510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K070747

B. Purpose for Submission:

New specimen matrix

C. Measurand:

Respiratory syncytial virus (RSV) antigen

D. Type of Test:

Dipstick immunoassay for the rapid, qualitative detection of RSV antigen

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

QuickVue® RSV Test

G. Regulatory Information:

1. Regulation section: 21CFR 866.3480; Respiratory syncytial virus serological reagents

2. Classification: Class: I

3. Product code: GQG, Antigens, CF (including CF controls), respiratory syncytial virus.

4. Panel: 83 Microbiology

H. Intended Use:

The QuickVue RSV test is a dipstick immunoassay, which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test

results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

2. Indication(s) for use: Same as intended use

3. Special conditions for use statement(s):

   Prescription Use Only

4. Special instrument requirements:

   None

I. Device Description:

The QuickVue RSV test is a dipstick immunoassay that allows the capture and visual detection of RSV antigen (viral fusion protein). The patient specimen is placed in the Extraction Tube containing the Extraction Reagent, enhancing the exposure of the viral fusion protein antigen. After extraction, the Test Strip is placed in the Extraction Tube where the RSV fusion proteins in the specimen will react with the reagents in the Test Strip.

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 type antigens are not present, or are present at very low levels, only a blue procedural Control Line will appear.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Viral cell culture, Quidel QuickVue® RSV Test

2. Predicate 510(k) number(s): k061008
   Comparison with predicate:

Table 1: Summary of Device Similarities and Differences

Features	QuickVue® RSV test (Proposed)	QuickVue® RSV test (K061008)
Intended Use	The QuickVue RSV test is a dipstick immunoassay which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.	The QuickVue RSV test is a dipstick immunoassay which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab or nasopharyngeal aspirate specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal swab, Nasopharyngeal aspirate, and Nasal/nasopharyngeal wash	Nasopharyngeal swab and Nasopharyngeal aspirate
Extract / Elute	Extraction reagent used for swab/aspirate/wash	Extraction reagent used for swab/aspirate
Read Result Time	15 Minutes	15 Minutes
Format	Lateral-flow immunoassay dipstick	Lateral-flow immunoassay dipstick
Control Features	Procedural Control Line Clearing of background	Procedural Control Line Clearing of background
External Controls	Positive RSV swab RSV negative swab coated with Streptococcus C antigen	Positive RSV swab RSV negative swab coated with Streptococcus C antigen

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

Lateral flow immunocapture assay

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Not applicable

   d. Detection limit:

   Not applicable

   e. Analytical specificity:

   Not applicable

   f. Assay cut-off:

   Not applicable

2. Comparison studies:

   a. Method comparison with gold standard:

   See clinical studies.

   b. Matrix comparison :

   Not applicable

3. Clinical studies :

   Quidel performed the following studies to establish the sensitivity and specificity of the QuickVue RSV Test with nasal/nasopharyngeal specimens:

   During the 2006/2007 flu season, the performance of the QuickVue RSV 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 two pediatric clinics and two hospital emergency departments in various geographical regions within the United States. In this multi-center, point-of-care (POC) field trial, nasal/nasopharyngeal wash specimens were collected from two hundred eighty-nine (289) patients. All clinical samples were collected from symptomatic patients less than six years of age. 60% were male and 40% were female.

On-site testing of a portion of nasal/nasopharyngeal wash was performed by physician office personnel with the QuickVue RSV test. All samples were freshly collected and tested within one hour. No samples were frozen prior to testing. The remaining sample was placed in viral transport media and transported to a reference laboratory for culture, where cells were inoculated with the specimen, incubated at 36°C for 48 hours, and then removed from culture and tested for RSV by direct fluorescent antibody (DFA) staining.

a. Clinical Sensitivity and specificity:

Results with Fresh Nasal/Nasopharyngeal Wash Specimens

Nasal/nasopharyngeal wash specimens from two hundred eighty-nine (289) patients were tested in QuickVue RSV and in cell culture. The QuickVue RSV test correctly identified 83% (100/121) RSV culture-positive specimens and 90% (152/168) RSV culture-negative specimens. These results are shown in Table 3.

Table 3
QuickVue RSV Nasal/Nasopharyngeal Wash Results versus Culture (<6 years of age)

	RSV Culture	
	+	-
QV Pos	100	16
QV Neg	21	152

Sensitivity = 100/121 = 83% (95% C.I. 75-88%)

Specificity = 152/168 = 90% (95% C.I. 85-94%)

PPV = 100/116 = 86%

NPV = 152/173 = 88%

Clinical sensitivity:	83% (100/121 (95% CI 75-88%)
Clinical specificity:	90%. (152/168) (95% CI 85-94%)

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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