



Easy Lab PRO Rapid RSV Test

FDA-cleared and CLIA-waived testing for the qualitative detection of RSV antigens

INTENDED USE

Verséa™ Easy Lab PRO Rapid RSV test is intended for the rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens in children less than 6 years and adults over the age of 60.

The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection. If the test result is negative but the donor has symptoms it is recommended that the result is confirmed by cell culture or DFA.



KEY FEATURES AND BENEFITS

- ✓ **CLIA waived, easy-to-use test requires no training**
- ✓ **4 easy steps, results in as little as 15 minutes**
- ✓ **Multiple sample types - nasopharyngeal swabs or aspirates**
- ✓ **Overall sensitivity 93.3% Overall specificity 97.7%**
- ✓ **Built-in control ensures accuracy**
- ✓ **Enables same-day diagnosis and treatment of RSV**

PACKAGE CONFIGURATIONS

Test Kit Includes:

- 20 Foil Packed Test Devices
- 20 Disposable Test Tubes
- 40 Disposable Pipettes
- 1 X 2.0 ml R1 (Extraction Reagent)
- 1 X 1.0 ml PC (Positive Control)
- 1 X 1.0 ml (Negative Control)
- 1 Product Insert

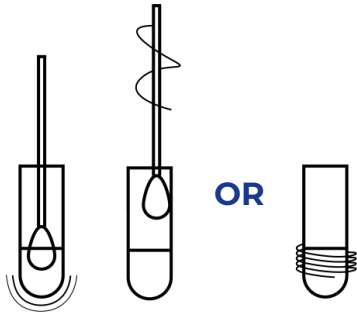
Kit Storage and Stability

Store at room temperature (2°C - 30°C / 35°F - 86°F) out of direct sunlight. Kit contents are stable until the expiration date printed on the package and kit contents. **DO NOT FREEZE.** Remove the test device from the foil pouch just prior to use.

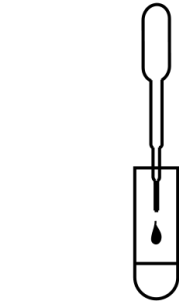
Unit Barcode



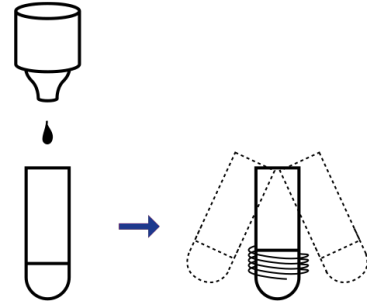
TEST PROCEDURE



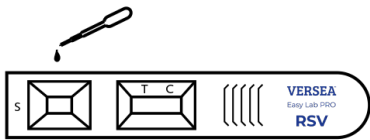
Gently agitate the nasal swab or aspirate sample. For swab sample, roll the swab against the inside of the transport tube or specimen container as you remove it and discard the used swab



Fill the disposable pipette to the second notch (160ul) with the nasal swab solution or nasal aspirate and add entire contents to the Extraction Tube



Add four (4) free falling drops of R1 to the Extraction Tube while holding the bottle vertically over the Tube and gently swirl the Extraction Tube to mix the sample and R1.

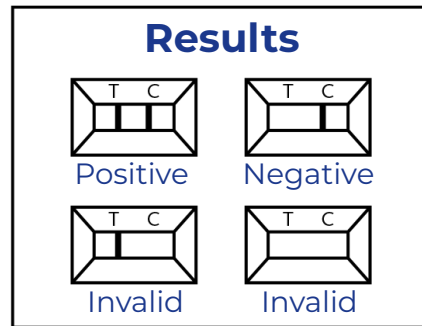


Draw entire contents of the Extraction Tube up into a clean Disposable Pipette and squeeze the entire contents onto the sample well of the Test Device.



15 MINUTES

The test results should be read between fifteen (15) and twenty-five (25) minutes after applying the extracted sample to the Test Device.



TEST COMPARISON CHART

Product Name	Verséa™ Easy Lab PRO	BD Directigen® EZ RSV	Binax NOW® RSV
Format	20 Cassettes	30 Cassettes	42 cards
CLIA Status	Waived	Moderate	Waived
Sample	Nasopharyngeal swab or aspirate	Nasopharyngeal swab or aspirate	Nasopharyngeal wash
Sensitivity	93.9%	80%	89%
Specificity	97.7%	91%	98%
Procedural Steps	4	5	3
Time to Result	15 minutes (can read up to 25 minutes)	15 minutes (can read up to 60 minutes)	15 minutes (+ or - 0 minutes)
Shelf Life	12 Months	12 Months	12 Months
Storage	Room Temperature	Room Temperature	Room Temperature

To order visit: rperryman@versea.com, or contact us at 1.619.961.5888