Clinical Validation report of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

Product name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

Package Specification: 25 tests/kit

Manufacturer: Hangzhou Realy Tech Co., Ltd
I. Clinical validation time
This clinical evaluation was conducted from November 2020 to January 2021.

II. Background information for clinical evaluation
Since December 2019, world has successively discovered multiple cases of patients with new-type coronavirus pneumonia. With the spread of the epidemic, China and abroad have also been found. As an acute respiratory infectious disease, the disease has been included in the Class B infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases, and is managed as a Class A infectious disease. Based on the current epidemiological investigation, the incubation period is 1-14 days, mostly 3-7 days. The main manifestations are fever, dry cough, and fatigue. A few patients have symptoms such as nasal congestion, runny nose, sore throat, myalgia and diarrhea. Severe patients usually have dyspnea and / or hypoxemia one week after the onset of symptoms, and severe patients can quickly progress to acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, coagulation dysfunction and multiple organ Functional failure, etc. It is worth noting that in the course of severe and critically ill patients, there may be moderate to low fever, even without obvious fever. Mild patients showed only low fever, mild fatigue, and no pneumonia. Judging from the current cases, most patients have a good prognosis, and a few patients are critically ill. The elderly and those with chronic underlying disease have a better prognosis. Symptoms in children are relatively mild.

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) developed by our company can help diagnose whether patients are infected with the Novel Coronavirus. It has further enriched the detection methods of Novel Coronavirus, expanded the supply of detection reagents, and fully served the needs of epidemic prevention and control.

III. Test purposes
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) produced by Hangzhou Realy Technology Co., Ltd. was used to verify the feasibility of clinical evaluation and the reliability of test results for Chinese subjects. The purpose of research of the clinical test is to calculate the consistency percentage of negative/positive and the total consistency percentage and Kappa coefficient by statistically analyzing test results through comparative experimental research.

IV. Test design
1. Test plan selection and reasons
In vitro diagnostic reagents for testing and reference reagents were used to conduct comparative research tests on clinically suspected Novel Coronavirus Nasal swab samples, and it was proved that the in vitro diagnostic reagents used in the test can achieve the expected assistance in infection of the Novel Coronavirus.

2. Sample volume required
The total number of clinical trials of this product is not less than 100 cases. The samples is classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the samples shall be tested via the qualitative test strip tested and by reference product from the same patient and then the test results of the product tested and the reference product shall be compared, with statistical analysis being made.

3. Sample inclusion/exclusion certification.
The positive group and negative group in this experiment are applicable to the following inclusion/exclusion criteria

**Positive group inclusion:**
- PCR Test is positive;

**Negative inclusion:**
- PCR test is negative;

**Sample collection, processing**
It is applicable to the diagnosis of the Novel coronavirus from the samples of Nasal swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

**Sample collection procedure:** Tilt the patient’s head back 70 degree, while gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinate). Rotate the swab five times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril. Slowly remove swab from the nostril.

**Caution:** If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

**Specimen preparation:**
1) Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.
2) Insert the swab into the extraction tube which contains Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab, remove the swab. The extracted solution will be used as test sample.

4. **In vitro diagnostic reagents and reference products for testing**

5.1 **Test in vitro diagnostic reagents**

**Name:** The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

**Specification:** 25 tests/kit

**REF:** K601416D

**LOT:** 202011098

**Expiry:** November, 2022 (Tentative)

**Storage Conditions:** Store in a dry place at 2-30°C, protected from light. After opening the inner package, the test card will become invalid due to moisture absorption. Please use it within 1 hour.

**Source:** Hangzhou Realy Tech Co., Ltd

5.2 **Reference products**

**Name:** Novel Coronavirus (2019-ncov) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

**Manufacturer:** Sansure Biotech Inc.

**Limit of detection:** The limit of detection of this kit is 200 copies/mL

**Storage Conditions:** Store in a dry place at 2-8°C, protected from light.

V. **Experiment method**

1. Get the Swab specimens from patients in positive and negative groups.
2. Pre-process the swab samples according to the instructions of The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab), and label the samples randomly.

2.1 Add 10 drops (about 0.3 ml) of the sample extraction buffer into the extraction tube.

2.2 Place the swab specimen in the SARS-Cov-2 antigen Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

2.3 Remove the swab while squeezing the swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

2.4 Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the Buffer. Place the test device on a clean and level surface.

3. The operation steps of the in vitro diagnostic reagents for the test are as follows. For details, please refer to the product instruction manual:

3.1 remove the test sample and required reagents from the storage conditions and equilibrate to room temperature (15-30°C).

3.2 When preparing for testing, open the aluminum foil bag from the tear. Remove the test card and lay it flat on a horizontal table.

3.3 Label the sample number on the test card.

3.4 Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer.

3.5 Time counting and interpret the results within 10 minutes.

Note: The detection steps need to be completed under protection against infection.

VI. Statistical methods of statistical analysis of clinical research data

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the product tested and the reference product, to validate the accuracy and applicability of the product in clinical applications. The product tested shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile, different types of sample of the subjects shall be subject to determination by the product tested synchronously, and then the determination results of both shall be compared. The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples, to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes.

B Statistical method

The products launched on the market shall be subject to comparative study and evaluation. Kappa inspection: each sample shall be tested with the product tested and the reference product respectively, and then the consistency in statistical results of these two inspection methods shall be compared.
through Kappa inspection. The data shall be subject to Kappa inspection and analysis and the Kappa coefficient shall be calculated. Favorable consistency can be proven if Kappa is $\geq 0.8$. The consistency in test results of the product tested and the reference product is evaluated as per the evaluation standards.

**VII Standards of clinical evaluation**

The coincidence rate shall be calculated by comparing with the reference product whose marketing is approved. The product performance shall meet the following requirements.

1) Coincidence rate of negative: the sample whose test results are negative for both the product tested and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 95%.

2) Coincidence rate of positive: the sample whose test results are positive for both the product tested and the reference product and the proportion in the sample whose test results are positive for the reference product shall be more than 85%.

3) Total coincidence rate: the sample whose test results are the same for the product tested and the reference product and its proportion in the total number of samples shall be more than 90%.

<table>
<thead>
<tr>
<th>Method</th>
<th>2019-nCoV nucleic acid test kit (RT-PCR)</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)</td>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>positive</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>negative</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Total Results</td>
<td>A+C</td>
<td>B+D</td>
</tr>
</tbody>
</table>

Clinical sensitivity $\text{Clinical sensitivity} = \frac{A}{A+C} \times 100\%$

Clinical specificity $\text{Clinical specificity} = \frac{D}{B+D} \times 100\%$

Accuracy: $\text{Accuracy} = \frac{A+D}{(A+B+C+D)} \times 100\%$

If the coincidence rate of positive/negative can meet clinical requirements, two methods or products are considered as equivalent; If the coincidence rate of positive/negative is greatly different, the clinical scheme should be re-designed.

4) Kappa consistency analysis shall be adopted for statistical analysis of reference reagents.

The results of the product tested are statistical materials and can be per the table below:

<table>
<thead>
<tr>
<th>Method</th>
<th>2019-nCoV nucleic acid test kit (RT-PCR)</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)</td>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>positive</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>negative</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Total Results</td>
<td>A+C</td>
<td>B+D</td>
</tr>
</tbody>
</table>

$P_{0} = \frac{(A+D)}{(A+B+C+D)} \times 100\%$

$P_{e} = \frac{(A+B)(A+C) + (A+B)(B+D)}{(A+B+C+D)}$ $\times (A+B+C+D)$

Kappa: $P_{0} - P_{e}$/(1-$P_{e}$)

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If conducting Kappa consistency analysis for the base data above, high consistency can be judged if the Kappa coefficient is >0.8, and both systems are considered as equivalent. Consistency is considered if 0.4<Kappa coefficient <0.8, and the coincidence rate of positive/negative shall be compared, with statistical analysis being made. Two such systems are considered as inconsistent and inequivalent if the Kappa coefficient is <0.4.

VIII Provisions for amendments to clinical validation
In general, the clinical validation should not be changed. Any modification to the project during the test should be explained, and the time, reason, process of change, and whether there is a record of the change are explained in detail and its impact on the evaluation of the entire research result is explained.

IX. Results and Analysis of Clinical Tests
In total, 195 test samples are included for the unit and all test samples included are tested. There are 186 positive test samples.

<table>
<thead>
<tr>
<th>Days from diagnosis</th>
<th>Positive</th>
<th>Negative</th>
<th>Total Number Tested</th>
<th>Detectable rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3</td>
<td>132</td>
<td>3</td>
<td>135</td>
<td>97.78%</td>
</tr>
<tr>
<td>4-7</td>
<td>54</td>
<td>6</td>
<td>60</td>
<td>90%</td>
</tr>
<tr>
<td>Total</td>
<td>186</td>
<td>9</td>
<td>195</td>
<td>/</td>
</tr>
</tbody>
</table>

Statistics on test results and those of the product tested are as follows:

<table>
<thead>
<tr>
<th>Method</th>
<th>2019-nCoV Nucleic Acid Test Kit (RT-PCR)</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (nasal swab)</td>
<td>Results</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>186</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>9</td>
<td>430</td>
</tr>
<tr>
<td>Total Results</td>
<td>195</td>
<td>430</td>
</tr>
</tbody>
</table>

Clinical sensitivity = 95.38 % (95%CI* 91.34% to 97.67%)
Clinical specificity = 430/430>99.9% (95%CI* 98.93% to 100%)
Accuracy=98.56% (95%CI* 97.24% to 99.28%)

P0=0.99
PE=0.58
Kappa:( P0 - PE)/(1-pE) =0.97
*.95% confidence interview

According to the above table, 430 are proven negative of 430 negative specimens, 186 are proven positive of 195 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.97>0.8, indicating favorable and high consistency of two methods and equivalence of two such systems.

X Analysis on consistency in Test Results

<table>
<thead>
<tr>
<th>Consistency result number</th>
<th>RdRP gene Ct/Cq value</th>
<th>N gene Ct/Cq value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximum</td>
<td>Minimum</td>
</tr>
<tr>
<td>186</td>
<td>33.96</td>
<td>14.15</td>
</tr>
</tbody>
</table>
According to the test result, there are 186 samples have the consistency results for rapid test and RT-PCR. For qualitative rapid test, the result will showed positive, negative and invalid, for RT-PCR detection, the Ct/Cq value will indicate the result. Ct/Cq value > 40 means the detection result is negative, in our validation test, the amount of both RdRP and N gene Ct/Cq value are all below 40 is 195. The median of RdRP gene Ct/Cq value is 22.72, while the RdRP gene Ct/Cq value is 23.03.

### XI Analysis on Inconsistency in Test Results

<table>
<thead>
<tr>
<th>NO.</th>
<th>Age</th>
<th>Gender</th>
<th>Rapid Test</th>
<th>Ct/Cq value (RT-PCR)</th>
<th>Clinical diagnostic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RdRP</td>
<td>N gene</td>
</tr>
<tr>
<td>11</td>
<td>74</td>
<td>M</td>
<td>Negative</td>
<td>&gt;40</td>
<td>32.12</td>
</tr>
<tr>
<td>37</td>
<td>32</td>
<td>M</td>
<td>Negative</td>
<td>&gt;40</td>
<td>31.62</td>
</tr>
<tr>
<td>70</td>
<td>82</td>
<td>F</td>
<td>Negative</td>
<td>30.21</td>
<td>&gt;40</td>
</tr>
<tr>
<td>93</td>
<td>29</td>
<td>M</td>
<td>Negative</td>
<td>&gt;40</td>
<td>30.56</td>
</tr>
<tr>
<td>107</td>
<td>83</td>
<td>M</td>
<td>Negative</td>
<td>19.08</td>
<td>&gt;40</td>
</tr>
<tr>
<td>123</td>
<td>42</td>
<td>F</td>
<td>Negative</td>
<td>&gt;40</td>
<td>29.62</td>
</tr>
<tr>
<td>146</td>
<td>16</td>
<td>M</td>
<td>Negative</td>
<td>&gt;40</td>
<td>26.56</td>
</tr>
<tr>
<td>163</td>
<td>76</td>
<td>F</td>
<td>Negative</td>
<td>31</td>
<td>&gt;40</td>
</tr>
<tr>
<td>184</td>
<td>26</td>
<td>M</td>
<td>Negative</td>
<td>&gt;40</td>
<td>28.16</td>
</tr>
</tbody>
</table>

### XII Discussion and Conclusions

1. **Discussion**

A Results of comparative analysis of the product tested and the reference product:

Test results of Swab specimen tested and the reference result: both the coincidence rate of negative/positive and the total coincidence rate are larger than 85%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

2. **Test Conclusions**

By analyzing the test results of the product tested and the reference product, the consistency percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems and can be used for auxiliary diagnosis of those suffering from pneumonia triggered by COVID-19.

### XIII. Quality control methods

On-site quality control

1. During the course of this study, clinical implementors appointed clinical inspectors to conduct regular on-site supervision visits to the research hospital. Through monitoring visits, it was found that all the contents of the research plan were strictly observed, and the correctness of the research data was also guaranteed. Participating researchers have undergone unified training, unified recording methods and judgment standards. The entire clinical trial process is conducted under strict operation, and the test content is complete and authentic. All observations and findings in the clinical trials have been verified and the data are reliable. The conclusions in the clinical trials are derived from the original data.

2. Quality control of clinical experiment process

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During the evaluation, quality control was performed daily to ensure that the product was under control. Strict quality control is performed for each trial to ensure the quality of clinical trials.

**XIV. Prediction of adverse events**

Because the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) is an in vitro diagnostic reagent product, no direct contact with patients is required in clinical trials, no test report is provided to patients, and the test results are only used for comparative studies. It involves personal privacy, does not serve as a basis for auxiliary diagnosis, does not bring any risk to the subject, and does not cause adverse events.

**References:**

1. The "Technical Review Points for the Registration of New Coronavirus Antigen / Antibody Detection Reagents in 2019 (Trial)" issued by the State Drug Administration Medical Device Technical Evaluation Center on February 25, 2020;
2. "Pneumonitis Diagnosis and Treatment Program for New Coronavirus Infection (Trial Version 7)" issued by the National Health Committee on February 19, 2020.
Annex I: Package Insert

**Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (nasal swab)**

**Package Insert**

**INTENDED USE**

The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (nasal swab) is an in vitro diagnostic test for the qualitative detection of Coronavirus Disease 2019 (COVID-19) in human nasal swab specimens using the rapid immunochromatographic method as an aid in the diagnosis of novel coronavirus infection. It will provide information for clinicians to diagnose confirmed novel coronavirus disease.

**SUMMARY**

The novel coronavirus testing is in operation that causes an acute respiratory disease. People are generally susceptible. Currently, the pathogen is the novel coronavirus, and the main route of infection, a respiratory infection, can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, with a median of 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. The disease is diagnosed through polymerase chain reaction (PCR) tests, chest CT imaging, or serological tests. The novel coronavirus is a respiratory virus that primarily affects the respiratory tract. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), an enveloped, single-stranded positive-sense RNA virus, is the cause of the Coronavirus disease (COVID-19). The novel coronavirus is contagious. SARS-CoV-2 has several structural proteins, including spike (S), envelope (E), membrane (M), and nucleoprotein (N). At present, there are many variants of the Novel Coronavirus (SARS-CoV-2), and the NI90Y mutation and its spurious variants have also affected this disease. Because the infection is transmitted in the air, the transmission is generally through airborne droplets. The coughing process of infected individuals effectively spreads the novel coronavirus from the respiratory tract of sick persons. Therefore, in addition to personal protection, there is also epidemic prevention. The novel coronavirus test results are not effective for the primary diagnosis of non-coronavirus disease.

**PRINCIPLE**

The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (nasal swab) uses highly sensitive monoclonal antibodies to novel coronavirus. The test area is composed of the following three parts: sample pad, reagent pad, and control area. The monoclonal antibodies in the reagent pad are coated with two antibodies specific to novel coronavirus antigens. The monoclonal antibodies against novel coronavirus will remain intact in the presence of high concentrations of novel coronavirus antigens, while the antibodies against novel coronavirus will be effectively removed when the novel coronavirus concentration is low. The test area is coated with a group of antibodies specific to novel coronavirus antigens. When the antigen concentration is low, the test area will be blocked, and a negative result will be obtained. When the antigen concentration is high, the test area will not be blocked, and a positive result will be obtained.

**REAGENT**

The reagent contains the antibody-gold conjugate with the monoclonal antibodies. The reagent is a freeze-dried product that remains stable during the storage and transportation. The reagents are available as a dry agent for use in the test. The reagents should be used within 1 year from the date of manufacture. The reagents should be used within 1 year from the date of manufacture. The reagents should be used within 1 year from the date of manufacture.

**PRECAUTIONS**

- **Storage:**
  - Do not store at temperatures below 0°C or above 37°C.
  - Protect from light.
- **Validity:**
  - The test results are valid for 1 hour after preparation.
- **Test:**
  - Perform the test at room temperature (15-30°C).
  - Do not use the device if the packaging is damaged or expired.
- **Sample:**
  - A nasal aspirate containing an adult device is not damaged before opening for use.
- **Test:**
  - Perform the test at room temperature (15-30°C).

**STORAGE AND STABILITY**

The test area is stored in a dry place. The test area is stable at room temperature (15-30°C) for at least 1 year. After effusing the reagents, store the test area at room temperature (15-30°C) for at least 1 year. After effusing the reagents, store the test area at room temperature (15-30°C) for at least 1 year. After effusing the reagents, store the test area at room temperature (15-30°C) for at least 1 year.

**SPECIMEN COLLECTION AND PREPARATION**

- **Specimen:**
  - Collection:
    - The patient's head should be tilted 45 degrees. While gently tilting the head, insert ansa swab less than one cm (0.5 cm - 1 cm) into the nasal lumen on the side to be tested. Rotate the swab three times against the nasal wall. Using the same swab repeat the collection procedure with this second nostril.
    - Caution: If the swab stick breaks during specimen collection, discard, repeat specimen collection with a new swab.

**LIMITATIONS**

- **Validity:**
  - The test results are not affected by the following factors:
    - The presence of other respiratory viruses.
    - The presence of bacterial infections.
    - The presence of bacterial infections.
    - The presence of bacterial infections.

**INTERPRETATION OF RESULTS**

(See also the figure for interpretation)

**INTRA-TEST VARIABILITY**

(See also the figure for interpretation)

**INTER-TEST VARIABILITY**

(See also the figure for interpretation)

**INTER-TEST VARIABILITY**

(See also the figure for interpretation)

**REFERENCES**

(See also the figure for interpretation)

**ACKNOWLEDGEMENTS**

(See also the figure for interpretation)

**CONFLICT OF INTERESTS**

(See also the figure for interpretation)

**CONTACT INFORMATION**

(See also the figure for interpretation)

**EQUIPMENT**

(See also the figure for interpretation)

**REFERENCES**

(See also the figure for interpretation)

**TABLES**

(See also the figure for interpretation)

**FIGURES**

(See also the figure for interpretation)

**Annex I: Package Insert**

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**Package Insert**

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- Storage:
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- Validity:
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- Test:
  - Perform the test at room temperature (15-30°C).
  - Do not use the device if the packaging is damaged or expired.
- Sample:
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    - Caution: If the swab stick breaks during specimen collection, discard, repeat specimen collection with a new swab.

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  - The test results are not affected by the following factors:
    - The presence of other respiratory viruses.
    - The presence of bacterial infections.
    - The presence of bacterial infections.
    - The presence of bacterial infections.

**INTERPRETATION OF RESULTS**

(See also the figure for interpretation)

**INTRA-TEST VARIABILITY**

(See also the figure for interpretation)

**INTER-TEST VARIABILITY**

(See also the figure for interpretation)

**REFERENCES**

(See also the figure for interpretation)

**ACKNOWLEDGEMENTS**

(See also the figure for interpretation)

**CONFLICT OF INTERESTS**

(See also the figure for interpretation)

**CONTACT INFORMATION**

(See also the figure for interpretation)

**EQUIPMENT**

(See also the figure for interpretation)

**REFERENCES**

(See also the figure for interpretation)

**TABLES**

(See also the figure for interpretation)

**FIGURES**

(See also the figure for interpretation)
<table>
<thead>
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<th>1:20</th>
<th>1:40</th>
<th>1:80</th>
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<td>Human rhinovirus (SAR-Cov-2 Type 51)</td>
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**Interfering Substances Reaction**

When tested using the Novel Coronavirus (2019-nCoV) Antigen Rapid Test Device (nasal swab), there were no interferences between the device samples and the potential interfering substances listed below that might cause false-positive or negative results for SARS-CoV-2 antigen.

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<td>Whole Blood</td>
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<tr>
<td>Blood</td>
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</tr>
<tr>
<td>Non-Ionic Phosphate Buffer</td>
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<td>Sodium Hypochlorite</td>
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<tr>
<td>Deionized Water</td>
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<tr>
<td>Ethylenediaminetetraacetic acid</td>
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<td>Other interferents</td>
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**Symbols**

- **NS**: In vitro diagnostic medical device
- **EC**: Storage temperature: 2-8°C
- **REP**: Manufacturer authorized representative in the European Union
- **EC**: Use by date
- **EC**: Contraindication or use
- **QRT**: Batch code

**File No. MF-K601416D-0051**
Version: 1.1
Effective date: 2021-03-06
## Annex II: Information of sample

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<th>NO.</th>
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<th>Date of sampling</th>
<th>Days from diagnose</th>
<th>Clinical symptoms</th>
<th>Clinical diagnose</th>
<th>Rapid Test</th>
<th>Ct/Cq value (RT-PCR)</th>
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