STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: Respiratory Syncytial Virus	**Revision Date:** 20-April-2018	**Issue Date:** 20-April-2016
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Distribution: Microbiology Test Manual	**Page:** 1 of 6	
Approved by: S. Asmussen, Manager of Diagnostic Services	**Signed by:** 	

PURPOSE:

The purpose of this procedure is to allow the user to test specimens for Respiratory Syncytial Virus (RSV).

INTRODUCTION:

Respiratory Syncytial Virus (RSV) is a virus that may respiratory illness in patients of any age. In infants and young children, it is the most important cause of bronchiolitis and pneumonia. Re-infection throughout life is common but is generally milder. In adults and older children, RSV generally manifests as an upper respiratory infection. Peak incidence of disease occurs in winter to early spring.

RSV is transmitted through contact with infected secretions/droplets. Transmission may occur by direct or close contact, by items in the environment that are contaminated, or by large droplet aerosols within five feet of the patient. Aerosols are created during coughing, sneezing, or suctioning. RSV has been recovered from dry inanimate surfaces such as counter tops after six hours at room temperature. Self-inoculation can occur through touching one's eyes or nose with contaminated hands.

The incubation period is usually 2 to 8 days. Viral shedding is usually 3 to 8 days, but in infants may continue for 3 to 4 weeks.

PRINCIPLE:

This test is ready to use and is based on the homogenous membrane system technology with colloidal gold particles. A nitrocellulose membrane is sensitized with a monoclonal

antibody directed against one epitope of the F protein of the RSV. Another monoclonal antibody directed against a second epitope of the F protein is conjugated to colloidal gold particles. This conjugate is immobilized on a polyester membrane. This test is aimed to the detection of RSV in nasopharyngeal secretions after several days in order to reach a better sensitivity.

When the strip is dipped into the extraction solution of NPS, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample material come into contact with the anti-RSV antibody that is adsorbed onto the nitrocellulose strip. If the sample contains RSV, the conjugate-RSV complex will remain bound to the anti-RSV antibody absorbed onto the nitrocellulose. The result is visible after extraction period within 15 minutes in the form of a red line that develops on the strip. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.

SAMPLE INFORMATION:

Type	Nasopharyngeal aspirate or swab submitted in Universal Transport Media (UTM). A nasal swab is not recognized as a good specimen collection method. It is strongly recommended to avoid the use of sputum
Source	Patient younger than 2 years old for testing at Stanton; Otherwise forward directly to DynaLife.
Volume	8 drops of sample (0.25mL)
Stability	Test as soon as possible after collection
Storage Requirements	Specimen can be stored at 2 – 8 °C for 24 hours. Allow samples to warm to room temperature and swirl gently before testing.
Criteria for rejection and follow up action	1. Unlabeled or mislabeled specimen 2. Specimen not properly collected 3. Specimens treated with formaldehyde or its derivatives.

REAGENTS and/or MEDIA:

- RSV KIT Coris REF#C-1006
- RSC Positive Control Coris REF#C-1086
- Sterile Saline For Negative Control

SUPPLIES:

- 12x75mm Test Tubes
- Graduated, Disposable Pipettes
- Timer

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures.

- Lab gown must be worn when performing activities with potential pathogens.
- Gloves must be worn when direct skin contact with infected materials is unavoidable.
- Eye protection must be used where there is a known or potential risk of exposure to splashes.
- **RSV testing should be conducted in a biological safety cabinet (BSC).**
- The use of needles, syringes, and other sharp objects should be strictly limited.

QUALITY CONTROL:

Positive Control: set upon opening a new box

Generate a TQC order via the TQC Order Entry Function

Step	Action
Performing RSV Quality Control	
1	In TQC – add **SCRSV** order in Order Entry
2	Mix 4 drops of Positive Control with 8 drops of extraction buffer
3	Stir thoroughly to homogenize the solution
4	Immerse the sensitized strip in the direction indicated by the arrows. **Note: To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line placed under the brown arrow.
5	Set timer for 15 minutes and incubate at room temperature.
6	Interpret results
7	Record results in the TQC system – under Resulting Worklist →Microbiology results

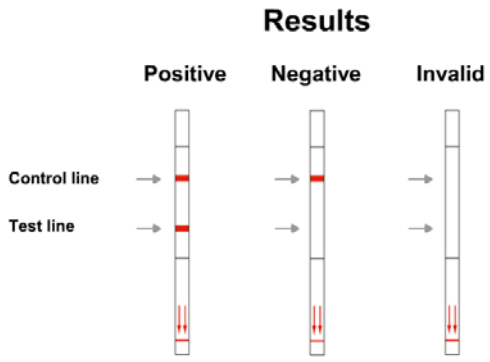
PROCEDURE INSTRUCTIONS:

Step	Action
Performing a PYR Test	
1	Mix 0.25 mL (8 drops) of sample with 0.25 mL (8 drops) of extraction buffer
2	Stir thoroughly to homogenize the solution
3	Immerse the sensitized strip in the direction indicated by the arrows. **Note: To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line placed under the brown arrow.
4	Set timer for 15 minutes and incubate at room temperature.
5	Interpret results
6	Record results directly in Result Entry

INTERPRETATION OF RESULTS:

NOTE:

- If no lines are apparent - Test is Invalid and must be repeated
- If no Control line is apparent - Test is invalid and must be repeated



REPORTING RESULTS:

IF	THEN
Negative Result	Using keypad: **}RSVN NEG** RAPID RSV (RESPI-STRIP): NEGATIVE Sample has been referred to PLNA for further viral Investigation. A **VIRC** is automatically ordered upon resulting of the RSV
Positive Result	Using keypad: **}RSVP POS** RAPID RSV (RESPI-STRIP): POSITIVE Sample has been referred to PLNA for further viral Investigation. A **VIRC** is automatically ordered upon resulting of the RSV

NOTES AND PRECAUTIONS:

1. For in vitro Diagnostic Use.
2. The RSV Respi-Strips and buffer must not be frozen
3. Do not use kit past its expiration date.
4. Do not mix components from different kit lots.
5. Inadequate specimen collection or low levels of virus shedding may result in suboptimal performance and may yield false negative results.
6. A negative test result does not exclude infection with RSV nor is it intended to rule-out other microbial-caused respiratory infections.

REFERENCES:

- BioConcept, C. (2009, October). RSV Positive Control; Package Insert. *C-1086/TT* .
- Bioconcept, C. (2009, February). RSV Respi-Strip; Package Insert.
- Coris-Bioconcept, W. (2005). http://www.corisbio.com/public/product/RSVRespi-Strip.php. *How to use the Test* .

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	29-OCT-2010	Initial Release	M-L Dufresne
2.0	31Dec13	LIS updates	A.Darrach
3.0	31Mar16	Update of “Special Safety Precautions” to reflect risk assessment recommendations.	C. Russell