TESTAmed® DIAGNOSTICS

TESTAmed COVID-19 Antigen Rapid Test

Lateral Flow Chromatographic Immunoassay

Performance Summary

Table of Contents

TESTAmed COVID-19 Antigen Rapid Test.....1

Introduction.....1

Key Features.....1

Objective.....1

Product Specifications.....2

Instruction for Use.....3

Interpretation of Results.....3

Performance Evaluation.....4

Clinical Sensitivity and Specificity Evaluation.....4

Analytical Sensitivity – Limit of Detection (LoD).....6

Analytical Specificity – Cross-Reactivity Study.....9

Interference Studies.....11

Summary.....13

TESTAmed COVID-19 Antigen Rapid Test

Introduction

The coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). With the spread of the COVID-19 pandemic, the demand for tools to quickly scan for the disease has rapidly increased worldwide.

The TESTAmed COVID-19 Antigen Rapid Test is a lateral flow immunoassay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The sample material is obtained by using a nasopharyngeal swab during the acute phase of the infection. The virus detection takes place in 15 minutes, for quick and clear results.

The antigen test is confirmed to be sensitive to the new COVID-19 variants with spike protein mutations discovered in the UK and South Africa.

Key Features

- Accurate and Reliable – clinical study shows 94.2% sensitivity and 99.6% specificity
- Convenient – complete a test in 5 simple steps
- Rapid – results in only 15 minutes

Objective

This document was created to evaluate the clinical performance and reliability of TESTAmed COVID-19 Antigen Rapid Test according to clinical and laboratory standards. The goal is to demonstrate the excellent performance of this Lateral Flow Chromatographic Immunoassay.

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Product Specifications

Table 1 – TESTAmed COVID-19 Antigen Rapid Test Specifications

Test Principle	Lateral Flow Chromatographic Immunoassay
Target Antigen	SARS-CoV-2 Nucleocapsid Protein
Sample Type	Fresh Nasopharyngeal Swab Specimen
Limit of Detection (LoD)	1.26×10^2 $TCID_{50}$ per mL
Cross-Reactivity & Interferences	Viruses, Bacteria and Interferences tested do not cross-react or interfere
Reaction time	15 minutes

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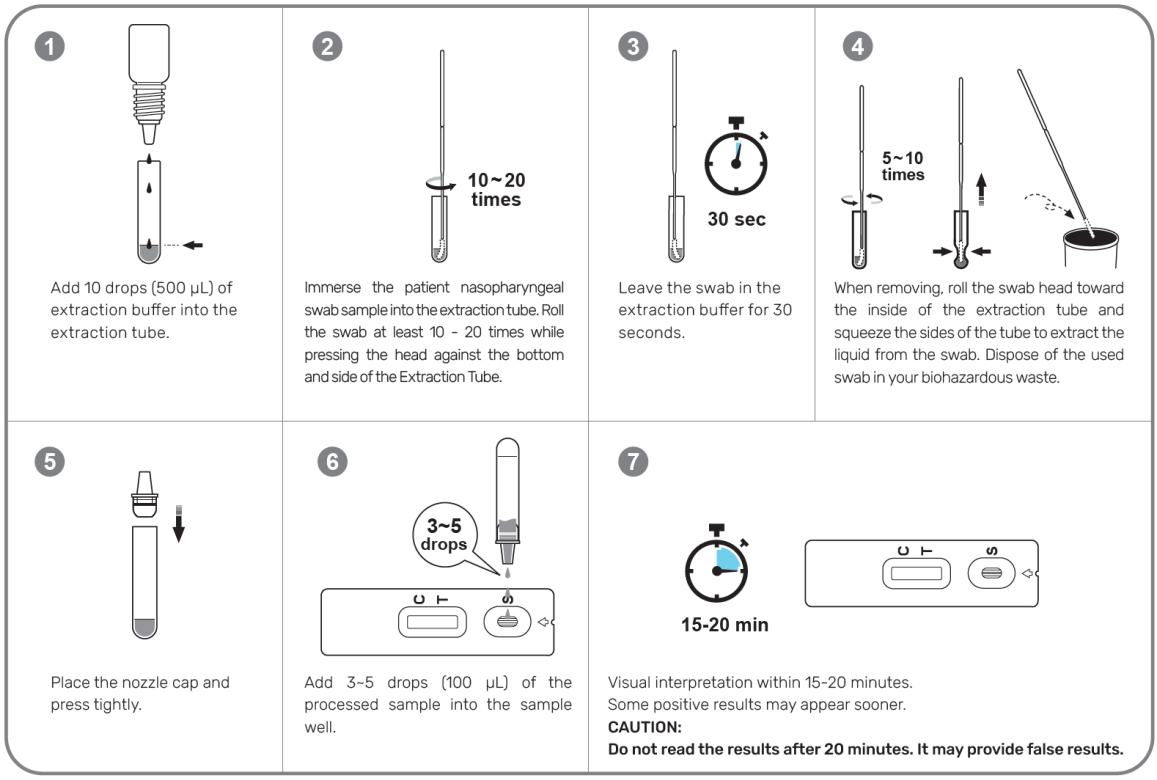
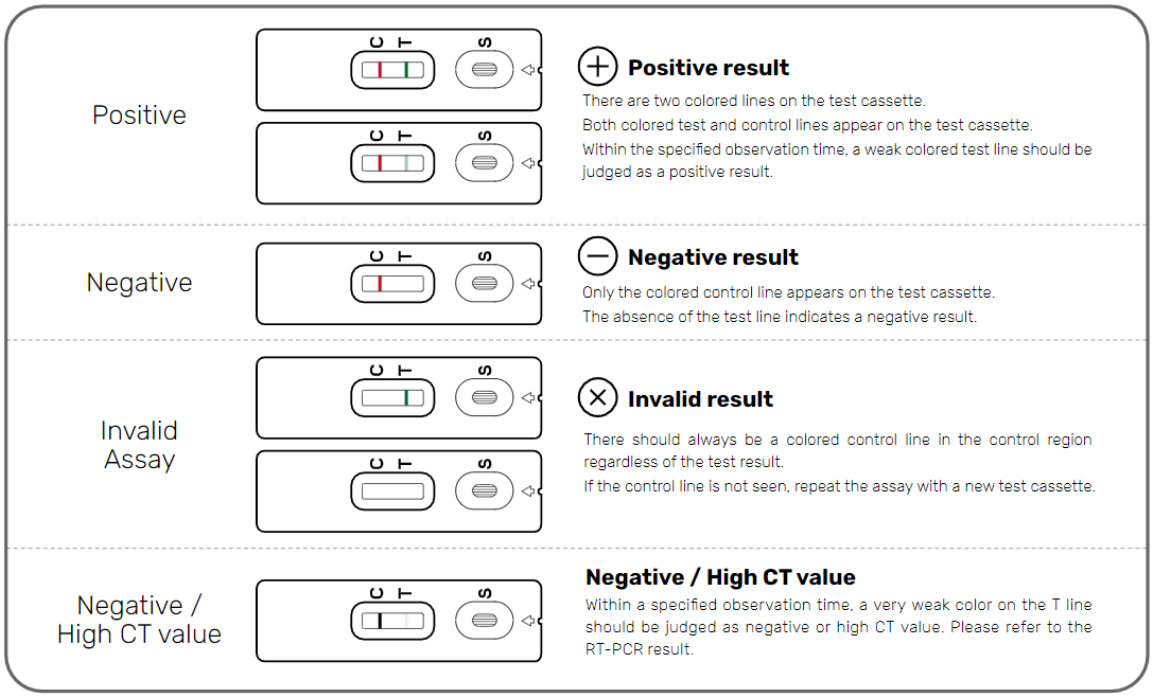
Instruction for Use



Interpretation of Results



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Performance Evaluation

Clinical Sensitivity and Specificity Evaluation

Objective

This clinical evaluation study is intended to evaluate the clinical sensitivity and clinical specificity of COVID-19 Antigen Rapid Test by comparing the test results to an RT-PCR test.

Clinical sensitivity and specificity of fresh nasopharyngeal swab specimens were measured by healthcare professionals or non-laboratory personnel in point-of-care settings or near-patient sites.

Method

Clinical sensitivity and specificity of fresh nasopharyngeal swab specimens were measured by healthcare professionals or non-laboratory personnel in point-of-care settings or near-patient sites. The study collected samples from subjects from Taiwan, USA and Bosnia with positive (+) and negative (-) results.

Table 2 – *Study Site Subjects*

Site	COVID-19 (+)	COVID-19 (-)	Total
Taiwan	36 subjects	100 subjects	136 subjects
USA	7 subjects	138 subjects	145 subjects
Bosnia	60 subjects	30 subjects	90 subjects
Total	103 subjects	268 subjects	371 subjects

Acceptance Criteria

Sensitivity = Positive Percent Agreement, PPA (%) ≥ 80% and ≥ 90% (Ct<30)

Specificity = Negative Percent Agreement, NPA (%) ≥ 97%

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Results

Overall

Test Device: TESTAmed COVID-19 Antigen Rapid Test

Comparator Method: RT-PCR test

Table 3 – *Clinical Performance of TESTAmed COVID-19 Antigen Rapid Test*

		PCR Test Results		
		POS	NEG	Subtotal
TESTAmed COVID-19 Antigen Rapid Test	Positive	97	1	98
	Negative	6	267	273
	Subtotal	103	268	371
Sensitivity		94.2% (95%CI: 87.9%-97.3%)		
Specificity		99.6% (95%CI: 97.9%-99.9%)		

Conclusion

The clinical performance of TESTAmed COVID-19 Antigen Rapid Test was determined by testing 103 positive and 268 negative specimens for SARS CoV-2 antigen (Ag). Based on the clinical study, the antigen test has a sensitivity of 94.2% (95%CI: 87.9%-97.3%) and specificity 99.6% (95%CI: 97.9%-99.9%)The results meet the acceptance criteria of sensitivity ≥ 80% and ≥ 90% (Ct<30), and specificity ≥ 97%.

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Analytical Sensitivity – Limit of Detection (LoD)

Objective

This study aims to determine the limit of detection (LoD) of the TESTAmed COVID-19 Antigen Rapid Test, and to simulate the detection method when using nasopharyngeal (NP) swabs.

Method

The Limit of Detection (LoD) of TESTAmed COVID-19 Antigen Rapid Test was determined using limiting dilutions of live SARS-CoV-2, isolate TWN/CGMH-CGU-01. In this study, all the SARS-CoV-2 serial dilutions were made in the SARS-CoV-2 negative nasopharyngeal swab pool. The material was supplied frozen at a concentration of $10^{5.4}$ $TCID_{50}$ per mL. The study to determine the TESTAmed COVID-19 Antigen Rapid Test LoD was designed to reflect the assay when using direct nasopharyngeal swab.

The LoD was determined in three steps:

1) LoD Screening: 10-fold dilutions of the live SARS-CoV-2 were made. These dilutions were tested in triplicate. The concentration demonstrating 3 of 3 positives was chosen for LoD range finding.
2) LoD Range Finding: Five (5) 2-fold dilutions of the suitable concentration were made. These dilutions were tested in triplicate. The concentration demonstrating 3 of 3 positives was chosen for LoD confirmation.
3) LoD Confirmation: The dilution was tested for a total of twenty (20) results for LOD confirmation.

Acceptance Criteria

The LoD concentration must be < 10^3 $TCID_{50}$/mL.

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Results

Table 4 – *The results of LoD Screening*

TESTAmed COVID-19 Antigen Rapid Test	Negative human clinical NP Swab pooled extraction	Spiked virus concentration ($TCID_{50}$/ml)					
	0	1	1/10	1/100	1/1000	1/10000	1/10000
	0	$10^{5.4}$	$10^{4.4}$	$10^{3.4}$	$10^{2.4}$	$10^{1.4}$	2.5
Test 1	-	+	+	+	+	-	-
Test 2	-	+	+	+	+	-	-
Test 3	-	+	+	+	+	-	-
Overall call rate	0/3 (0%)	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)	0/3 (0%)	0/3 (0%)

Table 5 – *The results of LoD Range Finding*

TESTAmed COVID-19 Antigen Rapid Test	Negative human clinical NP Swab pooled extraction	Spiked virus concentration ($TCID_{50}$/ml)					
	0	1/1000	1/2000	1/4000	1/8000	1/16000	1/32000
	0	$10^{2.4}$	$1.26x10^{2}$	$0.63x10^{2}$	$0.31x10^{2}$	$0.16x10^{2}$	$0.08x10^{2}$
Test 1	-	+	+	-	-	-	-
Test 2	-	+	+	-	-	-	-
Test 3	-	+	+	-	-	-	-
Overall call rate	0/3 (0%)	3/3 (100%)	3/3 (100%)	0/3 (0%)	0/3 (0%)	0/3 (0%)	0/3 (0%)

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Table 6 – *The results of LoD confirmation*

TESTAmed COVID-19 Antigen Rapid Test	Negative human clinical NP Swab pooled extraction	Spiked virus concentration ($TCID_{50}$/ml)		
	0	1/1000	1/2000	1/4000
	0	$10^{2.4}$	$1.26x10^2$	$0.63x10^2$
Test 1	-	+	+	-
Test 2	-	+	+	-
Test 3	-	+	+	-
Test 4	-	+	+	-
Test 5	-	+	+	-
Test 6	-	+	+	-
Test 7	-	+	+	-
Test 8	-	+	+	-
Test 9	-	+	+	-
Test 10	-	+	+	-
Test 11	-	+	+	-
Test 12	-	+	+	-
Test 13	-	+	+	-
Test 14	-	+	+	-
Test 15	-	+	+	-
Test 16	-	+	+	-
Test 17	-	+	+	-
Test 18	-	+	+	-
Test 19	-	+	+	-
Test 20	-	+	+	-
Overall call rate	0/20 (0%)	20/20 (100%)	20/20 (100%)	0/20 (0%)

Conclusion

Based on this test, the TESTAmed COVID-19 Antigen Rapid Test concentration of LoD was confirmed as 1.26×10^2 $TCID_{50}$ per mL

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Analytical Specificity – Cross-Reactivity Study

Objective

This study aims to demonstrate that the TESTAmed COVID-19 Antigen Rapid Test will not cross-react or interfere with the medically relevant levels of viruses and bacteria listed in the *results* section.

Method

Cross-reactivity of the TESTAmed COVID-19 Antigen Rapid Test was evaluated by testing various viruses (16) and bacteria (18). Each virus or bacteria was tested in triplicate in the absence or presence of 3.78×10^2 $TCID_{50}$/mL (3 LoD) of live SARS-CoV-2. The final concentration of each virus or bacteria was listed in the Table below. Testing was performed in triplicate.

Acceptance Criteria

The tested concentration of viruses or bacteria should not cross-react or interfere with the results of TESTAmed COVID-19 Antigen Rapid Test.

Results

Table 7 – *Cross Reactivity and Interference of Virus and Bacteria*

Virus/Bacteria	Concentration	Cross-Reactive Results	SARS-CoV-2 Concentration (3 LoD)	Interference Results
Human Coronavirus OC43	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Human Coronavirus 229E	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Influenza A · H1N1	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Influenza A · H3N2	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Influenza B · Victoria	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Influenza B · Yamagata	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Respiratory syncytial virus	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Rhinovirus	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Adenovirus type 1 (Adenoid 71)	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Adenovirus type 7	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Enterovirus 68	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 1	2.5×10^5 pfu/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive

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Human parainfluenza type 2	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 3	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 4	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Respiratory syncytial virus type B	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Bordetella pertussis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Chlamydia pneumoniae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Corynebacterium sp.	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Escherichia coli	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Hemophilus influenzae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Lactobacillus sp.	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Moraxella catarrhalis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Mycobacterium tuberculosis (avirulent)	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Neisseria meningitidis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Neisseria sp.	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Pseudomonas aeruginosa	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Staphylococcus aureus (Protein A producer)	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Staphylococcus epidermidis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Streptococcus pneumoniae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Streptococcus pyogenes	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Streptococcus salivarius	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Pooled human nasal wash – representative of normal respiratory microbial flora	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Mycoplasma pneumoniae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive

Conclusion

Cross-reactivity of the TESTAmed COVID-19 Antigen Rapid Test was evaluated by testing various viruses (16) and bacteria (18). Each virus or bacteria was tested in triplicate in the absence or presence of 3.78 x 10^2 $TCID_{50}$/mL (3 LoD) of live SARS-CoV-2.

Based on the data generated by this study, the tested viruses and bacteria do not cross-react or interfere with TESTAmed COVID-19 Antigen Rapid Test results.

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Interference Studies

Objective

This study aims to demonstrate that the TESTAmed COVID-19 Antigen Rapid Test results will not be interfered with 20 potential interfering substances and concentrations listed in the *results* section.

Method

Twenty (20) potentially interfering substances that may be found in the upper respiratory tract were selected and tested against the TESTAmed COVID-19 Antigen Rapid Test. Each substance was tested in triplicate in the absence or presence of 3.78×10^2 $TCID_{50}$/mL (3 LoD) of live SARS-CoV-2.

Acceptance Criteria

The tested concentration of interfering substance should not cross-react or interfere with the results of TESTAmed COVID-19 Antigen Rapid Test.

Results

Table 8 – *Cross Reactivity and Interference of Interfering Substances*

Interfering Substance	Active Ingredient	Concentration	Cross-Reactive Results	SARS-CoV-2 Concentration (3 LoD)	Interference Results
Ephrine Nasal Spray "GCPC"	Oxymetazoline	5% v/v	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Chloraseptic, Regular strength	Benzocaine / Menthol	1.5 mg/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Tamiflu	Oseltamivir	2.5 mg/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Physiomer Saline nasal spray	Saline	15% v/v	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Tobrex Eye Ointment	Tobramycin	51.4 µmol/L	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Sucrets	Dyclonine / Menthol	1.5 mg/mL	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
NeilMed NasoGEL Spray	sodium hyaluronate / Saline	5% v/v	Negative	3.78×10^2 $TCID_{50}$/mL	Positive
Acetaminophen	Acetaminophen	1324 µmol/L	Negative	3.78×10^2 $TCID_{50}$/mL	Positive

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Acetylsalicylic acid	Acetylsalicylic acid	3.62 mmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Ibuprofen	Ibuprofen	2.425 mmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Erythromycin	Erythromycin	81.6 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Fisherman's Friend	Menthol	1.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Plaquenil	Hydroxychloroquine sulphate	150 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
SUPEROCIN	Ciprofloxacin	30.2 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Zeffix	Lamivudine	1 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Blood (human)	Blood (human)	2.5% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Ricola	Menthol	1.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Mupirocin	Mupirocin	10 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Flonase	Fluticasone	5% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Purified mucin protein	Mucin protein	2.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive

Conclusion

The interference study of TESTAmed COVID-19 Antigen Rapid Test was evaluated by testing various interfering substances. Each interfering substance was tested in triplicate in the absence or presence of 3.78 x 10^2 $TCID_{50}$/mL (3 LoD) of live SARS-CoV-2.

Based on the data generated by this study, the tested interfering substances do not-cross-react or interfere with TESTAmed COVID-19 Antigen Rapid Test results.

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Summary

The results displayed throughout this report show that the TESTAmed COVID-19 Antigen Rapid Test provides excellent clinical performance results, with sensitivity of 94.2% (positive percent agreement) and specificity of 99.6% (negative percent agreement).

Additionally, the cross-reactivity study and interference study demonstrate the virus, bacteria, and substances tested throughout the study do not interfere with the TESTAmed COVID-19 Antigen Rapid Test results.

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