510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A. 510(k) Number

K231795

B. Applicant

Quidel Corporation

C. Proprietary and Established Names

QuickVue COVID-19 Test; QuickVue COVID-19 Test Control Swabs Set

D. Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QYT	Class II	21 CFR 866.3984 - Over-The-Counter Test To Detect Sars-Cov-2 From Clinical Specimens	Microbiology

II Submission/Device Overview:

A. Purpose for Submission:

To obtain 510(k) clearance for the QuickVue COVID-19 Test. The identical test is currently marketed as *QuickVue At-Home OTC COVID-19 Test* under Emergency Use Authorization, EUA210269 (OTC home use) and EUA210133 (Prescription Home Testing).

B. Measurand:

Nucleocapsid protein antigen from SARS-Coronavirus 2 (SARS-CoV-2)

C. Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A. Intended Use(s):

See Indications for Use below.

B. Indication(s) for Use:

The QuickVue COVID-19 Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19 within the first 5 days from symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

The QuickVue COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from January 2021 to February 2024 when COVID-19 variants Alpha, Delta, and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

C. Special Conditions for Use Statement(s):

OTC - Over The Counter

D. Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A. Device Description:

The QuickVue COVID-19 Test is a visually read lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus. The QuickVue COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.

The test package is composed of the following components:

- Test Strips (individually packaged)
- Prefilled Extraction Reagent Tubes
- Tube holder (built into the outer packaging)
- Strip Placement Card
- Disposable Nasal Swabs
- Package Insert

B. Principle of Operation:

To begin the test, a self-collected anterior nasal swab sample (age ≥14 years) or a nasal swab sample collected by another lay user (age ≥14 years) is inserted in the sample tube. The lysis reagent disrupts the virus particles in the specimen, exposing internal viral nucleocapsid antigens. The test strip is then placed in the reagent tube where the viral nucleocapsid antigens from the specimen will react with the SARS CoV-2 antibodies on the test strip. If the extracted specimen contains SARS-CoV-2 viral nucleocapsid antigens, a pink-to-red test line along with a blue procedural control line will appear on the test strip indicating a positive result. If SARS-CoV- 2 viral nucleocapsid antigens are not present, or are present at very low levels, only the blue procedural control line will appear.

The test strip has a chemically built-in control feature to ensure that each test run is performed properly. This blue procedural control line is the last line that the extracted specimen encounters before it enters the absorbent pad at the end of the test strip. The appearance of a blue procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test strip was maintained. If the blue procedural control line is not developed at 10 minutes, the test result is considered invalid. The two-color result format provides a simple interpretation for positive and negative results.

QVue Application: The QVue mobile application constitutes electronic labeling that allows for digitally guided testing of anterior nasal swab samples self-collected from lay users and reporting of results. The software application is intended for use with the QuickVue COVID-19 Test over the counter (OTC) device, as an alternative to the paper copy of the Instructions for Use (IFU) provided in the test kit. The QVue application is intended only to guide the user in the preparation and execution of the QuickVue COVID-19 Test.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Flowflex COVID-19 Antigen Home Test

B Predicate 510(k) Number(s):

K230828

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231795	K230828
Device Trade Name	QuickVue COVID-19 Test	Flowflex COVID-19 Antigen Home Test
Intended Use/ Indications for Use	The QuickVue COVID-19 Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19 within the first 5 days from symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. The QuickVue COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.	The Flowflex COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID 19 within the first 6 days of symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS- CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not

	This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from January 2021 to February 2024 when COVID-19 variants Alpha, Delta and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from December 2022 to March 2023 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab- based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
Regulation Number	21 CFR 866.3984	Same
Intended Use Population	Individuals with symptoms of COVID-19, within 5 days of symptom onset	Individuals with symptoms of COVID-19, within 6 days of symptom onset
Qualitative	Yes	Same
Analyte	SARS-CoV-2 nucleocapsid protein antigen	Same
Specimen Type	Direct anterior swab specimen	Same
Test principle	Lateral flow immunoassay	Same
Development time	10-15 min	15-30 min
Result Interpretation	Visually Read	Same
Utilizes Optional App to Guide Testing	Yes	Yes

The differences in the QuickVue COVID-19 Test (proposed device) and the ACON Flowflex COVID-19 Antigen Home Test (predicate device, K230828) are limited to the Intended Use population of the test and the development time. These differences do not affect the overall substantial equivalence of the proposed device to the predicate device in terms of the technological similarity, intended use, safety, and effectiveness.

VI Standards/Guidance Documents Referenced:

Document	Title	Publisher	Applicable Study
Nonbinding recommendations for premarket authorization of SARS CoV-2 antigen tests	Premarket Validation Recommendations for developers of in vitro diagnostic tests for SARS-CoV-2 antigen	FDA CDRH/OHT7/ DMD	All Studies
DEN220028/ Special controls for Over-the-counter test to detect SARS-CoV-2 from clinical specimens 21 CFR 866.3984	Reclassification order for DEN220028 and special controls under 21 CFR 866.3984	FDA/CDRH	All Studies
CLIA Waiver FDA Guidance	Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices - Guidance for Industry and Food and Drug Administration Staff (fda.gov)	FDA/CDRH	Flex Studies

VII Performance Characteristics (if/when applicable):

A. Analytical Performance:

1. Multi-lot Precision

The purpose of this study was to evaluate the lot-to-lot variability, repeatability, and precision for the QuickVue COVID-19 Test, using a panel of samples spiked with heat-inactivated SARS-CoV-2 and prepared in Negative Nasal Matrix (NNM).

The general procedure was to test a panel of samples that included a negative sample (NNM) and two (2) concentrations of heat-inactivated SARS-CoV-2 (WA1/2020, Lot number 062022) spiked in NNM at 1X LoD (low positive) and 4X LoD (moderate positive). Fifty microliters of each contrived sample were placed in a sample tube, allowed to soak onto a nasal swab, which was then tested in accordance with the device's IFU. Each sample panel was tested in 80 different events (2 replicates x 2 testing events/day x 20 days), using three (3) device lots and interpreted by two different operators. The results are summarized in Table 1 below. The agreement of obtained results with expected results was nearly 100% across all lots, operators, and days. Significant variability in results was not observed between the three independently manufactured lots.

Table 1: Summary of Precision Study Results

Lot	Negative		Low Positive (1X LoD)		Moderate Positive (4X LoD)	
	Operator 1	**Operator 2**	**Operator 1**	**Operator 2**	**Operator 1**	**Operator 2**
1	80/80	80/80	78/80	78/80	80/80	80/80
2	80/80	80/80	80/80	80/80	80/80	80/80
3	80/80	80/80	80/80	80/80	80/80	80/80
Total	240/240	240/240	238/240	238/240	240/240	240/240
%Agreement (95%CI)	**100%* [98.4% - 100.0%]**	**100%* [98.4% - 100.0%]**	**99.2%** [97.0% - 99.8%]**	**99.2% ** [97.0% - 99.8%]**	**100%** [98.4% - 100.0%]**	**100%** [98.4% - 100.0%]**

* Negative Agreement **Positive Agreement

2. Linearity:

Not applicable, the device is a binary qualitative assay.

3. Analytical Specificity/Interference:

a) Cross Reactivity/Microbial Interference

Potential cross-reactivity and microbial interference of the QuickVue COVID-19 Test were evaluated by testing twenty-one (21) microorganisms and thirty-nine (39) viruses, each individually prepared in negative clinical matrix.

Each organism and virus were tested in five (5) replicates in the absence or presence of 6.06E+04 $TCID_{50}$/mL (2X LoD) of heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020). None of the organisms and viruses below in Table 2 showed cross-reactivity and interference with the assay, at the concentrations listed, except for SARS-Coronavirus as was expected. Nineteen (19) specimens containing Coronavirus HKU1 were also tested with an EUA version of this test (EUA202086) and all resulted as negative.

Table 2: Cross-Reactivity/Microbial Interference Study Summary Results

Virus/Bacteria/Parasite	Strain	Concentration	Cross-Reactivity Negative agreement	Interference Positive Agreement
Adenovirus	Type 1	1.41E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 2	1.04E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 3	1.05E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)

Virus/Bacteria/Parasite	Strain	Concentration	Cross-Reactivity Negative agreement	Interference Positive Agreement
Adenovirus	Type 4	1.78E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 5	1.58E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 7	1.90E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 11	1.47E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 14	1.06E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 22	2.50E+06 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 31	1.06E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Adenovirus	Type 35	4.00E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Coronavirus	229e	1.26E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Coronavirus	NL63	1.06E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Coronavirus	OC43	1.28E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
MERS-CoV	None Specified	1.04E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
SARS-Coronavirus	None Specified	1.05E+05 $TCID_{50}$/mL	0% (5/5)	100.0% (5/5)
Cytomegalovirus	None Specified	1.13E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Enterovirus	Coxsackie	1.04E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Enterovirus	Echovirus	1.41E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Enterovirus	EV68	1.28E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Epstein Barr Virus	None Specified	1.96E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Influenza A	H1N1	1.04E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)

Virus/Bacteria/Parasite	Strain	Concentration	Cross-Reactivity Negative agreement	Interference Positive Agreement
Influenza A	pH1N1	1.21E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Influenza A	H3N2	1.05E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Influenza B	Victoria	1.51E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Influenza B	Yamagata	1.06E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Measles	None Specified	1.04E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Human Metapneumovirus	A1	1.19E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Mumps virus	None Specified	1.19E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Parainfluenza	Type 1	1.27E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Parainfluenza	Type 2	1.26E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Parainfluenza	Type 3	1.15E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Parainfluenza	Type 4	1.19E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Respiratory Syncytial Virus	Type A	1.26E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Respiratory Syncytial Virus	Type B	1.14E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Human Rhinovirus	Type A	1.06E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Human Rhinovirus	Type B	1.55E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Herpes Simplex Virus	Type 1	1.58E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Varicella-zoster virus	None Specified	1.21E+05 $TCID_{50}$/mL	100.0% (5/5)	100.0% (5/5)
Bordetella pertussis	A639	1.00E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Candida albicans	None Specified	1.83E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)

Virus/Bacteria/Parasite	Strain	Concentration	Cross-Reactivity Negative agreement	Interference Positive Agreement
Chlamydia pneumoniae	None Specified	1.45E+06 IFU/mL	100.0% (5/5)	100.0% (5/5)
Corynebacterium sp.	None Specified	1.00E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Escherichia coli	None Specified	1.72E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Haemophilus influenzae	None Specified	1.52E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Lactobacillus sp.	None Specified	1.58E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Legionella pneumophila	None Specified	1.00E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Moraxella catarrhalis	None Specified	1.04E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Mycoplasma pneumoniae	None Specified	1.35E+06 CCU/mL	100.0% (5/5)	100.0% (5/5)
Neisseria meningitides	None Specified	1.68E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Neisseria sp.	None Specified	1.23E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Pseudomonas aeruginosa	None Specified	1.16E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Pooled human nasal wash – representative of normal respiratory microbial flora	None Specified	N/A	100.0% (5/5)	100.0% (5/5)
Staphylococcus aureus	Type Not Specified	1.67E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Staphylococcus epidermidis	None Specified	1.53E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Streptococcus pneumoniae	None Specified	1.06E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Streptococcus pyogenes	None Specified	1.07E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Streptococcus salivarius	None Specified	1.05E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Mycobacterium tuberculosis avirulent	None Specified	1.16E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)

Virus/Bacteria/Parasite	Strain	Concentration	Cross-Reactivity Negative agreement	Interference Positive Agreement
Methicillin-resistant Staphylococcus aureus (MRSA)	None Specified	3.30E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)
Methicillin-susceptible Staphylococcus aureus (MSSA)	None Specified	3.67E+06 CFU/mL	100.0% (5/5)	100.0% (5/5)

b) Interfering Substances

Twenty-four (24) potentially interfering substances were evaluated with the QuickVue COVID-19 Test. Each substance was tested in five (5) replicates in the absence or presence of 6.06E+04 $TCID_{50}$/mL (2X LoD) of heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020). Except for Rheumatoid Factor, none of the substances listed in Table 3 interfered with the assay at the levels tested in either the presence or absence of SARS-CoV-2.

While there was no interference of Rheumatoid Factors with SARS-CoV-2 positive samples, in the absence of SARS-CoV-2, false positive results were observed with Rheumatoid Factor when tested at 112 IU/mL and 11.2 IU/mL in NNM. Rheumatoid Factor did not cross react at the final testing concentration of 1.12 IU/mL in NNM.

Table 3: Interfering Substances Study Results

Substances	Active Ingredient	Concentration	Positive Agreement (SARS CoV-2 Positive Samples)	Negative Agreement (SARS CoV-2 Negative Samples)
Throat lozenges	Menthol	700 mg/mL	100.0% (5/5)	100.0% (5/5)
Sore throat spray	Phenol	15% w/v	100.0% (5/5)	100.0% (5/5)
Mucin	Purified mucin protein	2.5 mg/mL	100.0% (5/5)	100.0% (5/5)
Whole Blood (human)	Whole blood	4% v/v	100.0% (5/5)	100.0% (5/5)
Leukocytes	Leukocytes	5.00E+06 cells/mL	100.0% (5/5)	100.0% (5/5)
Zinc (common ingredient in many nasal sprays)	Zinc	15% v/v	100.0% (5/5)	100.0% (5/5)
Nasal sprays	Cromolyn Oxymetazoline,	15% v/v	100.0% (5/5)	100.0% (5/5)
Nasal corticosteroids	Fluticasone	15% v/v	100.0% (5/5)	100.0% (5/5)
Nasal gel	Luffa opperculata, sulfur, Sodium Hyaluronate	5% w/v	100.0% (5/5)	100.0% (5/5)

Substances	Active Ingredient	Concentration	Positive Agreement (SARS CoV-2 Positive Samples)	Negative Agreement (SARS CoV-2 Negative Samples)
Homeopathic allergy relief	Alkalol	15% v/v	100.0% (5/5)	100.0% (5/5)
Anti-viral drugs	Molnupiravir (broad-spectrum antiviral)	2.5 mg/mL	100.0% (5/5)	100.0% (5/5)
Anti-viral drugs	Oseltamivir Phosphate (TamiFlu)	2.5 mg/mL	100.0% (5/5)	100.0% (5/5)
Anti-viral drugs	Ribavirin	2.5 mg/mL	100.0% (5/5)	100.0% (5/5)
Antibiotic, nasal ointment	Mupirocin	10 mg/mL	100.0% (5/5)	100.0% (5/5)
Hand sanitizer	Isopropyl alcohol	15% v/v	100.0% (5/5)	100.0% (5/5)
Lotion	Not specified	15% w/v	100.0% (5/5)	100.0% (5/5)
Hand Soap	Not specified	15% v/v	100.0% (5/5)	100.0% (5/5)
Rheumatoid Factor	Rheumatoid Factor	1.12 IU/mL	100.0% (5/5)	100.0% (5/5)
Homeopathic Alkalol	Thymol; Eucalyptol; Manitol; Camphor; Benzoin; Potassium Alum; Potassium Chlorate; Sodium Bicarbonate; Sodium Chloride; Oils of: Sweet Birch; Spearmint; Pine; Cinnamon	1:10 dilution	100.0% (5/5)	100.0% (5/5)
Cough syrup	Dextromethorphan	5%v/v	100.0% (5/5)	100.0% (5/5)
Nicotine or Tobacco	Nicotine	0.03 mg/mL	100.0% (5/5)	100.0% (5/5)
Analgesic ointment (Vicks VapoRub)	Camphor, eucalyptus oil, menthol	1% w/v	100.0% (5/5)	100.0% (5/5)
Petroleum Jelly (Vaseline)	White petroleum	1% w/v	100.0% (5/5)	100.0% (5/5)
Systemic antibiotic	Tobramycin	4 µg/mL	100.0% (5/5)	100.0% (5/5)

4. Assay Reportable Range:

Not applicable, the device is a binary qualitative assay.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a) Internal Controls

The test strip of the QuickVue COVID-19 Test has a chemically built-in control feature, using the blue procedural control line to ensure that each test run is performed properly. The procedural control line is the last line that the extracted specimen encounters before it enters

the absorbent pad at the end of the test strip. The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test strip was maintained. If the blue procedural control line does not develop at 10 minutes, the test result is considered invalid.

b) Sample Stability

Nasal swab samples (both NNM controls and moderate positive samples of heat inactivated SARS-CoV-2 WA1/2020 at 2X LoD, 6.06E+04 $TCID_{50}$/mL) were stored at ambient temperature (20-25°C) and refrigerated (2-8°C) over different lengths of time from 24 hours to 196 hours to evaluate specimen stability. Samples were removed from storage and tested according to the IFU. All samples tested produced 100% expected results for both storage conditions across all timepoints tested.

c) Reagent Stability (Shelf life)

In order to determine the stability of the QuickVue COVID-19 Test at the intended storage conditions, 15-30°C, three (3) test kits produced within one month were stored at 11°C and at 31°C for 11 months and were tested with NNM samples (i.e., negative) and samples prepared at 5X LoD spiked in NNM. The data obtained from this study currently supports a shelf life of 6 months.

d) Shipping Stability

In order to evaluate the stability of the test kit under different shipping conditions, kits from three lots were stored at: 60°C with 85% ±5% relative humidity for periods from 1 to 8 days. The stored test kits were tested in five (5) replicates daily through the entire test system including the sample application and processing step for each storage condition. All negative samples tested negative; all positive samples (5X LoD) tested positive over the 8-day time course.

In order to determine the effect of harsh shipping conditions on the performance of the QuickVue COVID-19 Test, kits from three (3) different lots were stored at either- 10°C or 40°C for periods of 8, 24, or 48 hours. All negative samples tested negative; all positive samples (5X LoD) tested positive in all storage conditions.

6. Detection Limit:

a) LoD Testing

The Limit of Detection (LoD) of the QuickVue COVID-19 Test was determined by evaluating different dilutions of heat-inactivated SARS-CoV-2 isolate USA-WA1/2020, and dilutions of SARS CoV-2 isolate Omicron BA.5, in NNM. The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The limit of detection was established in two (2) phases, a range finding and a confirmatory LoD study.

LoD Range Finding

Five serial dilutions were prepared by spiking heat inactivated SARS-CoV-2 WA1/2020 and Omicron BA.5 stocks into NNM. Five (5) replicates were tested on three (3) different product test lots for each dilution of each virus strain to determine the preliminary LoD concentration on the product. The lowest concentration with 5/5 positive results from each lot was considered the preliminary LoD for each virus strain. The results are summarized for each tested strain in Tables 4 and 5.

LoD Confirmation Testing

For each strain, the dilution above and below the determined preliminary LoD were tested on each lot. For each dilution and each lot, a total of twenty (n = 20) replicates were tested. To confirm the LoD for each lot, at least 19 of the 20 replicates were required to be positive (i.e., at least 95%). The results are summarized for each strain used in LoD testing in Tables 4 and 5.

Table 44: LoD Study Summary for SARS-CoV-2 WA1/2020

Analyte Concentration ($TCID_{50}$/Swab)	Analyte Concentration ($TCID_{50}$/mL)	Results (Combined 3 lots)	
		# Positive	%Positivity
Range Finding			
3.03E+03	6.05E+04	15/15	100.0%
1.52E+03	3.03E+04	15/15	100.0%
7.55E+02	**1.51E+04**	**15/15**	**100.0%**
3.78E+02	7.56E+03	7/15	46.7%
1.89E+02	3.78E+03	0/15	0.0%
Confirmation			
3.03E+03	6.05E+04	60/60	100.0%
1.52E+03	**3.03E+04**	**60/60**	**100.0%**
7.55E+02	1.51E+04	56/60	93.3%
3.78E+02	7.56E+03	4/60	6.7%

Table 55: LoD Study Summary for SARS CoV-2 Omicron BA.5

Analyte Concentration ($TCID_{50}$/Swab)	Analyte Concentration ($TCID_{50}$/mL)	Results (Combined 3 lots)	
		# Positive	%Positivity
Range Finding			
4.95E+03	9.90E+04	15./15	100.0%
2.48E+03	4.95E+04	15/15	100.0%
1.24E+03	**2.48E+04**	**15/15**	**100.0%**

6.20E+02	1.24E+04	3/15	46.7%
3.10E+02	6.19E+03	0/15	0.0%
Confirmation			
2.48E+03	4.95E+04	60/60	100.0%
1.24E+03	**2.48E+04**	**60/60**	**100.0%**
6.20E+02	1.24E+04	**5/60**	**8.3%**

The LoD for the QuickVue COVID-19 Test was confirmed to be 3.03E+04 $TCID_{50}$/mL (1.52E+03 per swab) and 2.48E+04 $TCID_{50}$/mL (1.24E+03 per swab) using SARS-CoV-2 strain WA1/2020 and SARS-CoV-2 Omicron BA.5 strains, respectively.

b) WHO Standard Testing

A study was performed to also determine the LoD for the QuickVue COVID-19 Test in nasal samples using the WHO International Standard for SARS-CoV-2 antigen as a standardized material.

As per the WHO instructions, the international standard material was reconstituted in 0.25 mL of ultra-pure water. Following reconstitution, the ampule was left at ambient temperature for 20 minutes and then mixed thoroughly, avoiding generation of excess foam. The reconstitution of the material yielded a final stock concentration equal to 5000 IU or 2.0 $x10^4$ IU/mL.

For each replicate, 50 µL of virus dilution was applied to a swab and the swab was processed according to the IFU. A preliminary LoD concentration was determined by testing a series of 2-fold dilutions of the antigen spiked into NNM in replicates of three (3). The lowest concentration with 3 out of 3 positive replicates was considered to be the preliminary LoD. The results of the preliminary LoD study are shown as Table 6:

Table 6: WHO SARS-CoV-2 Standard LoD Range Finding Results

Concentration of WHO International Standard for SARS-CoV-2 antigen applied to dry swab	Positive/ Tested
1.20 $x10^4$ IU/mL	3/3
1.00 $x10^4$ IU/mL	**3/3**
5.00 $x10^3$ IU/mL	0/3
2.50 $x10^3$ IU/mL	0/3
1.25 $x10^3$ IU/mL	0/3
6.25 $x10^2$ IU/mL	0/3
3.12 $x10^2$ IU/mL	0/3

The preliminary LoD, a dilution above, and a 3-fold dilution below was confirmed by testing an additional twenty (20) replicates per dilution. The results of this testing, as shown in Table 7 confirmed the LoD for the WHO International Standard Antigen to be 1.00 $x10^4$ IU/mL (5.00 $x10^2$ IU/swab).

Table 7: WHO SARS-CoV-2 Standard Confirmatory LoD Results

Concentration of WHO International Standard for SARS-CoV-2 antigen applied to dry swab	Positive/ Tested
1.20 x10^4 IU/mL	20/20
1.00 x10^4 IU/mL	**20/20**
3.00 x10^3 IU/mL	16/20

7. High Dose Hook Effect

The purpose of this study was to evaluate the effect of a high concentration of SARS antigen on the performance of the QuickVue COVID-19 Test. A series of five (5) different concentrations of heat-inactivated SARS-CoV2 (isolate WA1/2020), ranging from 3X LOD (9.09E+04 $TCID_{50}$/mL) to 1.09E+06 $TCID_{50}$/mL (35.9X LoD) were prepared and tested in five (5) replicates on the QuickVue COVID-19 Test, with two operators reading the test results. The testing was conducted according to the test's IFU and results are summarized in Table 8.

Table 8: High Dose Hook Effect Study Results

SARS-CoV-2 Concentration ($TCID_{50}$/mL)	Assay Results			
	Operator 1		Operator 2	
	# Positive	% Positivity	# Positive	% Positivity
1.09E+06	5/5	100.0%	5/5	100.0%
3.03E+05	5/5	100.0%	5/5	100.0%
2.12E+05	5/5	100.0%	5/5	100.0%
1.52E+05	5/5	100.0%	5/5	100.0%
9.09E+04	5/5	100.0%	5/5	100.0%

No high dose hook effect was observed for any of the dilutions tested from 1.09E+06 down to 9.09E+04 $TCID_{50}$/mL with the QuickVue COVID-19 Test.

8. Inclusivity (Analytical Reactivity)

Analytical reactivity for QuickVue COVID-19 Test was demonstrated using two additional strains/isolates of SARS CoV-2 virus. Heat-inactivated SARS-CoV-2 isolates for Omicron BA.1 and Delta strains were each diluted into NNM at different concentrations. Each concentration was tested with 5 replicates until two consecutive dilutions produced one or more negative replicates out of 5. These results are summarized in Table 9.

Table 9: Summary of SARS CoV-2 Inclusivity Testing

SARS-CoV-2 Variants	Lowest Concentration with 5/5 positive replicates [$TCID_{50}$/mL]
B.1.617.2 (Delta)	3.00E+04
BA.1 (Omicron)	7.08E+04

The QuickVue COVID-19 Test detected the viral strains/isolates SARS-CoV-2, Omicron BA.1 and SARS-CoV-2, Delta. The minimum detectable concentration of SARS-CoV-2 Omicron BA.1 was 7.08E+04 TCID50/mL. The minimum detectable concentration of SARS-CoV-2 Delta was 3.00E+04 TCID50/mL.

A plan has been established by the sponsor to closely monitor for the emergence of any circulating variants of concern. The plan includes the monitoring of publicly available databases and information from public health authorities, and a multi-tier approach that determines reactivity of the test with emerging variants (including *in silico* analysis, use of antibody escape mutational profile, and wet testing).

9. Assay Cut-Off:

Not applicable, the device is a binary qualitative assay.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable. See "C. Clinical Studies." for clinical performance.

2. Matrix Comparison:

   The QuickVue COVID-19 Test is only intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens. As no other specimen or sample type is claimed for this device, a Matrix Comparison study is not applicable.

C. Clinical Studies:

Clinical Sensitivity and Specificity:

Performance characteristics of the QuickVue COVID-19 Test were established during two prospective all-comers studies: 1) a study conducted from November 2023 to February 2024 to assess performance with contemporarily circulating variants and 2) an initial performance study conducted from January 2021 to May 2021. Both studies assessed performance of lay user collected anterior nares swabs and tested with the QuickVue as compared to anterior nares swab collected by a health care provider that were tested with a highly sensitive RT-

PCR comparator test. The demographics of the total combined sample cohort are summarized in Table 10:

Table 10: Overall Study Subject Demographics

Age Range (Years)	N	% of Total	# Male	% Male	#Female	% Female
2 to <18	133	15.1	50	37.6	83	62.4
18-65	710	80.9	286	40.3	424	59.7
>65	35	4	12	34.3	23	65.7
All Samples	**878**	**100**	**348**	**39.6**	**530**	**60.4**

The evaluable sample cohort included symptomatic subjects that had symptoms within 5 days post symptom onset (DPSO) and included ~18.5% low positive samples. The combined clinical performance for the Quick-Vue COVID-19 Test in both studies demonstrated a Positive Percent Agreement (PPA) of 82.0% and Negative Percent Agreement (NPA) of 99.1% when compared to an RT-PCR comparator, as shown in Table 11 below. PPA estimates and number of positives samples stratified by DPSO are provided in Table 12.

Table 11: Clinical Performance Symptomatic Subjects 0-5 DPSO, Combined Clinical Studies

QuickVue COVID-19 Test	Comparator		
	Positive	**Negative**	**Total**
Positive	164	5	169
Negative	36	575	611
Total	200	580	780
Positive Percent Agreement (PPA)	**82.0% (164/200)** (95% CI: 76.1% - 86.7%)		
Negative Percent Agreement (NPA)	**99.1% (575/580)** (95% CI: 97.0% - 99.6%)		

Table 12: PPA Breakdown by DPSO Combined Clinical Studies

# Days Since Symptom Onset	Quick-Vue Positives	Comparator Positives	Sensitivity/PPA % Detected/Comparator Positive
0	14	16	87.50% (14/16)
1	43	53	81.1% (43/53)
2	50	63	79.4% (50/63)
3	26	28	92.9% (26/28)
4	21	28	75.0 % (21/28)
5	10	12	83.3% (10/12)
Total	**160**	**200**	**82.0% (84/99)**

D. Clinical Cut-Off:

There is no clinical cut-off for this device. This section is therefore not applicable.

E. Expected Values/Reference Range:

A patient sample is expected to be negative for SARS-CoV-2.

F. Other Supportive Performance Characteristics Data

1. Flex Studies

To assess the robustness of the QuickVue COVID-19 Test, flex studies were conducted that assessed all major aspects of the test procedure (e.g., swab extraction time, open pouch time before analysis, development time, running steps out of order, swab agitation, sample buffer agitation) and variability of environmental test conditions that the test may be subjected to when in use (e.g., various temperature and humidity stress, strip disturbance, sample temperature, lighting). Testing was performed with contrived positive nasal swabs prepared by diluting heat inactivated SARS-CoV-2 virus into negative clinical nasal swab matrix at 2X LoD. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

2. Usability Studies

A usability study was conducted to validate the design of the QuickVue COVID-19 Test IFU and to assess the lay user's ability to understand the instructions for use and to perform testing using the components provided within the test kit.

The results of the usability testing demonstrated that the users sufficiently comprehend the test procedure as described in the IFU, indicated that the occurrence of user-related errors is low (≥96% correct execution of each procedural step), and the effect of errors is low (no invalid results were observed).

3. Lay User Readability Study

The purpose of this study was to determine whether lay users can adequately interpret QuickVue COVID-19 Test results on mock devices with varying signal strengths. Mock devices were prepared by taking high-resolution photographs of QuickVue test strips incubated in the following concentrations of heat-inactivated SARS-CoV-2: negative samples, 2X LoD, 5X LoD and devices with invalid results. Based on the results observed in the first day of testing (i.e., observed 80.7% correctly interpreted), a second day of testing was conducted to test two additional sample concentrations: 3X LoD and 4X LoD. Of the 57 participants from the first day of testing, 52 returned on the second day for testing. The five participants that did not return on the second day were replaced so the total number of subjects would remain 57. The age breakdown of the study participants is shown in Table 13 and the vison impairment status in Table 14.

Table 13:Age Cohort of QuickVue COVID-19 Test Operators

Age Cohort	n (%)	
	Day 1	Day 2
Under 20	16 (28.1%)	13 (22.8%)
20-30	10 (17.5%)	9 (15.8%)
31-54	20 (35.1%)	19 (33.3%)
55+	11 (19.3%)	16 (28.1%)

Table 14: Frequency of Vision Impairment Types Reported by QuickVue COVID-19 Test Operators

Type of Vision Impairment	n (%)	
	Day 1	Day 2
N/A	23 (40.4%)	19 (33.3%)
Near Sightedness	15 (26.3%)	20 (35.1%)
Far Sightedness	17 (29.8%)	14 (24.6%)
Near Sightedness & Far Sightedness	N/A	1 (1.8%)
Color Blindness	1 (1.8%)	N/A
Other	1 (1.8%)	N/A
Trifocal	N/A	1 (1.8%)
Cataracts/ Corrected Cataracts	N/A	2 (3.5%)

A summary of the results of the study is shown in Table 15. Positive samples with concentrations at 3-5X LoD were all correctly interpreted. The sample at 2X LoD concentration was interpreted incorrectly as negative 20% of the time. However, it is noted that these false negative results at 2X LoD were determined mostly by individuals with vision impairment (10/11). Individuals without vision impairment we able to correctly interpret the 2X LoD samples 95.6% of the time (n/N: 22/23). It is therefore recommended that users with conditions affecting their vision, such as far-sightedness, glaucoma, or color blindness, are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). A related warning statement will be included in the IFU.

Table 15: Overall results of Lay User Readability Study

Sample Condition	Study Day	Identified Correct/ Total	% Called Correctly
Negative	1	56/57	98.2
2X LoD	1	46/57	80.7
3X LoD	2	57/57	100.0
4X LoD	2	57/57	100.0
5X LoD	2	57/57	100.0
Invalid	1	54/57	94.7

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.