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Wantai SARS-CoV-2 Diagnostics

WANTAI SARS-CoV-2 Ag ELISA

Diagnostic Kit for SARS-CoV-2 Antigen (ELISA)

REF WS-1496 | V. 2021-01 [Eng.] | Σ 96 | IVD

Read the package insert carefully and completely before performing the assay. Follow the instructions and do not modify them. Only by strict adherence to these instructions, the erroneous results can be avoided and the optimal performance of the WANTAI SARS-CoV-2 Ag ELISA achieved.

INTENDED USE

The WANTAI SARS-COV-2 Ag ELISA is an enzyme-linked immunosorbent assay for qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal (NP)/oropharyngeal (OP) swab specimens and serum or plasma. It is intended for screening of patients suspected for infection with SARS-CoV-2 virus, and as an aid in the diagnosis of the coronavirus disease 2019 (COVID-19).

SARS-CoV-2 antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient's history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with nucleic acid assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

SUMMARY

Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure and death.

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 Novel Coronavirus, formerly known as 2019-nCoV and now known as SARS-COV-2, is a new strain of coronavirus that was first identified during the recent pandemic.

PRINCIPLE OF THE TEST

The WANTAI SARS-CoV-2 Ag ELISA employs solid phase, sandwich ELISA method for detection of antigens to SARS-CoV-2.

Polystyrene microwell strips are pre-coated with SARS-CoV-2 antibodies to capture SARS-CoV-2 antigens from specimens. Specific antigens, if present, will be bound to the solid phase pre-coated antibodies. After add SARS-CoV-2 antibodies conjugated to horseradish peroxidase (HRP-Conjugate), these HRP-conjugated antibodies will be bound to any antigen-antibody complexes previously formed and the unbound HRP-conjugate is then removed by washing. Chromogen solutions containing Tetramethyl benzidine (TMB) and urea peroxide are added to the wells and in presence of the coated antibody-antigen-conjugated antibody immunocomplex, the colorless chromogens are hydrolyzed by the bound HRP conjugate to a blue colored product. The blue color turns yellow after stopping the reaction with sulfuric acid. The amount of color intensity can be measured and is proportional to the amount of antibody captured in the wells, and to the specimen respectively. Wells containing specimens negative for SARS-CoV-2 antigen remain colorless.

COMPONENTS

IVD In Vitro Diagnostic Use Only

This kit contains reagents sufficient for testing of maximum of 91 specimens in a test run.

UUU | PLATE
Code 5 (1x96wells)
8×12/12×8-well per plate
MICROWELL PLATE: Blank microwell strips fixed on white strip holder. The plate is sealed in aluminum pouch with desiccant. Each well contains SARS-CoV-2 antibodies. The microwell strips can be broken to be used separately. Place unused wells or strips in the provided plastic sealable storage bag together with the desiccant and return to 2-8°C. Once opened, stable for 4 weeks at 2-8°C.

CONTROL | -
Code 8 (1x0.5ml per vial)
preserv.0.1% ProClin™ 300
NEGATIVE CONTROL: Colorless liquid filled in a vial with green screw cap. Protein-stabilized buffer tested non reactive for SARS-CoV-2 antigens. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

CONTROL | +
Code 7 (1x0.5ml per vial)
preserv.0.1% ProClin™ 300
POSITIVE CONTROL: Red-colored liquid filled in a vial with red screw cap. Protein-stabilized buffer tested reactive for SARS-CoV-2 antigens. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

HRP | CON
Code 6 (1x12ml per vial)
preserv.0.1% ProClin™ 300
HRP-CONJUGATE: Red-colored liquid in a white vial with red screw cap. Horseradish peroxidase-conjugated SARS-CoV-2 antibodies. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

DIL | SPE
Code 9 (1x3ml per vial)
preserv.0.1% ProClin™ 300
SPECIMEN DILUENT: Green-colored liquid in a white vial with blue screw cap. Buffer solution containing protein. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

SWAB | BUF
Code 10 (2x14ml per vial)
SWAB COLLETION BUFFER: Colorless liquid in a white vial with blue screw cap. Phosphate buffer. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

WASH | BUF | 20X
Code 1 (1x50ml per bottle)
DILUTE BEFORE USE!
detergent Tween-20
WASH BUFFER: Colorless liquid filled in a white bottle with white screw cap. Buffer solution containing surfactant. The concentrate must be diluted **1 to 20** with distilled/ deionized water before use. Once diluted, stable for 1 week at room temperature, or for 2 weeks when stored at 2-8°C.

CHROM | SOL | A
Code 2 (1x6ml per vial)
CHROMOGEN SOLUTION A: Colorless liquid filled in a white vial with green screw cap. Urea peroxide solution. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

CHROM | SOL | B
Code 3 (1x6ml per vial)
CHROMOGEN SOLUTION B: Colorless liquid filled in a black vial with black screw cap. TMB (Tetramethyl benzidine), N,N-dimethylformamide. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

STOP | SOL
Code 4 (1x6ml per vial)
STOP SOLUTION: Colorless liquid in a white vial with yellow screw cap. Diluted sulfuric acid solution (0.5M H_2SO_4). Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

- **PLASTIC SEALABLE BAG:** For enclosing the strips not in use — 1 unit
- **PACKAGE INSERT** — 1 copy
- **CARDBOARD PLATE COVER** — 2 sheets

To cover the plates during incubation and prevent evaporation or contamination of the wells.

MATERIALS REQUIRED BUT NOT PROVIDED

Freshly distilled or deionized water, any necessary personal protective equipment and timer, appropriate waste containers for potentially contaminated materials, dispensing system and/or pipette, disposable pipette tips, absorbent tissue or clean towel, dry incubator or water bath, 37±1°C, plate reader, single wavelength 450nm or dual wavelength 450/600~650nm, microwell aspiration/wash system, microbial swabs and viral transport media (VTM), 1.5ml centrifuge tube.

SPECIMEN COLLECTION, TRANSPORTING AND STORAGE

Sample Requirements: It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after seven days of symptoms were more likely to produce negative results when compared to an RT-PCR test. Inadequate specimen collection, improper specimen handling and/or transport may yield false negative results.
1. Either fresh serum or plasma specimens can be used with this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum/plasma must be separated from the clot as early as possible as to avoid haemolysis of the RBC. Care should be taken to ensure that the serum specimens are clear and not contaminated by microorganisms. Any visible particulate matters in the specimen should be removed by centrifugation at 3000 RPM (round per minutes) for 20 minutes at room temperature or by filtration.
2. Acceptable specimens for testing with this kit include oropharyngeal and nasopharyngeal swab specimens collected into VTM (without inactivator such as guanidine hydrochloride).

Sample Collection:
1. Plasma specimens collected into EDTA, sodium citrate or heparin can be tested, but highly lipaemic, icteric, or hemolytic specimens should not be used as they can give false results in the assay. Do not heat inactivate specimens. This can cause deterioration of the target analyte. Specimens with visible microbial contamination should never be used.
2. Oropharyngeal and nasopharyngeal swab：The swab should be a special purpose microbial swab (do not use common swabs). The head of the swab should be of medical grade artificial fiber, the material of the shaft should be plastic.
2.1 Sample treatment tube preparation: Add 12 drops (or 300μl) of swab collection buffer provided in this kit into 1.5ml centrifuge tube, as sample treatment tube.
2.2 Nasopharyngeal swab: Use a microbial swab to collect samples in the nasal area. Softly rotate and push the swab, insert the head of the microbial swab deep into the nasopharyngeal at the root of the nasal cavity, rotate a few times to obtain an abundant sample. See image 1.

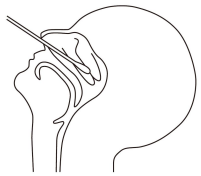

Image 1: nasopharyngeal sampling

2.3 Oropharyngeal swab: Use a microbial swab to wipe the posterior pharyngeal wall and tonsil on both sides with moderate force. Avoid touching the tongue.
2.4 Sample processing: After collecting the sample, insert the microbial swab into the sample collection buffer or VTM. Rotate several times against the inner wall of the tube to dissolve the sample in the solution as much as possible. Finally snap the head of the swab and leave it in the tube.

Sample Storage and Transportation: For separated aseptically serum or plasma specimens can be stored at 2-8°C for one week, or placed at below -15°C for long-term. Nasopharyngeal and oropharyngeal swabs specimens tested within 12 hours after collection can be stored at 2-8°C. For long-term storage, keep under -70°C. Avoid multiple freeze-thaw cycles (no more than 3 times). Before testing, balance the samples at room temperature. The frozen specimens should be mixed well before testing.

STORAGE AND STABILITY

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2-8°C, do not freeze. To assure maximum performance of the WANTAI SARS-CoV-2 Ag ELISA, during storage, protect the reagents from contamination with microorganism or chemicals.

PRECAUTIONS AND SAFETY

TO BE USED ONLY BY QUALIFIED PROFESSIONALS

The ELISA assays are time and temperature sensitive. To avoid incorrect result, ***strictly follow the test procedure steps and do not modify them***.

1. Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
2. Make sure that all reagents are within the validity indicated on the kit box and of the same lot. Never use reagents beyond their expiry date stated on labels or boxes.
3. **CAUTION - CRITICAL STEP**: Allow the reagents and specimens to reach room temperature before use. Shake reagent gently before use. Return at 2-8°C immediately after use.
4. Use only sufficient volume of specimen as indicated in the procedure steps. Failure to do so, may cause low sensitivity of the assay.
5. Do not touch the exterior bottom of the wells; fingerprints or scratches may interfere with the reading. When reading the results, ensure that the plate bottom is dry and there are no air bubbles inside the wells.
6. Never allow the microplate wells to dry after the washing step. Immediately proceed to the next step. Avoid the formation of air bubbles when adding the reagents.
7. Avoid long time interruptions of assay steps. Assure same working conditions for all wells.
8. Calibrate the pipette frequently to assure the accuracy of specimens/reagents dispensing. Use different disposal pipette tips for each specimen and reagents in order to avoid cross-contaminations.
9. Assure that the incubation temperature is 37°C inside the incubator.
10. When adding specimens, do not touch the well's bottom with the pipette tip.
11. When measuring with a plate reader, determine the absorbance at 450nm or at 450/600~650nm.
12. The enzymatic activity of the HRP-conjugate might be affected from dust and reactive chemical and substances like sodium hypochlorite, acids, alkalis etc. Do not perform the assay in the presence of these substances.
13. If using fully automated equipment, during incubation, do not cover the plates with the plate cover. The tapping out of the remainders inside the plate after washing, can also be omitted.
14. All specimens from human origin should be considered as potentially infectious. Strict adherence to GLP (Good Laboratory Practice) regulations can ensure the personal safety.
15. **WARNING:** Materials from human origin may have been used in the preparation of the Negative Control of the kit. These materials have been tested with tests kits with accepted performance and found negative for HBsAg and antibodies to HIV 1/2, HCV, TP. However, there is no analytical method that can assure that infectious agents in the specimens or reagents are completely absent. Therefore, handle reagents and specimens with extreme caution as if capable of transmitting infectious diseases. Bovine derived sera have been used for stabilizing of the positive and negative controls. Bovine serum albumin (BSA) and fetal calf sera (FCS) are derived from animals from BSE/TSE free-geographical areas.
16. Never eat, drink, smoke, or apply cosmetics in the assay laboratory. Never pipette solutions by mouth.
17. Chemical should be handled and disposed of only in accordance with the current GLP (Good Laboratory Practices) and the local or national regulations.
18. The pipette tips, vials, strips and specimen containers should be collected and autoclaved for not less than 2 hours at 121°C or treated with 10% sodium hypochlorite for 30 minutes to decontaminate before any further steps of disposal. Solutions containing sodium hypochlorite should NEVER be autoclaved. Materials Safety Data Sheet (MSDS) available upon request.
19. Some reagents may cause toxicity, irritation, burns or have carcinogenic effect as raw materials. Contact with the skin and the mucosa should be avoided but not limited to the following reagents: Stop solution, the Chromogens, and the Wash buffer.
20. The Stop solution 0.5M H_2SO_4 is an acid. Use it with appropriate care. Wipe up spills immediately and wash with water if come into contact with the skin or eyes.
21. ProClin™ 300 0.1% used as preservative, can cause sensation of the skin. Wipe up spills immediately or wash with water if come into contact with the skin or eyes.

INDICATIONS OF INSTABILITY DETERIORATION OF THE REAGENT: Values of the Positive or Negative controls, which are out of the indicated quality control range, are indicators of possible deterioration of the reagents and/or operator or equipment errors. In such case, the results should be considered as invalid and the specimens must be retested. In case of constant erroneous results and proven deterioration or instability of the reagents, immediately substitute the reagents with new one or contact Wantai technical support for further assistance.

Warning:
H317, H412, P273, P280, P333+P313, P363
ProClin™ 300

Danger:
H360D, P201, P280, P308+P313
N,N-dimethylformamide

PROCEDURE

Reagents preparation: Allow the reagents to reach room temperature. Check the Wash buffer concentrate for the presence of salt crystals. If crystals have formed, resolubilize by warming at 37°C until crystals dissolve. Dilute the Wash buffer (20X) as indicated in the instructions for washing. Use distilled or deionized water and only clean vessels to dilute the buffer. All other reagents are **READY TO USE AS SUPPLIED**.

Step 1 **Preparation:** Mark three wells as Negative control **(e.g. B1, C1, D1)**, two wells as Positive control **(e.g. E1, F1)** and one Blank (**e.g. A1**, neither specimens nor HRP-Conjugate should be added into the Blank well). If the results will be determined by using dual wavelength plate reader, the requirement for use of Blank well could be omitted. Use only number of strips required for the test.

Step 2 **Adding Diluent:** Add **20μl** of Specimen Diluent into each well except the Blank.

Step 3 **Adding Specimen:** Add **50μl** of Positive control, Negative control, and Specimen into their respective wells except the Blank. **Note: Use a separate disposal pipette tip for each specimen, Negative Control, Positive Control to avoid cross-contamination.** Mix by tapping the plate gently.

Step 4 **Adding HRP-Conjugate:** Add **100μl** of HRP-Conjugate into each well except the Blank.

Step 5 **Incubating:** Cover the plate with the plate cover and incubate **at 37°C for 90 minutes**.

Step 6 **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well **5 times** with diluted Wash Buffer. Each time allow the microwells to soak for **30-60 seconds**. After the final washing cycle, turn down the plate onto blotting paper or clean towel and tap it to remove any

remainders.

Step 7 **Coloring:** Add **50µl** of Chromogen Solution A and then **50µl** of Chromogen Solution B into each well including the Blank, mix gently. Incubate the plate **at 37°C for 30 minutes avoiding light**. The enzymatic reaction between the Chromogen solutions and the HRP-Conjugate produces blue color in Positive control and SARS-CoV-2 antigens positive specimen wells.

Step 8 **Stopping Reaction:** Using a multichannel pipette or manually, add **50µl** of Stop Solution into each well and mix gently. Intensive yellow color develops in Positive control and SARS-CoV-2 antigens positive specimen wells.

Step 9 **Measuring the Absorbance:** Calibrate the plate reader with the Blank well and read the absorbance at **450nm**. If a dual filter instrument is used, set the reference wavelength at **600~650nm**. Calculate the Cut-off value and evaluate the results. (**Note:** read the absorbance within **10 minutes** after stopping the reaction).

INSTRUCTIONS FOR WASHING

1. A good washing procedure is essential in order to obtain correct and precise analytical data.
2. It is therefore, recommended to use a good quality ELISA microplate washer, maintained at the best level of washing performances. In general, no less than **5 automatic washing cycles** of **350-400µl/well** are sufficient to avoid false positive reactions and high background.
3. To avoid cross-contaminations of the plate with specimen or HRP-conjugate, after incubation, do not discard the content of the wells but allow the plate washer to aspirate it automatically.
4. Assure that the microplate washer liquid dispensing channels are not blocked or contaminated and sufficient volume of Wash buffer is dispensed each time into the wells.
5. In case of manual washing, we suggest to carry out **5 washing cycles,** dispensing **350-400µl/well** and aspirating the liquid for **5 times**. If poor results (high background) are observed, increase the washing cycles or soaking time per well.
6. In any case, the liquid aspirated out the strips should be treated with a sodium hypochlorite solution at a final concentration of 2.5% for 24 hours, before they are wasted in an appropriate way.
7. The concentrated Wash buffer should be diluted **1 to 20** before use. If less than a whole plate is used, prepare the proportional volume of solution.

QUALITY CONTROL AND CALCULATION OF THE RESULTS

Each microplate should be considered separately when calculating and interpreting the results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each specimen absorbance (A) value to the Cut-off value (C.O.) of the plate. If the Cut-off reading is based on single filter plate reader, the results should be calculated by subtracting the Blank well A value from the print report values of specimens and controls. In case the reading is based on dual filter plate reader, do not subtract the Blank well A value from the print report values of specimens and controls.

Calculation of the Cut-off value (C.O.) = Nc + 0.06
(**Nc** = the mean absorbance value for three negative controls).
Important: If the mean A value of the negative controls is lower than 0.03, take it as 0.03.

Quality control (assay validation): The test results are valid if the Quality Control criteria are fulfilled. It is recommended that each laboratory must establish appropriate quality control system with quality control material similar to or identical with the patient specimen being analyzed.

- The A values of the Positive control must be ≥ cut-off value at 450/600~650nm or at 450nm after blanking.
- The A values of the Negative control must be < cut-off value at 450/600~650nm or at 450nm after blanking.

If one of the Negative control A values does not meet the Quality Control criteria, it should be discarded, and the mean value should be calculated by using the remaining two values. If more than one Negative control A values do not meet the Quality Control Range specifications, the test is invalid and must be repeated.

Example:

1. Quality Control
Blank well A value: A1= 0.025 at 450nm (Note: blanking is required only when reading with single filter at 450nm)

Well No.:	**B1**	**C1**	**D1**
Negative control A values after blanking:	0.020	0.012	0.016
Well No.:	**E1**	**F1**	
Positive control A values after blanking:	2.421	2.369	

All control values are within the stated quality control range
2. Calculation of Nc: = (0.020+0.012+0.016) / 3 = 0.016 (Nc is lower than 0.03, so take it as 0.03)
3. Calculation of the Cut-off: (C.O.) = 0.03 + 0.06 = 0.09

INTERPRETATIONS OF THE RESULTS

Negative Results: Specimens giving A value less than the Cut-off value are negative for this assay, which indicates that no SARS-CoV-2 antigens have been detected with the WANTAI SARS-CoV-2 Ag ELISA.

Positive Results: Specimens giving A value equal to or greater than the Cut-off value are considered initially reactive, which indicates that SARS-CoV-2 antigens have probably been detected with the WANTAI SARS-CoV-2 Ag ELISA. Retesting in duplicate of any initially reactive specimen is recommended. Repeatedly reactive specimens could be considered positive for SARS-CoV-2 antigens therefore there are serological indications for current coronavirus disease COVID-19.

Follow-up, confirmation and supplementary testing of any positive specimen with other analytical system (e.g. PCR) is required. Clinical diagnosis should not be established based on a single test result. It should integrate clinical and other laboratory data and findings.

PERFORMANCE DATA

The performance of the WANTAI SARS-COV-2 Ag ELISA was established on a panel of 114 frozen NP swabs from COVID-19 patients collected in 1mL VTM.

Table 1: Comparison between RT-PCR and WANTAI SARS-COV-2 Ag ELISA on patients with RT-PCR Ct≤30

WANTAI PCR	Positive (≤30Ct)	Negative	Total
Positive	14	0	14
Negative	1	67	68
Total	15	67	82
Sensitivity	93%		
Specificity	100%		
PPV	100%		
NPV	99%		

Table 2: Comparison between RT-PCR and WANTAI SARS-COV-2 Ag ELISA on patients with RT-PCR Ct≦35

WANTAI PCR	Positive (≤35CT)	Negative	Total
Positive	25	0	25
Negative	5	67	72
Total	30	67	97
Sensitivity	83%		
Specificity	100%		
PPV	100%		
NPV	76%		

Table 3: Comparison between RT-PCR and WANTAI SARS-COV-2 Ag ELISA According to Days from Onset of Symptoms

WANTAI PCR	Within 7 days of symptoms onset	after 7 days of symptoms onset
Positive	17	6
Negative	4	14
Total	21	20
Sensitivity	81%	30%

The results demonstrated that specimens obtained after 7 days of symptoms are more likely to produce negative results.

The cross-reactivity of the WANTAI SARS-COV-2 Antigen Rapid Test was evaluated by testing of a panel of high prevalence respiratory pathogens.

No.	Pathogen	Results
N1	Staphylococcus aureus	Neg
N2	S.pneumoniae	Neg
N3	Measles virus	Neg
N4	Mumps virus	Neg
N5	Ad type 3	Neg
N6	Mycoplaa Pneumoniae	Neg
N7	Parainfluenza virus 2	Neg
N8	HMPV	Neg
N9	Human coronavirus OC43	Neg
N10	Human coronavirus 229E	Neg
N11	Bordetella parapertussia	Neg
N12	Influenza B virus (Victoria)	Neg
N13	Influenza B virus (Y series)	Neg
N14	Influenza A H1N1(2009)	Neg
N15	Influenza A H3N2 virus	Neg
N16	Avian influenza virus H7N9	Neg
N17	Avian influenza virus H5N1	Neg
N18	EB virus	Neg
N19	Enterovirus CA16	Neg
N20	Rhinovirus	Neg

Precision: Two reproducibility reference samples CV1~CV2 were tested, the coefficient of variation (CV) were all <15%, and the CV of intra-day, inter-day, and different operators and locations were all <15%.

LIMITATIONS

1. Positive results must be confirmed with another available method and interpreted in conjunction with the patient clinical information.
2. Antibodies may be undetectable during the early stage of the disease and in some immunosuppressed individuals. Therefore, negative results obtained with SARS-CoV-2 Ag ELISA are only indication that the specimen does not contain detectable level of antigens and any negative result should not be considered as conclusive evidence that the individual is not infected with SARS-CoV-2.
3. If, after retesting of the initially reactive specimens, the assay results are negative, these specimens should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are related but not limited to inadequate washing step. For more information regarding Wantai ELISA Troubleshooting, please refer to Wantai's "ELISAs and Troubleshooting Guide", or contact Wantai technical support for further assistance.
4. The most common assay mistakes are: using kits beyond the expiry date, bad washing procedures, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add specimens or reagents, improper operation with the laboratory equipment, timing errors, the use of highly hemolyzed specimens or specimens containing fibrin, incompletely clotted serum specimens.
5. The prevalence of the marker will affect the assay's predictive values.
6. This kit is intended ONLY for testing of individual serum or plasma specimens, nasopharyngeal or oropharyngeal swab specimens. Do not use it for testing of cadaver specimens, saliva, urine or other body fluids, or pooled (mixed) blood.
7. This kit is a qualitative assay and the results cannot be used to measure antigen concentrations.

REFERENCES

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2. Bo Diao et. al. Diagnosis of Acute Respiratory Syndrome Coronavirus 2 Infection by Detection of Nucleocapsid Protein
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3. https://www.who.int/emergencies/diseases/novel-coronavirus-2019

SUMMARY OF THE MAJOR COMPONENTS OF THE KIT:

Use this summary only as a reference and always follow the comprehensive method sheet when performing the assay. Note: the components of individual kits are not lot- interchangeable.

1. Microwell plate	Code 5	one
2. Negative Control	Code 8	1x0.5ml
3. Positive Control	Code 7	1x0.5ml
4. HRP-Conjugate	Code 6	1x12ml
5. Specimen Diluent	Code 9	1x3ml
6. Swab Collection Buffer	Code10	2x14ml
7. Wash Buffer	Code 1	1x50ml
8. Chromogen Solution A	Code 2	1x6ml
9. Chromogen Solution B	Code 3	1x6ml
10. Stop Solution	Code 4	1x6ml

SUMMARY OF THE ASSAY PROCEDURE:

Use this summary only as a reference and always follow the detailed method sheet when performing the assay.

Add Specimen Diluent	20µl
Add Controls	50µl
Add Specimen	50µl
Add HPR-Conjugate	100µl
Incubate	90 minutes
Wash	5 times
Coloring	50µl A + 50µl B
Incubate	30 minutes
Stop the reaction	50µl stop solution
Read the absorbance	450nm or 450/600~650nm

EXAMPLE SCHEME OF CONTROLS / SPECIMENS DISPENSING:

	1	2	3	4	5	6	7	8	9	10	11	12
A	Blank	S3										
B	Neg.	…										
C	Neg.	…										
D	Neg.											
E	Pos.											
F	Pos.											
G	S1											
H	S2											

CE MARKING SYMBOLS:

IVD — **In Vitro Diagnostic Medical Device**
+2°C~+8°C Storage Conditions
Use By
LOT — **Batch**
Content Sufficient For <n> Tests
Instructions For Use
CE — **CE Marking – IVDD 98/79/EC**
EC REP — **EU Authorized Representative**
REF — **Catalog Number**
Manufacturer

UUU | PLATE — **MICROWELL PLATE**
CONTROL | - — **NEGATIVE CONTROL**
CONTROL | + — **POSITIVE CONTROL**
HRP | CON — **HRP-CONJUGATE**
DIL | SPE — **SPECIMEN DILUENT**
SWAB | BUF — **SWAB COLLETION BUFFER**
WASH | BUF | 20X — **WASH BUFFER**
CHROM | SOL | A — **CHROMOGEN SOLUTION A**
CHROM | SOL | B — **CHROMOGEN SOLUTION B**
STOP | SOL — **STOP SOLUTION**

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