aberrant growth.
Viability (confluency plate) (Visual observation method)	Sample material is viable.	Confluent growth on dilution plate, $>10^4$ cfu/vial.
Phenotypic testing	Sample material is evaluated with a defined battery of phenotypic tests including evaluation by bioMérieux VITEK® 2 Compact. Results are consistent with the organism being tested.	97% identification to *Neisseria meningitidis* using bioMérieux VITEK® 2 Compact.
Genotypic testing	Sample material is evaluated by 16S ribosomal gene sequencing. Results are consistent with the organism being tested.	Identification is consistent with the organism being tested.

Robbin L Smith

Digitally signed by Robbin L Smith
DN: cn=Robbin L Smith, o=ATCC, ou=Quality Assurance Specialist, email=rsmith@atcc.org, c=US
Date: 2019.05.20 11:31:46 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **700110™**

Lot Number: **70023759**

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-284 ™

Lot Number: 70023315

Classification: *Picornaviridae, Enterovirus,* Rhinovirus B

Agent: Human rhinovirus 14

Strain: 1059

Passage History: Submission Laboratory: Human kidney (HK) (3), KB (HeLa contaminant) (7), Human diploid (HD) (1), KB (HeLa contaminant) (7), HD (1), HeLa (3)
ATCC: H1 HeLa (ATCC® CRL-1958™) (8)

Fill Volume: 1.0 mL

Product Format: Fluid and cell lysate from infected cultures

Expiration Date: Not applicable

Storage Conditions: - 70°C or colder

Note: This product has undergone a reclassification or name change. The current product name is “Human rhinovirus 14”, while the vial labels for this lot have the former name of “Rhinovirus B”.

Test / Method	Specification	Result
Viability (Infectivity)*	PFU, IFU, $TCID_{50}$ or $CEID_{50}$ ≥ 5 x 10^3 per mL	Pass
Authentication**	Virus identity verified by Immunofluorescence, ELISA, and/or sequencing	Pass
Test for Mycoplasma Contamination		
Broth and agar culture (direct method)	None detected	None detected
DNA detection by PCR of test article nucleic acid	None detected	None detected
Sterility test (BacT/ALERT 3D)		
iAST bottle (aerobic) at 32.5°C, 14-day incubation	No growth	No growth
iNST bottle (anaerobic) at 32.5°C, 14-day incubation	No growth	No growth

***Titer notes:** 1.6 x 10^8 PFU/mL in 3 days on H1 HeLa cells (ATCC® CRL-1958™) at 33°C with 5% CO_2 and humidity. Tested on 19Jun2019.
****Authentication notes:** Genomic authentication was performed by Next Generation Sequencing (NGS) and results meet requirements of ≥ 750 bp with ≥ 99% homology to NCBI number K02121.1 (Human rhinovirus type 14 (HRV14), complete genome).

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2019.07.02 08:18:04 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company’s knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **VR-284 ™**

Lot Number: **70023315**

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 39393™

Lot Number: 99070 (reference 91-03)

Organism: *Propionibacterium freudenreichii*

Product Format: Bacterial cells suspended in an appropriate cryoprotectant

Expiration Date: Not applicable

Storage Conditions: 2°C to 8°C for freeze-dried cultures; - 80°C or colder for frozen cultures; Note: Do not store frozen vials in freezers with a defrost cycle, as this will expose the vials to increased temperatures.

Test / Method	Specification	Result
Purity (Visual observation method)	Sample material is inoculated onto non-selective media. Cultures are examined macroscopically and microscopically after incubation. Cultures show no evidence of aberrant growth.	No evidence of aberrant growth
Viability (confluency plate) (Visual observation method)	Sample material is viable.	Growth is observed.

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2021.04.22 07:44:39 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 9797DQ™

Lot Number: 70014398

Product Name: Quantitative Genomic DNA from *Bordetella pertussis*

Fill Volume: 102 µL

Product Format: Frozen microbial DNA

Expiration Date: Not applicable

Storage Conditions: - 20°C or colder

Test / Method	Specification	Result
DNA copy number by ddPCR	Report results	5.3 x 10^5 genome copies/µL
Inactivation of source organism (BSL 2 or higher) (Visual observation method)	No viable source organism detected	Pass; Testing was completed on DNA prior to quantitation and vialing

Jo Salisbury

Digitally signed by Jo Salisbury
DN: cn=Jo Salisbury, o=ATCC, ou=Quality Assurance, email=jsalisbury@atcc.org, c=US
Date: 2018.06.15 10:30:59 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-1826DQ™

Lot Number: 70027330

Product Name: Quantitative Genomic RNA from Enterovirus 68 Strain: Fermon

Classification: *Picornaviridae, Enterovirus, Enterovirus D*

Volume: 100 µL

Product Format: Total genomic material from a preparation of cell lysate and supernatant from infected cells

Expiration Date: Not applicable

Storage Conditions: - 70°C or colder

Test / Method	Specification	Result
RNA copy number by ddPCR	Report results	7.6 x 10^5 genome copies/µL
Authentication*	Sequence is consistent with that of infecting agent	Pass Testing was completed on material prior to vialing
Viral inactivation: ≥ 10% of input seed is incubated with host cells under appropriate growth conditions	No viable infecting agent detected by visual observation	Pass Testing was completed on material prior to vialing

***Authentication notes**: Genomic authentication was performed by Next Generation Sequencing (NGS) analyzing a ≥ 1000 bp region shown to have ≥ 99% homology to NCBI number AY426531.1 (Human enterovirus 68 strain Fermon, complete genome).

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2019.08.29 14:04:26 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-3262SD ™

Lot Number: 70037286

Product Name: Quantitative Synthetic Human coronavirus Strain HKU1 RNA

Product Format: Frozen synthetic nucleic acid

Expiration Date: 20JUL2025

Storage Conditions: –70 °C or colder

Test / Method	Specification	Result
qPCR Functionality and Identity (qPCR with construct-specific primers and probes)	PCR amplification plot with each Cq threshold value separated by approximately 3.32 cycles, or visually evenly spaced out	Pass
RNA copy number by ddPCR	1 x 10^5 to 1 x 10^6 genome copies/µL with a target of 5 x 10^5 genome copies/µL	5.5 x 10^5 genome copies/µL
Total volume (water and Biomatrica)	90 to 110 µL/vial	103 µL/vial

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2020.08.06 10:55:32 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-3263SD™

Lot Number: 70034817

Product Name: Quantitative Synthetic Human coronavirus Strain NL63 RNA

Product Format: Frozen synthetic nucleic acid

Expiration Date: 17APR2025

Storage Conditions: –70°C or colder

Test / Method	Specification	Result
qPCR Functionality and Identity (qPCR with construct-specific primers and probes)	PCR amplification plot with each Cq threshold value separated by approximately 3.32 cycles, or visually evenly spaced out	Pass
RNA copy number by ddPCR	1 x 10^5 to 1 x 10^6 genome copies/µL with a target of 5 x 10^5 genome copies/µL	1.5 x 10^5 genome copies/µL
Total volume (water and Biomatrica)	90 to 110 µL/vial	107 µL/vial

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2020.05.07 08:11:33 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 12600™

Lot Number: 70038915

Organism: *Staphylococcus aureus* subsp. *aureus*

Fill Volume: 0.25 mL

Note: If material is in lyophilized format, the fill volume denotes the volume filling into the vial prior to drying.

Product Format: Bacterial cells suspended in an appropriate cryoprotectant

Expiration Date: 30SEP2025

Storage Conditions: 2°C to 8°C for freeze-dried cultures

Test / Method	Specification	Result
Gram stain and cell morphology (Visual observation method)	Gram stain (when applicable) and cell morphology are consistent with the organism being tested.	Gram positive, non-motile cocci in singles, pairs, and short chains
Colony description (Visual observation method)	Colony description is consistent with the organism being tested.	Circular, entire, smooth, yellow, opaque, and convex
Purity (Visual observation method)	Sample material is inoculated onto non-selective media. Cultures are examined macroscopically and microscopically after incubation. Cultures show no evidence of aberrant growth.	No evidence of aberrant growth
Viability (confluency plate) (Visual observation method)	Sample material is viable.	Confluent growth on dilution plate, $>10^4$ cfu/vial
Viability (titer) (Titer method)	Sample material is checked for titer. Results are reported.	3.3×10^9 cfu/vial; Tested on 20Oct2020.
Phenotypic testing	Sample material is evaluated with a defined battery of phenotypic tests including evaluation by bioMérieux VITEK® 2 Compact. Results are consistent with the organism being tested.	99% identification to *Staphylococcus aureus* using bioMérieux VITEK® 2 Compact
Genotypic testing	Sample material is evaluated by 16S ribosomal gene sequencing. Results are consistent with the organism being tested.	Matches GenBank accession MN652637

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2020.11.30 09:37:51 -05'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **12600™**

Lot Number: **70038915**

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 12228D-5™

Lot Number: 70006950

Designation: *Staphylococcus epidermidis* genomic DNA

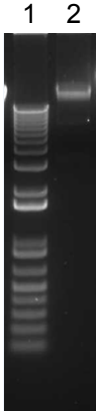
Fill Volume Prior to Drying: 80 µL

Product Format: Dried microbial DNA

Expiration Date: Not applicable

Storage Conditions: 2°C to 8°C

Test / Method	Specification	Result
OD_{260}/OD_{280} ratio (Spectrophotometer method)	1.6 to 2.1	1.8
Total amount of DNA (PicoGreen® measurement)	≥ 5 µg per vial	6 µg/vial
Agarose gel electrophoresis	High molecular weight chromosomal DNA; No visible RNA	High molecular weight chromosomal DNA; No visible RNA See photograph below
PCR Functionality	Successful PCR amplification of selected gene(s)	Successful PCR amplification of selected gene(s)
Sequencing of selected gene(s)	Consistent with source organism	Consistent with source organism



Lane 1 Invitrogen™ TrackIt™ 1 Kb Plus DNA Ladder
Lane 2: 12228D-5™

Jo Salisbury

Digitally signed by Jo Salisbury
DN: cn=Jo Salisbury, o=ATCC, ou=Quality Assurance, email=jsalisbury@atcc.org, c=US
Date: 2017.09.13 14:40:12 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **12228D-5™**

Lot Number: **70006950**

best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: 33400™

Lot Number: 70037946

Organism: *Streptococcus pneumoniae* Strain NCTC 7465

Fill Volume: 0.25 mL

Note: If material is in lyophilized format, the fill volume denotes the volume filling into the vial prior to drying.

Product Format: Bacterial cells suspended in an appropriate cryoprotectant

Expiration Date: 31AUG2025

Storage Conditions: 2°C to 8°C for freeze-dried cultures

Test / Method	Specification	Result
Gram stain and cell morphology (Visual observation method)	Gram stain (when applicable) and cell morphology are consistent with the organism being tested.	Gram-positive, non-motile cocci in singles, pairs, and short chains
Colony description (Visual observation method)	Colony description is consistent with the organism being tested.	Circular, entire, convex, smooth, and cream
Purity (Visual observation method)	Sample material is inoculated onto non-selective media. Cultures are examined macroscopically and microscopically after incubation. Cultures show no evidence of aberrant growth.	No evidence of aberrant growth
Viability (confluency plate) (Visual observation method)	Sample material is viable.	Confluent growth on dilution plate, $>10^4$ cfu/vial
Viability (titer) (Titer method)	Sample material is checked for titer. Results are reported.	1.4×10^6 cfu/vial Tested on 29SEP2020
Phenotypic testing	Sample material is evaluated with a defined battery of phenotypic tests including evaluation by bioMérieux VITEK® 2 Compact. Results are consistent with the organism being tested.	99% identification to *Streptococcus pneumoniae* using bioMérieux VITEK® 2 Compact
Genotypic testing	Sample material is evaluated by 16S ribosomal gene sequencing. Results are consistent with the organism being tested.	Matches GenBank accession AJ001247

Hiral Bhalani

Digitally signed by Hiral Bhalani
Date: 2020.10.26 16:11:43 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **33400™**

Lot Number: **70037946**

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

Certificate of Analysis

ATCC® Number: **12344D-5™**
Lot Number: **58267330**

Designation: ***Streptococcus pyogenes*** **T1 genomic DNA**

Test	Specifications	Results
OD_{260}/OD_{280} ratio	1.6 to 2.0	1.9
Concentration by PicoGreen® measurement	≥ 5 μg per vial	6 μg/vial
Functionality	Amplification of PCR product between 0.3 and 3 kb in length	Pass
Agarose gel electrophoresis	High molecular weight chromosomal DNA; No visible RNA in any of the lanes	High molecular weight chromosomal DNA; No visible RNA in any of the lanes; See photograph below
Sequencing of 16S ribosomal RNA gene (~500 bp)	Consistent with source organism	Consistent with source organism *Streptococcus pyogenes*
Inactivation of source organism (BSL 2 or higher)	BSL 1 – Not applicable BSL 2 – No viable source organism detected	BSL 2 – No viable source organism detected

Lane 1: Invitrogen™ TrackIt™ 1 Kb Plus DNA Ladder
Lane 2: 12344D-5

Kim Ellis

02 September 2008

Kim Ellis
Quality Control Manager; Quality, Compliance and Biosafety

Date

ATCC hereby represents and warrants that the material provided under this certificate has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

The ATCC trademark and trade name and any and all ATCC catalog numbers are trademarks of the American Type Culture Collection.

ATCC (American Type Culture Collection)
P.O. Box 1549
Manassas, VA 20108 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor.

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-3250SD™

Lot Number: 70037986

Product Name: Synthetic Human metapneumovirus RNA

Product Format: Frozen synthetic nucleic acid

Expiration Date: 26AUG2025

Storage Conditions: –70 °C or colder

Test / Method	Specification	Result
qPCR Functionality and Identity (qPCR with construct-specific primers and probes)	PCR amplification plot with each Cq threshold value separated by approximately 3.32 cycles, or visually evenly spaced out	Pass
RNA copy number by ddPCR	1 x 10^5 to 1 x 10^6 genome copies/µL with a target of 5 x 10^5 genome copies/µL	3.3 x 10^5 genome copies/µL
Total volume (water and Biomatrica)	90 to 110 µL/vial	98 µL/vial

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2020.09.09 06:36:27 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: VR-1558™

Lot Number: 70036255

Classification: *Coronaviridae, Betacoronavirus*

Agent: Betacoronavirus 1 (Human coronavirus OC43)

Strain: OC43

Passage History: Submission laboratories: Unknown, HRT-18 (7)
ATCC: HCT-8 (ATCC CCL-244™) (4)

Fill Volume: 1 mL

Product Format: Fluid and cell lysate from infected cultures

Expiration Date: Not applicable

Storage Conditions: - 70°C or colder

Test / Method	Specification	Result
Viability (Infectivity)*	PFU, IFU, $TCID_{50}$ or $CEID_{50}$ ≥ 5 x 10^3 per mL	Pass
Authentication**	Virus identity verified by Immunofluorescence, ELISA, and/or sequencing	Pass
Test for Mycoplasma Contamination		
Broth and agar culture (direct method)	None detected	None detected
DNA detection by PCR of test article nucleic acid	None detected	None detected
Sterility test (BacT/ALERT 3D)		
iAST bottle (aerobic) at 32.5°C, 14-day incubation	No growth	No growth
iNST bottle (anaerobic) at 32.5°C, 14-day incubation	No growth	No growth

***Titer notes:** 1.6 x 10^6 $TCID_{50}$/mL in 11 days on HCT-8 cells (ATCC® CCL-244™) at 33°C with 5% CO_2 and humidity. Tested on 05Jul2020.

****Authentication notes:** Genomic authentication was performed by Next Generation Sequencing (NGS) and results meet requirements of ≥ 1000 bp with ≥ 98% homology to NCBI number AY585228.1 (Human coronavirus OC43 strain ATCC VR-759, complete genome).

Jo Salisbury

Digitally signed by Jo Salisbury
Date: 2020.08.04 12:03:37 -04'00'

Quality Assurance Specialist; Quality Assurance

ATCC hereby represents and warrants that the material provided under this certificate is pure and has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and correct to the best of the company's knowledge and belief. This certificate does not extend to the growth and/or passage of any living organism or cell line beyond what is supplied within the container received from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor

CERTIFICATE OF ANALYSIS

ATCC® Number: **VR-1558™**

Lot Number: **70036255**

This product is intended to be used for laboratory research use only. It is not intended for use in humans, animals, or for diagnostics. Appropriate Biosafety Level (BSL) practices should always be used with this material. Refer to the Product Information Sheet for instructions on the correct use of this product.

ATCC products may not be resold, modified for resale, used to provide commercial services, or to manufacture commercial products without prior written agreement from ATCC.

ATCC
10801 University Boulevard
Manassas, VA 20110-2209 USA
www.atcc.org

800-638-6597 or 703-365-2700
Fax: 703-365-2750
E-mail: tech@atcc.org
or contact your local distributor