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# QUICKVUE<sup>®</sup>

## Influenza A+B TEST

**CLIA Complexity: WAIVED**

### **INTENDED USE**

The QuickVue Influenza A + B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal wash and/or nasal aspirate specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative test results should be confirmed by cell culture. The test is intended for professional and laboratory use.

### **SUMMARY AND EXPLANATION**

Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.<sup>1</sup>

Influenza antigens may be detected in clinical specimens by immunoassay. The QuickVue Influenza A+B test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza antigens. The test is specific to influenza types A and B antigens with no known cross-reactivity to normal flora or other known respiratory pathogens.

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## **PRINCIPLE OF THE TEST**

The QuickVue Influenza A+B test involves the extraction of influenza A and B viral antigens. The patient specimen is placed in the Extraction Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After extraction, the Test Strip is placed in the Extraction Reagent Tube where nucleoproteins in the specimen will react with the reagents in the Test Strip.

If the extracted specimen contains influenza A or B antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. The Test Line for influenza A or B will develop at separate specified locations on the same Test Strip. If influenza A or B antigens are not present, or are present at very low levels, only the blue procedural Control Line will appear.

## **REAGENTS AND MATERIALS SUPPLIED**

### ***25-Test Kit: Catalog Number 20183***

#### **■ Shelf box containing:**

- ▶ Individually Packaged Test Strips (25): Mouse monoclonal anti-influenza A and anti-influenza B antibodies
- ▶ Extraction Reagent Solution (25): Vials with 340 µL of salt solution
- ▶ Extraction Tubes (25): Lyophilized buffer with detergents and reducing agents
- ▶ Disposable Droppers (25)
- ▶ Sterile Nasal Swabs (25)
- ▶ Positive Influenza Type A Control Swab (1): Swab is coated with non-infectious recombinant influenza A antigen
- ▶ Positive Influenza Type B Control Swab (1): Swab is coated with non-infectious recombinant influenza B antigen
- ▶ Negative Control Swab (1): Swab is coated with formalin-inactivated, non-infectious Streptococcus C antigen
- ▶ Package Insert (1)
- ▶ Procedure Card (1)

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## **MATERIALS NOT SUPPLIED**

- Specimen containers
- Timer or watch

## **WARNINGS AND PRECAUTIONS**

- For *in vitro* diagnostic use.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Use of Nitrile or Latex gloves is recommended when handling patient samples.<sup>2</sup>
- Dispose of containers and used contents in accordance with Federal, State and Local requirements.
- The Test Strip must remain sealed in the protective foil pouch until use.
- The Extraction Reagent Solution contains salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
- To obtain accurate results, you must follow the Package Insert.
- Use the Transport Media recommended in the Package Insert.
- Although this test has been shown to detect cultured avian influenza viruses, including avian Influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.

## **KIT STORAGE AND STABILITY**

Store the kit at room temperature, 59–86°F (15–30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

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## SPECIMEN COLLECTION AND STORAGE

### ***Nasal Swab Sample:***

#### ***For proper test performance, use the swabs supplied in the kit.***

It is important to obtain as much secretion as possible. Therefore, to collect a nasal swab sample, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.

### ***Nasopharyngeal Swab Sample:***

It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal swab sample, carefully insert the sterile swab into the nostril that presents the most secretions under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times.

### ***Nasal Wash or Aspirate Sample:***

#### ***For Older Children and Adults:***

With the patient's head hyper-extended, instill about 2.5 mL of sterile, normal saline (not supplied in the kit) into one nostril with a syringe. To collect the wash, place a clean, dry specimen container directly under the nose with slight pressure on the upper lip. Tilt the head forward and allow the fluid to run out of the nostril into the specimen container. Repeat for the other nostril and collect the fluid into the same specimen container.

#### ***For Younger Children:***

The child should sit in the parent's lap facing forward, with the child's back against the parent's chest. The parent should wrap one arm around the child in a manner that will restrain the child's body and arms.

Fill an aspiration bulb or bulb syringe with up to 2.5 mL of sterile, normal saline (depending on the size of the child), and instill the saline into one nostril while the head is tilted back. Release the pressure on the bulb to aspirate the specimen back into the bulb. Transfer the specimen into a clean, dry specimen container. Repeat the process for the child's other nostril and transfer the specimen into the same specimen container.

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## **SAMPLE TRANSPORT AND STORAGE**

Samples should be tested as soon as possible after collection. If transport of the samples is required, the following Transport Media are recommended and have been tested and shown not to interfere with the performance of the test: Hank's Balanced Salt Solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2–8°C), or at room temperature (15–30°C), in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash specimens may also be stored frozen (-70°C or colder) for up to one month.

## **QUALITY CONTROL**

### ***Built-in Control Features***

The QuickVue Influenza A+B test contains built-in procedural control features. The manufacturer's recommendation for daily control is to document these built-in procedural controls for the first sample tested each day.

The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural Control Line provides several forms of positive control by demonstrating 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.**

A built-in negative control is provided by the clearing of red background color, verifying that the test has been performed correctly. Within 10 minutes, the result area should be white to light pink and allow the clear interpretation of the test result. If background color appears and interferes with interpretation of the test result, the result is considered invalid. Should this occur, review the procedure and repeat the test with a new Test Strip.

### ***External Quality Control***

External controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that positive and negative controls be run every 25 tests and as deemed necessary by your internal quality control procedures.

If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

External Positive and Negative Control Swabs are supplied in the kit and should be tested using the Nasal Swab Test Procedure provided in this Package Insert or in the Procedure Card.

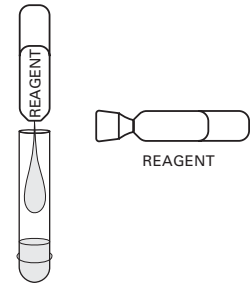
## TEST PROCEDURE

**All clinical specimens must be at room temperature before beginning the assay.**

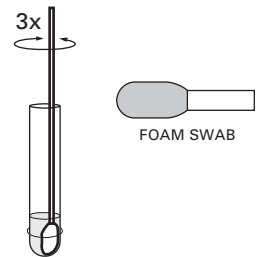
**Expiration date:** Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

### Nasal/Nasopharyngeal Swab Procedure

1. Dispense all of the Extraction Reagent Solution from the Reagent Tube. Gently swirl the Extraction Tube to dissolve its contents.



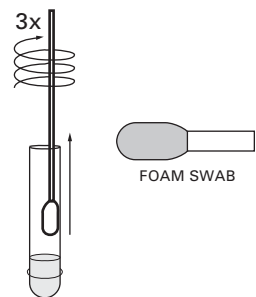
2. Place the patient swab with sample into the Extraction Tube. Roll the swab at least three (3) times while pressing the head against the bottom and side of the Extraction Tube.



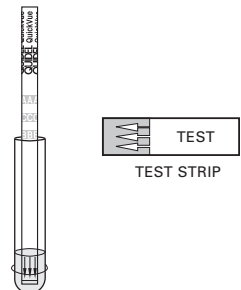
**Leave the swab in the Extraction Tube for one (1) minute.**



3. Roll the swab head against the inside of the Extraction Tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.



4. Place the Test Strip into the Extraction Tube with the arrows on the Test Strip pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

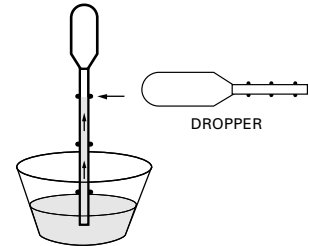


5. Read result at ten (10) minutes. Some positive results may appear sooner. Do not read result after ten (10) minutes.

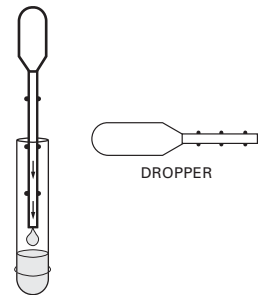


***Nasal Wash/Nasal Aspirate Procedure***

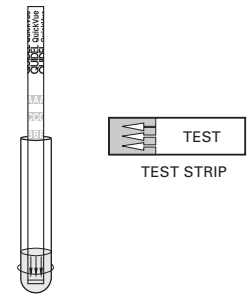
1. Fill the dropper to the top/uppermost notch with nasal wash or nasal aspirate sample.



2. Add entire contents of the dropper to the Extraction Tube. Swirl the Extraction Tube gently to dissolve its contents.



3. Place the Test Strip into the Extraction Tube with the arrows on the Test Strip pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.



4. Read result at ten (10) minutes. Some positive results may appear sooner. Do not read after ten (10) minutes.



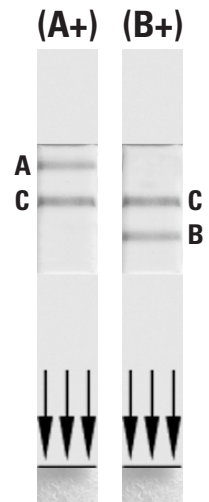
## INTERPRETATION OF RESULTS

### **Positive Result:**

At ten minutes, **ANY** shade of a pink-to-red Test Line forms, either above or below the blue control line, **AND** the appearance of a blue procedural Control Line indicates a positive result for the presence of influenza A and/or B viral antigen.

Hold the test strip with the **arrows pointed down**.

- If the red line is **above** the Control Line, the test results are positive for type A. See image to the immediate right (A+).
- If the red line is **below** the Control Line, the test results are positive for type B. See image to the far right (B+).



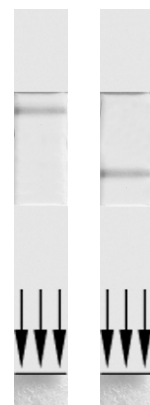
### **Negative Result:**

At ten minutes, the appearance of **ONLY** the blue procedural Control Line indicates the sample is negative for influenza A and B viral antigen. A negative result should be reported as a presumptive negative for the presence of influenza antigen.



### **Invalid Result:**

**If at ten minutes, the blue procedural Control Line does not appear**, even if any shade of a pink-to-red Test Line appears, **the result is considered invalid**. If at ten minutes, the background color does not clear and it interferes with the reading of the test, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new Test Strip.



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## LIMITATIONS

The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from nasal swab, nasopharyngeal swab, nasal wash and nasal aspirate specimens.

Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.

Test Results must be evaluated in conjunction with other clinical data available to the physician.

A negative test result may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection.

Negative test results are not intended to rule-out other non-influenza viral infections.

## EXPECTED VALUES

Seasonal outbreaks of influenza occur worldwide in both the northern and southern hemispheres causing widespread illness each winter. The average attack rate of influenza is 26–33 cases per 100 people per year. The risk of hospitalization is roughly 1/300 of those infected among the very young and elderly. Approximately 36,000 deaths in the U.S. are attributed to influenza or its complications each year. Ninety percent (90%) of deaths occur in those 65 years of age and older. During each of three major epidemics occurring in 1957 and 1968, more than 40,000 people died of influenza in the U.S. alone. In the 1918 pandemic, an estimated 50 million deaths resulted worldwide. In the multi-center clinical study conducted by Quidel during an influenza season in North America, an illness prevalence of 24% for type A and 15% for type B influenza was observed.

## PERFORMANCE CHARACTERISTICS

### QuickVue Influenza A+B Test Performance vs. Cell Culture

#### *Background on the 2005 Clinical Studies*

In the 2005 clinical study, the performance of the QuickVue Influenza A+B test was compared to cell culture methods and confirmed with DFA in a multi-center field clinical study during influenza season in Australia. This study was conducted at eight General Practice physician offices located across the Sydney metropolitan area in New South Wales, Australia. In this multi-center, point-of-care (POC) field trial, two (2) nasal or two (2) nasopharyngeal swab specimens were collected from each of a total of 238 patients. All clinical samples were collected from symptomatic patients. Thirty-four (34%) of the population tested was pediatric (<18 years), 66% adult, 58% male and 42% female.

On-site testing of one nasal swab specimen in the QuickVue Influenza A+B test was performed by physician office personnel within one hour of collection. The patient's nasal swab was incubated for one minute with the Extraction Reagent Solution before addition of the dipstick. The other swab was placed in viral transport media and stored at 2–8°C for up to 18 hours prior to culture. Madin-Darby Canine Kidney (MDCK) cells were inoculated with a portion of the nasal or nasopharyngeal swab specimen and incubated at 36°C for 48–96 hours. The inoculated cells were recovered from tissue culture and tested for influenza A or B by direct fluorescent antibody (DFA) staining.

***Background on the 1998/1999 Clinical Studies***

In the winter of 1998/1999, the performance of the QuickVue Influenza A+B test was compared to cell culture methods in a multi-center, point of care (POC) field clinical study that was conducted in pediatric, adult and geriatric patient populations in three geographically distinct regions in the United States. In this multi-center, point-of-care (POC) field trial, a combination of nasal swabs and nasal wash/aspirate specimens were collected from a total of two hundred seventy-five (275) patients.

On-site testing of the nasal swab and nasal wash or nasal aspirate specimens in the QuickVue Influenza A+B test was performed by physician office personnel within one hour of specimen collection. The patient's nasal swab was swirled three times in the Extraction Reagent Solution and removed before addition of the dipstick. Viral transport media was added to all nasal specimens intended for culture transport. Swab specimens in viral transport media and nasal wash/aspirate specimens were stored at 2–8°C for up to 24 hours prior to culture. Rhesus Monkey Kidney (RMK) cells or Madin-Darby Canine Kidney (MDCK) cells were inoculated with a portion of the nasal swab specimen and nasal wash/aspirate and tested for the appearance of cytopathic effect (CPE). Infected cells were recovered from tissue culture and confirmed for influenza A or B by direct fluorescent antibody (DFA) staining. A total of 363 specimens were tested from 275 patients (270 nasal swabs and 93 nasal wash/aspirate specimens).

***Results with Nasal Swab Specimens (2005 Clinical Study)***

Nasal swab specimens from one hundred twenty-two patients were tested in QuickVue Influenza A+B and in cell culture. The QuickVue Influenza A+B test correctly identified 94% (16/17) culture-positive influenza A specimens, 74% (14/19) culture-positive influenza B specimens, 90% (95/105) culture-negative for influenza A, and 97% (100/103) culture-negative for influenza B. These results with nasal swabs are shown in Table 1.

**Table 1**  
**QuickVue Influenza A+B Nasal Swab Results versus Culture**

TYPE A			TYPE B		
	Culture			Culture	
	+	-		+	-
QV Pos	16	10*	QV Pos	14	3**
QV Neg	1	95	QV Neg	5	100
<b>Sens</b> = 16/17 = 94% (95% C.I. 71–100%)			<b>Sens</b> = 14/19 = 74% (95% C.I. 51–89%)		
<b>Spec</b> = 95/105 = 90% (95% C.I. 83–95%)			<b>Spec</b> = 100/103 = 97% (95% C.I. 91–99%)		
<b>Accur</b> = 111/122 = 91% (95% C.I. 84–95%)			<b>Accur</b> = 114/122 = 93% (95% C.I. 87–97%)		
<b>PPV</b> = 16/26 = 62%			<b>PPV</b> = 14/17 = 82%		
<b>NPV</b> = 95/96 = 99%			<b>NPV</b> = 100/105 = 95%		

\*Of the 10 discrepant results, 7 were positive by the QuickVue test and by an investigational RT-PCR.

\*\*Of the 3 discrepant results, 2 were positive by the QuickVue test and by an investigational RT-PCR.

**Results with Nasal Swab Specimens (1998/1999 Clinical Study)**

Compared to culture and confirmed for influenza A or B by DFA, the QuickVue Influenza A+B test correctly identified 46/64 (72%) type A positive specimens, 29/40 (73%) type B positive specimens, and 159/166 (96%) negative specimens. These results with nasal swabs are shown in Table 2.

**Table 2**  
**QuickVue Influenza A+B Nasal Swab Results versus Culture**

TYPE A			TYPE B		
	Culture			Culture	
	+	-		+	-
QV Pos	46	7	QV Pos	29	7
QV Neg	18	159	QV Neg	11	159
<b>Sens</b> = 46/64 = 72% (95% C.I. 60–82%)			<b>Sens</b> = 29/40 = 73% (95% C.I. 57–84%)		
<b>Spec</b> = 159/166 = 96% (95% C.I. 91–96%)			<b>Spec</b> = 159/166 = 96% (95% C.I. 91–98%)		
<b>Accur</b> = 205/230 = 89% (95% C.I. 84–93%)			<b>Accur</b> = 188/206 = 91% (95% C.I. 87–94%)		
<b>PPV</b> = 46/53 = 87%			<b>PPV</b> = 29/36 = 81%		
<b>NPV</b> = 159/177 = 90%			<b>NPV</b> = 159/170 = 94%		

**Results with Nasopharyngeal Swab Specimens (2005 Clinical Study)**

Nasopharyngeal swab specimens from one hundred sixteen patients were tested in QuickVue Influenza A+B and in cell culture. The QuickVue Influenza A+B test correctly identified 83% (20/24) culture-positive influenza A specimens, 67% (8/12) culture-positive influenza B specimens, and 89% (82/92) culture-negative for influenza A, and 98% (102/104) culture-negative for influenza B. These results with nasopharyngeal swabs are shown in Table 3.

**Table 3  
QuickVue Influenza A+B Nasopharyngeal Swab Results versus Culture**

TYPE A			TYPE B		
		Culture			Culture
		+	-	+	-
		Sens = 20/24 = 83% (95% C.I. 64–94%)			
		Spec = 82/92 = 89% (95% C.I. 81–94%)			
		Accur = 102/116 = 88% (95% C.I. 81–93%)			
		PPV = 20/30 = 67%			
		NPV = 82/86 = 95%			
		Sens = 8/12 = 67% (95% C.I. 39–87%)			
		Spec = 102/104 = 98% (95% C.I. 93–100%)			
		Accur = 110/116 = 95% (95% C.I. 89–98%)			
		PPV = 8/10 = 80%			
		NPV = 102/106 = 96%			
QV Pos	20	10*	8	2**	
QV Neg	4	82	4	102	

\*Of the 10 discrepant results, 4 were positive by the QuickVue test and by an investigational RT-PCR.

\*\*Of the 2 discrepant results, 1 was positive by the QuickVue test and by an investigational RT-PCR.

**Results with Frozen Nasal Washes (2005 Study)**

The performance of the QuickVue Influenza A+B test was further evaluated in the year 2005 in a retrospective study with 149 frozen, clinical, nasal wash specimens. All clinical samples were collected from symptomatic patients visiting a physician’s office in the Northeastern region of the United States. Ninety-five percent (95%) of the population tested was pediatric (<18 years), 5% adult, 46% male and 54% female.

Nasal Wash specimens from one hundred forty-nine patients were tested in QuickVue Influenza A+B and in cell culture. The QuickVue Influenza A+B test correctly identified 86% (56/65) culture-positive influenza A specimens and 95% (80/84) culture-negative specimens as shown in Table 4. No influenza B samples were evaluated in this study.

**Table 4**  
**QuickVue Influenza A+B Frozen Nasal Wash Results versus Culture**

		<b>Culture</b>		
		+	-	
QV Pos	56	4*		
QV Neg	9**	80		

**TYPE A**

**Sens** = 56/65 = 86%  
(95% C.I. 76–93%)

**Spec** = 80/84 = 95%  
(95% C.I. 88–99%)

**Accur** = 136/149 = 91%  
(95% C.I. 86–95%)

**PPV** = 56/60 = 93%

**NPV** = 80/89 = 90%

\*Of the 4 discrepant results, 1 was positive by the QuickVue test and by an investigational RT-PCR. There was too little volume in 1 sample to be analyzed by RT-PCR.

\*\*Of the 9 discrepant results, 2 of 5 samples were negative by the QuickVue test and by an investigational RT-PCR. There was too little volume in 4 samples to be analyzed by RT-PCR.

**Results with Fresh Nasal Wash/Aspirate Specimens (1998/1999 Clinical Study)**

Compared to culture and confirmed for influenza A or B by DFA, the QuickVue Influenza A+B test correctly identified 10/13 (77%) type A positive specimens, 9/11 (82%) type B positive specimens, and 68/69 (99%) negative specimens. These samples were tested within one hour of collection and had not been frozen. These results with nasal wash/aspirate specimens are shown in Table 5.

**Table 5**  
**QuickVue Influenza A+B Fresh Nasal Wash/Aspirate Results versus Culture**

		<b>Culture</b>		
		+	-	
QV Pos	10	1		
QV Neg	3	68		

**TYPE A**

**Sens** = 10/13 = 77%  
(95% C.I. 49–93%)

**Spec** = 68/69 = 99%  
(95% C.I. 91–100%)

**Accur** = 78/82 = 95%  
(95% C.I. 88–98%)

**PPV** = 10/11 = 91%

**NPV** = 68/71 = 96%

		<b>Culture</b>		
		+	-	
QV Pos	9	1		
QV Neg	2	68		

**TYPE B**

**Sens** = 9/11 = 82%  
(95% C.I. 51–96%)

**Spec** = 68/69 = 99%  
(95% C.I. 91–100%)

**Accur** = 77/80 = 96%  
(95% C.I. 89–99%)

**PPV** = 9/10 = 90%

**NPV** = 68/70 = 97%

**ANALYTICAL SPECIFICITY AND CROSS-REACTIVITY**

The QuickVue Influenza A+B test was evaluated with a total of 62 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10<sup>7</sup> and 10<sup>9</sup> org/mL. Viral isolates were evaluated at a concentration of at least 10<sup>4</sup>–10<sup>8</sup> TCID<sub>50</sub>/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10<sup>2</sup> TCID<sub>50</sub>/mL. None of the organisms or viruses listed below gave a positive result in the QuickVue Influenza A+B test.

**Bacterial Panel:**

- |                                     |                                   |
|-------------------------------------|-----------------------------------|
| <i>Acinetobacter calcoaceticus</i>  | <i>Mycoplasma pneumoniae</i>      |
| <i>Bacteroides fragilis</i>         | <i>Neisseria gonorrhoeae</i>      |
| <i>Bordetella pertussis</i>         | <i>Neisseria meningitidis</i>     |
| <i>Branhamella catarrhalis</i>      | <i>Neisseria sicca</i>            |
| <i>Candida albicans</i>             | <i>Neisseria subflava</i>         |
| <i>Corynebacterium diphtheriae</i>  | <i>Proteus vulgaris</i>           |
| <i>Enterococcus faecalis</i>        | <i>Pseudomonas aeruginosa</i>     |
| <i>Escherichia coli</i>             | <i>Serratia marcescens</i>        |
| <i>Gardnerella vaginalis</i>        | <i>Staphylococcus aureus</i>      |
| <i>Haemophilus influenzae</i>       | <i>Staphylococcus epidermidis</i> |
| <i>Klebsiella pneumoniae</i>        | <i>Streptococcus mutans</i>       |
| <i>Lactobacillus casei</i>          | <i>Streptococcus pneumoniae</i>   |
| <i>Lactobacillus plantarum</i>      | <i>Streptococcus pyogenes</i>     |
| <i>Legionella pneumophila</i>       | <i>Streptococcus sanguis</i>      |
| <i>Listeria monocytogenes</i>       | <i>Streptococcus sp. Gp. B</i>    |
| <i>Mycobacterium avium</i>          | <i>Streptococcus sp. Gp. C</i>    |
| <i>Mycobacterium intracellulare</i> | <i>Streptococcus sp. Gp. F</i>    |
| <i>Mycobacterium tuberculosis</i>   | <i>Streptococcus sp. Gp. G</i>    |
| <i>Mycoplasma orale</i>             |                                   |

**Viral Panel:**

- |                              |                                   |
|------------------------------|-----------------------------------|
| Adenovirus 5 (Ad. 75)        | Human Rhinovirus 2 (HGP)          |
| Adenovirus 7 (Gomen)         | Human Rhinovirus 14 (1059)        |
| Adenovirus 10 (J.J.)         | Human Rhinovirus 16 (11757)       |
| Adenovirus 18 (D.C.)         | Measles (Edmonston)               |
| Coronavirus OC43             | Mumps (Enders)                    |
| Coxsackievirus A9 (Bozek)    | Parainfluenza virus 1 (Sendai)    |
| Coxsackievirus B5 (Faulkner) | Parainfluenza virus 2 (CA/Greer)  |
| Cytomegalovirus (Towne)      | Parainfluenza virus 3 (C243)      |
| Echovirus 2 (Cornelis)       | Respiratory Syncytial virus (A-2) |
| Echovirus 3 (Morrissey)      | Respiratory Syncytial virus       |
| Echovirus 6 (D'Amori)        | (Subgroup A, Long chain)          |
| Herpes simplex virus 1       | Rubella (RA 27/3)                 |
| Herpes simplex virus 2       | Varicella-Zoster (Ellen)          |

**ANALYTICAL SENSITIVITY**

Analytical sensitivity was established using a total of fifty (50) human epidemic strains of influenza viruses: thirty-seven (37) influenza A and thirteen (13) influenza B.

<b>Viral Strain</b>	<b>Viral Type</b>	<b>Sub-Type</b>	<b>Minimum Detectable Level (pfu/mL)</b>	<b>Viral Strain</b>	<b>Viral Type</b>	<b>Sub-Type</b>	<b>Minimum Detectable Level (pfu/mL)</b>
Hong Kong	A	H3N2	6.60 x 10 <sup>-1</sup>	Shangdong	A	H3N2	8.40 x 10 <sup>3</sup>
Beijing/32/92	A	H3N2	3.30 x 10 <sup>0</sup>	Maryland/91	A	H1N1	1.00 x 10 <sup>4</sup>
Duck/England	A	H11N6	6.70 x 10 <sup>0</sup>	Japan/305/57	A	H2N2	1.30 x 10 <sup>4</sup>
Shanghai/11	A	H3N2	6.70 x 10 <sup>0</sup>	Johannesburg/94	A	H3N2	1.44 x 10 <sup>4</sup>
Shanghai/16	A	H3N2	1.00 x 10 <sup>1</sup>	Brazil	A	H1N1	1.70 x 10 <sup>4</sup>
Duck/Alberta	A	H1N1	3.30 x 10 <sup>1</sup>	Sydney	A	H3N2	2.00 x 10 <sup>4</sup>
Victoria	A	H3N2	3.30 x 10 <sup>1</sup>	Bangkok	A	H3N2	3.30 x 10 <sup>4</sup>
Singapore/1/57	A	H2N2	6.70 x 10 <sup>1</sup>	Wuhan	A	H3N2	3.30 x 10 <sup>4</sup>
Port Chalmers	A	H3N2	1.24 x 10 <sup>2</sup>	Equine/Miami	A	H3N8	1.70 x 10 <sup>5</sup>
Gull/Maryland	A	H13N6	1.30 x 10 <sup>2</sup>	Beijing/353/89	A	H3N2	3.30 x 10 <sup>5</sup>
USSR	A	H1N1	2.00 x 10 <sup>2</sup>	Singapore/86	A	H1N1	6.60 x 10 <sup>5</sup>
Puerto Rico/8/34	A	H1N1	2.60 x 10 <sup>2</sup>	Texas/91	A	H1N1	1.60 x 10 <sup>7</sup>
New Jersey	A	H1N1	2.70 x 10 <sup>2</sup>	Victoria	B		1.40 x 10 <sup>4</sup>
Taiwan	A	H1N1	3.30 x 10 <sup>2</sup>	Taiwan	B		1.10 x 10 <sup>2</sup>
Tokyo/3/67	A	H2N2	3.40 x 10 <sup>2</sup>	Panama	B		1.00 x 10 <sup>0</sup>
Bayern	A	H1N1	6.60 x 10 <sup>2</sup>	Ann Arbor	B		3.30 x 10 <sup>2</sup>
Sichuan	A	H3N2	6.60 x 10 <sup>2</sup>	Singapore	B		3.30 x 10 <sup>2</sup>
Beijing/352/89	A	H3N2	7.70 x 10 <sup>2</sup>	Lee	B		6.60 x 10 <sup>2</sup>
NWS/33	A	H1N1	1.00 x 10 <sup>3</sup>	Hong Kong	B		7.00 x 10 <sup>2</sup>
Fort Warren/1/50	A	H1N1	1.70 x 10 <sup>3</sup>	Beijing/184/93	B		1.66 x 10 <sup>3</sup>
Mississippi	A	H3N2	1.70 x 10 <sup>3</sup>	California	B		3.30 x 10 <sup>3</sup>
Texas/77	A	H1N1	3.30 x 10 <sup>3</sup>	Maryland	B		6.60 x 10 <sup>3</sup>
Fort Monmouth/1/47	A	H1N1	6.70 x 10 <sup>3</sup>	Yamagata/16/88	B		6.70 x 10 <sup>3</sup>
Duck/Ukraine	A	H3N8	3.30 x 10 <sup>1</sup>	Harbin	B		1.40 x 10 <sup>4</sup>
Aichi	A	H3N2	3.20 x 10 <sup>3</sup>	Stockholm	B		3.30 x 10 <sup>5</sup>

Analytical sensitivity was further evaluated using a total of twenty-one (21) influenza A viruses isolated from birds and mammals. The QuickVue Influenza A+B test was shown to detect all the strains examined.

<b>Viral Strain</b>	<b>Viral Type</b>	<b>Viral Subtype</b>
Duck/Tottori/723/80	A	H1N1
Duck/Hokkaido 17/01	A	H2N2
Duck/Mongolia/4/03	A	H3N8
Duck/Czech/56	A	H4N6
Hong Kong/483/97	A	H5N1
Hong Kong/156/97	A	H5N1
Chicken/Yamaguchi/7/04	A	H5N1
A/Chicken/Vietnam/33/04*	A	H5N1
A/Vietnam/3028/04	A	H5N1
A/Thailand/ MK2/04	A	H5N1
Duck/Pennsylvania/10128/84	A	H5N2
Turkey/Massachusetts/3740/65	A	H6N2
Seal/Massachusetts/1/80	A	H7N7
Turkey/Ontario/67	A	H8N4
Turkey/Wisconsin/66	A	H9N2
Chicken/Germany/N/49	A	H10N7
Duck/England/56	A	H11N6
Duck/Alberta/60/76	A	H12N5
Gull/Maryland/704/77	A	H13N6
Mallard/Astrakhan/263/82	A	H14N5
Duck/Australia/341/83	A	H15N8

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## **INTERFERING SUBSTANCES**

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the QuickVue Influenza A+B test at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Guaiacol glyceryl ether (20 mg/mL); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20 mg/mL).

## **TRANSPORT MEDIA**

Transport Media were spiked with Limit of Detection (LOD) levels of Influenza A, Influenza B, or an equal volume of buffer only. The spiked media were stored refrigerated (2–8°C) or at room temperature (15–30°C) for up to eight hours prior to testing. Three of the Transport Media performed optimally, giving positive QuickVue Influenza A+B test results when spiked with LOD levels of virus and negative results when spiked with buffer and stored for eight hours at either temperature. The following Transport Media are recommended for use with the QuickVue Influenza A+B test:

- Hank's Balanced Salt Solution
- M5 Media
- Saline

The BD Universal, M4-3, M4-RT, Copan UTM, Liquid Amies-D, Amies Clear, and Modified Stuart's transport media are not compatible with this device.

## **PRECISION STUDIES**

The total, within-run, and between-run performance of the QuickVue Influenza A+B test was evaluated for precision. A panel consisting of two different levels of influenza A antigen (Johanneburg/82/96; weak positive and strong positive) and two different levels of influenza B antigen (Harbin/7/94; weak positive and strong positive) were repeated five times with a single lot of QuickVue Influenza A+B test on three different days. One hundred percent (100%) accuracy was obtained for all specimens tested.

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## **PHYSICIAN OFFICE LABORATORY (POL) STUDIES**

An evaluation of the QuickVue Influenza A+B test was conducted at three Physicians' Offices using a panel of 180 coded specimens. Testing was performed by physician office personnel with diverse educational backgrounds and work experiences at three different locations. The proficiency panel contained negative, low positive and moderate positive specimens. Each specimen level was tested at each site in replicates of at least six over a period of three days.

The results obtained at each site agreed >99% with the expected results. No significant differences were observed within run (six replicates), between runs (three different days) or between sites (three POL sites).

## **ASSISTANCE**

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number (800) 874.1517 (toll-free in the U.S.A.) or (858) 552.1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m., Pacific Time, U.S.A. If outside the United States contact your local distributor or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com).

## **REFERENCES**

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2. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (1999).

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Covered by U.S. Patent Number 4,943,522; European Patent Number 0 296 724; other patents pending.

**REF** 20183 – QuickVue Influenza A+B 25 Test Kit

**IVD**



**EC REP**

MDSS  
Burckhardtstrasse 1  
30163 Hannover, Germany



**Quidel Corporation**  
Worldwide Headquarters  
10165 Mckellar Court  
San Diego, CA 92121 USA  
[www.quidel.com](http://www.quidel.com)

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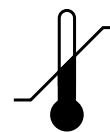
Authorized representative

**IVD**

For *in vitro* diagnostic use



Manufacturer



Temperature