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QUICK REFERENCE INSTRUCTIONS (QRI)

ADALTIS

RAPiDgen®

SARS-CoV-2 Ag Test

REF RE161000EU Σ20 RE161000EUP Σ1 IVD CE

A rapid, easy-to-use test for the detection of SARS-CoV-2 Antigen (nucleocapsid protein) from human nasal secretion samples collected with a sterile nasal swab.

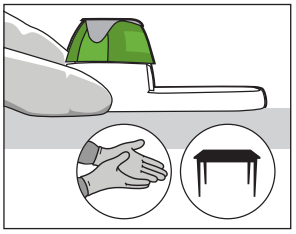
- This test is for use by healthcare workers and labs only
- The test is intended for all ages

HIGHLIGHTS

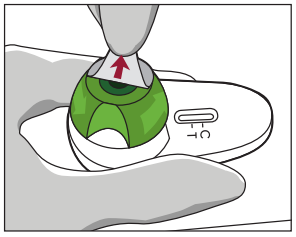
- Wear gloves before using the test.
- Read and follow the directions carefully for an accurate result.
- You need good lighting to view the test result.
- Use a flat, horizontal surface when performing the test.
- Do not use this test if you drop the device after taking off the aluminum seal from the green cap.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Use only sterile swabs included in kit to obtain nasal specimens.
- Please ensure that an appropriate amount of sample is used for testing in order to avoid deviation of results

INSTRUCTIONS FOR USE

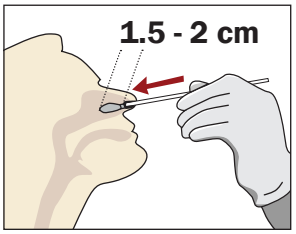
1 **1a.** Tear open the foil pouch to remove the test device. Place the device upright, on a **flat, horizontal surface**. Keep the device in this position while you perform the test.



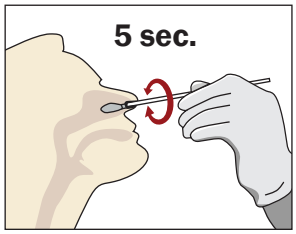
1b. Firmly hold the device upright. Carefully remove the aluminum seal. Be careful not to spill the liquid in the bottom of the green cap.



2 **2a.** Remove the swab from the wrapper. Have patient blow his/her nose. Tilt head back slightly. Gently insert the swab into the middle part of the nostril 1.5-2 cm.

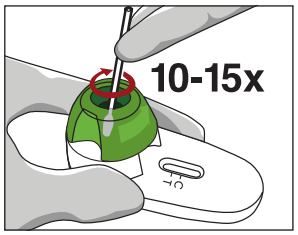


2b. Rotate the swab for 5 sec along the sidewall of the patient's nose. Slowly pull the swab out while rotating it. Repeat procedure in opposite nostril using the same swab.

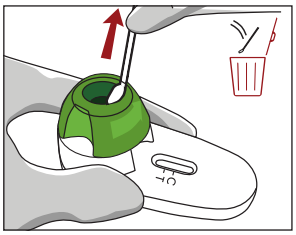


3 **3a.** Place the swab into the opening of the green cap.

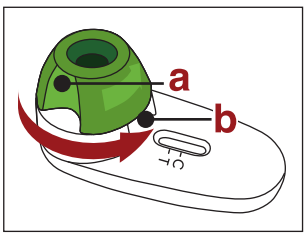
Swirl the swab 10 – 15 times.



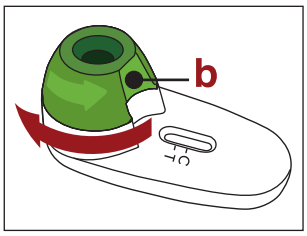
3b. Press the swab gently against the inside of the green cap and then remove it. Dispose of the swab in the according to safety regulations.



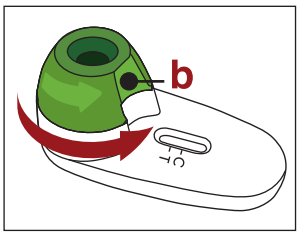
4 **4a.** Firmly holding the device **upright on a flat, horizontal surface**, turn the green cap from position a to **position b**.



4b. Turn the green cap back to **position a**. **Repeat 4a & 4b two more times.**



4c. Firmly holding the device upright on a flat, horizontal surface, turn the green cap from position a to **position b**.



5 Read the results after 10 minutes.

5a. Start timing. Wait for the colored lines to appear. Read your result at **10 minutes**.
NOTE: **If a green line at the "C" (Control Line) does not appear, repeat Steps 4a and 4b.**

5b. If two colored lines do not appear, wait **10 more minutes** to read your result (total time **20 minutes**).
NOTE: **Do not read after 20 minutes as your result will no longer be accurate.**

Turn the page over for steps to read and interpret your results. ➤

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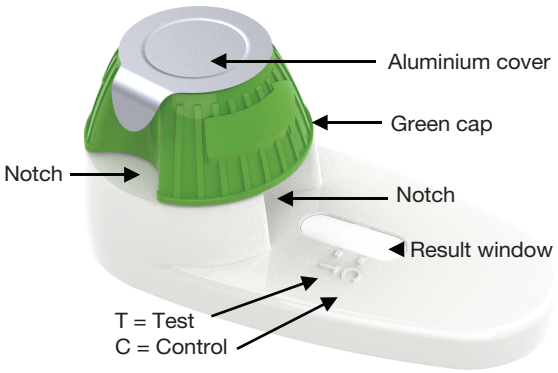
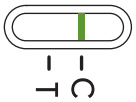
QUICK REFERENCE INSTRUCTIONS (QRI)



Sterile nasal swab

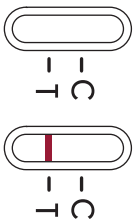
6 Steps to Read and Interpret the Results:

Look for a green line at the “C” (Control line). If a line appears at the “C”, your test is working proprly. It does not matter how light or dark the line is.



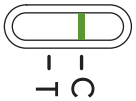
INVALID RESULT

If no green line appears at the “C”, your test is not working properly (INVALID). Retest using a new device and swab.



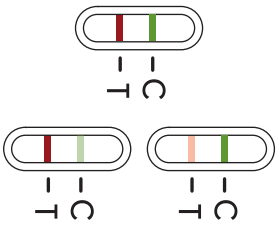
NEGATIVE RESULT

If a line aapears only at the “C” (green), and no line at the “T” (red test line), your test result is NEGATIVE.



POSITIVE RESULT

If a line appears at the “C” (green) and at the “T” (red), your test result is POSITIVE. It does not matter if one of the lines is lighter or darker than the other.



After reading the results, dispose of the device and the swab according to safety regulations.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Refer to www.adaltis.net for the Safety Data Sheet

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RE161000EU RE161000EUP

Kit content:

- Foil pouch containing a single-use-test device ..... x 20 ..... x 1
- Individually wrapped sterile swab ..... x 20 ..... x 1
- Package insert ..... x 1 ..... x 1
- Quick Reference Instructions (QRI) ..... x 1

Materials required but not supplied:

- Watch / timer, medical gloves

PRODUCT INFORMATION

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature (2-30°C). DO NOT FREEZE.
- The test device must remain in the sealed pouch until use.
- The test device is stable through the expiration date printed on the sealed pouch. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

- Do not use if the sealed foil pouch is torn or perforated.
- The test only works if you follow the instructions carefully.
- Do not use if the aluminium cover on the test device is damaged.
- Do not use if any of the package contents are missing, broken, or have been opened.
- Do not open any of the contents of the kit until you are ready to begin your test.
- The RAPiDgen® SARS-CoV-2 Ag Test can only be used once.
- Do not use the test device after the expiration date stamped on the outside of the box.
- Store in a dry place at room temperature between 2-30°C.
- Not to be taken internally.
- Throw the device and swab according to safety regulations.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Use only sterile swabs included in kit to obtain nasal specimens.

LIMITATIONS

1. The RAPiDgen® SARS-CoV-2 Ag test is for in vitro diagnostic use only.
2. Being a qualitative test, no conclusions of a quantitative nature may be derived following its results.
3. The SARS-Cov-2 Ag test will indicate the presence of SARS-Cov-2 nucleocapsid protein antigens in nasal swab specimens only, while performance with other specimens has not been assessed.
4. The test detects SARS-CoV-2 nucleocapsid protein antigens of both viable and non-viable SARS-CoV-2 virus.
5. A negative test result may also stem from an antigen level below the detection limit of the test, or from improper specimen collection, handling, storage and preparation. Therefore, a negative result does not eliminate the possibility of SARS-CoV-2 infection and should not be used as the sole basis of diagnosis, exclusion of infection or infection status.
6. For patient management a negative result should be considered as presumptive and confirmation with other methods (molecular, culture, or ELISA) may be performed as required.
7. A negative result does not rule in or rule out infection with other bacterial or viral pathogens including other coronavirus stains. If a differentiation of specific SARS viruses and strains is required, additional testing is needed.
8. Positive test results do not rule out co-infections with other pathogens.
9. Positive test results do not differentiate between SARS-CoV strains.

Sensitivity and Specificity

For all study participants the antigen rapid test correctly identified 91.87% of infected participants, and 99.04% of non-infected participants (Table 1).
For patients with a relatively high viral load (Ct≤30), the relative sensitivity was 95.74% (N=188) (Table 1).
For patients tested by self-collection and testing, the relative sensitivity was 87.23% (Ct≤30, N=47), and the relative specificity 98.68% (N=151).
(Table 13.2 in IFU).

(Clinical evaluation info find in section13.1IFU).

Analytical Sensitivity - Limit of Detection (LoD):

The study used “ZeptoMetrix / 0810589CFHI /2020 / Italy” strain. The titer of cultured virus was confirmed by PCR. The cell is inactivated and spiked into Nasal swab specimen. The LoD is 4×10^2 $TCID_{50}$/mL. (Table 13.3 IFU).

- There was no cross-reaction with potential cross-reactive agents listed. (Table 13.4 IFU).
- There was no interference for potential interfering substances listed. (Table 13.5 in IFU).
- High-dose Hook Effect: SARS-CoV-2 cultured virus was spiked into specimen. SARS-CoV-2 cultured virus did not show hook-effect at 1 X 108 $TCID_{50}$/mL. (Table 13.6 IFU).

For further information

Please read the **Instructions for use** for more complete information. You can get it free of charge from Internet web site: **www.adaltis.net**;

If the Instructions for Use of a specific product cannot be found in the web site please contact our Customer Care:
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e-mail: **info@adaltis.net**

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