Instructions for SuperFlex™
Anti-SARS-CoV-2 IgG Kit

v 1.0
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**Intended Use**

The SuperFlex™ Anti-SARS-CoV-2 IgG kit product is an immunoassay intended for qualitative detection of anti-SARS-CoV-2 IgG in human serum, plasma (EDTA, sodium citrate) and venous whole blood on Automated chemiluminescence analyzer. This test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies to SARS-CoV-2 virus may persist following infection and if the presence of antibodies confers protective immunity. Testing is limited to professional use.

The SuperFlex Anti-SARS-CoV-2 IgG Kit is for professional *in vitro* diagnostic use only.

**Summary & Explanation of the Test**

Coronaviruses can be divided into four general categories: α, β, γ and δ. Of the coronaviruses discovered to date, seven types can make people sick. In addition to the three coronaviruses, SARS-CoV, MERS-CoV, SARS-CoV-2, the other four types of human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63 and HCoV-HKU1 type) can often cause people to suffer from mild or moderate upper respiratory illness, such as a cold.

COVID-19 is caused by infection with the virus “SARS-CoV-2”. Reported illnesses have ranged from very mild (including some with no reported symptoms) to severe. Some infected patients may express the symptoms of fever, fatigue, dry cough, and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. which can be life-threatening.

Symptomatic, pre-symptomatic and asymptomatic SARS-CoV-2 carriers all can be potential sources for viral transmission.¹ Currently, no specific treatments or vaccines are available for COVID-19. Real-time reverse transcription polymerase chain reaction (RT-PCR) detecting viral genes is the current gold standard for the diagnosis of COVID-19. Upper respiratory specimen, such as nasopharyngeal swab and oropharyngeal swab, are commonly used for diagnostic testing.²

The specific antibodies are produced gradually by the immune response system when infected with SARS-CoV-2. A few days to 2 weeks after the onset of symptoms, the specific IgG antibodies can be detected.³ The results may vary by time when specimens are collected. The presence of IgG antibodies is indicative of patient having been infected in the past, recovered from the disease and possibly become immune.⁴
**Test Principle**

SuperFlex Anti-SARS-CoV-2 IgG Kit is performed using superparamagnetic microparticles together with direct chemiluminescence technology to detect anti-SARS-CoV-2 IgG in human serum, plasma (EDTA, sodium citrate) and venous whole blood specimens. A specimen is added to a specimen well, and then bound with the magnetic particles coated with SARS-CoV-2 antigen. After washing, acridinium ester labeled anti-human IgG antibody is added to form an immunocomplex. Unbound substances are removed by washing and the luminescence value of the chemiluminescence reaction is measured under the action of pre-trigger and trigger solution. The luminous intensity is positively correlated with the concentration of the Anti-SARS-CoV-2 IgG in the specimen.

<table>
<thead>
<tr>
<th>Test Type</th>
<th>System</th>
<th>Incubation Time</th>
<th>Time to first result</th>
<th>Incubation Temperatures</th>
<th>Specimen Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunometric</td>
<td>SuperFlex</td>
<td>360s+240s</td>
<td>15mins</td>
<td>35°C</td>
<td>20μL</td>
</tr>
</tbody>
</table>

**Reagents & Materials Provided**

<table>
<thead>
<tr>
<th>SARS-CoV-2-SG-C</th>
<th>Name</th>
<th>Quantity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reagent strip (STR)</td>
<td>50 Strips</td>
<td>One strip is only used for one test. Containing magnetic particles coated with SARS-CoV-2 antigen buffer, acridinium ester labeled anti-human IgG antibody buffer, washing solution and pre-trigger solution, preservative: sodium azide (0.1%).</td>
</tr>
<tr>
<td>2</td>
<td>Calibrator S1</td>
<td>1.0 mL × 1 bottle</td>
<td>Containing anti-SARS-CoV-2 antibody, Tris-HCl buffer with protein (bovine) stabilizer, preservative: sodium azide (0.1%).</td>
</tr>
<tr>
<td>3</td>
<td>Control 1</td>
<td>1.0 mL × 1 bottle</td>
<td>Negative control containing Tris-HCl buffer with protein (bovine) stabilizer, preservative: sodium azide (0.1%).</td>
</tr>
<tr>
<td>4</td>
<td>Control 2</td>
<td>1.0 mL × 1 bottle</td>
<td>Positive control containing anti-SARS-CoV-2 antibody, Tris-HCl buffer with protein (bovine) stabilizer, preservative: sodium azide (0.1%).</td>
</tr>
<tr>
<td>5</td>
<td>Calibration card</td>
<td>1 piece</td>
<td>Containing factory generated master curve and lot number information.</td>
</tr>
</tbody>
</table>

*Note: Kits with different lot numbers cannot be mixed for use.*

**Instrumentation & Software Required**

- The SuperFlex software and “CoV2IgG” protocol must be installed on the instrument
- Automated chemiluminescence analyzer manufactured by Suzhou Sym-Bio Lifescience Co., Ltd. Type: SuperFlex (REF SUPERFLEX-C)
- SuperFlex software: Version 1.00

For additional information, please refer to the instructions for use of SuperFlex.
Materials Required but Not Provided

- SuperFlex Trigger Solution manufactured by Suzhou Sym-Bio Lifescience Co., Ltd (REF SDX-56343)
- Disposable tip (REF SDX-56344)
- Waste liquid collecting box (REF SDX-56345)
- Hitachi Analyzer Specimen Cup, polystyrene (Cat No.: 127-0016-HIT)
- Disposable gloves, Biohazard disposal container, Collection devices (for venous whole blood, serum, plasma)

Warnings & Precautions

1. For professional use only.
2. The product must only be used by trained laboratory personnel in a professional laboratory. Only personnel proficient in handing infectious materials and the use of SuperFlex system should perform this procedure.
3. Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient specimens. Wash hands thoroughly after handling specimens and kit reagents.
5. Read the instruction for use carefully before using this assay.
6. Do not use the reagent strip if the aluminum foil is not sealed or is pierced.
7. Each reagent strip is for single use only.
8. Do not mix reagents, calibrators and controls from different lots.
9. Do not use reagents beyond the expiration date indicated on the label.
10. Once the package has been opened, the kit shall be stored at 2-8°C in the dark.
11. All patient specimens should be handled as if infectious, heat-inactivated at 56°C for 30 minutes before tested, using good laboratory procedures as outlined in Biosafety in Microbiological and Biomedical Laboratories and in the CLSI Document M29-A4.5
12. All human-sourced materials and all consumables contaminated with potentially infectious materials should be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.6
13. Dispose of all specimens inactivated and materials used in the test procedure into a biohazard waste container. Proper handling and disposal methods should be established according to local disposal regulations, avoiding contaminating the environment.
14. Used strips should be regarded as infectious substances and operated and processed strictly in accordance with laboratory biosafety requirements.
15. If spillage occurs, immediately disinfect with a solution including at least 0.5% sodium hypochlorite.
16. Strictly follow procedures and guidelines provided in the instructions for use of SuperFlex.
17. For troubleshooting information, refer to the instrument for use of SuperFlex, Section 11.
18. Do not use the obvious microbial contamination strips, please visually inspect the strip prior to use.

20. Device components contain sodium azide (0.1%), which may react with copper, lead, brass, or solder in plumbing systems to form an accumulation of explosive azides (lead & copper azide) if not disposed of appropriately. Sink disposal should be avoided whenever possible. Flush with copious amounts of water to avoid accumulation of deposits.

Reagent Storage

1. Store the SuperFlex Anti-SARS-CoV-2 IgG kit at 2-8°C in the dark until expiration date indicated on the package.
2. Do not freeze reagents.
3. Store all remaining reagents at 2-8°C.
4. If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.
5. Once opened, the reagents of Calibrator S1, Control 1 and Control 2 can be stored for 7 days at 2-8°C.

Specimen Collection & Preparation

Specimen Type
- Serum
- EDTA and citrate plasma
- Venous Whole blood

Specimen Collection and Transport
- Draw blood specimen into a collection tube by venipuncture using standard procedure. 
- Follow the instructions provided with collection device for use and processing of the specimen.
- If the specimens need to transport, it should comply with the corresponding regulations about the transport of clinical specimens.
- Serum and EDTA/citrate plasma specimens can be shipped at 2-8 °C or -20°C or colder. Venous whole blood specimens can only be shipped at 2-8 °C.

Specimen Storage
- Serum and plasma (EDTA and citrate) can be stored at 18-28 °C for up to 24 hours and 2-8 °C for up to 3 days. If specimens are not tested in 3 days, it is recommended to store at -20°C or colder for no more than one month. Freeze and thaw specimens no more than one time.
- Venous Whole blood specimens can be stored at 2-8 °C for up to 24 hours. Do not freeze venous whole blood.

Specimen Preparation
- Follow the instructions provided with collection device for use and processing of the specimens.
- All specimens must be heat-inactivated for 30 minutes at 56°C.
- Specimens should be free of bubbles. Remove bubbles with a disposable tip to keep the consistency in results.
• For serum and plasma specimens, the specimens must be centrifuged prior to testing for accurate results.
• For venous blood specimens, make sure it well mixed before tested. Do not shake venous whole blood specimen violently, which may cause hemolysis.
• Before analysis, make sure that all testing specimens have been equilibrated to a temperature of 18-28°C.
• Frozen specimens must be completely thawed and mixed thoroughly before recentrifuged.
• Transfer specimens to Hitachi Analyzer Specimen Cup carefully when the specimen volume is less than 500 µL.

Calibration

Calibration Procedure

• Calibration curve and calibrator are lot specific and contained on calibration card.
• A lot specific Calibration curve is established for each reagent lot by the manufacturer. The instrument specific Cutoff Value is determined by the test signal (RLU) of calibrator S1 automatically by SuperFlex system.
• Cutoff value = a x Signal of Cal S1
• Scan the bar code on calibration card and input the lot-specific calibration curve into SuperFlex software automatically. Then scan the bar code on Cal S1 bottle and insert the reagent strips into the appropriate position on the instrument. All the assay steps are performed automatically by the instrument.
• Calibration results are assessed against a range of quality parameter. Test the Control 1 and Control 2 to determine the validity of the calibration.
• Perform calibration again if a new reagent lot is to be used, or it has reached the end of the calibration cycle period (28 days) or if the controls are not within target ranges.
• If calibration fails, please refer to the instruction for use for more information.
• For a detailed calibration process, refer to the instruction for use of SuperFlex, Section 9.4.

Traceability of Calibration

Calibration of the SuperFlex Anti-SARS-CoV-2 IgG kit is traceable to reference material of NO. GBW(E)091109, which is called human IgG monoclonal antibody to spike glycoprotein solution reference material of 2019 novel coronavirus (2019-nCoV) and produced by Chinese National Institute of Metrology.

Quality Control

• Two controls are included in each kit.
• Quality controls are lot specific with established value ranges.
• The validity of calibration must be checked using these controls.
• Test quality controls as normal specimens every day, check the controls values. If the results fall outside the acceptable range, please retest the controls or recalibration.
• Good laboratory practice requires that controls be processed to verify the performance of the test.
Testing Procedure

- The SuperFlex instrument should be installed at professional lab under the condition of 35-70% humidity and 15-30°C. Testing procedures should be performed by professional and trained personnel.
- Reagent strip preparation: take required reagents out of the refrigerator. If magnetic particles are attached to aluminum film or aperture wall, gently turn the strip upside down four times. Avoid making bubbles.
- Specimen preparation: the specimen volume is 20 µL for each test. If loading for collection tube, the total specimen volume is more than 500 µL. If the specimen volume is less than 500uL but more than 100uL, transfer the specimen liquid into 2.0mL Hitachi Analyzer Specimen Cup, polystyrene (Cat No.: 127-0016-HIT). Make sure that there are no air bubbles before loading.
- Loading specimen: place collection tubes in the specimen tube holder and then load it into the corresponding position in the instrument.
- Loading reagent strips: Insert the required number of reagent strips into the corresponding channels of the instrument according to the on-screen instructions. Ensure that they are inserted completely and are not loose.
- Click the options on the screen in accordance to different specimen types to run. All steps are automatically completed by the instrument.
- Remove the test strip from the instrument and dispose of the used strips into an appropriate recipient.
- For optimal performance, it is important to perform routine maintenance as described in the instruction for use of SuperFlex, Section 10.
- For a completed description of how to run an assay, please refer to the instruction for use of SuperFlex, Section 9.

Results

Cutoff Value Determination

Cutoff value determination was conducted based on guidance from the National Committee for Clinical Laboratory Standards (NCCLS) Protocol C28-A3, Human serum, EDTA plasma, citrate plasma and venous whole blood from 120 cases of healthy individuals, respectively, were evaluated using SuperFlex Anti-SARS-CoV-2 IgG kit, 90% confidence intervals was taken.

Calculation

The SuperFlex system calculates the Cutoff value based on the mean calibrator value. Results are reported by dividing the specimen result by the stored Cutoff value.

\[
\text{Results} = \frac{\text{Signal for test sample}(S)}{\text{Cutoff value}(CO)}
\]

Interpretation of Test Results

Patient specimen results will be displayed with a “Negative” or “Positive” label.

<table>
<thead>
<tr>
<th>Result(S/CO)</th>
<th>Test Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1.0</td>
<td>Negative</td>
<td>Specimen is negative for anti SARS-CoV-2 IgG</td>
</tr>
<tr>
<td>≥ 1.0</td>
<td>Positive</td>
<td>Specimen is positive for anti SARS-CoV-2 IgG</td>
</tr>
</tbody>
</table>
1. **Results must be in conjunction with the clinical evaluation and medical history of patient for interpretation.**

2. The S/CO of 1.0 was established by the Chinese population. Each laboratory should investigate the transferability of the expected S/CO values to its own patient population and if necessary, determine its own reference S/CO value.

3. If there is any suspicion of the result, please contact your local representative.

### Limitations of Procedure

1. Correct specimen handling and experimental operation procedures, with specified SuperFlex instrument and trigger solution, are necessary for a reliable result.

2. Test results of the kit should not be used as the sole evidence for clinical diagnosis. The result should only be interpreted in conjunction with clinical examination, clinical history, and other clinical information of patient.

3. Negative results do not rule out SARS-CoV-2 infection, especially in those who have been in contact with the confirmed positive patients. Further testing should be considered for a confirmed result.

4. Specimens with positive results should be confirmed with clinical findings and local disease prevalence before a diagnostic determination is made.

5. False negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone mutations in the recognized epitope.

6. Patients who have used immunoglobulins for immunotherapy treatment or patients who have frequent contact with animals may produce heterophile antibodies, such as human anti-mouse antibody (HAMA). These antibodies can interfere with the immunoassay. Although this kit is specifically designed to reduce the effects of HAMA (Roche HAMA serum type 1 1:20 dilution) in the specimen, the results of patients suspected of having this antibody need to be carefully checked.

7. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

8. If symptoms persist and the result from SuperFlex Anti-SARS-CoV-2 IgG kit is negative, it is recommended to re-specimen the patient a few days later or test with an alternative test device.

9. The listed below substances/conditions may have the potential for wrong testing results (both false negative and false positive).
   - Specimens with elevated IgA levels.
   - Samples from pregnant women, especially multipara (women who had more than one pregnancy).
   - Samples of individuals treated with relevant medicines like common anti-hypertensive drugs, common anti-diabetic drugs, drugs currently used against COVID-19 in clinical studies (e.g. hydroxychloroquine).
   - Specimens with common human pathogenic coronaviruses like HCoV-HKU1, -NL63, -OC43, or -229E, SARS-CoV (-1) and MERS-CoV.
   - Specimens with influenza viruses like H1N1, H3N2.
Performance Characteristics

1. Analytical Sensitivity
The analytical sensitivity is verified with in-house developed control material, which can be calibrated to the reference material of GBW(E)091109, controlling a consistent analytical sensitivity over various batches.

2. Analytical Specificity

Class Specificity
The anti-human IgG antibody used in the SARS-CoV-2 IgG assay demonstrates class-specific reactivity only to human IgG isotypes. No binding interactions were observed to human IgM.

Cross-Reactivity
The SuperFlex Anti-SARS-CoV-2 IgG kit was evaluated for potential cross-reactivity from individuals with other medical conditions. A total of 50 specimens from 10 different categories were tested. 50 specimens were negative by the SARS-CoV-2 IgG assay. The data are summarized in the following table.

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Number of Specimens</th>
<th>Negative</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-influenza A</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Anti-influenza B</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Anti-HBV</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Anti-HIV</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>ANA</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Anti-respiratory syncytial virus</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Measles virus</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Herpes simplex</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>mycoplasma pneumoniae antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

Interfering Substance
Interference of the SuperFlex Anti-SARS-CoV-2 IgG kit was evaluated, by spiking the substance shown in the table below into negative samples, no false positive results were observed. Note: Only the possibility of false positive results has been verified.

<table>
<thead>
<tr>
<th>Interfering substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>bilirubin</td>
<td>66mg/dL</td>
</tr>
<tr>
<td>hemoglobin</td>
<td>5mg/mL</td>
</tr>
<tr>
<td>blood lipid</td>
<td>1000mg/dL</td>
</tr>
<tr>
<td>rheumatoid factor</td>
<td>1000IU/dL</td>
</tr>
<tr>
<td>immunoglobulin</td>
<td>2.5g/dL</td>
</tr>
<tr>
<td>HAMA</td>
<td>1:20(Roche HAMA serum type 1)</td>
</tr>
</tbody>
</table>
3. Accuracy
Accuracy of the SuperFlex Anti-SARS-CoV-2 IgG kit was evaluated by testing external quality assessment substances, consisting of the COVID-19 convalescent plasma with negative PCR result, provided by National Center for Clinical Laboratories of China (NCCL). For more information please refer to http://www.nccl.org.cn. The coincidence rate with the results published by NCCL is 100%.

4. Precision

Repeatability
A study was performed by using 1 lot of SuperFlex Anti-SARS-CoV-2 IgG kit, 1 instrument and negative/low positive/moderate positive specimens. The panel specimens were tested in 10 replicates under the same condition. The percent coefficient of variation (%CV) was determined with a variance component analysis.

<table>
<thead>
<tr>
<th>Repeatability</th>
<th>Negative</th>
<th>Low positive</th>
<th>Moderate positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>%CV</td>
<td>8.41%</td>
<td>6.90%</td>
<td>4.94%</td>
</tr>
</tbody>
</table>

Reproducibility
A five days reproducibility study was performed by using 1 lot of SuperFlex Anti-SARS-CoV-2 IgG kit, 1 instrument and negative/low positive/moderate positive specimens. The panel specimens were tested in duplicates per run, 2 runs per day for 5 days. The intra-assay, inter-assay, total standard deviation (SD) and percent coefficient of variation (%CV) were determined with a variance component analysis.

<table>
<thead>
<tr>
<th>Specimens</th>
<th>N</th>
<th>Mean (S/CO)</th>
<th>Within run</th>
<th>Between run</th>
<th>Between day</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SD  CV%</td>
<td></td>
<td>SD  CV%</td>
<td>SD  CV%</td>
<td>SD  CV%</td>
</tr>
<tr>
<td>Negative</td>
<td>20</td>
<td>0.62 0.05 7.46%</td>
<td>0.01 2.27%</td>
<td>0.03 4.37%</td>
<td>0.06 8.94%</td>
<td></td>
</tr>
<tr>
<td>Low Positive</td>
<td>20</td>
<td>1.13 0.08 6.83%</td>
<td>0.00 0.00%</td>
<td>0.04 3.17%</td>
<td>0.09 7.53%</td>
<td></td>
</tr>
<tr>
<td>Moderate Positive</td>
<td>20</td>
<td>3.73 0.20 5.26%</td>
<td>0.07 2.10%</td>
<td>0.00 0.00%</td>
<td>0.21 5.66%</td>
<td></td>
</tr>
</tbody>
</table>
5. Matrix Equivalency

40 groups of homologous specimens (serum, EDTA plasma, citrate plasma and venous whole blood) were evaluated, which contained 20 groups of negative specimens and 20 groups of positive specimens. For negative groups, results from different specimen types were negative. For positive groups, the passing-bablok regression between EDTA plasma, citrate plasma and venous whole blood with serum were performed respectively. The slope of different type specimens was between 0.9-1.1.

6. Clinical Performance Characteristics

All clinical performances were evaluated using Chinese population in different areas.

Clinical Sensitivity

To estimate the positive percent agreement (PPA), 31 EDTA plasma specimens collected from patients confirmed to be SARS-CoV-2 positive by PCR were tested. Of the 31 PCR positive specimens, 28 were positive in the SuperFlex Anti-SARS-CoV-2 IgG kit and 3 were negative. For 28 of the 31 specimens the date of specimen collection, date of PCR testing and date of onset of symptoms were provided. The results are summarized in the tables below.

<table>
<thead>
<tr>
<th>Days between PCR positive and Serum Collection</th>
<th>Positive Number</th>
<th>Negative Number</th>
<th>Total Number</th>
<th>PPA (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-7</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>100% (20.65, 100)</td>
</tr>
<tr>
<td>8-14</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>50% (15.00, 85.00)</td>
</tr>
<tr>
<td>&gt; 14</td>
<td>21</td>
<td>0</td>
<td>21</td>
<td>100% (84.54, 100)</td>
</tr>
<tr>
<td>Not Provided</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>75% (30.06, 95.44)</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>3</td>
<td>31</td>
<td>90.32% (75.10, 96.65)</td>
</tr>
</tbody>
</table>

Clinical Specificity

120 healthy individuals (no COVID-19 infection history, no COVID-19 symptoms and had no contact with SARS-CoV-2 infected patients within in 14 days) with negative PCR result were tested resulting in 100% clinical specificity (95% CI: 97.35-100%).
Clinical Agreement of PCR
The SuperFlex Anti-SARS-CoV-2 IgG kit showed 90.32% (28/31) positive agreement (95% CI: 75.10–96.65%), and 100% (120/120) negative agreement with PCR result.

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>SuperFlex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>28</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>120</td>
<td>123</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>120</td>
<td>151</td>
</tr>
</tbody>
</table>

Positive agreement rate = \( \frac{True\ Positives}{True\ positives + False\ Negatives} \times 100\% = \frac{28}{28 + 3} \times 100\% = 90.32\% \)

Negative agreement rate = \( \frac{True\ Negatives}{True\ Negatives + False\ Positives} \times 100\% = \frac{120}{120 + 0} \times 100\% = 100\% \)

Total agreement rate = \( \frac{True\ Negatives + False\ Positives}{Total} \times 100\% = \frac{120 + 28}{151} \times 100\% = 98.01\% \)

Clinical Agreement of Antibody Test
The clinical agreement of antibody test was evaluated by testing 155 Ab positive specimens and 100 negative specimens in total. The Ab positive citrate plasma specimens were collected from blood blank, which had been screened positive by certified ELISA Ab kit. The negative serum specimens were collected from ICL, which had been confirmed negative by PCR. Simultaneously test the above specimens with comparator method (ELISA IgG Kit) and analysis the clinical agreement.

<table>
<thead>
<tr>
<th></th>
<th>Comparator Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>SuperFlex</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>145</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
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Positive agreement rate = \( \frac{True\ Positives}{True\ positives + False\ Negatives} \times 100\% = \frac{145}{145 + 0} \times 100\% = 90.32\% \)

Negative agreement rate = \( \frac{True\ Negatives}{True\ Negatives + False\ Positives} \times 100\% = \frac{110}{110 + 0} \times 100\% = 100\% \)

Total agreement rate = \( \frac{True\ Negatives + False\ Positives}{Total} \times 100\% = \frac{145 + 110}{255} \times 100\% = 98.01\% \)
References


Revision History

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<th>Date</th>
<th>Description</th>
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<td>July 13, 2020</td>
<td>New document</td>
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Symbol Explanation

- **IVD** - *In vitro* diagnostic medical device
- **REF** - List number
- **CONTROL** - Negative control
- **LOT** - Lot number
- **CONTROL** - Positive control
- **Manufacturer**
- **Keep away from sunlight**
- **Date of Manufacture**
- **Temperature limitation**
- **Expiration date**
- **Consult instructions for use**
- **Authorized Representative**
- **This way up**
- **Recyclable**
- **Caution**
- **Flammable**
- **Corrosive**
- **Health Hazards**