Wantai SARS-CoV-2 Diagnostics

WANTAI SARS-CoV-2 IgG ELISA (Quantitative)

Diagnostic Kit for Quantitative Detection of IgG Antibody to SARS-CoV-2 (ELISA)

REF WS-1396 | 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 WANTAI SARS-CoV-2 IgG ELISA achieved.

INTENDED USE

The WANTAI SARS-CoV-2 IgG ELISA (Quantitative) is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for quantitative detection of IgG-class antibodies to SARS-CoV-2 virus in human serum or plasma. The WANTAI SARS-CoV-2 IgG ELISA (Quantitative) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or as an aid in individual vaccination management decisions. The quantitative result obtained with this kit is as a reference for clinician only, cannot be used as the sole basis for further individual vaccination and treatment.

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, acute respiratory distress syndrome (ARDS), 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 COVID-19 pandemic.

PRINCIPLE OF THE TEST

The WANTAI SARS-CoV-2 IgG ELISA (Quantitative) employs solid phase, indirect ELISA method for detection of IgG-class antibodies to SARS-CoV-2 in two-step incubation procedure. Polystyrene microwell strips are pre-coated with SARS-CoV-2 recombinant antigen. During the first incubation step, SARS-CoV-2 IgG antibodies, if present, will be bound to the solid phase pre-coated antigens. The wells are washed to remove unbound serum proteins and then, anti-human IgG antibodies (anti-IgG) conjugated to horseradish peroxidase (HRP-Conjugate) is added. During the second incubation step, these HRP-conjugated antibodies will be bound to any antigen-antibody (IgG) 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 antigen-antibody-anti-IgG (HRP) 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 absorbance value (A value) can be measured and is proportional to the titer of IgG antibody in the specimen. The IgG antibody titer in the specimen can be calculated by double logarithmic curve fitted with the standard concentration and A value. Wells containing specimens negative for SARS-CoV-2 IgG 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 recombinant SARS-CoV-2 antigen. 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.

STANDARD
- (1 ampoule)
preserv.0.4% ProClin™ 300

STANDARD: Lyophilized in ampoule.
Lyophilized, SARS-CoV-2 IgG antibodies in newborn calf serum buffer.
Should be reconstituted with distilled or deionized water to the working concentration. Once prepared, stable for 7 days at 2-8°C.

HRP | CON
Code 6 (1x12ml per vial)
preserv.0.15% ProClin™ 300

HRP-CONJUGATE: Red-colored liquid in a white vial with red screw cap.
Horseradish peroxidase-conjugated anti-human IgG antibodies.
Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

DIL | SPE
Code 9 (2x12ml per vial)
preserv.0.2% 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.

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, disposable gloves 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.

SPECIMEN COLLECTION, TRANSPORTING AND STORAGE

1. **Specimen Collection**: No special patient's preparation required. Collect the specimen in accordance with the normal laboratory practice. 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 3000-5000 RPM (round per minutes) for 20 minutes at room temperature or by filtration.
2. 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***. Specimens with visible microbial contamination should never be used.
3. The WANTAI SARS-CoV-2 IgG ELISA (Quantitative) is intended ONLY for testing of individual serum or plasma specimens. Do not use the assay for testing of cadaver specimens, saliva, urine or other body fluids, or pooled (mixed) blood.
4. **Transportation and Storage:** Specimens can be stored at 2-8°C for one week. For longer-term storage, specimens should be stored frozen (-15°C or lower) with no more than three freeze-thaw cycles. For shipment, specimens should be packaged and labeled in accordance with the existing local and international regulations for transportation of clinical specimens and ethological agents.

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 WANTAI SARS-CoV-2 IgG 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:** Bovine derived sera have been used for stabilizing of the Standard. 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 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 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.
22. Standards should be used for each test run, and the test results must be calculated with the standard curve of the same test run, otherwise it may lead to large deviation in the quantitative results.
23. Abnormal points in the standard curve may cause deviation of the test results of the whole plate, so each prepared standard should be tested in duplicate to improve the test accuracy. When only one of Standards has a significant increase or decrease, and it is caused by human error, this point can be discarded and the standard curve can be drawn with other Standards.

INDICATIONS OF INSTABILITY DETERIORATION OF THE REAGENT: Values of the Standard, 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 **Standards preparation:** Add distilled or deionized water into ampoule according to the volume indicated on the label of ampoule to reconstitute the lyophilized standard. After 2-3 minutes, the standard is completely dissolved, gently mix until it is homogeneous, then 16.0U/ml standard is ready to use. Use doubling dilution method to dilute 16.0U/ml standard with Specimen Diluent to 8.0U/ml, 4.0U/ml, 2.0U/ml, 1.0U/ml and 0U/ml (Specimen Diluent is used as 0U/ml). Then the final concentrations of the ready-to-use Standards are 16.0U/ml, 8.0U/ml, 4.0U/ml, 2.0U/ml, 1.0U/ml and 0U/ml respectively.

Step 2 **Numbering Wells:** Set two wells for each standard and one well for Blank (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. Each prepared standard should be tested in duplicate.

Step 2 **Adding Diluent:** Add **100µl** of Specimen Diluent into each well except Blank well.

Step 3 **Adding Specimen:** Add **10µl** of specimen and the prepared Standards into their respective wells except the Blank well and mix by tapping the plate gently. **Note: Use a separate disposable pipette tip for each specimen to avoid cross-contamination.**

Step 4 **Incubating:** Cover the plate with the plate cover and incubate **at 37°C for 30 minutes**.

Step 5 **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 6 **Adding HRP-Conjugate:** Add **100µl** of HRP-Conjugate into each well except the Blank well.

Step 7 **Incubating:** Cover the plate with the plate cover and incubate **at 37°C for 30 minutes**.

Step 8 **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 9 **Coloring:** Add **50µl** of Chromogen Solution A and then **50µl** of Chromogen Solution B into each well including the Blank well, mix gently. Incubate the plate **at 37°C for 15 minutes avoiding light**. The enzymatic reaction between the Chromogen solutions and the HRP-Conjugate produces blue color in the Standards wells and SARS-CoV-2 IgG antibody positive specimen wells.

Step 10 **Stopping Reaction:** Using a multichannel pipette or manually, add **50µl** of Stop Solution into each well and mix gently. Intensive yellow color develops in the Standards wells and SARS-CoV-2 IgG antibody positive specimen wells.

Step 11 **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

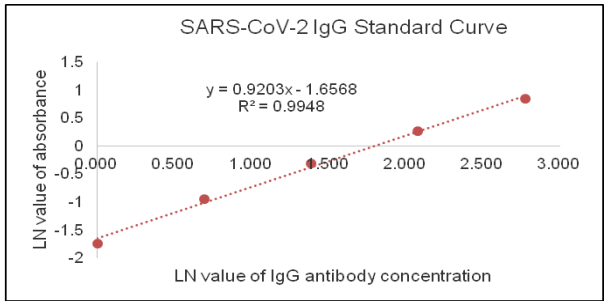
If the result reading is based on single filter plate reader, the results should be calculated by subtracting A value of the Blank well from the print report values of specimens and standards. In case the reading is based on dual filter plate reader, do not subtract the A value of Blank well from the print report values of specimens and standards.

The detection range of this kit is 1.0U/ml~16.0U/ml. If the concentration of the SARS-CoV-2 IgG antibody in specimen is higher than 16.0U/ml, it is necessary to redo the test after diluting the specimen with Specimen Diluent.

1. Use the antibody concentrations of the Standards (1.0U/ml~16.0U/ml) and the mean value of its corresponding absorbance values to do double logarithmic curve to obtain the linear regression equation. Substitute the logarithmic value of the absorbance of the specimen into the linear regression equation to obtain the SARS-CoV-2 IgG antibody concentration of the corresponding specimen.

2. An example is as follows:
Take the natural logarithmic value of each value: take the natural logarithmic value (LN value) of the IgG antibody concentration of the Standard as the independent variable (X), and the natural logarithm value (LN value) of the corresponding absorbance as the dependent variable (Y), the linear regression equation is calculated as follows: Y = 0.9203X - 1.6568. The data and graph are as follows:

IgG antibody concentration of Standard (U/ml)	1.0	2.0	4.0	8.0	16.0
LN value	0	0.693	1.386	2.079	2.773
A value of Standard	0.175	0.387	0.733	1.304	2.308
LN value	-1.746	-0.949	-0.311	0.265	0.836



If the absorbance value at 450nm/630nm of a specimen measured is A=0.715, its LN value calculated is -0.335, which is substituted into the equation, the SARS-CoV-2 IgG antibody concentration is: EXP{(-0.335+1.6568)/0.9948} ≈ 4.21U/ ml. (This standard curve is for illustration only)

3. If any following result is obtained, the test results should be considered invalid, it is necessary to repeat the test:
(1) R^2<0.9801; (2) A value of 16.0U/ml Standard <0.5; (3) A value of 0U/ml Standard >0.1.

PERFORMANCE CHARACTERISTICS

Prospective clinical validation study of the WANTAI SARS-CoV-2 IgG ELISA (Quantitative) was conducted at two sites in China in 2020. Serum and plasma specimens were evaluated from 351 subjects. Out of the 351 samples, 154 subjects were COVID-19 cases confirmed positive by an RT-PCR assay while 197 subjects were confirmed PCR negative. All patients who were confirmed positive exhibited clinical signs or symptoms of COVID-19.

Of the 154 positive samples, 125 were positive on the WANTAI SARS-CoV-2 IgG ELISA (Quantitative), and of the 197 negative samples, 196 were negative. The kit demonstrated the Positive Percent Agreement (PPA) of 81.17% (125/154), the Negative Percent Agreement (NPA) of 99.49% (196/197). The kit demonstrated the PPA of 94.94% (75/79) for ≥ 15 days from onset of symptoms, as indicated in the tables below.

Cases		PCR Comparator SARS-CoV-2 results		Total
		Positive	Negative	
WANTAI SARS-CoV-2 IgG ELISA (Quantitative)	Positive	125	1	126
	Negative	29	196	225
Total		154	197	351
PPA		81.17% (95%CI: 74.26%-86.56%)		
NPA		99.49% (95%CI: 97.18%-99.91%)		

Days from onset of symptoms	Total PCR Positive Samples	Number of Wantai Positive Result	PPA	95% CI
≤ 7	20	8	40.00%	21.88% - 61.34%
8 - 14	55	42	76.36%	63.65% - 85.63%
≥ 15	79	75	94.94%	87.69% - 98.01%
Total Subjects	154			

Retrospective analysis of the 75 positive samples (≥ 15 days from onset of symptoms) was conducted to measure the levels of IgG antibodies in the specimens. 100% of these specimens had IgG concentration of 100U/ml.

In the linear range of 1.0U/ ml to 16.0U/ ml, the linear correlation coefficient R^2 is ≥0.9801.

340 negative specimens were tested with this kit, the concentration of SARS-CoV-2 IgG antibody detected were all less than 1.0U/ ml.

To evaluate the potential cross-reactivity of the WANTAI SARS-CoV-2 IgG ELISA (Quantitative) to antibodies to other viruses that may be present in the population, the following viruses and autoimmune conditions were assessed. No false positive results were observed with the WANTAI SARS-CoV-2 IgG ELISA (Quantitative).

Specimen	No.	Lot #1		Lot #2		Lot #3		Specificity
		+	-	+	-	+	-	
Flu A	8	0	8	0	8	0	8	100%
Flu B	6	0	6	0	6	0	6	100%
HCV	6	0	6	0	6	0	6	100%
HBV	6	0	6	0	6	0	6	100%
ANA	5	0	5	0	5	0	5	100%
RSV	13	0	13	0	13	0	13	100%
Rhinovirus	6	0	6	0	6	0	6	100%

Specimen	No.	+	-	Specificity
alpha COV 229E	5	0	5	100%
alpha COV NL63	5	0	5	100%
beta COV OC43	7	0	7	100%
beta COV HKU1	4	0	4	100%

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. This kit is intended for quantitative detection of the concentration of SARS-CoV-2 IgG antibody produced by individuals with vaccine immunization or patients with recent or prior infection, the results are for clinical reference only.
2. Positive results must be confirmed with another available method and interpreted in conjunction with the patient clinical information.
3. Antibodies may be undetectable during the early stage of the disease and in some immunosuppressed individuals. Therefore, negative results obtained with WANTAI SARS-CoV-2 IgG ELISA (Quantitative) are only indication that the specimen does not contain detectable level of IgG antibodies and any negative result should not be considered as conclusive evidence that the individual is not infected with SARS-CoV-2.
4. 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.
5. 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.
6. The prevalence of the marker will affect the assay's predictive values.
7. This kit is intended ONLY for testing of individual serum or plasma specimens. Do not use it for testing of cadaver specimens, saliva, urine or other body fluids, or pooled (mixed) blood.

REFERENCES

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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	1x
2. Standard	-	1x
3. HRP-Conjugate	Code 6	1x12ml
4. Specimen Diluent	Code 9	1x12ml
5. Wash Buffer	Code 1	1x50ml
6. Chromogen Solution A	Code 2	1x6ml
7. Chromogen Solution B	Code 3	1x6ml
8. 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	100μl
Add Standards/Specimen	10μl
Incubate	30 minutes
Wash	5 times
Add HPR-Conjugate	100μl
Incubate	30 minutes
Wash	5 times
Coloring	50μl A + 50μl B
Incubate	15 minutes
Stop the reaction	50μl stop solution
Read the absorbance	450nm or 450/600~650nm

EXAMPLE SCHEME OF STANDARDS / SPECIMENS DISPENSING:

	1	2	3	4	5	6	7	8	9	10	11	12
A	Blank	STD4	S4									
B	STD1	STD5	S5									
C	STD1	STD5	…									
D	STD2	STD6										
E	STD2	STD6										
F	STD3	S1										
G	STD3	S2										
H	STD4	S3										

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
STANDARD	STANDARD
HRP | CON	HRP-CONJUGATE
DIL | SPE	SPECIMEN DILUENT
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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