# Clinical Study Report of <br> VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Test 

Performance Evaluation--Clinical Study Report

Document No.: TF0025-002
Date of Issue: Nov 11, 2020
Ver 2.0

## 1. Introduction

VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab or throat swab specimen.

## 2. Objective

Compare the clinical performance of VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Test with SARS-CoV-2 RT-PCR Test \& CT by 552 clinical samples.

## 3. Method

### 3.1 Instruments and Materials

VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Rapid Test, Lot: T2007001, SARS-CoV-2 RT-PCR test kit, CT

### 3.2 Samples

Total 552 subjects were invited to participate in this comparison study at 3 clinical sites. All nasal swab samples were obtained from the subjects were analyzed by RT-PCR for the presence of SARS-CoV-2 and CT method was employed to confirm the infection. From the 552 subjects, 431 are negative for SARS-CoV-2 infection and 121 are positive.

Table 1 - Distribution of SARS-CoV-2 clinical specimen tested by RT-PCR \& CT

| SARS-CoV-2 clinical sample (by RT-PCT \& CT) | Quantity |
| :---: | :---: |
| Negative | 431 |
| Positive | 121 |
| Total | 552 |

## Note:

Both nasal swab specimen and throat swab specimen can be used by VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Rapid Test to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on both nasal swab specimens and throat swab specimens, no statistic difference was observed among those specimens.

### 3.3 Procedure

## 1) Specimen collection

## - Nasal swab specimen

In this clinical studies, 552 specimens are collected from the nasal swabs. It is important to obtain as much
secretion as possible.

Insert the sterile swab into one nostril. The swab tip should be inserted up to 2.5 cm ( 1 inch ) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).
Oropharyngeal and Nasopharyngeal are also acceptable for VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Test.

## - Oropharyngeal swab specimen (optional)

It is important to obtain as much secretion as possible. Insert the sterile swab into throat that presents the most secretion from the red area of the throat wall and maxillary tonsils to collect throat swab specimen. Rub the bilateral throat tonsils and throat wall moderately to obtain the specimen. Please do not touch the tongue when remove the swab.

## - Nasopharyngeal swab specimen (optional)

It is important to obtain as much secretion as possible. Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 5 times then remove it from the nasopharynx.


Nasal swab


Oropharyngeal swab


Nasopharyngeal swab

## 2)Specimen handling

Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

## 3)Testing Procedure

Allow the Test Devices and Extraction Solution to equilibrate to $15-30^{\circ} \mathrm{C}$ prior to testing.

1. Add $300 \mu \mathrm{~L}$ extraction solution into extraction tube on tube stand. Please avoid bubbles when operation.

2. Collect specimen refer to Specimen Collection.
3. Insert sterile swab with collected specimen into extraction tube. Roll the swab 5 times. while pressing the head against the bottom and side of the extraction tube. Roll the swab head against the inside of the extraction tube when remove it. Try to release as much liquid as possible. Dispose of the used swab in the biohazard waste.

4. Put on the tube tip.

5. Take out a test device from sealed foil pouch and put it on a clean and level surface
6. Apply 3 drops (about $60 \mu \mathrm{~L}$ ) of extracted specimen onto the specimen well. Please avoid bubbles when operation.

7. Read the test result at 15 minutes. Don't read the result after 20 minutes.


15 min

## Note:

- Do not interchange or mix extraction solution from different lots.
- Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.
- Please follow local regulations to handle the used materials.


### 3.4 Interpretation of Test Results

## Positive result:

Both the quality control line C and the detection line T appear.

## Negative result:

Only the quality control line C appears, with no other line appearing on the detection line.

## Invalid result:

Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.


Positive: Both detection line ( $T$ ) and quality control line (C) appear purplish-red in the detection area.


Negative: Only the quality control line (C) appears in the detection area.


Invalid: No purplish-red quality control line (C) appears in the detection area no matter the detection ( $T$ ) line is colored or not.

## 4. Results and Conclusions

| VivaDiagTM SARS-CoV-2 | PCR (CT value<30) |  |  |
| :---: | :---: | :---: | :---: |
| Ag Rapid Test | Positive | Negative | Total |
| Positive | 115 | 0 | 115 |
| Negative | 6 | 431 | 437 |
| Total | 121 | 431 | 552 |
| Sensitivity | $95.04 \%$ |  |  |
| Specificity | $(115 / 121,95 \% \mathrm{Cl}, 89.60 \% \sim 97.71 \%)$ |  |  |
| Accuracy | $100 \%$ |  |  |
| $(431 / 431,95 \% \mathrm{Cl}, 99.12 \% \sim 100 \%)$ |  |  |  |
| $98.91 \%$ |  |  |  |

The VivaDiagTM SARS-CoV-2 Ag Test showed a clinical sensitivity of 95.04\%.
The VivaDiagTM SARS-CoV-2 Ag Test showed a clinical specificity of $100 \%$.
The VivaDiagTM SARS-CoV-2 Ag Test showed a clinical accuracy of 98.91\%.

From the results of 552 negative and positive samples, we can confirm that VivaDiag ${ }^{\text {TM }}$ SARS-CoV- 2 Ag test has good clinical performance compare with RT-PCR \& CT.

## 5. Testing data

### 5.1 Results of negative samples

Table 2 - Results of negative samples were tested with VivaDiag™ SARS-CoV-2 Ag Test and SARS-CoV-2
RT-PCR and CT

| Sample | $\begin{aligned} & \text { Clinical } \\ & \text { Site } \end{aligned}$ | Date of testing | $\begin{aligned} & \text { VivaDiag™ } \\ & \text { SARS- } \\ & \text { CoV-2 Ag } \end{aligned}$ | $\begin{gathered} \text { PCR \& } \\ \text { CT } \end{gathered}$ | CT Value of PCR | VivaDiag ${ }^{\text {TM }}$ SARS-CoV2 Ag coincidence |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 2 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 3 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 4 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 5 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 6 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 7 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 8 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 9 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 10 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 11 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 12 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 13 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 14 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 15 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 16 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 17 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 18 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 19 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 20 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 21 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 22 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 23 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 24 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 25 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 26 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 27 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 28 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 29 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 30 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 31 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 32 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 33 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 34 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 35 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 36 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 37 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 38 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 39 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 40 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 41 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |


| 42 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 43 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 44 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 45 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 46 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 47 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 48 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 49 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 50 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 51 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 52 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 53 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 54 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 55 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 56 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 57 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 58 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 59 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 60 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 61 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 62 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 63 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 64 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 65 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 66 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 67 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 68 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 69 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 70 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 71 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 72 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 73 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 74 | No. 1 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 75 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 76 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 77 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 78 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 79 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 80 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 81 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 82 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 83 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 84 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 85 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 86 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 87 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 88 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 89 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 90 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 91 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |


| 92 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 93 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 94 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 95 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 96 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 97 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 98 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 99 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 100 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 101 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 102 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 103 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 104 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 105 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 106 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 107 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 108 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 109 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 110 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 111 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 112 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 113 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 114 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 115 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 116 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 117 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 118 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 119 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 120 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 121 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 122 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 123 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 124 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 125 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 126 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 127 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 128 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 129 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 130 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 131 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 132 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 133 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 134 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 135 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 136 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 137 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 138 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 139 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 140 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 141 | No. 1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |


| 142 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| 143 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 144 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 145 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 146 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 147 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 148 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 149 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 150 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 151 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 152 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 153 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 154 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |
| 155 | No.1 | 16-Aug-20 | Negative | Negative | UNDET | Yes |


| Sample | Clinical Site | Date of testing | $\begin{aligned} & \text { VivaDiag™ } \\ & \text { SARS- } \\ & \text { CoV-2 Ag } \end{aligned}$ | PCR \& CT | CT Value of PCR | VivaDiag ${ }^{\text {TM }}$ SARS-CoV2 Ag coincidence |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 156 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 157 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 158 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 159 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 160 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 161 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 162 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 163 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 164 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 165 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 166 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 167 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 168 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 169 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 170 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 171 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 172 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 173 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 174 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 175 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 176 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 177 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 178 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 179 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 180 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 181 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 182 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 183 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 184 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 185 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |


| 186 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 187 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 188 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 189 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 190 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 191 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 192 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 193 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 194 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 195 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 196 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 197 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 198 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 199 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 200 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 201 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 202 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 203 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 204 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 205 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 206 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 207 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 208 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 209 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 210 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 211 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 212 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 213 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 214 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 215 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 216 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 217 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 218 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 219 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 220 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 221 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 222 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 223 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 224 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 225 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 226 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 227 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 228 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 229 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 230 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 231 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 232 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 233 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 234 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 235 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |


| 236 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 237 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 238 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 239 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 240 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 241 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 242 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 243 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 244 | No. 2 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 245 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 246 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 247 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 248 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 249 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 250 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 251 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 252 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 253 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 254 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 255 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 256 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 257 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 258 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 259 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 260 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 261 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 262 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 263 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 264 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 265 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 266 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 267 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 268 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 269 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 270 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 271 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 272 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 273 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 274 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 275 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 276 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 277 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 278 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 279 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 280 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 281 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 282 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 283 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 284 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 285 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |


| 286 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 287 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 288 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 289 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 290 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 291 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 292 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 293 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 294 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 295 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 296 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 297 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 298 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 299 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 300 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 301 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 302 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 303 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 304 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 305 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 306 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 307 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 308 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 309 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 310 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 311 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 312 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 313 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 314 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |
| 315 | No. 2 | 18-Aug-20 | Negative | Negative | UNDET | Yes |


| Sample | Clinical Site | Date of testing | $\begin{aligned} & \text { VivaDiag™ } \\ & \text { SARS- } \\ & \text { CoV-2 Ag } \end{aligned}$ | PCR \& CT | CT Value of PCR | VivaDiag ${ }^{\text {TM }}$ SARS-CoV2 Ag coincidence |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 316 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 317 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 318 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 319 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 320 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 321 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 322 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 323 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 324 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 325 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 326 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 327 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 328 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 329 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 330 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |


| 331 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 332 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 333 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 334 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 335 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 336 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 337 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 338 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 339 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 340 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 341 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 342 | No. 3 | 15-Aug-20 | Negative | Negative | UNDET | Yes |
| 343 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 344 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 345 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 346 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 347 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 348 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 349 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 350 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 351 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 352 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 353 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 354 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 355 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 356 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 357 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 358 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 359 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 360 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 361 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 362 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 363 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 364 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 365 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 366 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 367 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 368 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 369 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 370 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 371 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 372 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 373 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 374 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 375 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 376 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 377 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 378 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 379 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 380 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |


| 381 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 382 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 383 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 384 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 385 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 386 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 387 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 388 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 389 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 390 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 391 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 392 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 393 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 394 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 395 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 396 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 397 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 398 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 399 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 400 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 401 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 402 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 403 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 404 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 405 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 406 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 407 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 408 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 409 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 410 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 411 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 412 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 413 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 414 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 415 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 416 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 417 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 418 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 419 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 420 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 421 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 422 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 423 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 424 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 425 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 426 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 427 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 428 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 429 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |
| 430 | No. 3 | 20-Aug-20 | Negative | Negative | UNDET | Yes |

### 5.2 Results of positive samples

Table 3 - Results of positive samples were tested with VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Rapid Test and SARS-
CoV-2 RT-PCR and CT

| sample | Clinical Site | Date of testing | Days from onset of symptoms | VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag | PCR \& CT | Value of PCR | $\begin{aligned} & \text { VivaDiag }^{\text {TM }} \\ & \text { SARS-CoV- } \\ & 2 \mathrm{Ag} \\ & \text { coincidence } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1 | No. 1 | 15-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 2 | No. 1 | 15-Aug-20 | 0 | Positive | Positive | <30 | Yes |
| 3 | No. 1 | 15-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 4 | No. 1 | 16-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 5 | No. 1 | 16-Aug-20 | 4 | Positive | Positive | <30 | Yes |
| 6 | No. 1 | 16-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 7 | No. 1 | 16-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 8 | No. 1 | 16-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 9 | No. 1 | 16-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 10 | No. 1 | 16-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 11 | No. 1 | 18-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 12 | No. 1 | 18-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 13 | No. 1 | 18-Aug-20 | 3 | Positive | Positive | <30 | Yes |
| 14 | No. 1 | 18-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 15 | No. 1 | 18-Aug-20 | 5 | Negative | Positive | <30 | No |
| 16 | No. 1 | 18-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 17 | No. 1 | 18-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 18 | No. 1 | 18-Aug-20 | 5 | Negative | Positive | <30 | No |
| 19 | No. 1 | 18-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 20 | No. 1 | 18-Aug-20 | 6 | Positive | Positive | <30 | Yes |
| 21 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 22 | No. 2 | 20-Aug-20 | 3 | Positive | Positive | <30 | Yes |
| 23 | No. 2 | 20-Aug-20 | 5 | Positive | Positive | <30 | Yes |
| 24 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 25 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 26 | No. 2 | 20-Aug-20 | 6 | Negative | Positive | <30 | No |
| 27 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 28 | No. 2 | 20-Aug-20 | 3 | Positive | Positive | <30 | Yes |
| 29 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 30 | No. 2 | 20-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 31 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 32 | No. 2 | 20-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 33 | No. 2 | 20-Aug-20 | 3 | Positive | Positive | <30 | Yes |
| 34 | No. 2 | 20-Aug-20 | 0 | Positive | Positive | <30 | Yes |
| 35 | No. 2 | 20-Aug-20 | 2 | Positive | Positive | <30 | Yes |
| 36 | No. 2 | 22-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 37 | No. 2 | 22-Aug-20 | 0 | Positive | Positive | <30 | Yes |
| 38 | No. 2 | 22-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 39 | No. 2 | 22-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 40 | No. 2 | 22-Aug-20 | 4 | Positive | Positive | <30 | Yes |
| 41 | No. 2 | 25-Aug-20 | 1 | Positive | Positive | <30 | Yes |
| 42 | No. 2 | 25-Aug-20 | 2 | Positive | Positive | <30 | Yes |


| 43 | No.2 | 25-Aug-20 | 3 | Positive | Positive | $<30$ |
| :---: | :---: | :---: | :---: | :--- | :--- | :--- |
| 44 | No.2 | 25-Aug-20 | 1 | Positive | Positive | $<30$ |
| 45 | No.2 | 25-Aug-20 | 1 | Positive | Positive | $<30$ |
| 46 | No.2 | 25-Aug-20 | 2 | Positive | Positive | $<30$ |
| 47 | No.2 | 25-Aug-20 | 1 | Positive | Positive | $<30$ |
| 48 | No.2 | 25-Aug-20 | 3 | Positive | Positive | $<30$ |
| 49 | No.2 | 25-Aug-20 | 1 | Positive | Positive | $<30$ |
| 50 | No.2 | 25-Aug-20 | 5 | Negative | Positive | $<30$ |
| 51 | No.2 | 25-Aug-20 | 3 | Positive | Positive | $<30$ |
| 52 | No.2 | 25-Aug-20 | 2 | Positive | Positive | $<30$ |
| 53 | No.2 | 25-Aug-20 | 5 | Positive | Positive | $<30$ |
| 54 | No.3 | 20-Aug-20 | 1 | Positive | Positive | $<30$ |
| 55 | No.3 | 20-Aug-20 | 6 | Positive | Positive | $<30$ |
| 56 | No.3 | 20-Aug-20 | 2 | Positive | Positive | $<30$ |
| 57 | No.3 | 20-Aug-20 | 3 | Positive | Positive | $<30$ |
| 58 | No.3 | 20-Aug-20 | 5 | Positive | Positive | $<30$ |
| 59 | No.3 | 21-Aug-20 | 2 | Positive | Positive | $<30$ |
| 60 | No.3 | 21-Aug-20 | 2 | Positive | Positive | $<30$ |
| 6 Yes |  |  |  |  |  |  |
| 61 | No.3 | 21-Aug-20 | 6 | Positive | Positive | $<30$ |
| 62 | No.3 | 21-Aug-20 | 2 | Positive | Positive | $<30$ |
| 63 | No.3 | 21-Aug-20 | 7 | Negative | Positive | $<30$ |
| 64 | No.3 | 21-Aug-20 | 9 | Negative | Positive | $<30$ |
| 65 | No.3 | 21-Aug-20 | 1 | Positive | Positive | $<30$ |
| 66 | No.3 | 21-Aug-20 | 2 | Positive | Positive | $<30$ |
|  |  |  | Yos |  |  |  |
|  |  |  |  | Yes |  |  |

Table 4 - Results of positive samples were tested with VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag Rapid Test and SARS-CoV-2 RT-PCR and CT (Complementary Clinical Study on Oct 2020)

| sample | Clinical Site | Date of testing | Days from onset of symptoms | $\begin{aligned} & \text { VivaDiag™ } \\ & \text { SARS- } \\ & \text { CoV-2 Ag } \end{aligned}$ | PCR \& CT | Value of PCR | VivaDiag ${ }^{\text {TM }}$ SARS-CoV-2 Ag coincidence |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1 | No. 1 | 26-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 2 | No. 1 | 26-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 3 | No. 1 | 26-Oct-20 | 4 | Positive | Positive | <30 | Yes |
| 4 | No. 1 | 26-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 5 | No. 1 | 26-Oct-20 | 2 | Positive | Positive | <30 | Yes |
| 6 | No. 1 | 26-Oct-20 | 2 | Positive | Positive | く30 | Yes |
| 7 | No. 1 | 26-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 8 | No. 1 | 28-Oct-20 | 2 | Positive | Positive | <30 | Yes |
| 9 | No. 1 | 28-Oct-20 | 3 | Positive | Positive | <30 | Yes |
| 10 | No. 1 | 28-Oct-20 | 5 | Positive | Positive | <30 | Yes |
| 11 | No. 1 | 28-Oct-20 | 2 | Positive | Positive | <30 | Yes |
| 12 | No. 1 | 28-Oct-20 | 2 | Positive | Positive | <30 | Yes |
| 13 | No. 1 | 28-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 14 | No. 1 | 30-Oct-20 | 2 | Positive | Positive | <30 | Yes |
| 15 | No. 1 | 30-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 16 | No. 1 | 30-Oct-20 | 3 | Positive | Positive | <30 | Yes |
| 17 | No. 1 | 30-Oct-20 | 1 | Positive | Positive | <30 | Yes |
| 18 | No. 1 | 30-Oct-20 | 4 | Positive | Positive | く30 | Yes |


| 19 | No． 1 | 30－Oct－20 | 1 | Positive | Positive | ＜30 | Yes |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 20 | No． 2 | 27－Oct－20 | 4 | Positive | Positive | ＜30 | Yes |
| 21 | No． 2 | 27－Oct－20 | 1 | Positive | Positive | ＜30 | Yes |
| 22 | No． 2 | 27－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 23 | No． 2 | 27－Oct－20 | 3 | Positive | Positive | く30 | Yes |
| 24 | No． 2 | 27－Oct－20 | 5 | Positive | Positive | ＜30 | Yes |
| 25 | No． 2 | 27－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 26 | No． 2 | 27－Oct－20 | 2 | Positive | Positive | く30 | Yes |
| 27 | No． 2 | 27－Oct－20 | 4 | Positive | Positive | ＜30 | Yes |
| 28 | No． 2 | 27－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 29 | No． 2 | 27－Oct－20 | 3 | Positive | Positive | ＜30 | Yes |
| 30 | No． 2 | 29－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 31 | No． 2 | 29－Oct－20 | 1 | Positive | Positive | ＜30 | Yes |
| 32 | No． 2 | 29－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 33 | No． 2 | 29－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 34 | No． 2 | 29－Oct－20 | 3 | Positive | Positive | ＜30 | Yes |
| 35 | No． 2 | 29－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 36 | No． 2 | 29－Oct－20 | 1 | Positive | Positive | ＜30 | Yes |
| 37 | No． 2 | 29－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 38 | No． 3 | 26－Oct－20 | 5 | Positive | Positive | ＜30 | Yes |
| 39 | No． 3 | 26－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 40 | No． 3 | 26－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 41 | No． 3 | 26－Oct－20 | 4 | Positive | Positive | ＜30 | Yes |
| 42 | No． 3 | 26－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 43 | No． 3 | 26－Oct－20 | 3 | Positive | Positive | ＜30 | Yes |
| 44 | No． 3 | 26－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 45 | No． 3 | 26－Oct－20 | 1 | Positive | Positive | く30 | Yes |
| 46 | No． 3 | 26－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 47 | No． 3 | 25－Aug－20 | 2 | Positive | Positive | ＜30 | Yes |
| 48 | No． 3 | 25－Aug－20 | 3 | Positive | Positive | ＜30 | Yes |
| 49 | No． 3 | 28－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 50 | No． 3 | 28－Oct－20 | 1 | Positive | Positive | ＜30 | Yes |
| 51 | No． 3 | 28－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 52 | No． 3 | 28－Oct－20 | 1 | Positive | Positive | ＜30 | Yes |
| 53 | No． 3 | 28－Oct－20 | 4 | Positive | Positive | ＜30 | Yes |
| 54 | No． 3 | 28－Oct－20 | 2 | Positive | Positive | ＜30 | Yes |
| 55 | No． 3 | 28－Oct－20 | 3 | Positive | Positive | ＜30 | Yes |

## 6．Reference

WHO－Instructions and requirements for Emergency Use Listing（EUL）submission：In vitro diagnostics detecting SARS－CoV－2 nucleic acid and rapid diagnostics tests detecting SARS－CoV－2 antigens．

