Quidel Corporation
Suzanne Thomas
Sr. Regulatory Affairs Manager
10165 McKellar Court
San Diego, California 92121

March 22, 2024

Re: K231795
Trade/Device Name: QuickVue COVID-19 Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-The-Counter Test To Detect SARS-CoV-2 From Clinical Specimens
Regulatory Class: Class II
Product Code: QYT
Dated: June 16, 2023
Received: June 20, 2023

Dear Suzanne Thomas:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.S., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231795

Device Name
QuickVue COVID-19 Test

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

I. Submitter

Quidel Corporation
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San Diego, CA 92121
Telephone: (800) 874-1517

Submission Contact

Suzanne Thomas
Sr. Regulatory Affairs Manager
678-727-8786
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Date Prepared

March 22, 2024

Proprietary and Established Names

QuickVue COVID-19 Test

Common Name

Coronavirus Antigen Detection Test

II. Device Classification

Product	Product Code	Classification	Regulatory Section	Description
Assay	QYT	II	21 CFR 866.3984	Over-the-Counter COVID-19 antigen test

Panel

Microbiology

Predicate Device

ACON Flowflex COVID-19 Antigen Home Test (K230828; cleared 11/09/2023)

III. Device Description

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

To begin the test, a self-collected anterior nasal swab sample (in individuals aged 14 and older or individuals between the age of 2 to 14 a swab collected by a parent or guardian), or a healthcare collected anterior nasal swab sample is inserted into the pre-filled reagent tube. The 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 in the specimen will react with the reagents in 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.

Assay Components

Component	2-Test	4-Test	25-Test
Individually Packaged Test strips	2	4	25
Reagent Tubes containing Reagent Solution	2	4	25
Nasal Swabs	2	4	25
User Instructions	1	1	1
Strip Placement Card	2	2	2
QVue Mobile Application (Optional)	Available for download using the QR code located on the Unit Carton		

IV. Intended 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.

V. Comparison with Predicate Device

Features	Proposed Device QuickVue COVID-19 Test	Predicate Device Flowflex COVID-19 Antigen Home Test K230828
Intended 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-	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 COVID19 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 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)

	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.	should be considered in situations where a new virus or variant is suspected.
Qualitative	Yes	Same
Analyte	SARS-CoV-2 nucleocapsid protein antigen	Same
Intended Use Population	Individuals with symptoms of COVID-19	Same
Specimen Type	Direct anterior nasal swab specimens	Same
Test Principle	Lateral flow immunoassay	Same
Format	Test strip	Test cassette
Development Time	10 min	15-30 min
Storage	Room Temperature (15°C – 30°C)	Same
Use Setting (OTC or Rx)	OTC	OTC
Rapid test	Yes	Same
Result Interpretation	Visual read	Same
Utilizes App to display results	Optional	Optional

VI. Performance Data

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate device. The performances studies included:

Limit of Detection

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 negative nasal matrix (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 for the QuickVue COVID-19 Test using SARS-CoV-2 strain WA1/2020 was confirmed to be 3.03E+04 $TCID_{50}$/mL. The limit of detection for the QuickVue COVID-19 Test with SARS-CoV-2 strain Omicron BA.5 was confirmed to be 2.48E+04 $TCID_{50}$/mL.

Analyte Strain	**LoD Concentration ($TCID_{50}$/mL)**	**LoD Concentration ($TCID_{50}$/Swab)**
WA1/2020/ Alpha	3.03E+04	1.52E+03
Omicron / BA.5	2.48E+04	1.24E+03

Inclusivity (Analytical Reactivity)

Analytical reactivity for QuickVue COVID-19 Test was demonstrated using 2 additional strains/isolates of SARS CoV-2 virus. Heat-inactivated SARS-CoV-2 isolates Omicron BA.1 and Delta stocks 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.

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 $TCID_{50}$/mL. The minimum detectable concentration of SARS-CoV-2, Delta was 3.00E+04 $TCID_{50}$/mL.

Cross Reactivity/Microbial Interference

The cross-reactivity and potential interference were evaluated by testing various microorganisms (21), viruses (39), and negative matrix (1) with the QuickVue COVID-19 Test. Each organism and virus were tested in five (5) replicates in the absence or presence of 6.06E+04 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020). None of the organisms and viruses below in **Table 1** showed cross-reactivity and interference in the assay at the concentrations listed except for SARS-Coronavirus. Cross-reactivity was observed on SARS-Coronavirus sample as expected.

Table 1. Cross-Reactivity/Microbial Interference Study Results

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Adenovirus	Type 1	1.41E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 2	1.04E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 3	1.05E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 4	1.78E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 5	1.58E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 7	1.90E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 11	1.47E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 14	1.06E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 22	2.50E+06	$TCID_{50}$/mL	No	No
Adenovirus	Type 31	1.06E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 35	4.00E+05	$TCID_{50}$/mL	No	No
Coronavirus	229e	1.26E+05	$TCID_{50}$/mL	No	No
Coronavirus	NL63	1.06E+05	$TCID_{50}$/mL	No	No

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Coronavirus	OC43	1.28E+05	$TCID_{50}$/mL	No	No
MERS-CoV	None Specified	1.04E+05	$TCID_{50}$/mL	No	No
SARS-Coronavirus	None Specified	1.05E+05	$TCID_{50}$/mL	Yes	No
Cytomegalovirus	None Specified	1.13E+05	$TCID_{50}$/mL	No	No
Enterovirus	Coxsackie	1.04E+05	$TCID_{50}$/mL	No	No
Enterovirus	Echovirus	1.41E+05	$TCID_{50}$/mL	No	No
Enterovirus	EV68	1.28E+05	$TCID_{50}$/mL	No	No
Epstein Barr Virus	None Specified	1.96E+05	$TCID_{50}$/mL	No	No
Influenza A	H1N1	1.04E+05	$TCID_{50}$/mL	No	No
Influenza A	pH1N1	1.21E+05	$TCID_{50}$/mL	No	No
Influenza A	H3N2	1.05E+05	$TCID_{50}$/mL	No	No
Influenza B	Victoria	1.51E+05	$TCID_{50}$/mL	No	No
Influenza B	Yamagata	1.06E+05	$TCID_{50}$/mL	No	No
Measles	None Specified	1.04E+05	$TCID_{50}$/mL	No	No
Human Metapneumovirus	A1	1.19E+05	$TCID_{50}$/mL	No	No
Mumps virus	None Specified	1.19E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 1	1.27E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 2	1.26E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 3	1.15E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 4	1.19E+05	$TCID_{50}$/mL	No	No
Respiratory Syncytial Virus	Type A	1.26E+05	$TCID_{50}$/mL	No	No
Respiratory Syncytial Virus	Type B	1.14E+05	$TCID_{50}$/mL	No	No
Human Rhinovirus	Type A	1.06E+05	$TCID_{50}$/mL	No	No
Human Rhinovirus	Type B	1.55E+05	$TCID_{50}$/mL	No	No
Herpes Simplex Virus	Type 1	1.58E+05	$TCID_{50}$/mL	No	No

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Varicella-zoster virus	None Specified	1.21E+05	$TCID_{50}$/mL	No	No
Bordetella pertussis	A639	1.00E+06	CFU/mL	No	No
Candida albicans	None Specified	1.83E+06	CFU/mL	No	No
Chlamydia pneumoniae	None Specified	1.45E+06	IFU/mL	No	No
Corynebacterium sp.	None Specified	1.00E+06	CFU/mL	No	No
Escherichia coli	None Specified	1.72E+06	CFU/mL	No	No
Haemophilus influenzae	None Specified	1.52E+06	CFU/mL	No	No
Lactobacillus sp.	None Specified	1.58E+06	CFU/mL	No	No
Legionella pneumophila	None Specified	1.00E+06	CFU/mL	No	No
Moraxella catarrhalis	None Specified	1.04E+06	CFU/mL	No	No
Mycoplasma pneumoniae	None Specified	1.35E+06	CCU/mL	No	No
Neisseria meningitides	None Specified	1.68E+06	CFU/mL	No	No
Neisseria sp.	None Specified	1.23E+06	CFU/mL	No	No
Pseudomonas aeruginosa	None Specified	1.16E+06	CFU/mL	No	No
Pooled human nasal wash – representative of normal respiratory microbial flora (Wet-testing)	None Specified	N/A	N/A	No	No
Staphylococcus aureus	Type Not Specified	1.67E+06	CFU/mL	No	No
Staphylococcus epidermidis	None Specified	1.53E+06	CFU/mL	No	No
Streptococcus pneumoniae	None Specified	1.06E+06	CFU/mL	No	No
Streptococcus pyogenes	None Specified	1.07E+06	CFU/mL	No	No
Streptococcus salivarius	None Specified	1.05E+06	CFU/mL	No	No
Mycobacterium tuberculosis avirulent	None Specified	1.16E+06	CFU/mL	No	No

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Methicillin-resistant Staphylococcus aureus (MRSA)	None Specified	3.30E+06	CFU/mL	No	No
Methicillin-susceptible Staphylococcus aureus (MSSA)	None Specified	3.67E+06	CFU/mL	No	No

* Nineteen (19) specimens containing Coronavirus HKU1 were tested with an EUA version of this test (EUA203086) and all resulted as negative.

Interfering Substances

Twenty-four (24) potentially interfering substances were evaluated with the QuickVue COVID-19 Test to verify if endogenous and exogenous substances that may be present in respiratory specimens interfere with the detection of SARS-CoV-2 in 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 of heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020). None of the substances listed in **Table 2** interfered with the assay at the levels tested.

Table 2. Interfering Substances Study Results

Substances	Active Ingredient	Concentration
Throat lozenges, oral anesthetic and analgesic	Menthol	700 mg/mL
Sore throat spray	Phenol	15% w/v
Mucin bovine submaxillary gland, type I-S or pooled mucous	Purified mucin protein	2.5mg/mL
Whole Blood (human)	Whole blood	4% v/v
Leukocytes	Leukocytes	5.00E+06 cells/mL
Zinc (common ingredient in many nasal sprays)	Zinc	15% v/v
Nasal sprays or drops	Cromolyn, Oxymetazoline	15% v/v
Nasal corticosteroids .	Fluticasone	15% v/v
Nasal gel	Luffa opperculata, sulfur, Sodium Hyaluronate	5% w/v
Homeopathic allergy relief, or nasal wash	Alkalol	15% v/v
Anti-viral drugs	Molnupiravir (broad-spectrum antiviral)	2.5 mg/mL
Anti-viral drugs	Oseltamivir Phosphate (TamiFlu)	2.5 mg/mL
Anti-viral drugs	Ribavirin	2.5 mg/mL
Antibiotic, nasal ointment	Mupirocin	10mg/mL
Hand sanitizer	Isopropyl alcohol	15% v/v
Lotion	Not specified	15% w/v

Substances	Active Ingredient	Concentration
Hand Soap	Not specified	15% v/v
Rheumatoid Factor	Rheumatoid Factor	1.12 IU/mL
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
Cough syrup (e.g., Robitussin)	Dextromethorphan	5%v/v
Nicotine or Tobacco	Nicotine	0.03 mg/mL
Analgesic ointment (Vicks® VapoRub®)	Camphor, eucalyptus oil, menthol	1% w/v
Petroleum Jelly (Vaseline®)	White petroleum	1% w/v
Systemic antibiotic	Tobramycin	4 µg/mL

Hook Effect

To ensure that a high concentration of SARS antigen does not interfere with a positive reaction in the QuickVue COVID-19 Test, a series of five (5) different concentrations of heat-inactivated SARS-CoV2 (isolate WA1/2020) were prepared in NNM and tested in five (5) replicates on the QuickVue COVID-19 Test. The results demonstrated that the QuickVue COVID-19 Test did not display a Hook (Prozone) Effect for any of the levels evaluated from very high to moderate positive inactivated virus concentrations, when tested from 1.09E+06 to 9.09E+04 $TCID_{50}$/mL (40X to 3X LoD). All spiked samples were 100% positive at all tested concentrations.

Flex Studies

A series of flex studies were performed by testing SARS-CoV-2 negative sample and SARS-CoV-2 positive sample (2XLoD) at various conditions per **Table 3** when use-related errors occur. The results demonstrate that the assay does not present a significant risk of an erroneous result when performed by the lay user.

Table 3. Flex Studies Conditions

Flex Study	Conditions
Operating Environment Flex	Operating temperature from 5°C to 45°C and relative humidity from 10% to 95%
Extraction Time Flex	Sample swab is placed in reagent tube for time duration from ten (10) seconds to one (1) hour.
Impact of Different Light Sources Flex	Different light sources including fluorescent, incandescent, and LED light.
Disturbance During Analysis	Strip is removed from the reagent tube for 30 seconds at 5 minutes of development time and placed back in tube. Knock over the reagent tube with strip inside immediately, 1 minute, and 5 minutes after adding strip in the tube, then immediately place upright.

Flex Study	Conditions
Open Pouch Flex	Strip is exposed to ambient air from 1 hour to 2.5 hours.
Development Time Flex	Strip is placed in reagent tube from 5 minutes to 30 minutes. After 10 minutes development time, strip is removed from the reagent tube and placed on bench top for 5 minutes before result reading.
Running Steps Out of Order Flex	After sample extraction, leave swab in reagent tube upon insertion of the test strip into the tube for 30 seconds and 10 minutes.
Swab Agitation Flex	Place the test swab into the liquid inside the reagent tube, and ensure it is touching the bottom. Do not stir, stir 10 times and stir continuously for 1 minute. Place the test swab into the liquid inside the reagent tube, do not touch the bottom or stir. Place the test swab into the liquid inside the reagent tube, and ensure it is touching the bottom. Stir 3-4 times. Do not apply pressure to the swab head.
Extraction Reagent Disturbance Flex	Shake the closed reagent tube 10 times, 30 seconds vigorously, and 60 seconds vigorously before testing. Drop the reagent tube 3 times from bench top height before testing.
Sample Temperature Flex	Cold sample is removed from refrigerated condition at 2-8°C and tested immediately.
Sample Stability	Nasal swab samples 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.

Precision

The lot-to-lot precision of the QuickVue COVID-19 Test was evaluated by using three (3) product lots. A series of coded, contrived samples were prepared as negative, low positive (1XLoD), and moderate positive (4XLoD) using heat inactivated SARS-CoV-2 (isolate USA-WA1/2020). Each sample was tested in duplicate in two (2) events per day over twenty (20) days with two (2) operators. The negative sample produced results with a lower 95% confidence interval limit ≥95% negative agreement. The low positive sample at 1XLoD produced results with a lower 95% confidence interval limit ≥95% positive agreement.

Table 4. Summary of Precision Qualitative Results

Lot	Negative*		Low Positive** (1XLoD)		Moderate Positive** (4XLoD)	
	Reader 1	**Reader 2**	**Reader 1**	**Reader 2**	**Reader 1**	**Reader 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%]**

Method Comparison

The performance of the QuickVue COVID-19 Test was compared to a SARS-CoV-2 RT-PCR assay in a prospective clinical study. Eight (8) clinical sites participated in the study. Samples were collected by lay users from themselves or collected for a household member. A total of 878 subjects were enrolled in this study, 39.6% male and 60.4% female. In symptomatic individuals tested within 5 days post symptom onset, the QuickVue COVID-19 Test detected SARS-CoV-2 with Positive Percent Agreement (PPA) of 82.0% and Negative Percent Agreement (NPA) of 99.1% in symptomatic individuals when compared to the result from an EUA extracted SARS-CoV-2 RT-PCR assay. Results are provided in **Table 5** and **Table 6**.

Table 5. QuickVue COVID-19 Test Performance Compared to SARS-CoV-2 RT-PCR Assay

	SARS-CoV-2 RT-PCR Assay Result		
	Pos	Neg	Total
QuickVue Pos	164	5	169
QuickVue Neg	36	575	611
Total	200	580	780

PPA = 82.0% (164/200) 95% CI: 76.1% - 86.7%

NPA = 99.1% (575/580) 95% CI: 98.0% - 99.6%

Positivity Rate by QuickVue Assay = 21.7% (169/780) 95% CI: 18.9% - 24.7%

Positivity Rate by Comparator Assay = 25.6% (200/780) 95% CI: 22.7% - 28.8%

PPA= Positive Percentage Agreement; NPA= Negative Percentage Agreement

Table 6. PPA results by DPSO

Days Since Symptom Onset	**# Specimens Tested**	**# Positive by QuickVue**	**# Positive by RT-PCR**	**PPA**
0	61	14	16	87.5%
1	203	45	53	81.1%
2	248	52	63	79.4%
3	148	27	28	92.9%
4	74	21	28	75.0%
5	46	10	12	83.3%

Conclusion

These studies demonstrated equivalent performance of the QuickVue COVID-19 Test to the predicate product ACON Flowflex COVID-19 Antigen Home Test (K230828).