VITASSAY

RSV

Rapid test for the qualitative detection of RSV from nasal swabs, nasopharyngeal wash or aspirate specimens.

IUE-7355039 Ed00 May 2016

CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay RSV is a rapid, immunochromatographic, one step assay for the qualitative detection of RSV from nasal swabs, nasopharyngeal wash or aspirate specimens.

Simple and highly sensitivity immunoassay to make a presumptive diagnosis of RSV respiratory infection

INTRODUCTION

Respiratory syncytial virus (RSV), a single-stranded RNA virus of the family Paramyxoviridae, is the leading cause of severe respiratory illness in infants and young children. A hallmark of RSV infection is incomplete immunity, leading to reinfection throughout life. Although reinfection is generally mild, certain adult populations can have severe illness with lower respiratory tract symptoms, resulting in hospitalization and death.

RSV likely spreads by close contact via direct inoculation of large-particle aerosols onto mucosa or self-inoculation after touching contaminated surfaces. The virus replicates in the nasal or ocular mucosal epithelium. Although RSV is relatively labile, the virus can survive for 6-12hr on countertops and other porous surfaces, providing the opportunity for environmental nosocomial transmission.

Children younger than 2 years of age, immunocompromised individuals, and adults with underlying respiratory dysfunction such as asthma or chronic obstructive pulmonary disease (COPD) are at greater risk for developing complications due to RSV. While most infections resolve without medical intervention, RSV infection can cause acute bronchiolitis and pneumonia in infants and elderly adults. Infection of the lower respiratory tract can cause severe pneumonia requiring hospitalization and resulting in mortality.

PRINCIPLE

Vitassay RSV is a qualitative immunochromatographic assay for the detection of RSV from nasal swabs, nasopharyngeal wash or aspirate specimens.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against RSV.

During the process, the sample reacts with the antibodies against RSV, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay RSV**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF) on the sealed pouch.

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **25** tests/kit **Vitassay RSV.** ▪ 1 Reagent B (sample diluent). ▪ 25 Swabs. ▪ 25 Disposable pipettes. ▪ 25 Testing tubes. ▪ Instructions for use. ▪ **Vitassay RSV Positive Control swab**+ instructions for use.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer. ▪ Vortex.

Vitassay
Parque Tecnológico WALQA
Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
www.vitassay.com

SPECIMEN COLLECTION

Samples should be collected in clean and dry containers.

Samples should be process as soon as possible after collection. If this is not possible, the samples can be store in the refrigerator (2-8ºC/35.6-46.4ºF) for 8 hours prior testing.

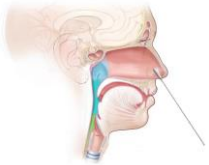
Samples must be brought to room temperature before testing.

Homogenize the samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

- **Nasal swab:**

1. Remove the swab from its packing.
2. Collect specimen with a sterile swab from one nostril.
3. Insert the swab into the nostril to the nasopharynx, rotating against the nasal wall (to ensure swab contains cells as well as mucus).
4. Repeat procedure using other nostril.
5. Process the swab as soon as possible after collecting the specimen.



- **Nasopharyngeal aspirate:**

For adults:

1. Place the irrigator up to the nose.
2. Let the sterile saline water run into the nose (2.5mL). It will run out the opposite side. Tilt and twist the irrigator side to side and up and down directing the water flow into all portions of the nasal cavity.
3. Collect the wash in a clean specimen container, tilt the head forward and allow the water with mucus to run out of the nostril into the specimen container. Repeat the mucus collection for the other nostril and collect it into the same container.

For children:

1. Use an aspiration bulb or bulb syringe to instill the saline water into one nostril leaning the children head.
2. Aspirate the mix of mucus-saline water into the bulb and transfer it into a clean container.
3. Repeat for the other nostril and transfer the fluid into the same specimen container.

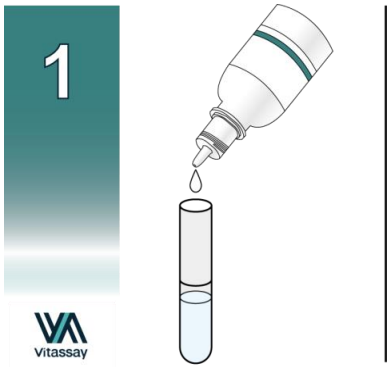
PROCEDURE

Allow the test, samples and controls to reach room temperature (15-30ºC/59-86ºF) prior to testing.

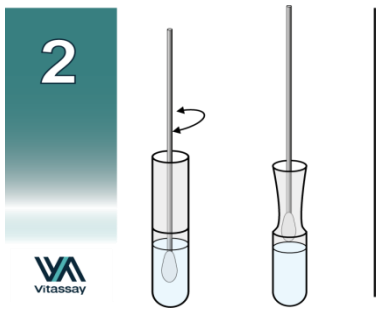
Do not open pouches until the performance of the assay.

Nasal swab procedure:

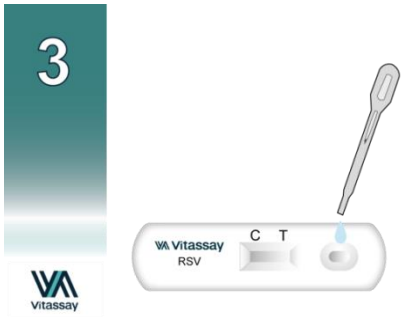
1. Add 15 drops (figure 1) Reagnt B and immediately put the swab into the tube.
2. Mix the solution by rotating the swab forcefully against the side of the tube at least 1 minute. Best results are obtained when the specimen is vigorously extracted in the solution (figure 2). Extract as much liquid as possible from the swab, squeezing the sides of the tube or rotating the swab against the side of the tube as the swab is withdrawn. Discard the swab.
3. Remove the **Vitassay RSV** from its sealed bag and using the pipette, dispense 4 drops from the testing tube into the circular window marked with letter S (figure 3).
4. Read the results at **10 minutes**. Do not read the test results later than 10 minutes.



Add 15 drops of Reagent B.



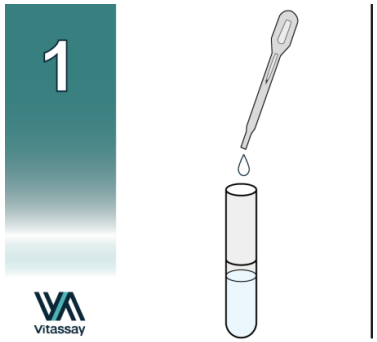
Put the swab into the tube, rotating 1 minute and extract the liquid.



Dispense 4 drops in the circular window marked with the letter S.

Nasopharyngeal wash or aspirate procedure

1. Add 6 drops (figure 1) of the nasopharyngeal wash or aspirate samples with a pipette and 9 drops (figure 2) of Reagent B in testing tube. Mixer with vortex at least 1 minute to homogenize. Best results are obtained when the specimen is vigorously extracted in the solution (figure 3).
2. Remove **Vitassay RSV** from its sealed bag just before using it.
3. Dispense exactly 4 drops from the testing tube, in the circular window marked with the letter S (figure 4).
4. Read the results at **10 minutes**. Do not read the test results later than 10 minutes.



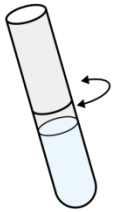
Add 6 drops of nasopharyngeal wash/aspirate.

Vitassay
Parque Tecnológico WALQA
Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
www.vitassay.com

2

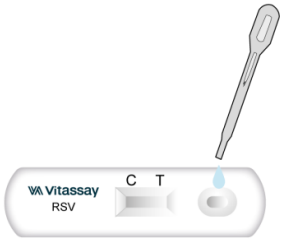
Add 9 drops of Reagent B.

3



Mix the solution with vortex 1 minute.

4



Dispense 4 drops in the circular window marked with the letter S.

If the test does not run due to the type of sample, stir the sample added in the sample window (S) with the pipette. If it does not work, dispense a drop of Reagent B until seeing the liquid running through the reaction zone.

INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one green line in the control zone (**C**)	There is no RSV presence. No infection caused by RSV.
	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	There is RSV presence. Infection caused by RSV.
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. **Note:** Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

QUALITY CONTROL

Internal procedural control is included in **Vitassay RSV**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay RSV** must be carried out within 2 hours of opening the sealed bag.
- It should only be used with nasal swabs, nasopharyngeal wash and aspirate samples. The use of other samples has not been established.
- The quality of **Vitassay RSV** depends on the quality of the sample; Proper nasal specimens must be obtained.
- The intensity of test line may vary from very strong (high antigens concentration) to faint (antigens concentration is close to the detection limit).
- Positive results determine the presence of Respiratory Syncytial Virus infection. A positive result should be followed up by a physician and must be based in the correlation of the results with further clinical observations.
- Negative results should not be considered as conclusive; it is possible that the antigens concentration in nasal samples is lower than the detection limit value. If symptoms or situation still persist, it is recommended that all negative results undergo confirmatory testing using other method and/or virus identification by cell culture or PCR.

EXPECTED VALUES

Although RSV infections occur frequently in all age groups, including the elderly, the burden of this virus is clearly greatest among the youngest infants who experience the highest rates of RSV-associated emergency department visits and hospitalizations.

Respiratory syncytial virus (RSV) is a major cause of morbidity in very young children. Globally in 2005, there were approximately 3.4 million (95% CI 2.8-4.3) episodes of severe RSV-associated childhood acute lower respiratory illness (ALRI) necessitating hospital admission. Premature infants and those born with congenital abnormalities are at risk of severe morbidity and higher risk of RSV hospitalization.

In temperate zones RSV causes seasonal epidemics in the winter.

PERFORMANCE CHARACTERISTICS

An evaluation, with nasal samples, was performed comparing **Vitassay RSV** and another rapid commercial test (BinaxNOW® RSV, Alere).

Results were as follows:

		BinaxNOW® RSV		
		Positive	**Negative**	**Total**
Vitassay RSV	**Positive**	18	0	18
	Negative	1	10	11
	Total	19	10	29

Vitassay RSV vs BinaxNOW® RSV			
Sensitivity	**Specificity**	**PPV**	**NPV**
95%	>99%	>99%	91%

The results showed that **Vitassay RSV** has a high sensitivity and specificity to detect Respiratory Syncytial Virus.

Cross reactivity

No cross reactivity was detected against organisms that cause other respiratory infections:

Influenza type A	*Influenza type B*	*Adenovirus*

REFERENCES

1. EDWARD e. WALSH; DERICK R. PETERSON; AJA E. KALKANOGLU; FRANCES EUN-HYUNG LEE; ANN R. FALSEY. "Viral Shedding and Immune Responses to Respiratory Syncytial Virus Infection in Older Adults". The Journal of Infectious Diseases 2013; 207:1424-32.

Vitassay
Parque Tecnológico WALQA
Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
www.vitassay.com

2. NUSRAT HOMAIRA; JOANNE SHEILS; SACHA STELZER-BRAID; KEI LUI; JU-LEE OIE; TOM SNELLING; ADAM JAFFE; WILLIAM RAWLINSON. "Respiratory Syncytial Virus is present in the neonatal intensive care unit". J. Med. Viral. 88: 196-201, 2016.

3. ROBERT JORDAN; MATT SHAO; RICHARD L. MACKMAN; MICHEL PERRON; TOMAS CIHLAR; SANDY A. LEWIS; EUGENE J. EISENBERG; ANNE CAREY; ROBERT G. STRICKLEY; JASON W. CHIEN; MARK L. ANDERON; HEATHER A. MCELIGOT ; NICOLE E. BEHRENS; LAUREL J. GERSHWIN. "Antiviral efficacy of a respiratory syncytial virus (RSV) fusion inhibitor in a bovine model of RSV infection". Antimicrobial Agents and Chemotherapy, August 2015, Vol 59, Number 8.

4. TERHO HEIKKINEN; HEIKKI VALKONEN; MATTI WARIS; OLLI RUUSKANEN. "Transmission of Respiratory Syncytial Virus Infection within families". Open Forum Infectious Diseases , 2014

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number

Vitassay