QUIDEL | QuickVue® RSV10 TEST

CLIA Complexity: Moderate

For *in vitro* diagnostic use.

℞ ONLY

INTENDED USE

The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by cell culture. The test is intended for professional and laboratory use.

SUMMARY AND EXPLANATION

RSV is a causative agent of highly contagious, acute, viral infection of the respiratory tract in pediatric populations.

Respiratory syncytial virus is a single-stranded RNA virus.[1] Nearly half of all children become infected by RSV in their first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons.[2] In the United States, RSV is estimated to be responsible for 73,400 to 126,300 hospitalizations annually for bronchiolitis and pneumonia alone among children younger than 1 year.[3] In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year.[4] Among children hospitalized with RSV infection, the mortality rate is estimated to be as low as 0.3% to 1.0%.[3,5] and in the range of 2.5% to 4.0% for children with underlying cardiac or pulmonary disease.[3, 5, 6]

PRINCIPLE OF THE PROCEDURE

The QuickVue RSV 10 test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of RSV antigens.

To begin the test, a lyophilized reagent must be rehydrated in the Reagent Tube. This reagent facilitates exposure of the appropriate viral antigens to the antibodies used in the test. For a liquid specimen such as a nasopharyngeal aspirate/wash, the specimen is added directly to the Reagent Tube and rehydrates the Reagent. When nasopharyngeal swabs are used, the Reagent is first rehydrated with the provided Reagent Solution and the swab specimen is then inserted into the Reagent Tube. This Reagent interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The Test Strip is added to the Reagent Tube now containing the specimen and Reagent Solution.

If the extracted specimen contains RSV 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 RSV antigen is not present, or is present at very low levels, only a blue procedural Control Line will appear.

REAGENTS AND MATERIALS SUPPLIED

25-Test Kit:

Shelf box containing:

- Individually Packaged Test Strips (25): Mouse monoclonal anti-RSV viral fusion protein and control line protein
- Reagent Tubes (25): Lyophilized buffer with detergents
- Reagent Solution (25): Vials with 340 µL salt solution
- Disposable Pipettes (25)
- Sterile Nasopharyngeal Swabs (25)
- RSV Positive Control Swab (1): Swab is coated with non-infectious RSV antigen
- Negative Control Swab (1): Swab is coated with formalin-inactivated, non-infectious Streptococcus C antigen
- Package Insert (1)
- Procedure Card (1)

MATERIALS NOT SUPPLIED

- Specimen containers
- Timer or watch

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use
- Performance characteristics have not been established for use with patients six years of age and older, nor for immunocompromised patients.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Use of Nitrile or Latex gloves is recommended when handling patient samples.[7]
- The Test Strip must remain sealed in the protective foil pouch until use.
- The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
- The QuickVue RSV 10 test must only be used with the lyophilized buffer and reagent solution provided in the kit.
- To obtain accurate results, you must follow the Package Insert instructions.
- Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Proper specimen collection, storage, and transport are critical to the performance of this test.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.[7,8,9,10]
- When collecting a nasopharyngeal swab specimen, use a nylon flocked nasopharyngeal swab.
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

KIT STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection and handling is critical to the performance of this test.[7,8,9,10]

Specimen Collection

Nasopharyngeal Swab Method:

Use the nasopharyngeal swab supplied in the kit.

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, and then remove it from the nasopharynx.

Nasopharyngeal Aspirate/Wash Method:

Follow your Institution's protocol for obtaining nasopharyngeal aspirate/wash specimens. **Use the minimal amount of saline that your procedure allows.** Alternatively, if your institution does not provide a protocol, then consider the following procedures that are used by clinicians:

To collect a nasopharyngeal aspirate sample: instill a few drops of sterile saline into the nostril to be suctioned. Insert the flexible plastic tubing along the nostril floor, parallel to the palate. After entering the nasopharynx, aspirate the secretions while removing the tubing. The procedure should be repeated for the other nostril if inadequate secretions were obtained from the first nostril.

To collect a nasopharyngeal wash sample: the child should sit in the parent's lap facing forward, with the child's head against the parent's chest. Fill the syringe or aspiration bulb with the minimal volume of saline required per the subject's size and age. Instill the saline into one nostril while the head is tilted back. Aspirate the wash specimen back into the syringe or bulb. The aspirated wash sample will likely be approximately 1 cc in volume.

Alternatively, following instillation of the saline, tilt the child's head forward and let the saline drain out into a clean collection cup.

Sample Transport and Storage

Specimens should be tested as soon as possible after collection. If transport of the specimens is required, the following transport media are compatible for use when specimens are stored at 2–25°C for up to twenty-four (24) hours prior to testing: BD Universal Viral Transport Media, Bartels Flextrans Media, Copan Universal Transport Media, Hanks Balanced Salt Solution, M5 Media, and Saline.

QUALITY CONTROL

There are two primary types of Quality Control for this device: the built-in control features defined below and the external controls.

Built-in Control Features

The QuickVue RSV 10 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 positive control by demonstrating sufficient flow has occurred and the functional integrity of the Test Strip was maintained. **If a blue procedural Control Line does not develop within 10 minutes on the Test Strip, then the test result is 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 remains and interferes with interpretation of the test result, then the test result is invalid.** Should this occur, review the procedure and repeat the test with a new patient sample and 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 once for each untrained operator, once for each new shipment of kits — provided that each different lot received in the shipment is tested — and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, state and federal regulations or accreditation requirements.

The Nasopharyngeal Swab Test Procedure described in the Package Insert should be used when testing the external controls.

If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens. Note that the External Positive Control Swab provided in the kit is a moderately high positive sample which may not represent the performance of a low positive RSV specimen in the QuickVue RSV 10 test.

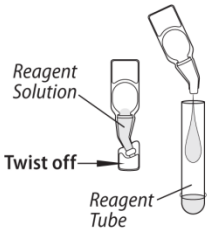
Additional Control Swabs may be obtained separately by contacting Quidel's Customer Support Services at (800) 874.1517 (toll-free in the U.S.A.) or (858) 552.1100.

TEST PROCEDURE

Test materials and 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.*

Nasopharyngeal Swab Test Procedure



1. Add the Reagent Solution to the Reagent Tube. Gently swirl the tube to dissolve its contents.

2. Immediately place the patient swab sample into the Reagent Tube. Roll the swab a minimum of three (3) times while pressing the head against the bottom and side of the Reagent Tube.

   Keep swab in the tube for one (1) minute.

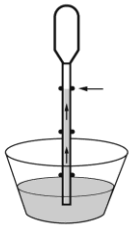
3. Express all liquid from the swab head by rolling it against the inside of the Reagent Tube as the swab is being removed. Discard the swab in accordance with your biohazard waste disposal protocol.

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

5. At ten (10) minutes, remove the Test Strip, and read result according to the Interpretation of Results section. Some positive results may appear sooner than 10 minutes.

Nasopharyngeal Aspirate/Wash Test Procedure

1. Fill the pipette to the top/uppermost notch with nasopharyngeal aspirate/wash sample.



2. Add entire contents (i.e., 300 µL) of the pipette to the Reagent Tube. Swirl the Reagent Tube gently to dissolve its contents.

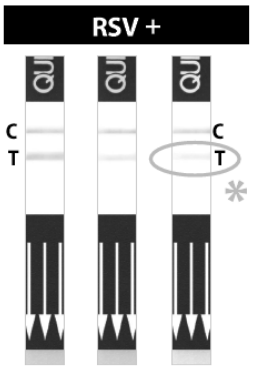
3. Place the Test Strip into the Reagent Tube with the arrows pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

4. At ten (10) minutes, remove the Test Strip, and read result according to the Interpretation of Results section. Some positive results may appear sooner than 10 minutes.

INTERPRETATION OF RESULTS

SEE Procedure Card for larger images of test results in color.

Positive Result*:
At ten (10) minutes, the appearance of **ANY shade of a pink-to-red Test Line AND** the appearance of a blue procedural Control Line indicates a positive result for the presence of RSV antigen. Results will remain stable for five (5) minutes after the recommended read time.



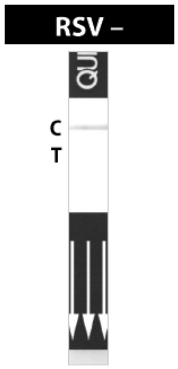
**A positive result does not rule out co-infections with other pathogens.*

***Look closely!** This is a positive result. Even if you see a very faint, pink Test Line and a blue Control Line, you must report the result as POSITIVE.

C = Control Line
T = Test Line

Negative Result:**
At ten (10) minutes, the appearance of **ONLY the blue procedural Control Line** indicates RSV antigen was not detected. Results will remain stable for five (5) minutes after the recommended read time.

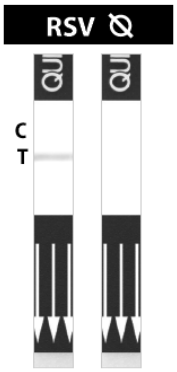
***A negative result does not exclude RSV infection. It is recommended that negative results be confirmed by cell culture.*



Invalid Result:
If at ten (10) minutes, the blue procedural Control Line does not appear, even if any shade of a pink-to-red Test Line appears, the result is invalid.

If at ten (10) minutes, the background color does not clear and it interferes with the reading of the test, the result is also invalid.

If the result is invalid, a new test should be performed with a new patient sample and a new Test Strip.



LIMITATIONS

- This test is suitable for the pediatric population (less than six years old) only.
- The contents of this kit are to be used for the qualitative detection of RSV fusion protein antigen from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
- Failure to follow the Test Procedure and Interpretation of Results may adverselyaffect test performance and/or invalidate the Test Results.
- Test Results must be evaluated in conjunction with other clinical data available tothe physician.
- Negative test results are not intended to rule in other non-RSV viral or bacterial infections.
- Positive test results do not rule out co-infections with other pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of diseaseis high. False positive test results are more likely during periods of low RSV activity when prevalence is moderate to low.

EXPECTED VALUES

The rate of positivity observed in RSV testing will vary depending on the method of specimen collection, handling/transport system employed, detection method utilized, time of year, age of the patient, and disease prevalence. The prevalence observed with culture during the clinical study was 20% (139/709).

PERFORMANCE CHARACTERISTICS

QuickVue RSV 10 Test Performance

Background on the Clinical Study

The performance of the QuickVue RSV 10 test was compared to viral cell culture methods and DFA in a multi-center clinical study during the RSV season in the United States. This study was performed by professional health care personnel at four distinct sites in various geographical regions within the United States. In this multi-center, point-of-care (POC) field trial, nasopharyngeal swabs and nasopharyngeal aspirate/wash specimens were collected from seven hundred nine (709) patients. Three hundred seventy-eight (378) provided a nasopharyngeal swab specimen and three hundred thirty-one (331) provided a nasopharyngeal aspirate/wash specimen. All clinical samples were collected from symptomatic patients (5 years of age and younger). 60% were male and 40% were female.

On-site testing of one nasopharyngeal swab specimen, or a portion of nasopharyngeal aspirate/wash specimen, was performed by physician office personnel with the QuickVue RSV 10 test. All samples were freshly collected and tested. The remaining sample was placed in viral transport media. Cell culture was performed either at the laboratory of the test site or at a local, readily accessible virus laboratory. Cells were inoculated with the specimen, incubated at 35°C to 37°C for 16 to 72 hours, and then removed from culture and tested for RSV by direct fluorescent antibody (DFA) staining.

Results with Nasopharyngeal Aspirate/Wash Specimens
Nasopharyngeal aspirate/wash specimens from three hundred thirty-one (331) patients were tested in QuickVue RSV 10 and in cell culture. The QuickVue RSV 10 test correctly identified 90% (62/69) RSV culture-positive specimens and 96% (251/262) RSV culture-negative specimens. These results are shown in Table 1.

Table 1
QuickVue RSV 10 Nasopharyngeal Aspirate/Wash Specimen Results versus Culture

	RSV Culture	
	+	–
QV Pos	62	11
QV Neg	7	251

Sensitivity: 62/69 = 90% (***95% C.I.*** 80%-95%)
Specificity: 251/262 = 96% (***95% C.I.*** 93%-98%)
PPV: 62/73 = 85%
NPV: 251/258 = 97%

Results with Nasopharyngeal Swab Specimens
Nasopharyngeal swab (Copan Diagnostics, item #501CS01.US) specimens from three hundred seventy-eight (378) patients were tested in QuickVue RSV 10 and in cell culture. The QuickVue RSV 10 test correctly identified 86% (60/70) RSV culture-positive specimens and 95% (292/308) RSV culture-negative specimens. These results are shown in Table 2.

Table 2
QuickVue RSV 10 Nasopharyngeal Swab Specimen Results versus Culture

	RSV Culture	
	+	–
QV Pos	60	16
QV Neg	10	292

Sensitivity: 60/70 = 86% (***95% C.I.*** 75%-92%)
Specificity: 292/308 = 95% (***95% C.I.*** 92%-97%)
PPV: 60/76 = 79%
NPV: 292/302 = 97%

REPRODUCIBILITY STUDIES

The reproducibility of the QuickVue RSV 10 test was evaluated at five different laboratories, one of which was Quidel. Three different operators at each site tested a series of coded, contrived samples, ranging from high negative to moderate positive. Each had been carefully seeded with graded doses of RSV. The inter-laboratory agreement (Table 3) for negative samples was 99.3 to 100% and 99.1 to 99.8% for positive samples. The intra-laboratory agreement (Table 4) for all samples ranged from 99.2 to 100%.

Table 3
QuickVue RSV 10 Reproducibility Study Inter-laboratory Agreement

Laboratory Site	High Negative Samples		Low Positive Samples		Moderate Positive Samples
	4.33 x 10^5 vp/mL*	**5.58 x 10^5 vp/mL**	**8.38 x 10^5 vp/mL**	**1.03 x 10^6 vp/mL**	**5.03 x 10^6 vp/mL**
1	90/90	90/90	87/90	89/90	90/90
2	90/90	90/90	90/90	89/90	89/90
3	90/90	90/90	90/90	90/90	90/90
4	90/90	90/90	89/90	90/90	90/90
5	90/90	87/0	90/90	90/90	90/90
Total	*450/450*	*447/450*	*446/450*	*448/450*	*449/450*
% Overall Agreement (95% C.I.)	100% (99.0%-100%)	99.3% (98.0%-99.9%)	99.1% (97.7%-99.7%)	99.6% (98.3%-100%)	99.8% (98.6%-100%)

*The concentration of virus particles (vp/mL) was determined by electron microscopic techniques.

Table 4
QuickVue RSV 10 Reproducibility Study Intra-laboratory Agreement

Laboratory Site	High Negative Samples		Low Positive Samples		Moderate Positive Samples	% Overall Agreement (95% C.I.)
	4.33 x 10^5 vp/mL*	**5.58 x 10^5 vp/mL**	**8.38 x 10^5 vp/mL**	**1.03 x 10^6 vp/mL**	**5.03 x 10^6 vp/mL**	
1	90/90	90/90	87/90	89/90	90/90	99.2% (506/510) (97.9-99.8%)
2	90/90	90/90	90/90	89/90	89/90	99.6% (508/510 (98.5-100%)
3	90/90	90/90	90/90	90/90	90/90	100% (510/510 (99.1-100%)
4	90/90	90/90	89/90	90/90	90/90	99.8% (509/510 (98.8-100%)
5	90/90	87/90	90/90	90/90	90/90	99.4% (507/510 (98.2-99.9%)

*The concentration of virus particles (vp/mL) was determined by electron microscopic techniques.

ANALYTICAL SENSITIVITY AND LIMIT OF DETECTION

The QuickVue RSV 10 test was shown to detect two different isolates of RSV A and one isolate of RSV B. In a separate experiment, the limit of detection was determined to be approximately 7.9 x 10^3 $TCID_{50}$ /mL for RSV A and 8.3 x 10^3 $TCID_{50}$ /mL for RSV B.

ANALYTICAL SPECIFICITY AND CROSS-REACTIVITY

A total of thirty-four (34) bacterial and fungal and thirty-five (35) viral isolates were tested in triplicate in the QuickVue RSV 10 test. None (i.e., 0/34 bacterial/fungal and0/35 viral isolates) of the microorganisms tested at

the levels indicated showed any sign of cross-reactivity in the assay. Flow of the sample and appearance of the Control Line were also not affected. These results (Tables 5 and 6) confirm high immunological specificity of the QuickVue RSV 10 test.

Table 5
Bacterial Panel*

Cross Reactant	Concentration
Bacteroides fragilis	1.0×10^9 org/mL
Bordetella pertussis	1.0×10^9 cfu/mL
Candida albicans	1.0×10^8 cfu/mL
Corynebacterium diphtheriae	1.0×10^7 cfu/mL
Enterococcus faecalis	1.0×10^7 org/mL
Escherichia coli	1.0×10^8 cfu/mL
Gardnerella vaginalis	1.0×10^6 org/mL
Haemophilus influenzae	1.0×10^8 cfu/mL
Klebsiella pneumoniae	1.0×10^9 cfu/mL
Lactobacillus casei	1.0×10^7 cfu/mL
Lactobacillus plantarum	1.0×10^7 cfu/mL
Legionella pneumophila	1.0×10^9 cfu/mL
Listeria monocytogenes	1.0×10^9 org/mL
Moraxella catarrhalis	1.0×10^9 cfu/mL
Mycobacterium avium	1.0×10^8 org/mL
Mycobacterium intracellulare	1.0×10^8 org/mL
Mycobacterium tuberculosis	1.0×10^7 org/mL
Mycoplasma pneumoniae	3.3×10^3 cfu/mL
Neisseria gonorrhoeae	5.0×10^7 org/mL
Neisseria meningiditis	1.0×10^8 cfu/mL
Neisseria sicca	1.0×10^9 cfu/mL
Neisseria subflava	1.0×10^6 cfu/mL
Pseudomonas aeruginosa	1.0×10^9 cfu/mL
Serratia marcescens	1.0×10^8 org/mL
Staphylococcus aureus	2.5×10^7 cfu/mL
Staphylococcus aureus (Cowan 1)	1.0×10^9 cfu/mL
Staphylococcus epidermidis	1.0×10^8 cfu/mL
Streptococcus mutans	5.0×10^8 org/mL
Streptococcus pneumoniae	5.0×10^5 cfu/mL
Streptococcus pyogenes Gp. A	1.0×10^8 org/mL
Streptococcus sanguis	5.0×10^8 org/mL
Streptococcus Gp. B	1.0×10^8 org/mL
Streptococcus Gp. C	1.0×10^8 cfu/mL
Streptococcus Gp. G	1.0×10^8 cfu/mL

*Standard microbiological methods were used for determining the concentrationof the bacteria and fungus.

Table 6
Viral Panel*

Cross Reactant	$TCID_{50}$/mL
Adenovirus 3	1.0×10^7
Adenovirus 4	1.0×10^4
Adenovirus 5	1.0×10^7
Adenovirus 7	1.0×10^4
Adenovirus 11	1.0×10^6
Adenovirus 18	1.0×10^7
Coronavirus (OC43)	1.0×10^6
Coronavirus 229E	1.0×10^6
Coxsackievirus B5 (Faulkner)	1.0×10^8
Echovirus Type 3	1.0×10^6
Herpes simplex type 1	1.0×10^6
Herpes simplex type 2	1.0×10^6
Influenza A/Fort Monmouth (H1N1)	1.0×10^6
Influenza A/New Jersey (H1N1)	1.0×10^6
Influenza A/Victoria (H3N2)	5.0×10^5
Influenza B/Allen	1.0×10^5
Influenza B/Hong Kong	1.0×10^6
Influenza B/Lee	1.0×10^6
Influenza B/Panama	1.0×10^7
Influenza C/Taylor/1233/47	1.0×10^5
Measles (Edmonston)	1.0×10^6
Metapneumovirus	1.0×10^6
Mumps (Enders)	1.0×10^5
Parainfluenza virus 1	1.0×10^6
Parainfluenza virus 3	1.0×10^6
Parainfluenza virus 4A	1.0×10^6
Rhinovirus Type 1	1.0×10^5
Rhinovirus Type 2	1.0×10^5
Rhinovirus Type 3	1.0×10^4
Rhinovirus Type 7	1.0×10^6
Rhinovirus Type 15	1.0×10^7
Rhinovirus Type 16	1.0×10^8
Rhinovirus Type 18	4.0×10^5
Rhinovirus Type 37	1.0×10^5
Varicella Zoster Virus	4.0×10^4 pfu/mL

*Standard microbiological methods were used for determining the concentration of the viruses.

INTERFERING SUBSTANCES

Several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the QuickVue RSV 10 test at the levels tested. These included the following: three OTC mouthwashes (25%); three OTC cough drops (15%); three nasal sprays/gel (10%); Blood (2%); Acetamidophenol (10 mg/mL); Acetylsalicylic Acid(20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Mucin (4 mg/mL); Guaiacol (20 mg/mL); Phenylephrine(50 mg/mL); Rimantadine (50 µg/mL); and Albuterol (20 mg/mL).

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S., contact your local distributor or technicalsupport@quidel.com.

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REF 20222 – QuickVue RSV 10 25 Test Kit

IVD

CE

EC REP

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GLOSSARY

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for 25 determinations
CONT Contents/Contains	CONTROL + Positive control
CONTROL − Negative control	