（本试剂盒仅供体外研究使用，不用于临床诊断！）

产品货号：E-EL-E606

产品规格：96T/48T/24T/96T*5

Elabscience® SARS-CoV-2 中和抗体酶联免疫吸附测定试剂盒使用说明书

SARS-CoV-2 Neutralization Antibody ELISA Kit

使用前请仔细阅读说明书。如果有任何问题，请通过以下方式联系我们：

电话：400-999-2100

邮箱：techsupport@elabscience.cn

网址：www.elabscience.cn

具体保质期请见试剂盒外包装标签。请在保质期内使用试剂盒。

联系时请提供产品批号(见试剂盒标签)，以便我们更高效地为您服务。

用途

该试剂盒用于体外定性检测人血清和血浆中抗SARS-CoV-2中和抗体。

检测原理

本试剂盒采用竞争 ELISA 法。用人 ACE2 蛋白包被于酶标板上，实验时样品（或质控品）中的抗 SARS-CoV-2 中和抗体与包被的人 ACE2 竞争辣根过氧化物酶标记的 RBD 的结合位点，游离的成分被洗去。加入显色底物(TMB)，TMB 在辣根过氧化物酶的催化下呈现蓝色，加终止液后变成黄色。用酶标仪在 450 nm 波长处测 OD 值，通过计算抑制率来定性判断抗 SARS-CoV-2 中和抗体是否在检测样本中存在。

试验所需自备物品

1. 酶标仪(450 nm波长滤光片)
2. 高精度移液器，EP管及一次性吸头：0.5-10μL, 2-20μL, 20-200μL, 200-1000μL
3. 37℃恒温箱，
4. 双蒸水或去离子水
5. 吸水纸
6. 加样槽

样品收集方法

(具体处理方法可参考官网：http://www.elabscience.cn/List-detail-241.html)

1. **血清**：全血样品于室温放置1小时或2-8℃过夜后于2-8℃，1000×g离心20分钟，取上清即可检测。
2. **血浆**：抗凝剂推荐使用EDTA-Na_2，样品采集后30分钟内于2-8℃，1000×g离心15分钟，取上清即可检测。

试剂盒组成及保存

未拆封的试剂盒可在 2-8℃保存 12 个月。试剂盒组分开封后请按照下表中的条件分别保存。

中文名称	规格	开封后保存条件
ELISA 酶标板 Micro ELISA Plate	96T：8 孔×12 条 48T：8 孔×6 条 24T：8 孔×3 条 96T*5：5 块 96T 酶标板	2-8℃，可存放 12 个月
阳性质控品 Positive Control	96T：2 支 48T/24T：1 支 96T*5：10 支	
阴性质控品 Negative Control	96T：2 支 48T/24T：1 支 96T*5：10 支	
浓缩 HRP 酶结合物 (100×) Concentrated HRP Conjugate (100×)	48T/24T ：1 支 60μL 96T：1 支 120μL 96T*5：5 支 120μL	
样品&质控稀释液 Sample & Control Diluent	24T/48T/96T：1 瓶 20mL 96T*5：5 瓶 20mL	2-8℃，可存放至有效期(12 个月)
酶结合物稀释液 HRP Conjugated Diluent	24T/48T/96T ：1 瓶 14mL 96T*5：5 瓶 14mL	
浓缩洗涤液 (25×) Concentrated Wash Buffer (25×)	24T/48T/96T ：1 瓶 30mL 96T*5：5 瓶 30mL	
底物溶液(TMB) Substrate Reagent	24T/48T/96T ：1 瓶 10mL 96T*5：5 瓶 10mL	
反应终止液 Stop Solution	24T/48T/96T ：1 瓶 10mL 96T*5：5 瓶 10mL	
封板覆膜 Plate Sealer	24T/48T/96T ：5 张 96T*5：25 张	
产品说明书 Manual	1 份	
质检报告 Certificate of Analysis	1 份	

说明：**浓缩HRP酶结合物(100×)**和**底物溶液(TMB)**请避光保存。
所有试剂瓶盖须旋紧以防止蒸发和微生物的污染。
试剂体积以实际发货版说明书为准。相关试剂在分装时会比标签上标明的体积稍多一些，请在使用时量取而非直接倒出。

注意事项

■ 试剂盒注意事项

1) 本试剂盒仅供体外研究使用。
2) 试验中请穿着实验服并戴乳胶手套做好防护工作。特别是检测血液或者其他体液样品时，请按国家生物试验室安全防护条例执行。
3) 刚开启的酶标板孔中可能会有少许水样物质，此为正常现象，不会对实验结果造成任何影响。暂时不用的板条应拆卸后放入备用铝箔袋，按照上述表格中保存条件存放。
4) 检测使用的酶标仪需要安装能检测450±10 nm波长的滤光片，光密度范围在0-3.5之间。建议使用时提前15分钟预热。
5) 请勿使用其他批号或其他来源的试剂混合或替代本试剂盒中的试剂。
6) 试验中所用的EP管和吸头均为一次性使用，严禁混用。
7) 请勿使用过期的试剂。

■ 样品注意事项

1) 收集血液的试管应为一次性无内毒素试管。避免使用溶血，高血脂样品。
2) 谨慎处理血清血浆样本。
3) 样品收集后若在3天内进行检测可保存于2-8℃，若不能及时检测，请按一次使用量分装，冻存于-20℃(1个月内检测)，或-80℃(3个月内检测)，避免反复冻融。在检测前，冷冻过的样本应缓慢地融化并离心除去冻融过程产生的沉淀物。样本需恢复至室温后混匀使用。

检测前准备工作

1. 提前20分钟从冰箱中取出试剂盒，平衡至室温(18-25℃)。如果试剂盒需分多次使用，请仅取出本次实验所需的酶标板条和试剂，剩余板条和试剂需按照指定条件保存。
2. **洗涤液：**将**浓缩洗涤液**用双蒸水稀释(1:24)。提示：从冰箱中取出的浓缩洗涤液可能有结晶，属于正常现象，可用40℃水浴微加热使结晶完全溶解后再配制洗涤液。当日使用。
3. **HRP酶结合物工作液：**实验前计算当次实验所需用量(以50 µL/孔计算)，实际配制时应多配制100-200 µL。使用前15分钟，将**浓缩HRP酶结合物**于800×g离心1分钟，以**酶结合物稀释液**将100×**浓缩HRP酶结合物**稀释成1×工作浓度(例如：10 µL浓缩液+990 µL稀释液)。HRP酶结合物工作液需要在2-8℃保存并在1天内使用。
4. **样品：**使用样品&质控品稀释液将样品稀释10倍。
5. **阳性质控品：**用0.3 mL样品&质控品稀释液溶解阳性质控品。
6. **阴性质控品：**用0.5 mL样品&质控品稀释液溶解阴性质控品。
7. 预处理过的样品和质控品均需要在2-8℃保存并在1天内使用。

操作步骤

1. 分别设定**样品孔，阳性质控孔和阴性质控孔**。加入 50 µL 预处理过的样品和质控品后(建议样品和质控品在检测中均设立复孔)，立即每孔加入配好的**HRP 酶结合物工作液** 50 µL。给酶标板覆膜，37℃孵育 60 分钟。提示：加样时将样品加于酶标板底部，尽量不触及孔壁，轻轻晃动混匀，避免产生气泡。加样时间宜控制在 10 分钟内。
2. 甩尽孔内液体，在洁净的吸水纸上拍干。每孔加**洗涤液** 350 µL，浸泡 1 分钟，吸去或甩掉酶标板内的液体，拍干。重复此洗板步骤 3 次。提示：此处可使用洗板机(参考北京拓普 DEM-3 型洗板机参数设置：2 点吸，每孔加入洗涤液 350 µL，振板 5 秒，吸液 0.5 秒)。洗板完成后请立即进行下步操作，不要让微孔板干燥。
3. 每孔加**底物溶液(TMB)** 90 µL，酶标板加上覆膜，37℃避光孵育 15 分钟左右。提示：根据实际显色情况酌情缩短或延长，但不可超过 30 分钟。
4. 每孔加**终止液** 50 µL，终止反应。提示：终止液的加入顺序应尽量与底物溶液的加入顺序相同。
5. 立即用酶标仪在 450 nm 波长测量各孔的光密度(OD 值)。

上样程序

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

Pos.：阳性质控品;
Neg.：阴性质控品;

操作一览表

对应板孔中加入 50μL 预处理的样品，阳性质控品和阴性质控品

↓

立即每孔加入 50μL HRP 结合物工作液

↓ 37℃, 60 min

弃掉板孔液体，洗板3次

↓

每孔加入 90μL 底物溶液

↓ 37℃, 15 min

每孔加入 50μL 终止液

↓

立即在450nm波长下读数，处理数据

质量控制

每次试验都需要通过质控品A450吸光度值来进行质量控制。

阴性质控品：OD＞1.2

阳性质控品：OD＜0.4

若质控品吸光度值不符合上述要求，表示测试无效，建议重复实验。

结果判断

样品抑制率按如下公式计算:

$$抑制率 = \left(1 - \frac{样品OD值}{阴性质控品OD值}\right) \times 100\%$$

1）阳性结果：抑制率≥20%

检测的样品被认为是抗SARS-CoV-2中和抗体阳性。

2）阴性结果：抑制率＜20%

检测的样品被认为是抗SARS-CoV-2中和抗体阴性。

说明： 阴性质控品的OD值用于抑制率的计算，阳性质控品的OD值仅用于评价结果的有效性。

性能评估

1. **精密度：** CV ≤ 15%。
2. **特异性**:与其他人类冠状病毒,包括 HCoV-HKU1, HCoV- OC43, HCoV-NL63, HCoV-229E,或非冠状病毒,包括甲型流感病毒(H1N1, H3N2, H5N1, H7N9), 乙型流感病毒(Yamagata, Victoria)、呼吸道合胞病毒、鼻病毒、腺病毒、肠病毒,巴尔病毒、麻疹病毒、人类巨细胞病毒、轮状病毒、诺瓦克病毒、腮腺炎病毒、带状疱疹病毒,或肺炎支原体的抗体/抗原阳性患者的血清样本无交叉反应。
3. **Cut-off 值：** 通过检测 500 名健康人群血清，以 98%检测值的临界值，即 <20%作为 cut-off 值。

声明

1. 限于现有条件及科学技术水平，尚不能对所有原料进行全面的鉴定分析，本产品可能存在一定的质量技术风险。
2. 本试剂盒在研发过程中去除/降低了生物学样本中的一些内源性干扰因素，并非所有可能影响的因素均已去除。
3. 最终的实验结果与试剂的有效性、实验者的相关操作以及当时的实验环境等因素密切相关，本公司只对试剂盒本身负责，不对因使用试剂盒所造成的样本消耗负责，请使用者使用前充分考虑到样本可能的使用量，预留充足的样本。
4. 为了达到好的实验结果，请只使用本公司试剂盒内提供的试剂，不要混用其他制造商的产品，严格按照说明书操作。
5. 由于操作过程中试剂制备以及酶标仪参数设置不正确，可能导致结果异常，实验前请仔细阅读说明书并调整好仪器。
6. 即使是相同人员操作也可能在两次独立实验中得到不同的结果，为保证结果的重现性，需要控制实验过程中每一步的操作。
7. 试剂盒发货前会经过严格的质检，然而，因为运输条件、实验设备差异等等因素影响，用户检测结果可能跟出厂数据不一致。不同批次间试剂盒间的差异也可能来自上述原因。
8. 本试剂盒未与其他厂家同类试剂盒或不同方法检测同一目的物的产品进行对比，所以不排除检测结果不一致的情况。
9. 试剂盒仅供研究使用，如将其用于临床诊断或任何其他用途，我公司将不对因此产生的问题负责，亦不承担任何法律责任。

SARS-CoV-2 Neutralization Antibody ELISA Kit

Catalog No: E-EL-E606
Size: 24T/96T/96T*5

Intended use

This ELISA kit applies to the in vitro qualitative determination of Neutralization antibodies against SARS-CoV-2 in human serum or plasma.

Test principle

This Test kit uses Competitive-ELISA as the method to qualitatively detect the Anti-SARS-CoV-2 Neutralization Antibody in the sample.

The micro ELISA plate provided in this kit is pre-coated with recombinant human ACE2. During the reaction, the SARS-CoV-2 Neutralization Antibody in the pretreated samples or controls competes with a fixed amount of human ACE2 on the solid phase supporter for sites on the Horseradish peroxidase (HRP) conjugated recombinant SARS-CoV-2 RBD fragment (HRP-RBD). After 37℃ incubation, the unbound HRP-RBD as well as any HRP-RBD bound to non-Neutralization antibody will be captured on the plate and eventually form the ACE2-RBD-HRP complex, while the circulating neutralization antibodies HRP-RBD complexes remain in the supernatant and are removed during washing. Then a TMB substrate solution is added to each well. The enzyme-substrate reaction is terminated by the addition of stop solution and the color change is measured spectrophotometrically at a wavelength of 450 nm ±2 nm. Compared with the inhibition ratio to judge whether SARS-CoV-2 Neutralization Antibody exists in the tested samples or not.

Other supplies required

Microplate reader with 450 nm wavelength filter
High-precision transfer pipette, EP tubes and disposable pipette tips
Incubator capable of maintaining 37℃
Deionized or distilled water
Absorbent paper
Loading slot

Kit components & Storage

An unopened kit can be stored at 2-8℃ for 12 months. After opening, store the items separately according to the following conditions.

<table>
<tr><th>Item</th><th>Specifications</th><th>Storage</th></tr>
<tr><td>Micro ELISA Plate
(Dismountable)</td><td>96T: 8 wells ×12 strips
48T: 8 wells ×6 strips
24T: 8 wells ×3 strips
96T*5: 5 plates, 96T</td><td rowspan="4">2-8℃, up to expiry date (12 months)</td></tr>
<tr><td>Positive Control</td><td>96T: 2 vials
48T/24T: 1 vial
96T*5: 10 vials</td></tr>
<tr><td>Negative Control</td><td>96T: 2 vials
48T/24T: 1 vial
96T*5: 10 vials</td></tr>
<tr><td>Concentrated HRP Conjugate (100×)</td><td>96T: 1 vial, 120 μL
48T/24T: 1 vial, 60 μL
96T*5: 5 vials, 120 μL</td></tr>
<tr><td>Sample & Control Diluent</td><td>96T/48T/24T: 1 vial, 20 mL
96T*5: 5 vials, 20 mL</td><td rowspan="5">2-8℃, up to expiry date (12 months)</td></tr>
<tr><td>HRP Conjugate Diluent</td><td>96T/48T/24T: 1 vial, 14 mL
96T*5: 5 vials, 14 mL</td></tr>
<tr><td>Concentrated Wash Buffer(25×)</td><td>96T/48T/24T: 1 vial, 30 mL
96T*5: 5 vials, 30 mL</td></tr>
<tr><td>Substrate Reagent</td><td>96T/48T/24T: 1 vial, 10 mL
96T*5: 5 vials, 10 mL</td></tr>
<tr><td>Stop Solution</td><td>96T/48T/24T: 1 vial, 10 mL
96T*5: 5 vials, 10 mL</td></tr>
<tr><td>Plate Sealer</td><td>96T/48T/24T: 5 pieces
96T*5: 25 pieces</td><td rowspan="3"></td></tr>
<tr><td>Product Description</td><td>1 copy</td></tr>
<tr><td>Certificate of Analysis</td><td>1 copy</td></tr>
</table>

Note: Concentrated HRP Conjugate(100×) and **Substrate Reagent** should be stored away from light.

All reagent bottle caps must be tightened to prevent evaporation and microbial pollution. The volume of reagents in partial shipments is a little more than the volume marked on the label, please use accurate measuring equipment instead of directly pouring into the vial(s).

Sample collection

(More detailed information please view our website: http://www.elabscience.cn/List–detail-241.html)

Serum: Allow samples to clot for 1 hour at room temperature or overnight at 2-8℃before centrifugation for 20 min at 1000×g at 2-8℃. Collect the supernatant to carry out the assay.

Plasma: Collect plasma using EDTA-Na_2 as an anticoagulant. Centrifuge samples for 15 min at 1000×g at 2-8℃ within 30 min of collection. Collect the supernatant to carry out the assay.

Note

■ **Note for kit**

1) For research use only. Not for use in diagnostic procedures.
2) Please wear lab coats, eye protection and latex gloves for protection. Please perform the experiment following the national security protocols of biological laboratories, especially when detecting blood samples or other bodily fluids.
3) A freshly opened ELISA plate may appear a water-like substance, which is normal and will not have any impact on the experimental results. Return the unused wells to the foil pouch and store according to the conditions suggested in the above table.
4) The microplate reader should be able to be installed with a filter that can detect the wave length at 450±2nm. The optical density should be within 0-3.5. Follow the Instructions of the Microplate Reader for set-up and preheat it for 15 min before OD measurement.
5) Do not mix or substitute reagents with those from other lots or sources.
6) Change pipette tips in between adding of each standard level, between sample adding and between reagent adding. Also, use separate reservoirs for each reagent.
7) The kit should not be used beyond the expiration date on the kit label.

■ **Note for sample**

1) Tubes for blood collection should be disposable and be non-endotoxin. Severe hemolysis, lipoid, or turbidity samples should not be used.
2) Handle all serum and plasma as if capable of transmitting infectious agents.
3) Samples should be assayed within 3 days when stored at 2-8℃, otherwise samples must be divided up and stored at -20℃ (≤ 1 month) or -80℃ (≤ 3 months). Avoid repeated freeze-thaw cycles. Prior to assay, the frozen samples should be slowly thawed and centrifuged to remove precipitates. Frozen samples must be mixed well and brought to room temperature before testing.

Reagent preparation

1. Bring all reagents to room temperature (18-25℃) before use. If the kit will not be used up in one assay, please only take out the necessary strips and reagents for present experiment, and store the remaining strips and reagents at required condition.
2. **Wash Buffer:** Dilute 30 mL of Concentrated Wash Buffer with 720 mL of deionized or distilled water to prepare 750 mL of Wash Buffer. Note: if crystals have formed in the concentrate, warm it in a 40℃ water bath and mix it gently until the crystals have completely dissolved.
3. **HRP Conjugate working solution:** HRP Conjugate is HRP Conjugated RBD. Calculate the required amount before the experiment (50 μL/well). In preparation, slightly more than calculated should be prepared. Centrifuge the Concentrated HRP Conjugate at 800×g for 1 min, then dilute the 100×**Concentrated HRP Conjugate** to 1× working solution with **HRP Conjugated Diluent**(Concentrated HRP Conjugate: HRP Conjugated Diluent= 1: 99). Note: The HRP Conjugate working solution should be stored at 2-8℃ and used within 1 day.
4. **Samples**: Dilute the tested serum or plasma at 10 fold by using the Sample & Control Diluent, mix thoroughly.
5. **Positive control**: Dissolve Positive Control with 0.3mL Sample & Control Diluent.
6. **Negative control**: Dissolve Negative Control with 0.5 mL Sample & Control Diluent.
7. Pre-treated Samples and Controls should be stored at 2-8℃ and used within 1 day.

Pipetting protocol

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

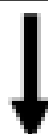
Pos.: Positive Control;
Neg.: Negative Control;

Assay procedure

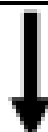
1. Determine wells for **Positive** and **Negative Controls** and **samples**. Add 50μL each pre-treated Samples and Controls into the appropriate wells (It is recommended that all samples and Controls be assayed in duplicate). Immediately add 50μL of **HRP Conjugate working solution** to each well. Cover the plate with the sealer provided in the kit. Incubate for 60 min at 37℃. Note: solutions should be added to the bottom of the micro TEST plate well, avoid touching the inside wall and causing foaming as much as possible.
2. Decant the solution from each well， add 350μL of **wash buffer** to each well. Soak for 30-60 seconds and aspirate or decant the solution from each well and pat it dry against clean absorbent paper. Repeat this wash step 3 times. Note: a microplate washer can be used in this step and other wash steps. Make the tested strips in use immediately after the wash step. Do not allow wells to be dry.
3. Add 90μL of **Substrate Reagent** to each well. Cover the plate with a new sealer. Incubate for about 15 min at 37℃. Protect the plate from light. Note: the reaction time can be shortened or extended according to the actual color change, but not more than 30min. Preheat the Microplate Reader for about 15 min before OD measurement.
4. Add 50μL of **Stop Solution** to each well. Note: adding the stop solution should be done in the same order as the substrate solution.
5. Determine the optical density (OD value) of each well at once with a micro-plate reader set to 450 nm.

Assay Procedure Summary

Add 50µL each pre-treated Samples and Controls into the appropriate wells

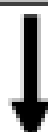


Immediately add 50µL of HRP Conjugate working solution to each well

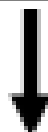


37℃, 60 min

Washing with 350 µL of diluted wash buffer per well for 3 times

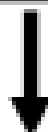


Add 90µL of TMB Substrate Reagent to each well



37℃, 15 min

Add 50µL of Stop Solution to each well



Read immediately at 450 nm

Quality control

For each assay, both Positive and Negative Controls must be included to validate the results. The OD450 of each Control must meet the requirements as follows, otherwise, the test is invalid and should be repeated.

OD of Negative Control＞1.2

OD of Positive Control＜0.4

Interpretation

The OD of the Negative Control is used to calculate the inhibition, and the OD of Positive Control is only used to evaluate the validity of the results. The inhibition of each sample can be calculated with the formulation as follows:

$$\text{Inhibition} = \left(1 - \frac{\text{OD value of Sample}}{\text{OD value of Negative Control}}\right) \times 100\%$$

Inhibition≥20%: Positive, Neutralization antibodies for SARS-CoV-2 are detected.

Inhibition＜20%: Negative, Neutralization antibodies for SARS-CoV-2 are not detected.

Analytical performance

4. Repeatability: the CV ≤ 15%
5. Analysis specificity: There is no cross-reaction with antibody/antigen positive sera samples from patients with other human coronaviruses (HCoV-HKU1, HCoV- OC43, HCoV-NL63, HCoV-229E), or non-coronaviruses, including influenza A virus (H1N1, H3N2, H5N1, H7N9), influenza B virus (Yamagata lineages, Victoria lineages), respiratory syncytial virus, rhinovirus, adenovirus, enterovirus, Epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, herpes zoster virus, or Mycoplasma pneumoniae.
6. The cut-off value was determined at 98% sensitivity of 500 healthy people sera, as < 20%.

Troubleshooting

If the results are not good enough, please take pictures and save the experimental data in time. Keep the used plate and remaining reagents. Then contact our technical support to solve the problem. Meanwhile, you could also refer to the following materia

Problem	Causes	Solutions
Poor standard curve	Inaccurate pipetting	Check pipettes.
	Improper standard dilution	Ensure briefly spin the vial of standard and dissolve the powder thoroughly by gentle mixing.
	Wells are not completely aspirated	Completely aspirate wells in between steps.
Low signal	Insufficient incubation time	Ensure sufficient incubation time.
	Incorrect assay temperature	Use recommended incubation temperature. Bring substrate to room temperature before use.
	Inadequate reagent volumes	Check pipettes and ensure correct preparation.
	Improper dilution	
	HRP conjugate inactive or TMB failure	Mix HRP conjugate and TMB, rapid coloring.
Deep color but low value	Plate reader setting is not optimal	Verify the wavelength and filter setting on the Microplate reader.
		Open the Microplate Reader ahead to pre-heat.
Large CV	Inaccurate pipetting	Check pipettes.
High background	Concentration of target protein is too high	Use recommended dilution factor.
	Plate is insufficiently washed	Review the manual for proper wash. If using a plate washer, check that all ports are unobstructed.
	Contaminated wash buffer	Prepare fresh wash buffer.
Low sensitivity	Improper storage of the ELISA kit	All the reagents should be stored according to the instructions.
	Stop solution is not added	Stop solution should be added to each well before measurement.

Declaration

1. Limited by current conditions and scientific technology, we can't conduct comprehensive identification and analysis on all the raw material provided. So there might be some qualitative and technical risks for users using the kit.
2. This assay is designed to eliminate interference by factors present in biological samples. Until all factors have been tested in the ELISA immunoassay, the possibility of interference cannot be excluded.
3. The final experimental results will be closely related to the validity of products, operational skills of the operators, the experimental environments and so on. We are only responsible for the kit itself, but not for the samples consumed during the assay. The users should calculate the possible amount of the samples used in the whole test. Please reserve sufficient samples in advance.
4. To get the best results, please only use the reagents supplied by the manufacturer and strictly comply with the instructions.
5. Incorrect results may occur because of incorrect operations during the reagents preparation and loading, as well as incorrect parameter settings of the Micro-plate reader. Please read the instructions carefully and adjust the instrument prior to the experiment.
6. Even the same operator might get different results in two separate experiments. In order to get reproducible results, the operation of every step in the assay should be controlled.
7. Every kit has strictly passed QC test. However, results from end users might be inconsistent with our data due to some variables such as transportation conditions, different lab equipment, and so on. Intra-assay variance among kits from different batches might arise from the above reasons too.
8. Kits from different manufacturers or other methods for testing the same analyte could bring out inconsistent results, since we haven't compared our products with those from other manufacturers.
9. The kit is designed for research use only, we will not be responsible for any issues if the kit is applied in clinical diagnosis or any other related procedures.