



Rapid Check® RSV Antigen Test Cassette

For Prescription Use Only | CLIA-Waived | For *In Vitro* Diagnostic Use

POC



Detect in Minutes, Protect with Confidence

The Rapid Check® RSV Antigen Test Cassette is a rapid, qualitative test for the 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.

See the Instructions for Use for the full intended use.

Key Features & Benefits

- **Rapid Detection For Efficient Patient Management**

Results available in just 15 minutes, enabling timely clinical decisions

- **User-Friendly, CLIA-Waived Testing**

Designed for ease of use by minimally trained healthcare professionals

- **Range of Sample Types**

Nasopharyngeal swab & nasal aspirates specimens

- **High Accuracy Test Performance***

PPA: 93.9%, NPA: 97.7%

- **Transport Medium Compatibility**

Allows for analysis of preserved or transported specimens

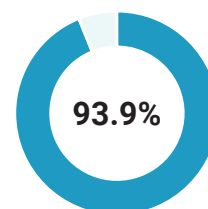
- **External Quality Controls Included**

Facilitating routine quality assurance and regulatory compliance

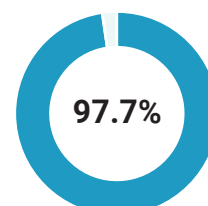
- **Extended Shelf Life That Spans Viral Seasonality**

24-month stability from date of manufacture at room temperature storage

Positive Percent Agreement (PPA)

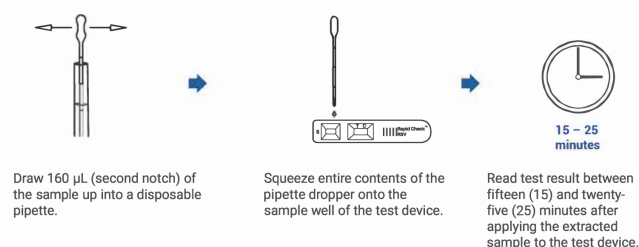
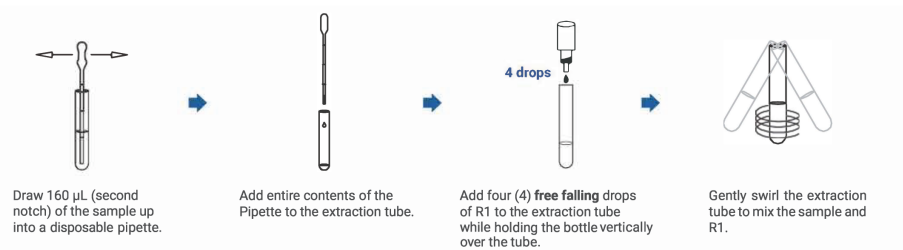


Negative Percent Agreement (NPA)

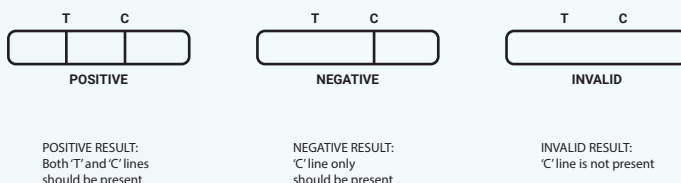


* Nasopharyngeal swab and nasal aspirates. Refer to the Instructions for Use for additional performance claims.

Test Procedure & Result Interpretation



RESULT INTERPRETATION



Please refer to the Instructions for Use for the complete, detailed test procedure and interpretation of results.

KIT CONTENTS

- 20 Individually Packaged Test Devices (Cassettes)
- 20 Nasopharyngeal Swabs
- 20 Extraction Tubes
- 20 Phosphate Buffered Saline (PBS) Vials*
- 20 Extractions Tubes
- 40 Disposable Pipettes
- 1 Positive Control Reagent (PC)
- 1 Negative Control Reagent (NC)
- 1 Extraction Reagent Solution (R1)
- 1 Instructions for Use (IFU)
- 1 Quick Reference Instructions (QRI)

* For specimen processing

Storage & Stability

Store the kit refrigerated or at room temperature 2-30°C (36-86°F). Keep dry and 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. The lot number and expiration date are listed on the label.

Ordering Information

Product Description	Catalog No.	Format	Kit Size
Rapid Check® RSV Rapid Antigen Test Cassette	GCRSV-502b-PBS	Cassette	20 Tests/Kit

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