

Diagnostic Kit for Interleukin-6 (Fluorescence Immunochromatographic Assay)

Instructions for Use

INTENDED USE

This kit is applicable to in vitro quantitative detection of interleukin-6 (IL-6) in human serum/plasma/whole blood/fresh finger terminal blood sample, and it's used for auxiliary diagnosis of bacterial infection. This kit only provides interleukin-6 (IL-6) test results, and results obtained shall be used in combination with other clinical information for analysis. It must only be used by healthcare professionals.

SUMMARY

Interleukin-6 is a polypeptide that consists of two glycoprotein chains, which has molecular weight of 130kd. As an important member of cytokine network, interleukin-6 (IL-6) plays a central role in acute inflammatory reaction, and it can mediate acute phase reaction of liver, and stimulate production of C-reactive protein (CRP) and fibrinogen. Many infectious diseases may lead to rise in serum IL-6 level, and IL-6 level is closely associated with patient outcomes. As a pleiotropic cytokine with extensive functions, IL-6 is secreted by T cell, B cell, mononuclear phagocyte, and endothelial cell, and it's a key part of inflammatory mediator network. Upon occurrence of inflammatory reaction, IL-6's produced first, which induces production of CRP and procalcitonin (PCT) upon its production. It will be produced rapidly in case of infection, internal and external injuries, surgical operation, stress reaction, brain death, tumorigenesis, and acute inflammatory reaction process of other circumstances. IL-6 is involved in occurrence and development of many diseases, its blood level is closely associated with inflammation, virus infection and autoimmune disease, and its changes happen earlier than CRP. According to research results, IL-6 level increases rapidly upon bacterial infection, PCT level increases after 2h, while CRP only increases rapidly after 6h. Abnormal secretion or gene expression of IL-6 can often lead to occurrence of a series of diseases, large amount of IL-6 can be secreted into blood circulation in a pathological state, and detection of IL-6 is of very great significance to disease diagnosis and prognostic judgment.

PRINCIPLE OF DETECTION

This kit uses double-antibody sandwich assay and fluorescence immunochromatographic assay of high specificity for quantitative detection of interleukin-6 (IL-6) in human serum/plasma/whole blood/fresh finger terminal blood sample. Test strip contains anti-IL-6 antibody pre-fixed to test area on membrane (T) and goat anti-chicken IgY antibody prefixed to control area (C), and marker pad contains pre-coated fluorescently labeled anti-IL-6 antibody and chicken IgY antibody. In the course of sample detection, IL-6 antigen in sample bonds with fluorescently labeled anti-IL-6 antibody and forms immune complex first. The complex and sample flow towards the direction of bibulous paper inside nitrocellulose membrane under immunochromatographic effect. The complex will bond with coated anti-IL-6 antibody when it passes test area (T), form the complex of 'anti-IL-6 antibody - IL-6 antigen - fluorescently labeled anti-IL-6 antibody' and agglutinate. Fluorescently labeled chicken IgY antibody bonds with coated goat anti-chicken IgY antibody when it passes control area (C), forms the complex of 'goat anti-chicken IgY antibody - fluorescently labeled chicken IgY antibody', and agglutinates. IL-6 concentration in sample is positively correlated with fluorescence intensity, and IL-6 concentration in sample can

be detected by fluorescence immunoanalyzer.

MAIN KIT COMPONENTS

Catalogue number	52323501	52323505	52323520	52323525
specification	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Components	1	5	20	25
Test device	1	5	20	25
Sample diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

- 1 Test line (T line): T line area of nitrocellulose membrane is coated with anti-IL-6 antibody.
- 2 Control line (C line): C line area of nitrocellulose membrane is coated with goat anti-chicken IgY antibody.
- 3 Labeling pad: It is coated with fluorescent-microsphere-labeled anti-IL-6 antibody and chicken IgY antibody.
4. Main component of sample diluent is 20mM, pH7.4 PBS solution.



Warning: The diluent includes 0.1% Proclin300

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

P280: Wear protective gloves/protective clothing/face protection.

P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2°C~30°C. The shelf life of the kit is 24 months.
2. Sample diluent shall be capped immediately upon unsealing and kept in cool place.
3. Do not use the kit after the expiration date

APPLICABLE INSTRUMENT

The test must be quantified with Igloo Reader Pro, available from goodscare GmbH, Germany.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedure.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2°C~8°C for up to 2 days.
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be

- tested immediately. If test cannot be performed in time, the separated samples can be stored at 2°C~8°C for 7 days. If frozen below -15°C, samples can be stored for 6 months.
6. Fresh terminal blood of fingertips should be used immediately after collection.
 7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.
 8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.
2. Before test, restore the reagent to room temperature.

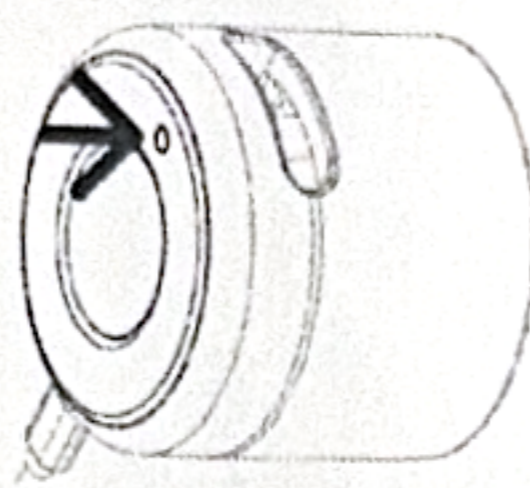

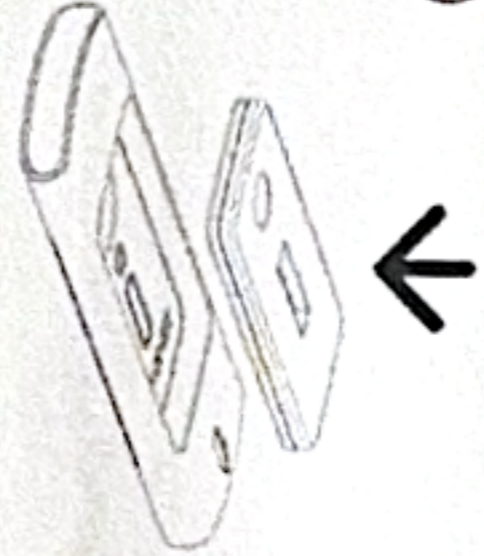
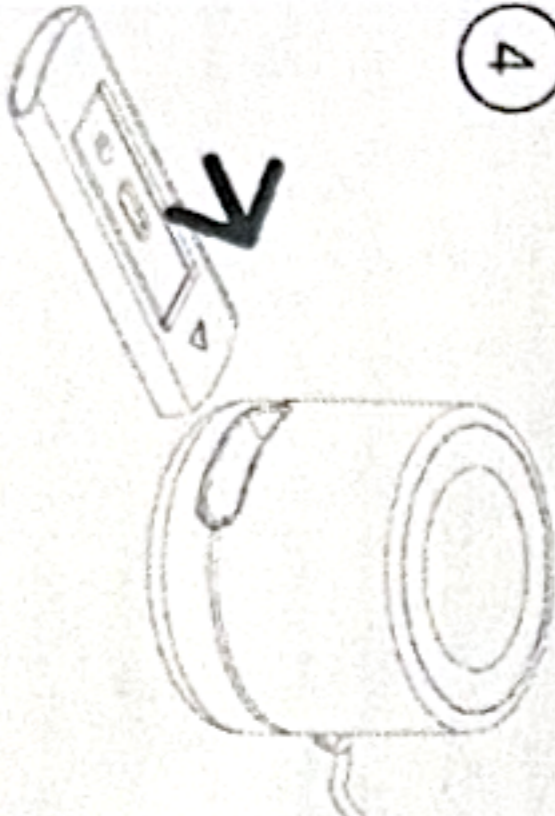


TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

I. 1: Drip the sample into the test device

- (1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;
- (2) Take out sample diluents, add 20μL of serum/plasma/whole blood/fresh finger terminal blood sample and mix;
- (3) Add 80μL of above mixed solution into the sample hole of test device;
- (4) Reaction time is 15 minutes.

Igloo Reader Pro Procedure

<p>1</p>  <p>To turn the reader on - press the power button on the circle-shaped rubber bottom of the device.</p>	<p>2</p>  <p>Press the button new measurement. Fill in Patient Identifier and other required data. Configure measurement timer and click Next.</p>	<p>3</p>  <p>As soon as the testing is completed, place the test cassette into the Adaptor supplied with Reader. Please check the "Correct Orientation" marked on the Adaptor for the test cassette.</p>
<p>4</p>  <p>Insert the adaptor with the test cassette into Reader to start the measurement. Please do it quickly so the measurement timer works correctly.</p>	<p>5</p>  <p>Measurement is now under way. Please make sure not to reject the adaptor or cassette during measurement.</p>	<p>6</p>  <p>Your first measurement is complete. Each test result can be exported or printed. * different units of measurement may apply depending on the test.</p>

REFERENCE INTERVAL

1. Through study on reference interval of IL-6 based on C28-A2 Define and Determine Reference Intervals in the Clinical Laboratory - Second Edition released by Clinical and Laboratory Standards Institute (CLSI) and WST 402-2012 Define and Determine the Reference Intervals in Clinical Laboratory, the reference interval of IL-6 obtained is: 7.0 pg/mL
2. Given geographical, race and age difference, different laboratories are recommended to develop IL-6 reference intervals of related clinical significance that suit populations of their own areas.

INTERPRETATION OF THE RESULT

1. Aforesaid data are reference intervals established for detection data of this kit, and different laboratories are recommended to develop reference intervals of related clinical significance for populations of their own areas.
 2. Physiological change, stress reaction and other statuses shall be excluded in case of measured concentration of sample IL-6 more than reference interval. Clinical symptom diagnosis shall be taken into consideration in case of real abnormalities. Aforesaid results are for reference only.
 3. Measured results of this method are only applicable to judgment by reference interval established by this method, which are not directly comparable with results of other methods.
 4. Other factors may also give rise to incorrect detection results, which include technical reasons, operational errors, and other sample related factors.
- *Invalid result: If the assay result is invalid, the Igloo Reader Pro will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result is obtained if it reappears, please contact the device manufacturer.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.
9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid

wrong result.

PRODUCT PERFORMANCE INDEX

Internal references of the enterprise are used for assessment, different performance indicators of the kit all meet criteria, and specific performance indicators are as follows:

1. Reportable range of reagent (kit): within the range of 3.0~40000.0 pg/mL;
2. Linearity range: linearity of reagent (kit) shall be within the range of 3.0~4000.0 pg/mL, and analytical performance shall meet following requirements:
 - a) Linear correlation coefficient (r) shall be ≥ 0.9900 .
 3. Accuracy: recovery shall be within the range of [85%~115%].
 4. Detection limit: ≤ 1.5 pg/mL.
 5. Repeatability: CV $\leq 15\%$.
 6. HOOK effect: there shall be no HOOK effect when IL-6 concentration is 60000 pg/mL.
 7. Specificity: no nonspecific reactions found during detection of following substances at concentrations indicated in the table.

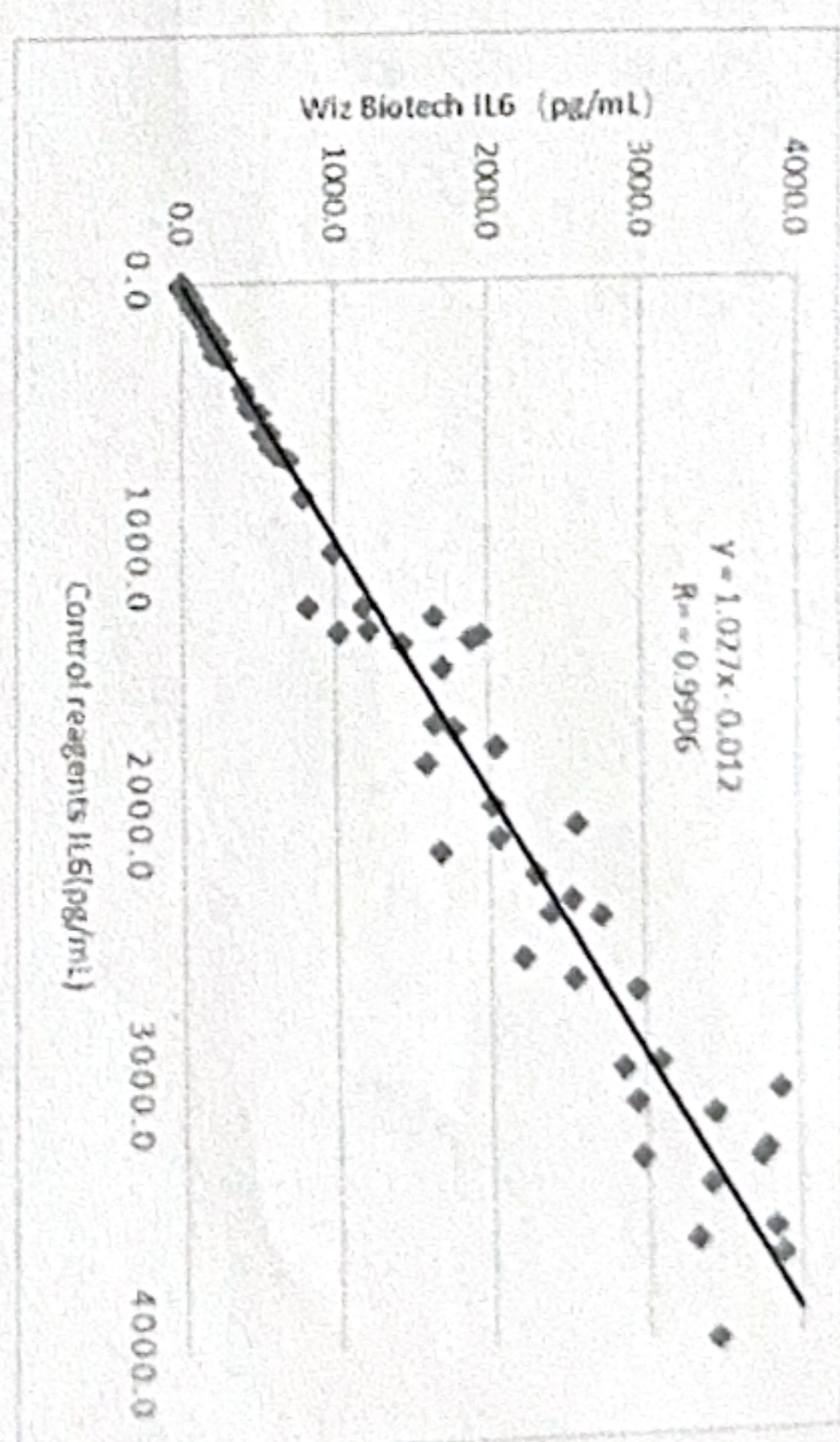
Substance	Concentration	Result
IL-1 α	50000 pg/mL	<1.5 pg/mL
IL-1 β	50000 pg/mL	<1.5 pg/mL
IL-2	50000 pg/mL	<1.5 pg/mL
IL-4	50000 pg/mL	<1.5 pg/mL
IL-8	50000 pg/mL	<1.5 pg/mL
TNF- α	50000 pg/mL	<1.5 pg/mL
Albumin	120 g/L	<1.5 pg/mL
Interferon	3 $\times 10^3$ IU/mL	<1.5 pg/mL
C-reactive protein	1 $\times 10^3$ mg/L	<1.5 pg/mL
Human katacalcin	1000 ng/mL	<1.5 pg/mL
Human calcitonin	100 ng/mL	<1.5 pg/mL
Human α -calcitonin gene-related peptide	1000 ng/mL	<1.5 pg/mL
Human β -calcitonin gene-related peptide	1000 ng/mL	<1.5 pg/mL

8. Interfering: no interference phenomena found during test of following substances at indicated concentrations.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	171 μ mol/L	Hemoglobin	2.5 g/L
Triglyceride	17 mmol/L	Rheumatoid factor	150 IU/mL

9. Clinical performance

Clinical performance of this product's assessed through collection of 183 cases of clinical samples. Corresponding marketed kit of electrochemiluminescence assay's used as reference reagent, detection results have been compared and their comparability has been studied through linear regression, and correlation coefficients of the two assays are $y = 1.027x - 0.012$ and $R = 0.9906$ respectively.



LIMITATION

1. This reagent is only used for testing human whole blood, serum, plasma, and fresh finger terminal blood.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18°C~25°C).
4. Linearity range of the kit is 3.0~4000.0 pg/mL. In case of high concentration sample more than linearity range of the kit, it shall be diluted to linearity range of the kit for determination and calculation. If accurate concentration needs to be determined. The maximum dilution ratio of this kit under condition of physiological saline or sample diluent is 10x, and the reportable range is 3.0~40000.0 pg/mL.
5. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.


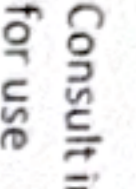



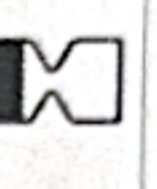



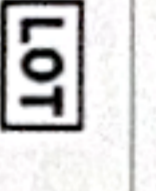


LITERATURE REFERENCES

[1] Tanaka T, Narazaki M, Kishimoto T. IL-6 in inflammation, immunity, and disease. Cold Spring Harb Perspect Biol. 2014;6(10): a016295. Published 2014 Sep 4.

[2] Akira S, Taga T, Kishimoto T. Interleukin-6 in biology and medicine. Adv Immunol. 1993; 54:1-78.

[3] Hodge DR, Hurt EM, Farrar WL. The role of IL-6 and STAT3 in inflammation and cancer. Eur J Cancer. 2005 Nov;41(16):2502-12.

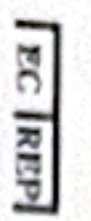
SYMBOLS

	Interpretation	Symbol	Interpretation	Symbol	Interpretation
	Consult instructions for use		Tests per kit		Manufacturer
	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2°C~30°C		Catalogue number		Batch code
	Authorized Representative in the European Community		Caution		

Xiamen Wiz Biotech Co., Ltd.

Address: 3-4 Floor, NO.16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R. China

Tel: +86-592-6808278 Fax: +86-592-6808279

 Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium



CE-01.01-2022.05.13 EN
F1F0223
V1.00(GOODSCARE GMBH)-20250429