

External Controls for StatusFirst® RSV

Rapid Immunoassay for the differential detection of RSV Antigen

External Positive and Negative Control Swabs

Materials:

- Positive external control swab-swab impregnated with RSV antigen (non-infective)
- Negative external control swab-swab impregnated with inactivated Group B Streptococcus antigen (non-infective)

Intended Use:

StatusFirst® RSV is an in vitro rapid qualitative test that detects RSV antigens directly from anterior nasal swab specimens obtained from patients with signs and symptoms of respiratory infection.

Good laboratory practice includes the use of external controls to ensure proper kit performance. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of **StatusFirst® RSV** kits to confirm the expected Q.C. results, using the external controls provided in the kit.

Testing of External Quality Controls:

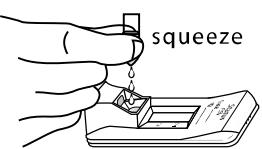
Test the control swabs in the same manner as patient specimens. When the positive control is tested, a reddish-purple line will appear at the Control (Ctrl) and RSV test line positions. When the negative control is tested, a reddish-purple line appears at the Ctrl position only. The Ctrl line should always appear; if the Ctrl line is not visible the test is invalid and should be repeated with a new control swab. Follow the procedure to perform external control swab testing as indicated below and use accompanying interpretation diagrams to interpret results. If the external controls do not perform as expected do not use the test results.

Precautions/Warnings

1. The control swabs are not to be used for collecting patient samples.
2. The use of positive and negative controls from other commercial kits has not been established with **StatusFirst® RSV** test.
3. It should be noted that the operators should discard gloves and/or wash hands after testing controls. False positive results are possible if the operator does not change gloves and/or wash hands after testing controls, before testing patient samples.

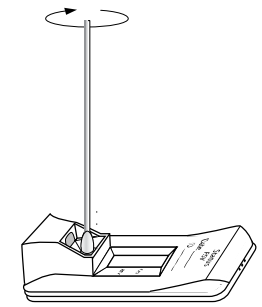
Test Procedure

1

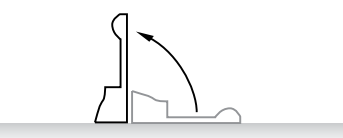


squeeze

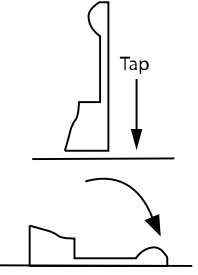
2



3



4



Tap

5

Tear the tab off the Extraction Reagent Capsule and dispense entire contents into the Extraction Well.

Insert the control swab in the Swab Stand.

- **Spin** swab 3 times to mix the specimen.
- **Let stand** 1 minute.
- **Spin** swab 3 times again.

Discard the swab.
Raise the device upright and **let stand** 1–2 seconds.

Gently **tap** device to ensure the liquid flows into the hole.

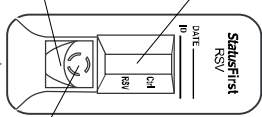
Then, lay the device back down.

Set a timer for 15 minutes.

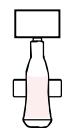
Read test results at 15 minutes.



Test device in foil pouch



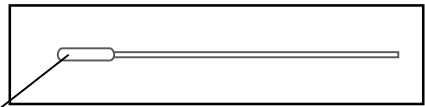
Extraction Well Result Window



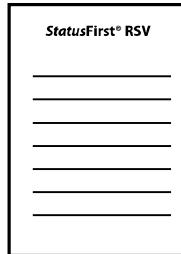
Reagent capsule



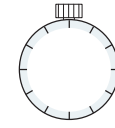
Swab tip



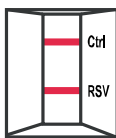
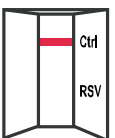
Swab in wrapper



QRI



Timer not provided

Expected External Control Results	
External Positive Control Swab	External Negative Control Swab
	
Note The above results are the only correct expected results for the Positive and Negative StatusFirst® RSV External Control Swabs. Any other results should be considered INVALID , and the test should be repeated with a new control swab and device.	

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