PURPOSE:

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

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:

Type	• RSV KIT by Coris BioConcept • RSC Positive Control by Coris BioConcept
Storage Requirements	• An unopened kit may be kept between 4 and 30°C and used until the shelf-life date indicated on packaging • The strips remain stable for 15 weeks (in closed container) after bottle opening if they are kept at between 4 and 30°C and in a dry environment • Avoid freezing strips and buffer

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

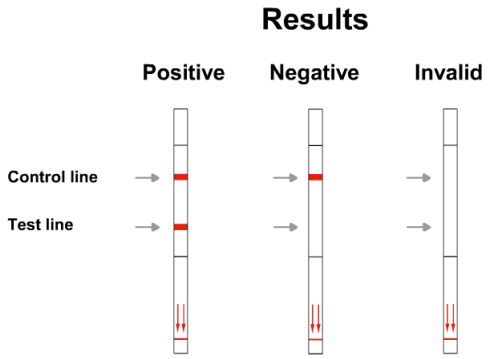
Generate a TQC order via the TQC Order Entry Function

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 RSV 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 • Phone results to ordering ward • Go to Order Entry; copy report to Chief Medical Officer of Health (HPU) and Infection Control Nurse (SOHS)

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
4.0	08-May-2017	Reviewed and revised; Reagent storage requirements added; Added notification instructions for positive results; Introduction and Principle sections removed; Updated to new format; New document number assigned (Old number MIC51700)	L. Steven

X

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