Reszon Diagnostics International Sdn. Bhd.
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Setia Alam, Seksyen U13, 40170 Selangor Darul Ehsan, Malaysia.

Reszon COVID-19 Rapid Antigen Test (Saliva sample)

(A rapid test for detection of COVID-19 antigen)

CE IVD

FOR PROFESSIONAL USE ONLY
NOT FOR HOME TESTING

INTENDED USE

Reszon COVID-19 Rapid Antigen Test *(Saliva sample)* is an immunochromatographic assay designed for the qualitative detection of specific SARS-CoV-2 antigen in human saliva specimen. It is intended to be used for the detection of SARS-CoV-2 virus infection. The results obtained should not be the sole determinant for clinical decision.

SUMMARY AND EXPLANATION OF THE TEST

A novel coronavirus (2019-nCoV, renamed as SARS-CoV-2 by WHO) was identified in early January 2020 as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.[1] It has since become an international health concern and declared a pandemic by WHO. According to WHO, laboratory tests in suspected cases of SARS-CoV-2 should be performed using samples collected from the upper respiratory tract, such as nasopharyngeal and oropharyngeal swab as well as lower respiratory specimens: sputum and/or endotracheal aspirate or bronchoalveolar lavage. However, these diagnostic methods have some disadvantages, such as patient discomfort and bleeding or coughing, may occasionally occur; risk of contamination by healthcare professionals, the need for specific equipment, in addition to the limitation of sputum samples.[2] Therefore, a lot of studies has been conducted using saliva as an alternative for diagnostic samples as saliva has several advantages, such as easy self-collection even at home, and no need of specialized personnel for sample collection. In addition, saliva collection is much more comfortable for the patient than nasopharyngeal swabs procedure. It also saves time, and is less costly, because it does not require the use of personal protective equipment nor viral transportation solution.[3] With the emergence of SARS-CoV-2, because of the simplicity of acquiring the saliva samples added to all the advantages stated before, the diagnosis through saliva made even more relevant in the current scenario and new studies have emerged to evaluate this method. Recent studies have shown high detection rate (80%-95%) when using saliva as specimens for laboratory diagnosis of respiratory viruses including SARS-CoV-2. [3,4,5,6]

PRINCIPLE OF THE TEST

The ***COVID-19 Rapid Antigen Test*** is a qualitative membrane-based assay for the detection of SARS-CoV-2 in saliva specimen. The target antigen in the specimen, if present, will react with gold conjugated anti-SARS-CoV-2 antibody and form an antibody-antigen complex. As this complex migrates along the length of the nitrocellulose membrane, it is captured by pre-coated anti-SARS-CoV-2 antibody located in the test (T) region on device test area, causing a pale to dark pink-purplish band. If the specimen does not contain SARS-CoV-2 antigens, no coloured line will appear in the test line region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS SUPPLIED

	RCV-RD0201S-01	RCV-RD0201S-10
COVID-19 Rapid Antigen Test cassette *individually sealed in foil pouch with desiccant*	1 pcs	10 pcs
Extraction Buffer	1 pcs	1 pcs
Extraction tube and dripper	1 set	10 sets
Saliva collection sponge	1 pcs	10 pcs
Saliva collection tube	1 pcs	10 pcs
Instruction for Use (product insert)	1 pcs	1 pcs

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Sample collection and preparation device and equipment
2. Clock or timer

STORAGE AND STABILITY

Store at 4-30ºC, do not freeze. Keep the test device sealed until used. Keep away from direct sunlight, moisture and heat.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostics use only. Not for Home Testing.
2. This product insert must be strictly followed in order to produce accurate test results.
3. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
4. All test devices, reagents and specimens must be at room temperature (15-30°C) before running the assay.
5. Do not use device if the sealed pouch is visibly damaged.
6. Do not use the kit contents beyond the expiration date.
7. Avoid cross-contamination by using a new specimen extraction tube and dripper for each specimen preparation.
8. Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste following the standard procedure.
9. Wear protective clothing such as lab coat, disposable gloves and eye protection gear when specimens are being tested.
10. Wipe any spills of samples specimen promptly with 1% sodium hypochlorite solution or other disinfectant.
11. Do not reuse test device.

LIMITATION OF THE TEST

1. This product is designed for use with saliva swab specimen only.
2. This test detects the presence of specific SARS-CoV-2 antigen in the specimen and should not be used as the sole criterion for the diagnosis of a SARS-CoV-2 viral infection.
3. The results obtained should be interpreted in conjunction with other diagnostic results and clinical information available to the physician.
4. The test is a qualitative assay and it is not for quantitative determination of antigen concentration level. The intensity of the band does not have linear correlation with the antigen titer of the specimen.
5. The performance of the test depends on antigen load in the specimen and may not correlate with PCR performed on the same specimen.
6. Inadequate or inappropriate specimen collection, storage, and transportation may cause false negative results.
7. If the test result is negative but symptoms persist, and a SARS-CoV-2 infection suspicion still exists, it is recommended to retest later or proceed follow-up testing using other clinical methods, for example RT-PCR method.
8. A negative result at any time does not exclude the possibility of an early infection of SARS-CoV-2 virus. A negative result can occur if the quantity of SARS-CoV-2 virus antigen present in the specimen is below the detection limits of the assay.

SAMPLE COLLECTION AND PREPARATION

Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste.

1. To collect **saliva specimen**
   - It is important to obtain as much saliva as possible. Insert a sterile saliva collector sponge into the mouth cavity for at least 3 minutes.
   - As the sponge will stimulate saliva production, gently bite and move the sponge around the mouth cavity to collect more saliva.
   - Put the sponge in saliva collector tube, then push and squeeze the sponge to collect the saliva at the bottom of the tube as much as possible, recap the saliva collection tube. Approximately 500 µl or more saliva should be collected.
   - Add 150 µl (~5 drops) of sample extraction buffer provided with the test kit to the extraction tube and transfer 100 µl (~3 drops) of saliva collected into the same extraction tube.
   - Cover the dripper head and mix the sample solution thoroughly.
2. Testing should be performed immediately after the specimen has been collected. Do not expose the specimen at room temperature for prolonged period. Samples are stable up to 30 mins when kept in the extraction buffer provided with the test kit.
3. If saliva collected not able to rewet the sponge, or less than 500 µl, or the saliva collected too high viscosity and fail to be transferred to the collection tube, a new saliva specimen should be collected. The subject maybe advises to drink a glass of plain water, wait for 10 minutes and repeat the saliva collection steps above.

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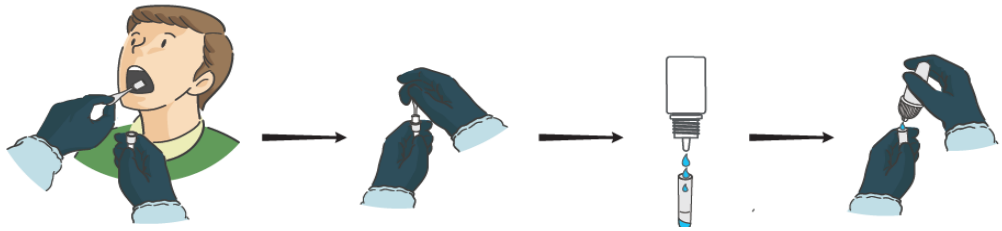
SAMPLE PREPARATION　サンプルの準備手順



唾液採取スポンジを、十分に唾液を吸収するまで最長３分程度、口の中で易しく噛んだり、軽く動かす

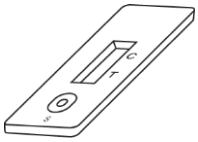
唾液が十分に吸収された後、スポンジを唾液採取ボトルに押し当て、唾液を0.5ml程度絞り出す

抽出チューブへバッファー液を５滴垂らす

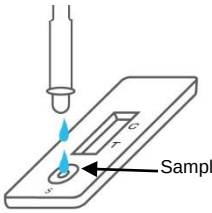
唾液採取ボトルから抽出チューブへ採取済みの唾液を３滴垂らし、チューブを軽く振るなどしてバッファー液と唾液をよく混合させる

ASSAY PROCEDURE　診断手順

1. 診断カセットをアルミパウチから取り出し、平らな作業台に設置する



2. 必要に応じて、検査者名や日付のラベル等を添付する

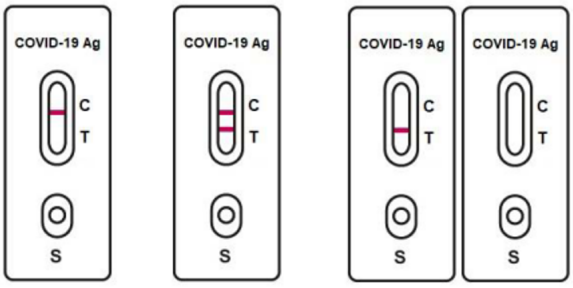


3. 抽出チューブから、診断カセットへ混合液を２滴垂らす。その際、気泡などが無い様注意する

4. 結果が出るまで10分から15分待つ

***20*分以上経過したあとに表示された結果は無効とする**

INTERPRETATION OF RESULTS　診断結果



1. **陰性**
   Cラインのみ表示された場合、SARS-CoV-2ウイルスへの抗原が確認されなかったことを表します。
   ＊COVID-19への感染の可能性を排除するものではございません。

2. **陽性**
   CとTラインの両方が表示された場合、SARS-CoV-2ウイルスへの抗原が確認されたことを表します。

3. **無効**
   Ｃラインが表示されない場合、結果を無効とします。

ASSAY INTERPRETATION GUIDELINES

Read the results within 15 minutes. Do not read the results after 20 minutes. Not following this procedure can lead to inaccurate results.

WARRANTY AND LIMITED LIABILITY

The performance characteristics stated were obtained by using the assay procedure in this insert. Failure to follow the assay procedure may derive inaccurate results. In such event, the manufacturer disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

The manufacturer will not be liable for any damage caused by misuse, improper handling and storage, non-compliance with warnings and procedures, damage caused by events occurring after the product is released, failure to ensure the product is in proper condition before use, or any warranty given by independent distributor.

REFERENCES

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china
2. Muniz IAF, Linden LV, ME, Rodrigues RCS, Souza JR, Oliveira RAS, et al. SARS-CoV-2 and saliva as a diagnostic tool: A real possibility. Pesqui Bras Odontopediatria Clín Integr. 2020; 20(supp1):e0112.
3. Azzi, L, Carcano, C, Giafagna, F, Grossi, P et al. Saliva is a reliable tool to detect SARS-CoV-2 Journal of Infection 81 (2020) e45–e50
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ORDER INFORMATION

Product Code	*Description*	*Packing Size*
RCV-RD0201S-01	**Reszon COVID-19 Rapid Antigen Test (with saliva collection set)**	**1 test / kit**
RCV-RD0201S-10	**Reszon COVID-19 Rapid Antigen Test (with saliva collection set)**	**10 tests / kit**

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