



# Savanna<sup>®</sup>

## RVP4 ASSAY

IVD

# QUICK REFERENCE INSTRUCTIONS

For use with Savanna instrument only.

**IMPORTANT!** The Package Insert can only be referenced once setup of Savanna instrument is complete. Read instructions carefully before beginning. The test procedure below is unique to the Savanna RVP4 Assay and may differ from other Savanna procedures.



Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

## Test Procedure

**Expiration date:** Check expiration date on each individual cartridge package or outer box before using. *Do not use any test past the expiration date on the label.*

**Do not use cartridge if any rips or tears are noticed in the outer packaging of the cartridge.**

Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.

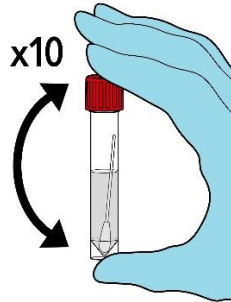
## Liquid Sample Transfer Procedure (Nasal/Nasopharyngeal Swab in Transport Medium)

1

Verify that Savanna is set up and ready to run selected tests. See the “Using Savanna” section for more information

2

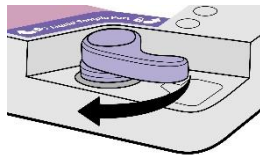
Mix patient sample completely before testing:  
**Ensure specimen cap is tightly sealed and vigorously invert the transport medium 10 times**, with the swab in the tube.



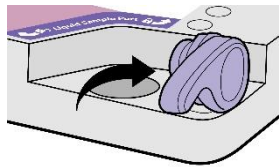
3

Place the cartridge flat with the Liquid Sample Port facing upward. Open the liquid sample port.

- a. Rotate the Liquid Sample Port handle to the left, then lift the port cap up and to the right side of the port.



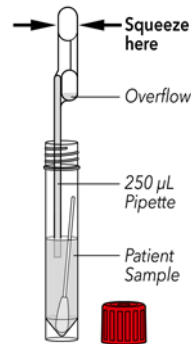
- b. The port cap is connected to the cartridge but may be lifted and set on its side in the imbedded port cap holder to the right of the sample port.



4

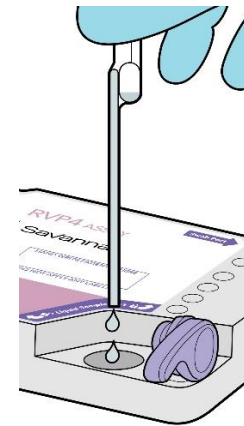
Transfer liquid sample from sample transport tube:

- a. Firmly squeeze the top bulb.  
b. Still squeezing, place the Pipette tip into the sample.  
c. With the Pipette tip still in the sample, release pressure on bulb to fill the Pipette.



5

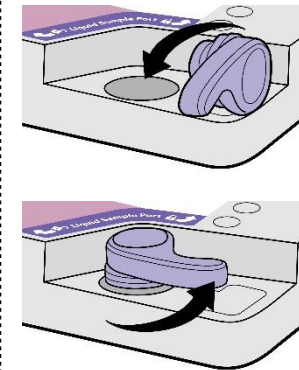
Transfer liquid sample to Cartridge:  
Firmly squeeze the top bulb to empty the contents of the pipette into the Liquid Sample Port on the cartridge.



6

**Close the Liquid Sample Port tightly.**

After loading, place port cap back onto sample port with handle in the unlock starting position. Turn handle to the right to close and seal the port tightly. The port handle should now be even against the side of the cartridge.



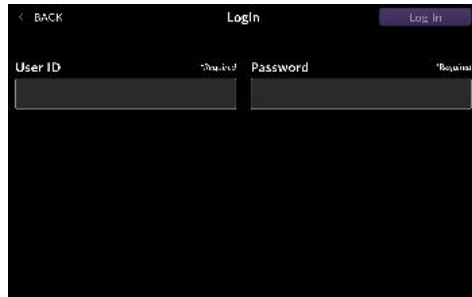
7

Proceed to the “Using Savanna” section to complete the test.

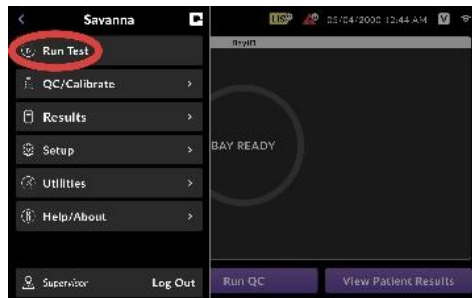
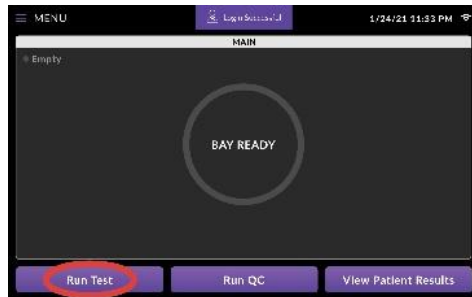
## RUN TEST

1. Input the User ID using the integrated barcode scanner or manually enter the data using the on-screen key pad.

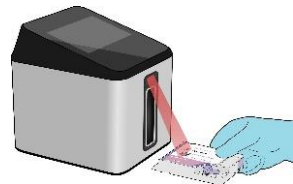
**NOTE:** If you mistakenly scan the incorrect barcode, select **Return to Login**. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.



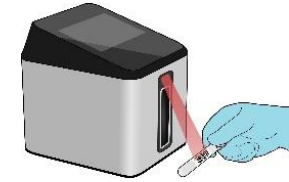
2. Start the test by pressing Run Test at the bottom of the home screen, or selecting Run Test from Menu > Run Test.



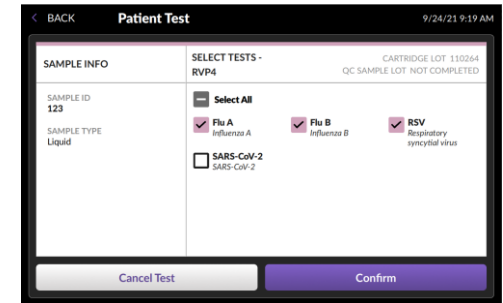
3. Scan Savanna RVP4 Assay cartridge. Refer to Package Insert for External QC guidelines.



4. Input the Patient ID and Order #, if applicable, using the barcode scanner or manually enter the data using the on-screen keypad. Press **Continue**.



5. Select or deselect targets to be reported in final result. Press **Confirm** to continue.



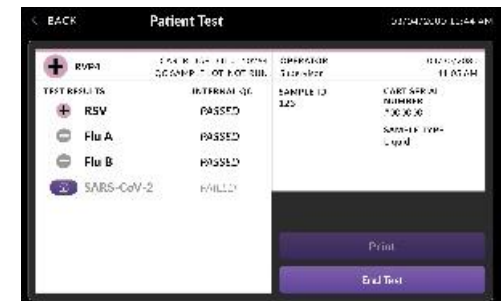
6. Insert the prepared RVP4 Assay cartridge into Savanna, following the insert direction on the cartridge label. The test will start automatically and complete in ~20 minutes.



7. The overall test result will display on the screen automatically once the test completes.








8. Press View result to display each target result. After that, press End Test and the bay door will open to eject the RVP4 Assay cartridge automatically. Remove the RVP4 Assay cartridge.




## Savanna Interpretation of Results

**Results:** The **View Result** screen will display results for the procedural control (Internal QC) as being “valid or invalid.” If the control is “invalid,” retest with a new patient sample with a new assay cartridge. Refer to RVP4 Package Insert or Savanna User Manual on how to unlock the Un-ordered analyte result.

Display	Test Result	Interpretation of Results
	Positive	The viral RNA for a respective virus was detected.
	Negative	The viral RNA for a respective virus was not detected and the Process Control was detected.
	Invalid	None of the analyte viral RNA or Process Control RNA in the respective master mix was detected. Re-process another aliquot of the same sample or obtain a new sample and re-test.
	Unlockable, Un-ordered	This analyte is not ordered, but could unlock the result in 48hours after the test is complete
	Invalid, Un-ordered	The analyte is not ordered. The result is invalid, or it has been over 48 hours since the test completed. The user cannot unlock the result.

## Savanna External Quality Control *(Run QC, one Positive and one Negative Controls)*

- 1 Select Run QC from  MENU > QC > Run QC or press Run QC on the home screen.
- 2 Scan a RVP4 cartridge in the kit to start.
- 3 Scan a QC barcode. Start from either the Positive sample or the Negative sample followed by the other control sample. Refer to the Package Insert of Savanna RVP Control Set on how to process the external QC samples.
- 4 Follow the Liquid Sample Transfer Procedure of this Quick Reference Instructions.
- 5 Follow the Using Savanna of this Quick Reference Instructions from step 6 to step 8. After each of the Positive and Negative test has run, the result will be displayed as “Passed” or “Failed.”
- 6 After both of the Positive and Negative tests are complete, the results will be displayed as “LOT QUALIFIED. Cartridge lot QC complete.”

## INTENDED USE

The Savanna RVP4 Assay (Respiratory Viral Panel-4) is a rapid, multiplexed nucleic acid test intended for use with the Savanna instrument for the simultaneous qualitative detection and differentiation of influenza A (Flu A), influenza B (Flu B), respiratory syncytial virus (RSV), and SARS-CoV-2 RNA isolated from human nasal or nasopharyngeal swabs in media obtained from patients with signs and symptoms of respiratory tract infection. This *in vitro* diagnostic test is intended to aid in the differential diagnosis of infections with these viruses.

The results of this test should not be used as the sole basis for diagnosis, treatment, or other management decisions and must be combined with clinical observations, patient history, and/or epidemiological information. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or, lower respiratory tract infection that is not detected by a nasal or nasopharyngeal swab specimen. Positive results do not rule out co-infection with other organisms; the agent(s) detected by the Savanna RVP4 Assay may not be the definite cause of disease. Additional laboratory testing (e.g., viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

The Savanna RVP4 Assay is intended for use by untrained operators. The assay may be used in near patient settings.

**Reference the Package Insert for *Warnings and Precautions, Limitations, Specimen Collection and Handling, Unlock the Unordered Test Results, and Quality Control.***

## ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Quidel Technical Support at 800.874.1517 (in the U.S.), [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com), or your local distributor. Reference [quidel.com](http://quidel.com) to see more options for Support.



Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert. Review all safety warnings and precautions in the Package Insert and Safety Data Sheet.



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