Report No./Version: Report$_{YK-IVD202302}$/V1.0

Clinical performance study of Blood glucose test strips (glucose oxidase method) Clinical Performance Study Report

IVD Medical Device Under Investigation: Blood glucose test strips (glucose oxidase method)

Size and Model Used in the Study: Y330, 50-piece package

Leading Study Site: The Second Affiliated Hospital of Nanjing Medical University

Coordinating Investigator (signature): Yibing Lu

Starting Date of the Study: May 30, 2023

Completion Date of the Study: July 10, 2023

Protocol No.: YK-IVD202302

Protocol Version and Date: V1.0 and April 11, 2023

Sponsor (stamp): Jiangsu Yuyue Kailite Biotechnology CO., LTD.

Document Retention Site: GCP Archives of the Second Affiliated Hospital of Nanjing Medical University, and Sponsor

July 17, 2023

Revision History			
Version	**Description of Change**	**Reviser**	**Date**
A/0	Creation	Yibing Lu	July 17, 2023

Table of Content

1. Summary

Test name	Clinical performance study of Blood glucose test strips (glucose oxidase method)
Test apparatus composition	Blood glucose meter, Blood glucose test strips, Blood glucose control solution
Specifications	Blood glucose test strip: Y330; Blood glucose meter: 582
Indications	Used for in vitro quantitative detection of glucose concentration in fresh fingertip capillary whole blood by healthcare professional in a medical unit or lay person at home.
Test apparatus management	Storage temperature of test strips: 4°C-30°C; Storage humidity of test strips: 10%-85% Normal test conditions: Temperature: 5°C-40°C; Humidity: 10%-85%
Test type	Self-matching clinical test for in vitro diagnostic reagents
Test purposes	(1) The Glucose/Lactic acid analyzer and supporting reagents produced by EKF-diagnostic GmbH with excellent performance on the market are selected as reference standards for professional glucose testing, to evaluate the accuracy of the Y330 Blood glucose test strips (glucose oxidase method) produced by Jiangsu Yuyue Kailite Biotechnology Co., Ltd. (equipped with a 582 blood glucose meter) as a self- testing device for its lay person testing results. (2) Comparing with the reference measurement program EKF, the system accuracy of the test product is evaluated through the comparison and analysis of the results of clinical fresh fingertip whole blood samples detection on the blood glucose monitoring system developed by Jiangsu Yuyue Kailite Biotechnology CO., LTD. and the reference measurement program EKF.
Test population	A total of 120 patients were screened, 120 were enrolled, and 120 were completed, of which 100 completed the self-testing. The baseline distribution of age, medical history and hematocrit of the 120 samples included in this clinical performance study is as follows: (1) Age: From 3to 84 years old,including 20 children; (2) Gender: Male 62(51.7%) cases, female 58 (48.3%) cases; (3) Medical history: Patients with diabetes; (4) HCT: 30.8%～51.2%.
Test start date	May 30,2023

Test completion date	July 10, 2023
Date of report writing	July 17, 2023
Sponsor	Jiangsu Yuyue Kailite Biotechnology CO., LTD.
Clinical research unit	The Second Affiliated Hospital of Nanjing Medical University
Statistical method	1. User performance evaluation 1.1 User accuracy evaluation 1) Relative deviation: Calculate the deviation between the user's self measured value and the EKF professional measured value, and the deviation should meet the corresponding acceptable standards. 2) Consistency analysis: Using the measured value of the control EKF as the X-axis and the measured value of the test reagent used by the user as the Y-axis, perform regression and correlation analysis, and provide regression scatter plots, regression equations with confidence intervals, and correlation coefficients. The regression coefficient is in the range of 0.9-1.1. 1.2 Clinical use performance evaluation Users use functional judgment to conduct descriptive statistical analysis. 1.3 Instructions for use evaluation A descriptive statistical analysis was conducted using a questionnaire survey. 2. System accuracy 1) Relative deviation: The results of each lot of reagents shall be counted separately, and the measured value deviation between the test group and the control group shall be calculated separately. The deviation shall meet the corresponding acceptable standards. 2) Consensus Error Grid (CEG) Analysis: Comprehensive statistics of the results of three lots of reagents were conducted, and a consensus error grid (CEG) analysis was conducted to analyze the distribution of measurement points in areas A, B, C, D, and E, requiring that the proportion of measurement points falling in areas A and B should not be less than 99%; The proportion required to fall in Zone A shall not be less than 95%. 3) Methodological consistency: Correlation coefficient: Calculate the correlation coefficient r, which is the test of the value range of the control method (X). As a control method, there is theoretically no error, but this is impossible to achieve in clinical laboratories. The EP9-A2 document states that "if the value range of the comparison method (X) is wide enough, this

	error of the comparison method can be ignored in the regression analysis.". The correlation coefficient r can be used to make a rough estimate of whether the value range of the control method (X) is wide enough. If $r \geq 0.975$ (or $r^2 \geq 0.95$), the value range of the control method (X) can be considered appropriate. If $r<0.975$ (or $r^2<0.95$), more samples must be analyzed to expand the data concentration distribution range, and then all data must be reanalyzed. Linear regression analysis: calculate a and b values, list linear regression equations, and calculate the 95% confidence interval of the regression coefficient and intercept. At the same time, conduct hypothesis testing on relevant evaluation indicators to analyze the consistency of the two detection methods. The regression coefficient is in the range of 0.9-1.1, and the significance level is assumed to be tested α 0.05.
Evaluation standard	The user performance evaluation is statistically analyzed using the relative deviation specified in EN ISO 15197-2015.The system accuracy was statistically analyzed using the relative deviation and consensus error grid analysis specified in EN ISO 15197-2015. User performance evaluation should meet the following criteria (1) and (4), indicating that the product meets expectations.The system accuracy evaluation should meet the following (2)、(3) and (4) criterias, indicating that the product meets expectations: (1) 95% of individual glucose measured values shall fall within either±0.83mmol/L(±15mg/dL) of measured values of the manufacturer's measurement procedure at glucose concentrations <5.55mmol/L(<100mg/dL) and within±15% at glucose concentrations ≥5.55mmol/L(≥100mg/dL). (2) 95% of the measured glucose values) shall fall within either ±0.83mmol/L(±15mg/dL) of the average measured values of the reference measurement procedure at glucose concentrations<5.55 mmol/L(<100mg/dL) or within±15% at glucose concentrations≥5.55mmol/L(≥100mg/dL). (3) 99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid(CEG). (4) Linear regression analysis is used to evaluate the consistency of the two methods, requiring $r \geq 0.975$ (or $r^2 \geq 0.95$), and a regression slope between 0.9-1.1. Criterion 2 shall be applied to each reagent lot individually. The measured values from each lot shall be analyzed and reported separately. Criterion 3 shall be applied to the 3 reagent lots taken together. All measured values from the 3 lots shall be combined before analysis and reporting.

Results	1.User performance evaluation (1) Analysis of user self-test results Healthcare providers supervising the study observed all subjects can operate the system, apply the sample and read the result correctly by self. The deviation diagram shows that 100 % of the detection points fall within the range of 95 % LoA, which meets the requirements of 95 % points falling within the range of 95 % LoA. When blood glucose concentration < 5.55 mmol/L(<100mg/dL), there are 30 cases and the deviation was 100% in the range of ± 0.83mmol/L(±15mg/dL) ; When blood glucose concentration ≥ 5.55 mmol/L(≥100mg/dL), there are 70 cases and the deviation 100% was within ± 15%. Compliance with EN ISO 15197 - 2015'When blood glucose concentration < 5.55 mmol/L(<100mg/dL), allowable deviation 95 % in the range of ± 0.83mmol/L(±15mg/dL) ; when blood glucose concentration ≥ 5.55 mmol/L(≥100mg/dL), allowable deviation 95% within ± 15%'. The correlation coefficient r is 0.9953, r^2 is 0.9906, and the correlation coefficient r meets the evaluation criteria of ' r ≥ 0.975 or r^2 ≥ 0.95 ' stipulated in EN ISO 15197-2015. The linear regression equation y =0.9833x + 2.3383, regression coefficient 0.9833, its 95 % confidence interval [0.9640,1.0025], significant test P < 0.05, in line with the ' regression coefficient in the range of 0.9-1.1, significant test P < 0.05 ' evaluation criteria, that is, the patient 's self-test and control EKF test results showed a linear correlation. (2) Analysis of Clinical use performance evaluation results During the test, there was no display failure of the meter, there was no startup or shutdown failure of the glucose meter, no automatic shutdown or abnormal interruption of the machine and other unqualified phenomena during the inspection process, which met the clinical needs. (3) Analysis of Instructions for use evaluation results The self-test patients were satisfied with the 19 contents of the questionnaire survey, and the overall evaluation was excellent, indicating that the product design met the product self-test design requirements, and the patient was easy to master the product self-test process and complete the self-test process. 2. System accuracy evaluation:Fresh fingertip capillary whole blood Deviation plots: The deviation plots of lot numbers RD1305016, RD1305017 and RD1305018 showed that the proportions of 95 % LoA were 100%, 100% and 100%, respectively. The comprehensive statistical deviation plots of three lot numbers showed that 100% of the detection values fell within the range of 95% LoA, which met the requirements of

	95% points falling within the range of 95% LoA. Accuracy: When blood glucose concentrations <5.55 mmol/L(<100mg/dL), the percentage of deviations from EKF measurements falling within ±15 mg/dL for lot RD1305016, RD1305017, RD1305018 and the three lots combined were 100%, 100%, 100% and 100% respectively. When blood glucose concentrations ≥ 5.55 mmol/L(≥100mg/dL), the percentage of deviations from EKF measurements falling within ±15% for lot RD1305016, RD1305017, RD1305018 and the three lots combined were 100%, 100%, 100% and 100% respectively. Compliance with EN ISO 15197 - 2015'When blood glucose concentration < 5.55 mmol/L(<100mg/dL), allowable deviation 95% in the range of ± 0.83mmol/L(±15mg/dL) ; when blood glucose concentration ≥ 5.55 mmol/L(≥100mg/dL), allowable deviation 95% within ± 15%'. Consensus error grid (CEG) : RD1305016,RD1305017 and RD1305018, three lots of comprehensive statistics 720 points, 720 points (100 %) all fall in area A, in line with EN ISO 15197-2015 ' 99% of the blood glucose measurements fall in the consensus error grid (CEG) area A and area B, 95% of the blood glucose measurements fall in the consensus error grid (CEG) area A ' evaluation criteria. Correlation coefficient and linear regression: the correlation coefficient r^2 of lot number RD1305016 is 0.9948, the regression coefficient is 0.9937, its 95 % confidence interval is [0.9845,1.0028], and the significance test P < 0.05; the correlation coefficient r^2 of lot number RD1305017 is 0.9942, the regression coefficient is 0.9950, its 95% confidence interval is [0.9853, 1.0047], the significance test P < 0.05; the correlation coefficient r^2 of lot number RD1305018 is 0.9935, the regression coefficient is 0.9948, its 95% confidence interval is [0.9845,1.0051], the significance test P < 0.05; the correlation coefficient r^2 of the comprehensive statistics of the three lot numbers is 0.9942, the regression coefficient is 0.9945, the 95% confidence interval is [0.9889,1.0001], and the significance test P < 0.05. The correlation coefficient and linear regression evaluation results are in line with EN ISO 15197-2015 ' $r^2 \geq 0.95$ ' and ' regression coefficient in the range of 0.9-1.1, significant test P < 0.05 ' evaluation criteria. 3. Product performance evaluation index results analysis As the blood glucose monitoring system, the clinical performance evaluation of the test reagent and the blood glucose meter is qualified, that is, the test reagent and the blood glucose meter can meet the clinical requirements. 4. Analysis of safety results During the whole clinical performance study, no adverse events, adverse reactions and serious adverse events occurred in the subjects. During the

	whole clinical performance study, no damage occurred to the researchers and the product was safe for clinical use.
Conclusion	1) User performance evaluation Healthcare providers supervising the study observed all subjects can operate the system, apply the sample and read the result correctly by self. All subjects passed the self-testing at one time. From the analysis of percentage data points versus plasma EKF values, the results showed that more than 95% of data points for fingertip sample site within both ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(100mg/dL) and 0.83mmol/L(±15 mg/dL) versus plasma EKF values when glucose concentration is <5.55mmol/L(100mg/dL). This indicates the system accuracy results for fingertip sample site meet the system accuracy criteria per EN ISO 15197:2015, Section 8.2. Besides, the patient 's self-test correlate well with control EKF test results. During the test, there was no display failure of the meter, there was no startup or shutdown failure of the glucose meter, no automatic shutdown or abnormal interruption of the machine and other unqualified phenomena during the inspection process, which met the clinical needs. Through the direct communication between professionals and users to understand the user's suggestions or opinions on all aspects of the detection system, users are asked to answer a questionnaire to evaluate their mastery of the detection system, and to evaluate whether the product manual is easy to understand and whether the instrument operation is convenient. The self-test patients were satisfied with the 19 contents of the questionnaire survey, and the overall evaluation was excellent, indicating that the product design met the product self-test design requirements, and the patient was easy to master the product self-test process and complete the self-test process. 2) System Accuracy Evaluation From the analysis of percentage data points within ±15% versus plasma EKF values, the results showed that more than 95% of data points for fingertip samples of each strip lot were within ±15% versus plasma EKF values when glucose concentration is ≥5.55 mmol/L(≥100mg/dL). The results showed that more than 95% of data points for fingertip of each strip lot were within ±0.83mmol/L(±15mg/dL) versus plasma EKF values when glucose concentration is <5.55 mmol/L(＜100mg/dL). The results showed that more than 95% of data points for fingertip samples of all 3 strip lots within both ±15% versus plasma EKF values when glucose concentration is ≥5.55 mmol/L(≥100mg/dL) and ±0.83mmol/L(±15mg/dL) versus plasma EKF values when glucose concentration is <5.55 mmol/L(＜100mg/dL). This indicates the system accuracy results for fingertip samples of all 3 strip

	lots meet the Acceptance Criteria A. From the analysis of Consensus Error Grid analysis, the results showed that more than 99% of data points for all 3 strip lots were within Zone A and B. This indicates the system accuracy results for fingertip samples and all 3 strip lots meet the Acceptance Criteria B. This indicates the accuracy study results demonstrate that the blood glucose test strips(glucose oxidase method) meet the system accuracy criteria (A and B) per EN ISO 15197:2015, Section 6.3.3 for fingertip samples. Besides, blood glucose test strips (glucose oxidase method) reading from fingertip samples correlate well with EKF test result.

2. Introduction

2.1 Description of the IVD medical device under investigation

2.1.1 In vitro diagnostic performance study reagent product name

Blood glucose test strip(glucose oxidase method).

2.1.2 Specification:

• Model: Y330

• Specification: 50pcs

2.1.3 Testing principle

The test strip absorbs the sample by capillary action. The sample quickly dissolves glucose oxidase (GOD), hexaammineruthenium (III) chloride, and some non-reactive substances in the reaction zone. The glucose in the sample reacts to produce a micro current that is detected by the blood glucose meter. The current intensity is directly proportional to the blood glucose concentration in the blood sample, and the blood glucose meter detects the micro-current and converts it into blood glucose concentration..

2.1.4 Main ingredients

The main ingredients of the test strip: 15% glucose oxidase (GOD), 16% hexaammineruthenium chloride, 69% non-reactive substances.

2.1.5 Matching device

Blood glucose meter: 582&710.

The model used in this clinical performance study : 582

2.1.6 Specimen type

Fresh fingertip capillary whole blood .

2.1.7 Metrological traceability

The system (blood glucose meters and test strips) is calibrated using venous blood with different blood glucose concentrations. It is traceable to NIST (National Institute of Standards and Technology) SRM (Standard Reference Material) 917c. Uncertainty: 1.72%(K=2）.

2.1.8 Manufacture

Name: Jiangsu Yuyue Kailite Biotechnology CO., LTD

Address: No.5 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA

SRN:CN-MF-000024635

2.1.9 Intended purpose and relevant clinical background

2.1.9.1 Intended purpose

Blood glucose test strips are used with automated blood glucose meters for in vitro quantitative detection of glucose concentration in fresh fingertip capillary whole blood.

●Test strips can be used for blood glucose monitoring by healthcare professional in a medical unit or lay person at home.

●Test strips can not be used for the diagnosis, screening of diabetes, or the adjustment of therapeutic drugs.

● It is used for people with diabetes.

● It is not intended for neonatal use.

2.1.9.2 Relevant clinical background

Clinical performance study is conducted in accordance with EN ISO 15197:2015, ISO 20916:2019 and other regulations, and the clinical performance study data obtained are used for overseas registration..

2.2 Clinical performance study protocol (CPSP)

2.2.1 General

This study adopts an observational experimental design, referring to the requirements of EN ISO 15197-2015, selecting 100 subjects, using one lot of reagents, and conducting a self test on one device. The Glucose/Lactic acid analyzer and supporting reagents produced by EKF-diagnostic

company with excellent performance on the market are selected as reference standards for professional glucose testing, to evaluate the accuracy of the Y330 Blood glucose test strips (glucose oxidase method) produced by Jiangsu Yuyue Kailite Biotechnology Co., Ltd. (equipped with yuwell blood glucose meter 582) as a self testing device for its lay person testing results. In addition, 120 subjects' fresh fingertip capillary whole blood were collected and tested using 3 lots of reagents, each lot being tested once using 2 devices; At the same time, the Glucose/Lactic acid analyzer was used to measure twice as a reference standard to evaluate the accuracy and safety of this product for quantitative detection of glucose concentration in fresh fingertip capillary whole blood in vitro.

Note: The number of samples is based on the actual number of participants. The number of self-test samples is at least 100, and the number of system accuracy samples is at least 120.

2.2.2 IVD medical device under investigation and comparator(s)

According to the requirements of EN ISO 15197-2015, it is compared with Glucose and lactate measuring Instruments developed by EKF-diagnostic GmbH. EKF products have been listed in China (imported instrument registration certificate number: 国械注进 20162220044, imported reagent registration certificate number: 国械注进 20152403862) and CE (IVDR Class A).

2.2.3 Subjects and specimen

2.2.3.1 Inclusion criteria for subjects

① Adult or pediatric, regardless of gender

Note：Adult:pediatric=5:1, uniform distribution of men and women, including all levels of education.

② Stable vital signs

③ Outpatients or ward patients, or other patients with diabetes

⑤ 30%≤ hematocrit (HCT)≤60%

Note: The hematocrit (HCT) index was relatively stable, and the HCT results within the first 5 days from the date of signing the informed consent could be used as screening values.

⑥Good compliance, voluntary participation in this clinical performance study and signing of the informed consent form.

2.2.3.2 Exclusion criteria for subjects

① Hematocrit (HCT)<30% or hematocrit (HCT)>60%

② The patient can't cooperate because of serious mental illness

③ Functions of people without reading ability

④ The researcher believes that it is not suitable to participate in this clinical performance study

2.2.3.3 Criteria and procedures for subject withdrawal or discontinuation

Whenever a patient withdraws from a clinical performance study for any reason, as long as they have not completed the collection and testing of blood samples specified in the clinical performance study, they will be considered as dropout cases. Common reasons are as follows:

① Subjects automatically exit

② Discontinued by the sponsor or researcher

③ Others

When a patient withdraws, the investigator must fill in the reason for the fall off in the case report form.

2.2.3.4 Starting date and completion date

This study began on May 30, 2023 and ended on July 10, 2023.

2.2.3.5 Method of specimen collection

Fresh capillary whole blood from the fingertip: When sampling, gently massage the fingertip to form blood droplets, wipe off the first drop of blood, and use the second drop of whole blood sample for testing. Immediately after that, use a micro blood sampling pipette to collect fingertip blood, load a 0.5ml heparin sodium anticoagulant tube, and complete the test within 20 minutes after blood collection.

Blood sample collection method: Collect fresh fingertip capillary whole blood according to clinical sterile blood collection routine.

Test location: It is required to complete the test in an independent test room, with a temperature of 5 ℃ - 40 ℃ and a humidity of 10% - 85%.

Hematocrit (HCT) is in the range of 30% to 60%.

2.2.3.6 Volume of specimens

Sample size for blood glucose test strips: 1.0μL each test

Sample size for EKF: 25μL each test

2.2.3.7 Specimen storage, handling, processing, transport and disposal

If the sample needs to be stored, it should be stored in a heparin sodium anticoagulant tube, and the test should be completed within 20 minutes after blood collection. Discarded specimens should be discarded in yellow medical waste bins and disposed of as hospital medical waste.

2.2.4 Clinical outcome/endpoints and acceptance criteria

2.2.4.1 User Performance Evaluation

(1) User Accuracy

Using a lot of test reagents, the accuracy of using this product to measure blood glucose by lay person was evaluated by comparing the fingertip blood glucose values measured by lay person with the reference blood glucose values measured by professionals (regular medical personnel trained in this clinical performance study and authorized by the main researcher as professionals) using EKF testing. The system accuracy evaluation should meet both of the following two criterias:

① 95% of individual glucose measured values shall fall within either±0.83mmol/L(±15mg/dL) of measured values of the manufacturer's measurement procedure at glucose concentrations<5.55mmol/L(<100mg/dL) and within ± 15% at glucose concentrations ≥ 5.55mmol/L(≥100mg/dL).

② Linear regression analysis is used to evaluate the consistency of the two methods, requiring r ≥ 0.975 (or r^2 ≥0.95), and a regression slope between 0.9-1.1.

(2) Clinical use performance evaluation

The clinical performance evaluation is mainly the evaluation of blood glucose monitoring system stability. The specific evaluation standards are as follows. If the following items are evaluated as "No", the cause of the failure needs to be specifically described:

Evaluation item 1： Blood glucose test strips and Blood glucose meter performance

Yes: The blood glucose test strip is inserted and the meter displays the blood drop symbol; the test strip feed port is brought into contact with the blood sample and the blood sample is automatically drawn in, with enough blood to fill the test strip reaction area; the blood glucose can display test results correctly;

No: The blood glucose meter does not display when blood test strips are inserted, and/or the blood sample is not automatically drawn in when the test strip feed port is brought into contact with the blood sample, and/or the blood sample is not sufficient to fill the test strip response area, the blood glucose can display test results correctly.

Evaluation item 2： Startup or shutdown of blood glucose meter

Yes: Normally start up and shut down.

No: Be unable to start up and/or shut down normally.

Evaluation item 3:whether it automatically shut down during the inspection

Yes: No automatic shutdown occurred during the inspection.

No: .There was an automatic shutdown during the inspection.

Evaluation item 4: Was there an abnormal interruption during the inspection due to the causes related to the machine

Yes: No abnormal interruption occurred

No: There was an abnormal interruption during the inspection due to the causes related to the machine;

(3) Instructions for use evaluation

A questionnaire is used to evaluate the user's knowledge of the test system, the ease of understanding the product manual and the ease of operation of the instrument, which may include：

1） Battery installation and replacement

2） Whether the test strip is easy to insert the detection device

3） Whether the device button is easy to use

4） Screen size and visibility is appropriate.

5） Are the values and warning signals displayed on the screen easy to read

6） Is the time and date easy to set

7） Ease of use for memory queries

8） Appropriate volume of blood for testing

9） Is the speed of obtaining results satisfactory

10） Is the displayed menu easy to operate and understand

11） Is it easy to install and remove blood collection needles

12） Is the blood collection pen easy to use

13） Do you understand the warnings displayed

14） Is the blood glucose detection system easy to use

15） Is the size of blood glucose meter suitable

16） Is the test strip easy to remove from the bottle, is it easy to pinch

17） Is it easy to sample in the detection area

18） Is the button on the detector easy to identify

19） Evaluate the product instructions

① Is the instruction size appropriate

② Is the text size in the instructions appropriate

③ Is the statement used in the instructions easy to understand

④ Is it easy to understand the contents described in the instructions

⑤ Whether the legend size in the instruction is appropriate

⑥ According to the description of the instructions, there is no need for professionals to help whether the test can be completed alone

⑦ According to the description of the instructions, there is no need for professionals to help the test results can be interpreted correctly.

20） Let the user make an overall evaluation of the blood glucose monitoring system, the evaluation results : strongly disagree, disagree, neutral, agree, strongly agree..

2.2.4.2 System Accuracy Evaluation

① Quantitative detection of the glucose concentration in fresh fingertip capillary whole blood , comparison with the test value of EKF to evaluate whether the system accuracy of the blood glucose test strips (glucose oxidase method) complies with the requirements of EN ISO 15197:2015 In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, i.e., 95% of the test deviations for each lot satisfy the measurement range ＜5.55mmol/L (100mg/dL), and the deviation does not exceed ± 0.83mmol/L (±15mg/dL), the measurement range≥5.55mmol/L (100mg/dL), the deviation does not exceed ±15%.

② Comprehensive statistics of the test results of three lots of reagents are conducted, and a consensus error grid (CEG) analysis is performed to calculate the number of data points and their percentage that fall in each zone, as well as the sum of Zone A and Zone B. The proportion that falls in Zone A and Zone B is required to be not less than 99%; The proportion required to fall in Zone A shall not be less than 95%.

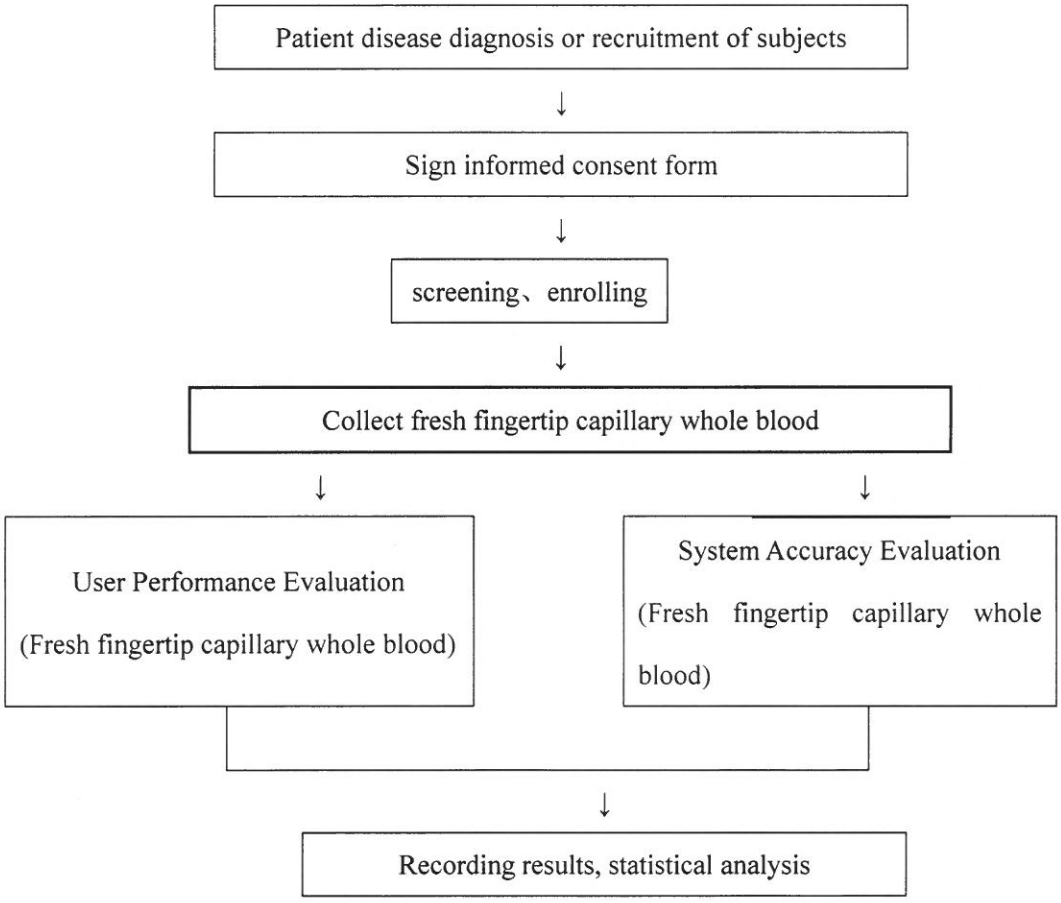
③ Linear regression analysis is used to evaluate the consistency of the two methods, requiring r $\geq$ 0.975 (or $r^2 \geq 0.95$), and a regression slope between 0.9-1.1.

2.2.5 Determination basis

EN ISO 15197:2015.

2.2.6 Procedures

2.2.6.1 Flow-chart of the clinical performance study



2.2.6.2 Flow-table and schedule plan

Study phase	Visit 1 (screening period)	Visit 2 (group entry, test)
Visit window	-5～0 days	Enroll and test on the same day
Informed consent	●	—
Base line condition	●	—
Medical history	●	—
Blood routine	●	—
Inclusion / exclusion criteria	●	—
Clinical performance evaluation index	—	●
Adverse events	—	●
Equipment defects	—	●
Serious adverse event	—	●

2.2.6.3 Clinical performance study conduct

(1) Study operation

1) Test environment requirements:

During blood glucose testing, excessive changes in ambient temperature and humidity should be avoided to affect the test results.

- The ambient temperature range: 5 ℃ - 40 ℃.
- The ambient relative humidity range is 10% - 85%.

2) Test reagent operation and quality control

① Blood glucose test strips operation

Step 1: Insert the test strips

After taking out a piece of test strips, please immediately close the cover of the test strips cylinder, insert the test strips strap Yuwell face up into the test strips slot of the blood glucose meter, push the test strips to the bottom, and the blood glucose meter will automatically start up. Please ensure that the correction code displayed on the screen matches the correction code on the test strips.

Please complete the blood glucose test within 3 minutes of starting the machine.

Step 2: Inhalation of blood samples

When the blood droplet symbol is displayed on the screen, contact the blood sample through the blood inlet port of the test strips, and the blood sample will be automatically inhaled. Please ensure that the blood sample fills the reaction area of the test strips.

Step 3: Read the results

After the countdown, the instrument displays the blood glucose test results. The test results are displayed in mmol/L (mg/dL).

If too many blood samples are extruded for testing to contaminate the test strips or too few blood samples do not fill the reaction zone, please take a new piece of test strips for testing.

② Quality control

The control solution is used to check whether the blood glucose monitoring system work properly and whether the use method is correct. To obtain accurate results, follow these guidelines:

Before testing, the test strips, blood glucose meter, and quality control solution should be placed at room temperature (20 ℃ - 25 ℃) for at least 30 minutes.

Before use, shake up the quality control solution.

After discarding the first drop of quality control solution, wipe the dropper head.

Each bottle of quality control solution can be measured at least 50 times.

The test result is not within the quality control range (range: see the label on the bottle or the label on the box), indicating that the blood glucose monitoring system is unstable. Please immediately replace the test strips and perform quality control again. If the results are still not within the scope of quality control, immediately stop the blood glucose test and contact the dealer or customer service personnel.

3) Use and Quality Control of EKF

The EKF should use suitable reference materials to verify the accuracy and precision of this method before testing. After the verification results meet the requirements, conduct operational testing and quality control according to the instructions.

(2) User Performance Evaluation Procedure

User accuracy evaluation

1) Each lay person to be evaluated should carefully read the product manual provided by Jiangsu Yuyue Kailite Biotechnology Co., Ltd., and professionals cannot provide any guidance or assistance to the user.

2) After the user is familiar with the entire operation process, the user prepares himself, such as installing a battery, and becoming familiar with meter operation.

3) After the meter is ready, insert the test strip. After hearing the beep, the blood glucose meter automatically turns on and displays the code. Check whether the code on the test strip bottle is consistent with the code displayed on the blood glucose meter.

4) The user disinfects the test site and begin the test. First, the user performs acupuncture blood collection and uses the instrument to perform a test, and records the test results.

Note:User techniques in operating the system, applying the sample and reading the result shall be observed by the healthcare providers supervising the study.

The human factors observations shall be documented in the study report.

If the subject reports that a mistake has been made in performing self-testing, such as applying blood to the reagent incorrectly, or obtains a non quantitative result, the subject shall be allowed to repeat self-testing and the study staff shall document the mistake in the study report.

The results of incorrectly performed tests shall be excluded from the determination of acceptability of the blood-glucose monitoring system. A maximum of three exclusions due to incorrectly performed self-testing shall be allowed per subject.

The number and specific nature of incorrectly performed tests shall be described in the study report.

5) After the user completes the test, professionals immediately collect blood samples (fingertip blood) using heparin sodium anticoagulant micro blood collection tubes, conduct a test with reference EKF for centrifugation to determine the reference glucose concentration, and record the test results.

Note:If a meter is to be used by more than one subject. The meter shall be cleaned and disinfected after each user following the infection control procedures appropriate for facility to avoid the transfer of blood-borne pathogens.

Clinical use performance evaluation

The clinical use performance evaluation includes product stability evaluation, including whether the glucose meter is turned on and off, whether it is automatically turned off in the inspection process, and whether there is abnormal interruption due to machine reasons in the process.

Instructions for use evaluation

The evaluation method shall be conducted by a questionnaire designed to assess whether the users understood how to use the device correctly.

A typical questionnaire may consist of a series of statements, where evaluation participants are asked to indicate their degree of agreement with each statement on a scale of 1 to 5 (1 = strongly disagree; 3 = neutral; 5 = strongly agree).

Study participants shall also be given an opportunity to provide unrestricted comments on their experience when using the bloodglucose monitoring system and the instructions for use.

To avoid biasing the study results, the questionnaire shall be completed after the subject's self-testing has been completed.

(3)System accuracy evaluation procedure

1) Fresh Fingertip Whole Blood evaluation procedure

For the same sample, reagents from the same vial should be used for testing. The evaluation process should be conducted in the following order:

a) Use 3 reagent lots, 12 vials of reagent each lot numbered 1-12; Take out 12 vials of reagent from the first lot .

b) Needle the distal finger pulp of the first subject to collect fresh capillary whole blood.

c) Discard the first drop of blood, immediately collect fingertip blood with a micro blood sampling pipette, load it with a 0.5 ml heparin sodium anticoagulant tube, centrifuge within 20 minutes to complete the EKF measurement, and record the measured value, which is the first measured value in the clinical performance study.

d) After that, take out two test strips from the reagent vial numbered 1, measure the blood glucose concentration in the above samples (i.e. fingertip blood in vivo after collecting fingertip blood with a micro blood sampling straw) on two blood glucose meters at the same time, and record the measured values.

e) After each test of 10 subjects, replace the reagent vial, take a test strip from the next numbered

reagent vial, and conduct the next round of 10 subjects testing, followed by a cycle.

f) Take the reagents from the second and third lots and repeat the above d-e steps respectively.

g) After the measurement of all three lots of reagents is completed, discard a drop of blood from the fingertip, and immediately collect the fingertip blood with a micro blood sampling pipette. Install a 0.5ml heparin sodium anticoagulant tube. Centrifuge within 20 minutes to complete the EKF measurement. Record the measured value, which is the last measured value in the clinical performance study.

h) Verify the stability of the sample through the first and last measurements, that is, if the deviation between the two measurements is>4% when the blood glucose concentration is ≥ 5.55mmol/L (≥ 100mg/dL) or>0.22mmol/L (>4mg/dL) when the blood glucose concentration is<5.55mmol/L (<100mg/dL), it indicates that the sample is unstable and should be removed. The rejected samples should be replaced with other samples within the same concentration range.

i) Repeat step b-h to test the next subject.

Note:If a meter is to be used by more than one subject. The meter shall be cleaned and disinfected after each user following the infection control procedures appropriate for facility to avoid the transfer of blood-borne pathogens.

(4)Special situation description

The clinical diagnosis of hypoglycemia is that the blood glucose level is less than 2.77mmol/L, and hypoglycemia has become one of the acute complications of diabetes, which seriously threatens the life safety of patients, and can cause up to 10% of patients with type I diabetes to die. Once clinical hypoglycemia occurs, it is necessary to immediately give oral glucose water or intravenous injection of 50% glucose solution to rapidly increase blood glucose. Therefore, in this clinical performance study, capillary whole blood samples with blood glucose concentrations<2.77mmol/L (50mg/dL) will be processed in vitro to obtain relevant concentrations. In addition, samples with extremely high blood glucose concentrations (>22.20mmol/L) are relatively rare in clinical performance study. If they are not detected during clinical performance study, samples with extremely high blood glucose concentrations will be obtained by adding glucose.

- Treatment method for blood samples with extremely low blood glucose

concentration<2.77mmol/L (50 mg/dL):

① Collect fingertip capillary whole blood using heparin sodium anticoagulant micro blood collection tubes, each 30 μL (micro liters) or Above;

② Measure the blood glucose levels of fresh fingertip capillary whole blood of the subjects using the control EKF;

③ After collecting the blood sample, seal the two ends of the blood collection tube and let it stand still;

④ Soaking time (at a temperature of 30 ℃): Blood glucose value: 4-6 mmol/L, let stand for more than 8 hours, 6-8 mmol/L, let stand for more than 12 hours, target blood glucose value after standing is<50mg/dL;

⑤ Before use, the blood sample that has been left standing should be sucked up and down using a micro pipette to mix the blood sample evenly;

⑥ Perform test reagent testing and control EKF testing according to clinical requirements.

- Treatment method for extremely high blood glucose concentration samples (>400mg/dL):

① Collect fingertip capillary whole blood using heparin sodium anticoagulant micro blood collection tubes, 30 each μL (micro liters) or above;

② Add 20% mass fraction of glucose storage solution, $V_{addition\ amount(\mu L)} = (C_{target\ blood\ glucose\ value\ (mg/dL)} - C_{actual\ blood\ glucose\ value\ (mg/dL)}) \times V_{blood\ sample\ volume(\mu L)} /20000$.

Table 1 Distribution of samples with different blood glucose concentrations

Bin #	Percentage of samples (%)	Glucose concentration mmol/L (mg/dL)
1	5	≤2.77 mmol/L（50 mg/dL）
2	15	>2.77～4.44mmol/L（>50～80mg/dL）
3	20	>4.44～6.66mmol/L（>80～120mg/dL）
4	30	>6.66～11.10mmol/L（>121～200mg/dL）
5	15	>11.10～16.65mmol/L（>200～300mg/dL）
6	10	>16.65～22.20mmol/L（>300～400mg/dL）
7	5	>22.20（>400mg/dL）

If the study population does not provide a sufficient number of fresh capillary blood samples with

very low and very high glucose concentrations, modified capillary blood samples in which the glucose concentration has been raised or lowered may be substituted to achieve the required distribution, subject to the following limitations.

Bin2: at least 8 blood samples shall be unaltered.

Bin3 to 5: all blood samples shall be unaltered.

Bin6: at least 5 blood samples shall be unaltered.

2.2.7 Statistical design

2.2.7.1 User performance evaluation

2.2.7.1.1 User Accuracy

1) Relative deviation

Calculate the deviation between the user's self measured value and the EKF professional measured value, and the deviation should meet the corresponding acceptable standards.

2) Consistency analysis

Using the measured value of the control EKF as the X-axis and the measured value of the test reagent used by the user as the Y-axis, perform regression and correlation analysis, and provide regression scatter plots, regression equations with confidence intervals, and correlation coefficients. The regression coefficient is in the range of 0.9-1.1.

2.2.7.1.2 Evaluation of clinical use performance

Users use functional judgment to conduct descriptive statistical analysis.

2.2.7.1.3 Evaluation of instructions for use

A descriptive statistical analysis was conducted using a questionnaire survey.

2.2.7.2. System accuracy

1) Relative deviation

The results of each lot of reagents shall be counted separately, and the measured value deviation between the test group and the control group shall be calculated separately. The deviation shall meet the corresponding acceptable standards.

2) Consensus Error Grid (CEG) Analysis

Comprehensive statistics of the results of three lots of reagents were conducted, and a consensus error grid (CEG) analysis was conducted to analyze the distribution of measurement points in

areas A, B, C, D, and E, requiring that the proportion of measurement points falling in areas A and B should not be less than 99%; The proportion required to fall in Zone A shall not be less than 95%.

3) Methodological consistency

Correlation coefficient: Calculate the correlation coefficient r, which is the test of the value range of the control method (X). As a control method, there is theoretically no error, but this is impossible to achieve in clinical laboratories. The EP9-A2 document states that "if the value range of the comparison method (X) is wide enough, this error of the comparison method can be ignored in the regression analysis.". The correlation coefficient r can be used to make a rough estimate of whether the value range of the control method (X) is wide enough. If $r \geq 0.975$ (or $r^2 \geq 0.95$), the value range of the control method (X) can be considered appropriate. If $r<0.975$ (or $r^2<0.95$), more samples must be analyzed to expand the data concentration distribution range, and then all data must be reanalyzed.

Linear regression analysis: calculate a and b values, list linear regression equations, and calculate the 95% confidence interval of the regression coefficient and intercept. At the same time, conduct hypothesis testing on relevant evaluation indicators to analyze the consistency of the two detection methods. The regression coefficient is in the range of 0.9-1.1, and the significance level is assumed to be tested α 0.05.

2.2.8 Sample size

The evaluation of system accuracy shall be performed with fresh fingertip capillary whole blood samples, each with sufficient volume for the blood-glucose monitoring system measurements and reference measurements specified in the study protocol.

The blood glucose concentration in the sample should cover the linear range of the test reagent (0.6 mmol/L to 33.3 mmol/L) (10 mg/dL to 600 mg/dL).

The glucose concentrations shall be distributed in the bins specified in Table 1. Once a concentration bin is filled with samples, no additional samples shall be added to that bin.

3.Results

3.1 Details of enrolment for each site

A total of 120 patients were screened, 120 were enrolled, and 120 were completed, of which 100

completed the self-testing.

3.2 Qualification of the study site operators

Medical personnel with GCP certificates in medical device clinical performance study institutions.

3.3 User Performance Evaluation

3.3.1 Analysis data set and Baseline data

Healthcare providers supervising the study observed all subjects can operate the system, apply the sample and read the result correctly by self.

A total of 100 cases were screened and enrolled, and all cases were completed. The user performance evaluation was conducted in an independent room of the Second Affiliated Hospital of Nanjing Medical University. The testing environment was strictly controlled in the room, namely, the temperature range was 5 ℃ - 40 ℃, the relative humidity range was 10% - 85%, and the hematocrit (HCT) was within the range of 30% - 60%.

The baseline distribution of age, gender, medical history, education level and hematocrit of the 100 samples included in this clinical performance study is as follows:

- Age: From 18 to 79 years old;
- Gender: Male 48(48%) cases, female 52 (52%) cases;
- Medical history: Patients with diabetes;
- Education level: 11 cases in primary school, 27 cases in junior high school, 25 cases in senior high school, 18 cases in junior college, 18 cases in undergraduate course, and 1 cases with master's degree or above;
- HCT: 30.8%～51.2%.

3.3.2 Statistical analysis of user self-testing results

3.3.2.1 Bias analysis

Healthcare providers supervising the study observed all subjects can operate the system, apply the sample and read the result correctly by self.

The bias results are analyzed by using "difference plot" and "data table", See Figure 1 and Table 2.The bold lines in each plot represent system accuracy criteria of ±15mg/dL (vs. plasma EKF) when <100 mg/dL and ±15% bias (vs. plasma EKF) when ≥100 mg/dL.

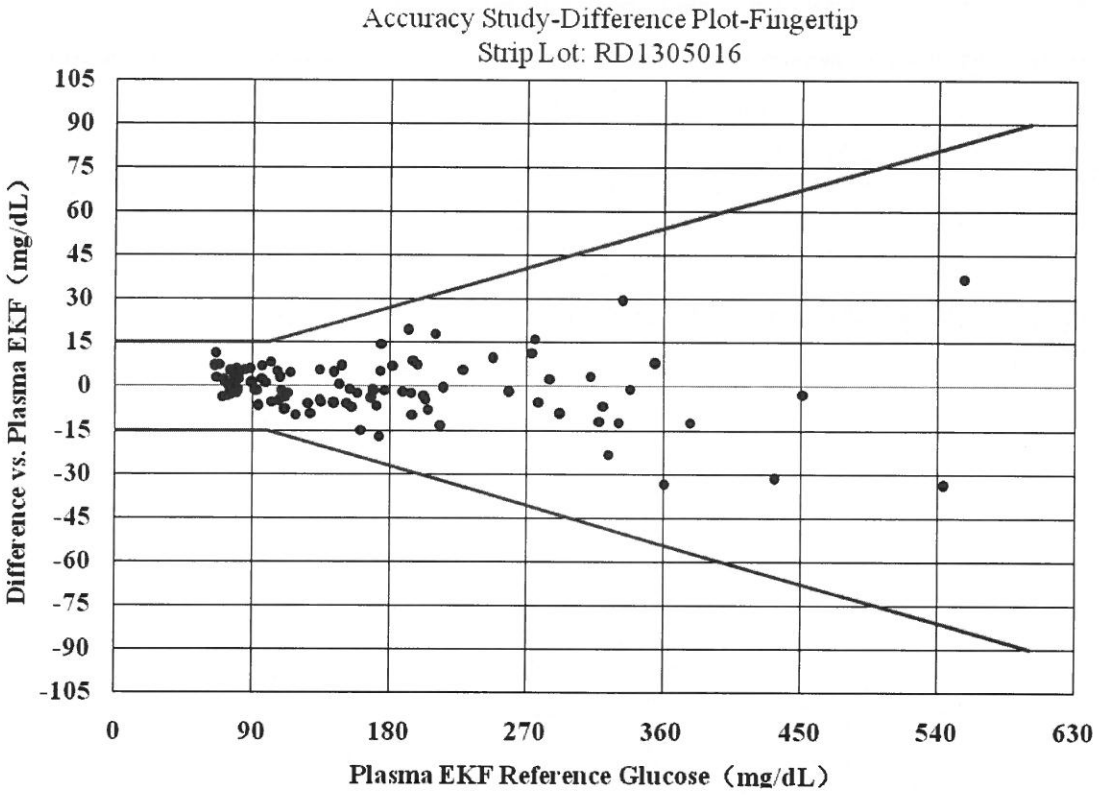


Figure 1 Fingertip sample-difference plot of strip lot RD1305016

Table 2 Fingertip sample-statistics of strip lot RD1305016

Fingertip sample Result (vs.Plasma EKF with Fingertip sample)		
strip Lot: RD1305016		
User accuracy Result for Glucose Concentration <5.55mmol/L(<100mg/dL)		
Within±0.28mmol/L (Within±5mg/dL)	Within±0.56mmol/L (Within±10mg/dL)	Within±0.83mmol/L (Within±15mg/dL)
21/30 (70.0%)	29/30 (96.7%)	30/30 (100%)
User accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
52/70 (74.3%)	69/70 (98.6%)	70/70(100%)
User accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL) and <5.55mmol/L(<100mg/dL)		
Within ± 15% or Within ±0.83mmol/L(±15 mg/dL)		
100/100(100%)		

From the analysis of percentage data points versus plasma EKF values, the results showed that more than 95% of data points for fingertip sample site within both ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(≥100mg/dL) and ±0.83mmol/L(±15 mg/dL) versus plasma EKF values when glucose concentration is <5.55mmol/L(<100mg/dL). This indicates the system accuracy results for fingertip sample site meet the system accuracy criteria per EN ISO 15197:2015, Section 8.2.

3.3.2.2 Regression analysis and correlation coefficient

The test results are also analyzed by using "regression analysis". In the two-dimensional rectangular coordinates, the vertical axis Y represents the blood glucose level detected by the blood glucose test strip, and the horizontal axis X represents the value of the plasma blood glucose levels measured by EKF.

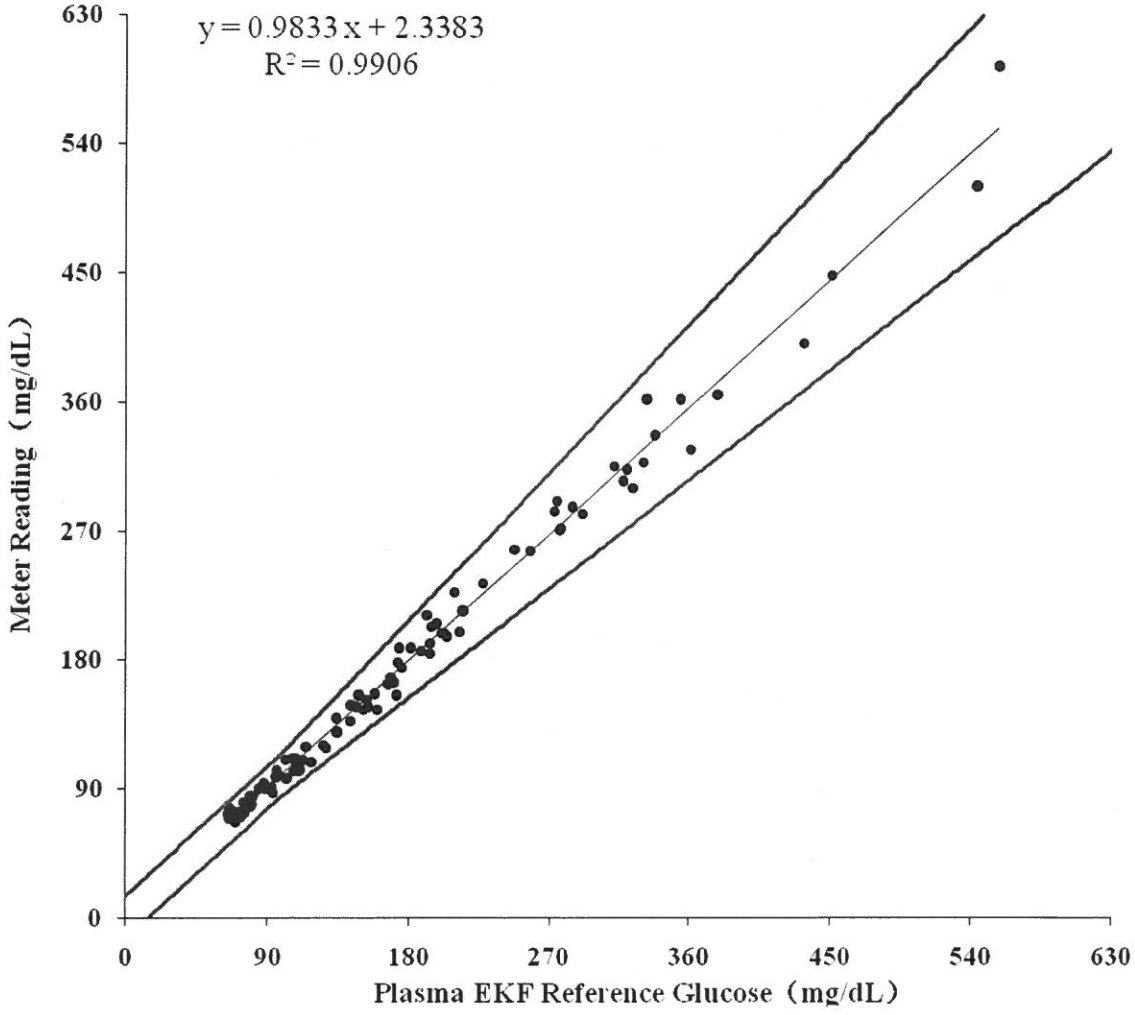


Figure 2 Fingertip sample-the linear regression of strip lot RD1305016

Table 3 Fingertip sample-summary table of coefficient

Linear Regression Summary Table: **Meter Reading (y) vs. Plasma EKF Value (x) (EKF using fingertip sample)**						
Sample Site	Strip Lot	Slope	Intercept	R	R^2	N
Fingertip	RD1305016	0.9833	2.3383	0.9953	0.9906	100
Confidence Interval: Lower 95%		0.9640	-1.5822	—		
Confidence Interval: Upper 95%		1.0025	6.2589	Z=101.39, P<0.0001		

From regression analysis, the correlation coefficient (R) for fingertip sample site was >0.975. The results indicate the Blood glucose test strip (glucose oxidase method) test reading correlates well with the EKF reference instrument value.

3.3.3 Clinical use performance evaluation

The clinical use performance evaluation includes product stability evaluation, including whether the glucose meter is turned on and off, whether it is automatically turned off in the inspection process, and whether there is abnormal interruption due to machine reasons in the process.

During the test, there was no display failure of the meter, there was no startup or shutdown failure of the glucose meter, no automatic shutdown or abnormal interruption of the machine and other unqualified phenomena during the inspection process, which met the clinical needs.

3.3.4 Instructions for use evaluation

Through the direct communication between professionals and users to understand the user 's suggestions or opinions on all aspects of the detection system, users are asked to answer a questionnaire to evaluate their mastery of the detection system, and to evaluate whether the product manual is easy to understand and whether the instrument operation is convenient. The self-test patients were satisfied with the 19 contents of the questionnaire survey, and the overall evaluation was excellent, indicating that the product design met the product self-test design requirements, and the patient was easy to master the product self-test process and complete the self-test process.

3.4 System Accuracy Evaluation

System accuracy evaluation of the detection of glucose concentration in the fresh fingertip capillary whole blood.

3.4.1 Sample inclusion and baseline analysis

120 subjects were planned to be included, and 120 cases were actually included. The baseline distribution of age, medical history and hematocrit of the 120 samples included in this clinical performance study is as follows:

- Age: From 3to 84 years old,including 20 children aged 3-15years;
- Gender: Male 62(51.7%) cases, female 58 (48.3%) cases;
- Medical history: Patients with diabetes;
- HCT: 30.8%～51.2%.

120 cases met the requirements specified in the test program without shedding or removing samples. The distribution of samples are shown in Table 4 .

Table 4 The distribution of samples

No. of enrolled samples	No. of completed samples	Completition rate (%)	No. of shedding samples	Shedding rate (%)	No. of removing sample	Removing rate (%)
120	120	120	0	0.00	0	0.00

The effective samples tested in this study were 120cases. The blood glucose concentration of the samples was distributed according to the results of fingertip capillary whole blood EKF test, which basically met the blood glucose distribution requirements stipulated in the clinical performance study scheme, as shown in Table 5.

Table 5 The distribution of 120 samples

glucose concentration	sample requirements	effective samples
≤2.77 mmol/L（50 mg/dL）	6	6
>2.77～4.44mmol/L（>50～80mg/dL）	18	18
>4.44～6.66mmol/L（>80～120mg/dL）	24	24
>6.66～11.10mmol/L（>121～200mg/dL）	36	36
>11.10～16.65mmol/L（>200～300mg/dL）	18	18

>16.65～22.20mmol/L（>300～400mg/dL）	12	12
>22.20（>400mg/dL）	6	6

Sample collection instruction:

- In this clinical performance study, 6 blood samples with blood glucose < 50 mg/dL , 1 were fresh clinical samples, and the remaining 5 were obtained from blood samples (>50mg/dL) incubating for several hours at room temperature. Detailed treatment methods are shown in Table 6.
- In this clinical performance study, among the 6 blood samples with blood glucose concentration of >400mg/dL, 4 were fresh clinical samples, and the remaining 2 was added with adding 20% mass fraction glucose storage solution to obtain blood glucose >400mg/dL samples. Detailed treatment methods are shown in Table 6.
- In addition, 2 children with blood glucose concentrations greater than 300mg/dL and less than 400mg/dL were added with adding 20% mass fraction glucose storage solution to obtain. Detailed treatment methods are shown in Table 6.

Table 6 List of sample treatment with blood glucose concentration

subject No.	sample No.	Original glucose（mg/dL）	process method	Glucose concentration after processing（mg/dL）	
				P.EKF reading1	P.EKF reading2
081	230630081	80.3	Incubate for about 4 hours and 40 minutes	44.6	43.8
082	230630082	67.5	Incubate for about 5 hours and 24 minutes	45.8	45.7
083	230630083	64.7	Incubate for about 5 hours and 50 minutes	26.4	26.4
084	230630084	65.8	Incubate for about 6 hours and 13 minutes	35.3	35.4
085	230630085	65.5	Incubate for about 6 hours and 23 minutes	29.8	29.6
087	230630087	110.0	Add 4.77μl 20% mass fraction glucose storage solution to 200μl blood	589.9	589.7
094	230630094	60.3	Add5.34μl 20% mass fraction glucose storage solution to	579.3	580.0

			200μl blood		
096	230630096	85.86	Add3.10μl 20% mass fraction glucose storage solution to 200μl blood	388.4	389.3
097	230630097	56.88	Add3.03μl 20% mass fraction glucose storage solution to 200μl blood	355.6	354.3

3.4.2 Data analysis

3.4.2.1 Bias analysis

The bias results are analyzed by using "difference plot" and "data table", See Figure3-6 and Table 7-10.The bold lines in each plot represent system accuracy criteria of ±0.83mmoL(±15 mg/dL) (vs. plasma EKF) when <5.55mmol/L(100mg/dL) and ±15% bias (vs. plasma EKF) when ≥5.55mmol/L(100mg/dL).

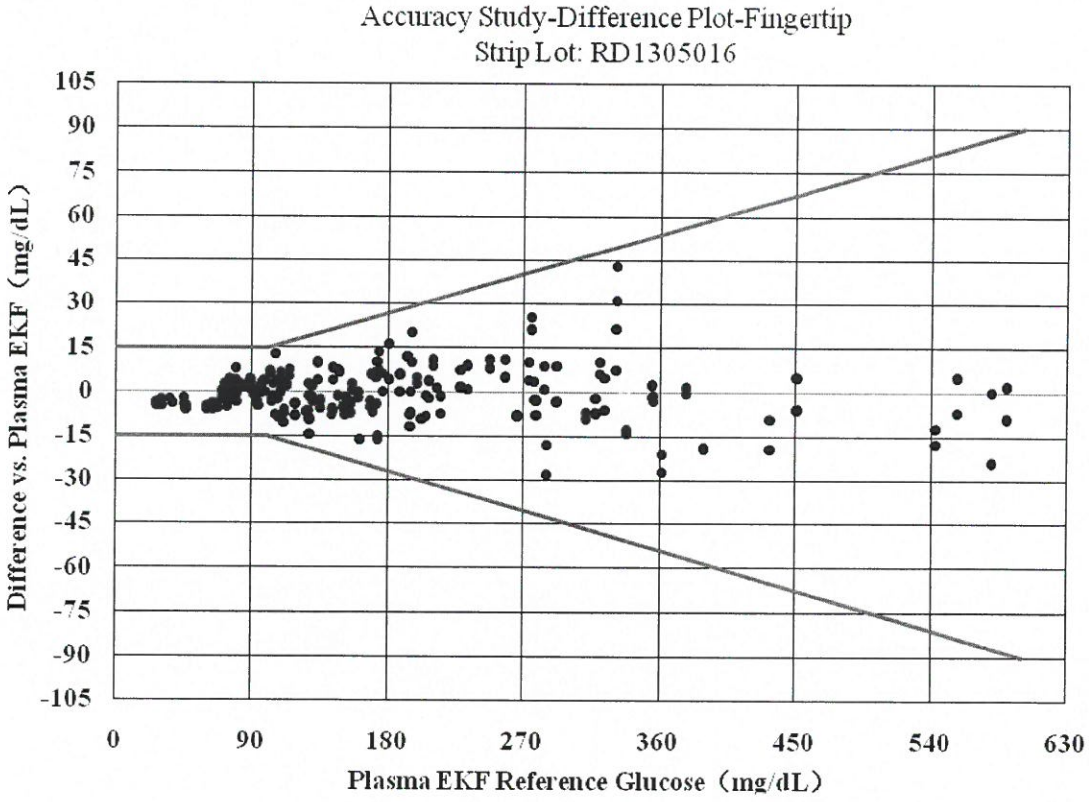


Figure 3 Fingertip sample-difference plot of strip lot RD1305016

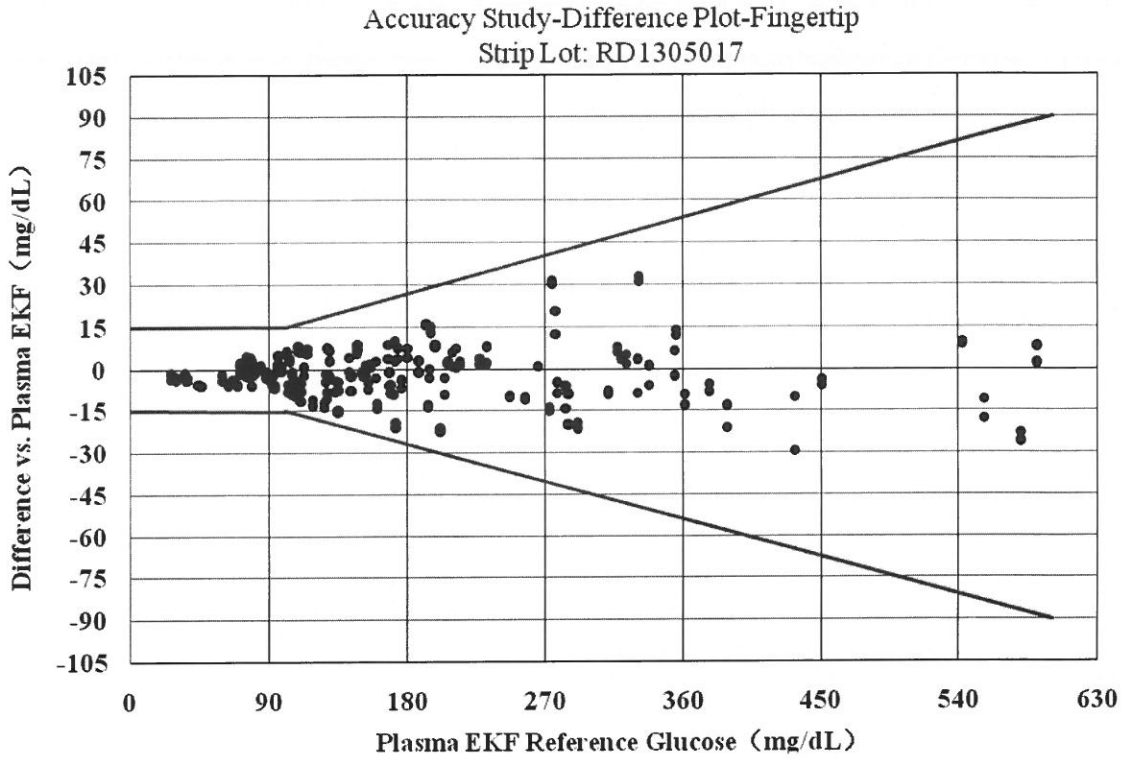


Figure 4 Fingertip sample-difference plot of strip lot RD1305017

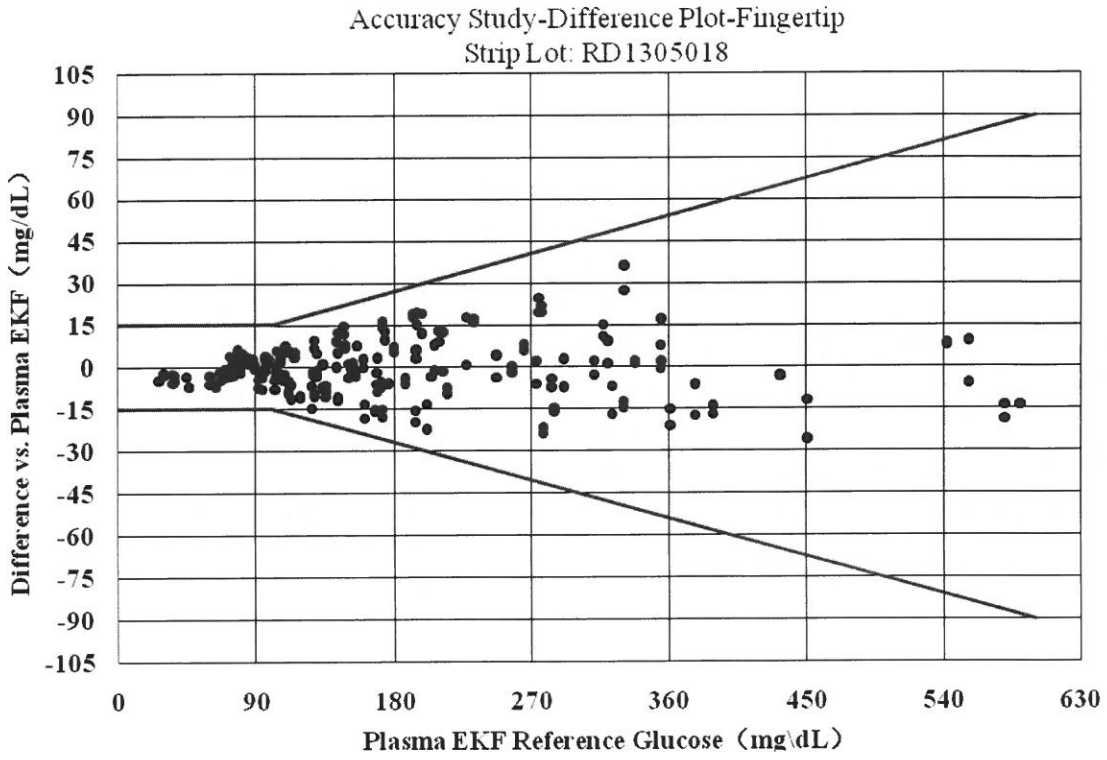


Figure 5 Fingertip sample-difference plot of strip lot RD1305018

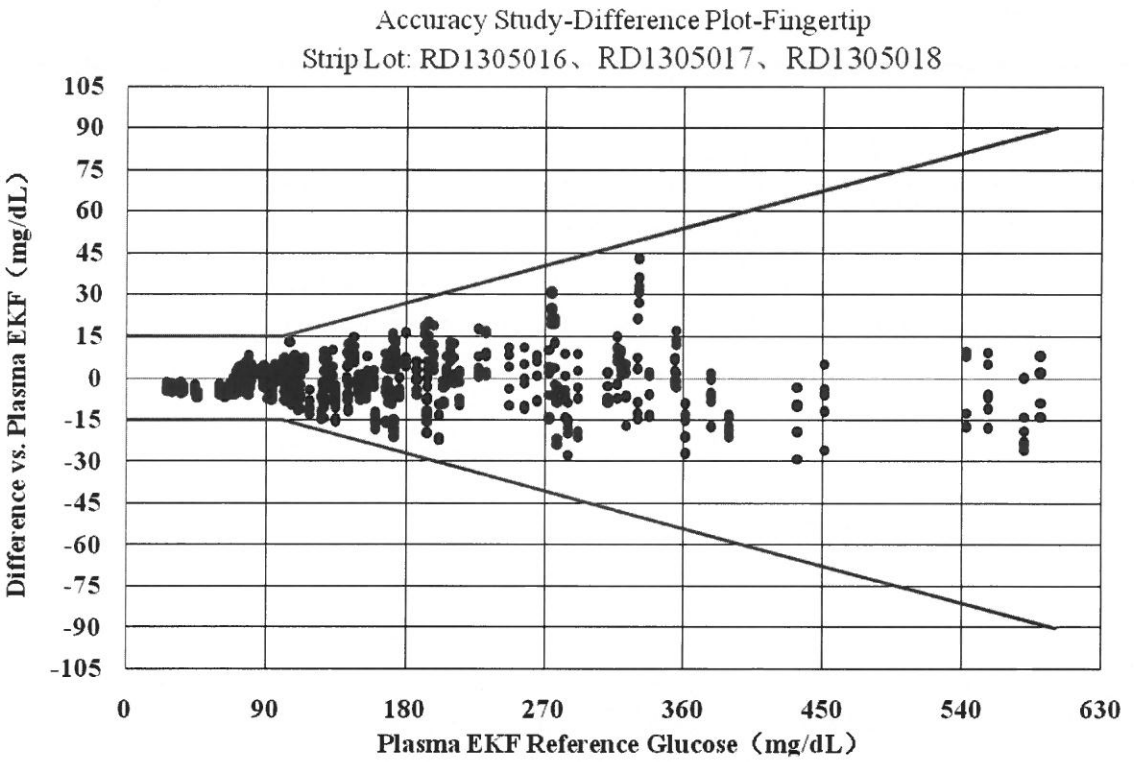


Figure 6 Fingertip sample-difference plot of strip lot RD1305016、RD1305017、RD1305018

Table 7 Fingertip sample-statistics of strip lot RD1305016

Fingertip sample Result (vs.Plasma EKF with Fingertip sample)		
strip Lot: RD1305016		
System Accuracy Result for Glucose Concentration <5.55mmol/L(<100mg/dL)		
Within±0.28mmol/L (Within±5mg/dL)	Within±0.56mmol/L (Within±10mg/dL)	Within±0.83mmol/L (Within±15mg/dL)
63/68 (92.6%)	68/68 (100%)	68/68 (100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
126/172 (73.3%)	166/172 (96.5%)	172/172 (100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL) and <5.55mmol/L(<100mg/dL)		
Within ± 15% or Within ±0.83mmol/L (±15 mg/dL)		
240/240 (100%)		

Table 8 Fingertip sample-statistics of strip lot RD1305017

Fingertip sample Result (vs.Plasma EKF with Fingertip sample)		
strip Lot: RD1305017		
System Accuracy Result for Glucose Concentration <5.55mmol/L(<100mg/dL)		
Within±0.28mmol/L (Within±5mg/dL)	Within±0.56mmol/L (Within±10mg/dL)	Within±0.83mmol/L (Within±15mg/dL)
56/68 (82.6%)	68/68 (100%)	68/68 (100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
110/172 (64.0%)	159/172 (92.4%)	172/172 (100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL) and <5.55mmol/L(<100mg/dL)		
Within ± 15% or Within ±0.83mmol/L（±15mg/dL)		
240/240 (100%)		

Table 9 Fingertip sample-statistics of strip lot RD1305018

Fingertip sample Result (vs.Plasma EKF with Fingertip sample)		
strip Lot: RD1305018		
System Accuracy Result for Glucose Concentration <5.55mmol/L (<100mg/dL)		
Within±0.28mmol/L (Within±5mg/dL)	Within±0.56mmol/L (Within±10mg/dL)	Within±0.83mmol/L （Within±15mg/dL)
56/68 (82.4%)	68/68 (100%)	88/68 (100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L (≥100mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
101/172 (58.7%)	165/172 (95.9%)	172/172 100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL) and <5.55mmol/L (<100mg/dL)		
Within ± 15% or Within ±0.83mmol/L（±15mg/dL)		
240/240 (100%)		

Table 10 Fingertip sample-summary statistics of strip lot RD1305016、RD1305017、RD1305018

Fingertip sample Result (vs.Plasma EKF with Fingertip sample)		
strip Lot: RD1305016、RD1305017、RD1305018		
System Accuracy Result for Glucose Concentration <5.55mmol/L(<100mg/dL)		
Within±0.28mmol/L (Within±5mg/dL)	Within±0.56mmol/L (Within±10mg/dL)	Within±0.83mmol/L (Within±15mg/dL)
175/204 (85.8%)	204/204 (100%)	204/204(100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
337/516(65.3%)	490/516 (95.0%)	516/516 (100%)
System Accuracy Result for Glucose Concentration ≥5.55mmol/L(≥100mg/dL) and <5.55mmol/L(<100mg/dL)		
Within ± 15% or Within ±0.83mmol/L （±15mg/dL)		
720/720 (100%)		

From the analysis of percentage data points within ±15% versus plasma EKF values, the results showed that more than 95% of data points for each lot for fingertip sample site were within ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(≥100mg/dL). The results showed that more than 95% of data points for each for fingertip sample site were within ±0.83mmol/L(±15mg/dL) versus plasma EKF values when glucose concentration is <5.55mmol/L(<100mg/dL). The results showed that more than 95% of data points for all 3 strip lots were for fingertip sample site within both ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(≥100mg/dL) and ±0.83mmol/L(±15mg/dL) versus plasma EKF values when glucose concentration is <5.55mmol/L(<100mg/dL) This indicates the system accuracy results for fingertip sample site meet the Acceptance Criteria A.

3.4.2.2 Consensus Error Grid Analysis

The Consensus Error Grid is divided into five zones. The clinical significance of each zone is as follows:

- Zone A: Clinically accurate (no effect on clinical behavior);

- Zone B: Clinically acceptable (changes in clinical behavior, no or almost no effect on clinical outcomes);
- Zone C: Changes in clinical behavior (may have effect on clinical outcomes);
- Zone D: Changes in clinical behavior (may result in significant clinical risk);
- Zone E: Changes in clinical behavior (may result in dangerous consequences).

In the two-dimensional orthogonal coordinates, the vertical axis Y represents the blood glucose level detected by the blood glucose test strip, and the horizontal axis X represents the mean value of the plasma blood glucose levels measured by EKF at two different times. Percentages in Zone A and B and in Zone C, D and E are calculated, and "99% of the measured values of all 3 strip lots fall in Zone A and B of the consensus error analysis diagram". See Figure 7 and Table 11.

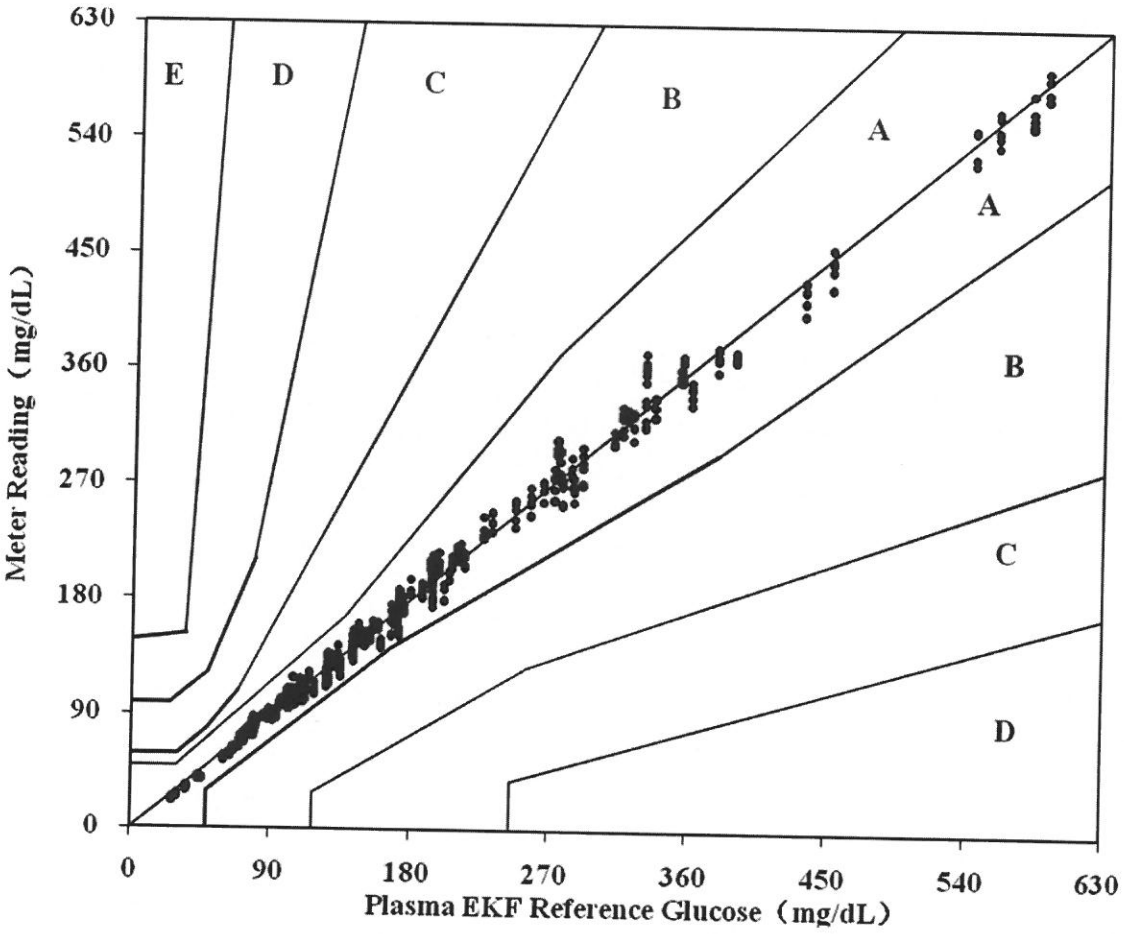


Figure 7 Fingertip sample-consensus error grid

Table 11 The percentages of statistics of five zones

CEG	Zone A	Zone B	Zone C	Zone D	Zone E	Total
Number	720	0	0	0	0	720
percentages %	100%	0%	0%	0%	0%	100%

From the analysis of Consensus Error Grid analysis, the results showed that more than 99% of data points for all 3 strip lots for fingertip sample site were within Zone A and B. This indicates the system accuracy results for fingertip sample site meet the Acceptance Criteria B.

3.4.2.3 Regression analysis and correlation coefficient

The test results are also analyzed by using "regression analysis". In the two-dimensional rectangular coordinates, the vertical axis Y represents the blood glucose level detected by the blood glucose test strip, and the horizontal axis X represents the mean value of the plasma blood glucose levels measured by EKF at two different times.

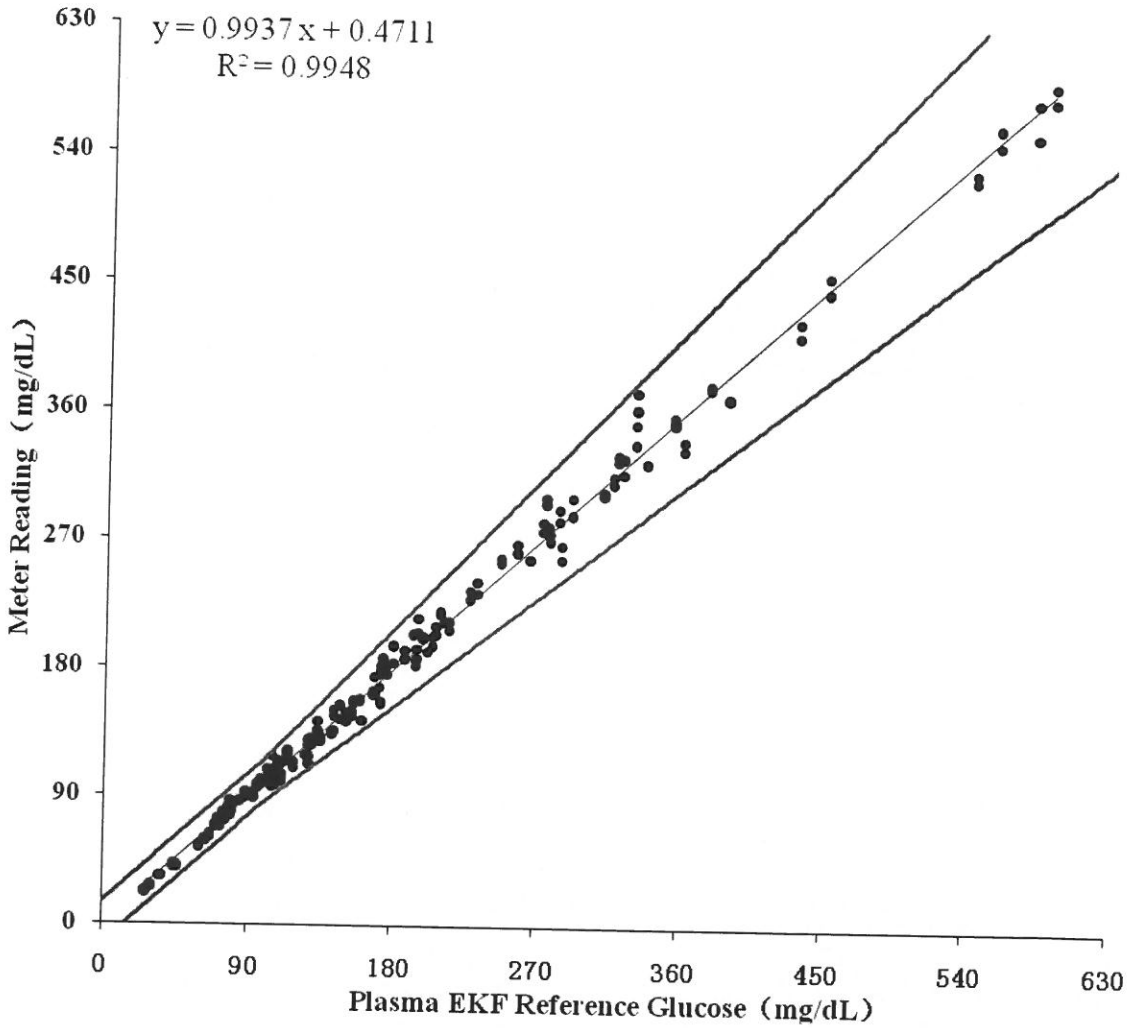


Figure 8 Fingertip sample-the linear regression of strip lot RD1305016

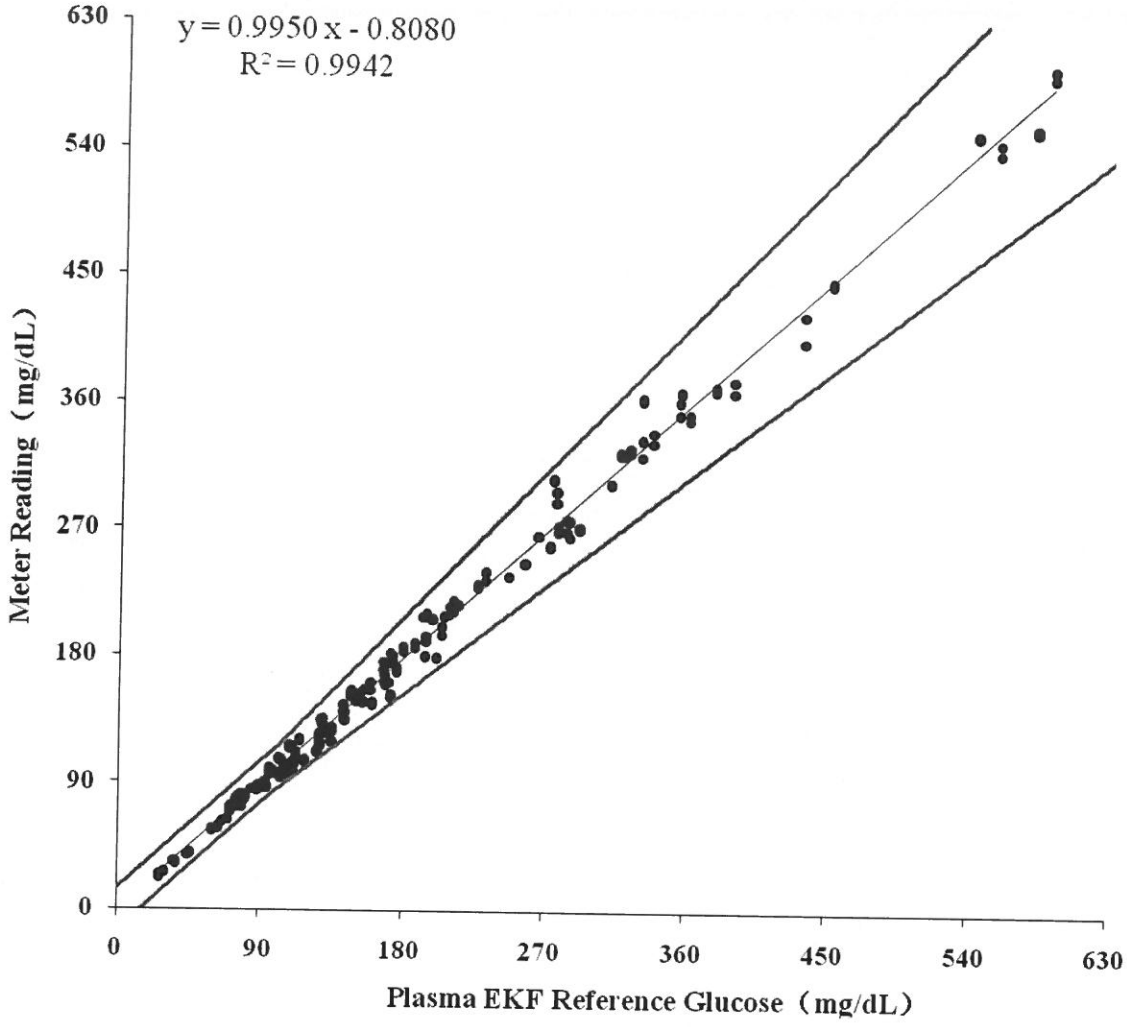


Figure 9 Fingertip sample-the linear regression of strip lot RD1305017

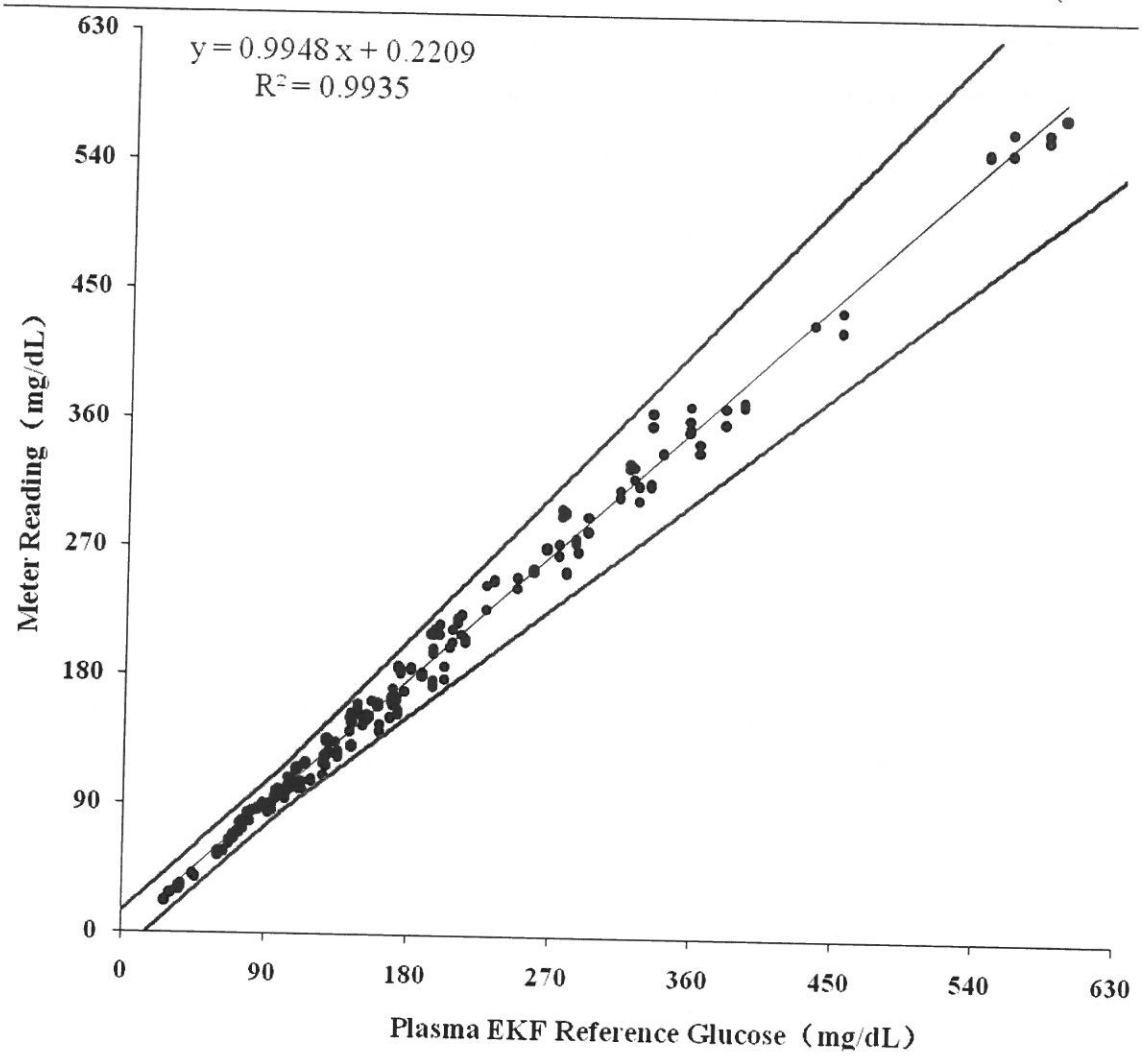


Figure 10 Fingertip sample-the linear regression of strip lot RD1305018

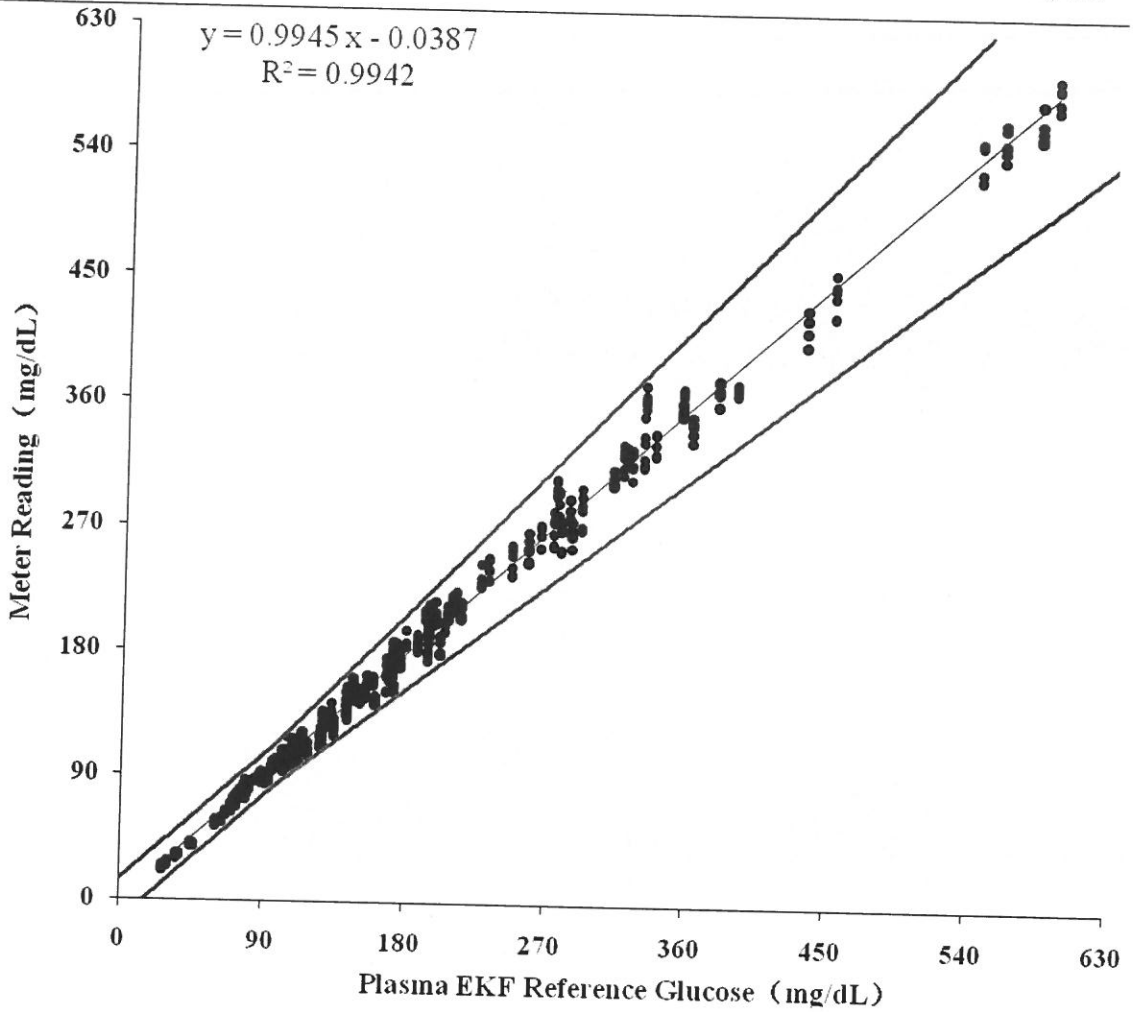


Figure 11 Fingertip sample-the linear regression of strip lot RD1305016、RD1305017、RD1305018

Table 12 Fingertip sample-summary table of coefficient

Linear Regression Summary Table (Individual lot and all 3 lots combined data): Meter Reading (y) vs. Plasma EKF Value (x) (EKF using fingertip sample)						
Sample Site	Strip Lot	Slope	Intercept	R	R^2	N
Fingertip	RD1305016	0.9937	0.4711	0.9974	0.9948	240
Confidence Interval: Lower 95%		0.9845	-1.4825			
Confidence Interval: Upper 95%		1.0028	2.4248	Z=213.84, P<0.0001		
Fingertip	RD1305017	0.9950	-0.8080	0.9971	0.9942	240
Confidence Interval: Lower 95%		0.9853	-2.8760			
Confidence Interval: Upper 95%		1.0047	1.2599	Z=202.29, P<0.0001		
Fingertip	RD1305018	0.9948	0.2209	0.9967	0.9935	240
Confidence Interval: Lower 95%		0.9845	-1.9745			

Confidence Interval: Upper 95%		1.0051	2.4163	Z=190.51, P<0.0001		
Fingertip	RD1305016, RD1305017 and RD1305018	0.9945	-0.0387	0.9971	0.9942	720
Confidence Interval: Lower 95%		0.9889	-1.2308			
Confidence Interval: Upper 95%		1.0001	1.1535	Z=349.53, P<0.0001		

From regression analysis, the correlation coefficients (R) for all 3 strip lots for fingertip sample site were >0.975. The results indicate the blood glucose test strip (glucose oxidase method) test reading correlates well with the EKF reference instrument value.

3.5 Product performance evaluation index results analysis

As the blood glucose monitoring system, the clinical performance evaluation of the test reagent and the blood glucose meter is qualified, that is, the test reagent and the blood glucose meter can meet the clinical requirements.

3.6 Safety analysis

No adverse events and reactions occurred during the whole clinical performance study

No serious adverse events or device defects occurred during the whole clinical performance study.

3.7 Accountability of specimens

A total of 120 patients were screened and enrolled, and 120 were valid samples.

3.8 Risk-benefit assessment

Blood glucose test strips are used for in vitro quantitative detection of glucose concentration in fresh fingertip capillary whole blood .

During the entire clinical performance study, there was no damage to the subjects and medical staffs.

So, the benefits more than the risks.

4. Discussion

Blood glucose test strips (glucose oxidase method) reading from fingertip samples correlate well with EKF test result. The clinical use of experimental reagents is safe and meets the requirements of clinical patient self-testing and professional use.

5. Overall conclusions

1) User Performance Evaluation

From the analysis of percentage data points versus plasma EKF values, the results showed that more than 95% of data points for fingertip sample site within both ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(≥100mg/dL) and ±0.83mmol/L(±15mg/dL) versus plasma EKF values when glucose concentration is <5.55mmol/L(<100mg/dL). This indicates the user accuracy results for fingertip sample site meet the user accuracy criteria per EN ISO 15197:2015, Section 8.2.

Besides, the patient 's self-test correlate well with control EKF test results.

During the test, there was no display failure of the glucose meter, there was no startup or shutdown failure of the glucose meter, no automatic shutdown or abnormal interruption of the machine and other unqualified phenomena during the inspection process, which met the clinical needs.

Through the direct communication between professionals and users to understand the user's suggestions or opinions on all aspects of the detection system, users are asked to answer a questionnaire to evaluate their mastery of the detection system, and to evaluate whether the product manual is easy to understand and whether the instrument operation is convenient. The self-test patients were satisfied with the 19 contents of the questionnaire survey, and the overall evaluation was excellent, indicating that the product design met the product self-test design requirements, and the patient was easy to master the product self-test process and complete the self-test process.

2) System Accuracy Evaluation

From the analysis of percentage data points within ±15% versus plasma EKF values, the results showed that more than 95% of data points for fingertip samples of each strip lot were within ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(≥100mg/dL). The results showed that more than 95% of data points for fingertip samples of each strip lot were within ±0.83mmol/L(±15mg/dL) versus plasma EKF values when glucose concentration is <5.55mmol/L(<100mg/dL). The results showed that more than 95% of data points for fingertip samples of each strip lot within both ±15% versus plasma EKF values when glucose concentration is ≥5.55mmol/L(≥100mg/dL) and ±0.83mmol/L(±15mg/dL)versus plasma EKF values when glucose concentration is <5.55mmol/L(<100mg/dL). This indicates the system accuracy results for

fingertip samples of all 3 strip lots meet the Acceptance Criteria A.

From the analysis of Consensus Error Grid analysis, the results showed that more than 99% of data points for all 3 strip lots were within Zone A and B. This indicates the system accuracy results for fingertip samples of all 3 strip lots meet the Acceptance Criteria B.

This indicates the accuracy study results demonstrate that the blood glucose test strips (glucose oxidase method) meet the system accuracy criteria (A and B) per *EN ISO 15197:2015*, Section 6.3.3 for fingertip sample.

Besides, blood glucose test strips (glucose oxidase method) reading from fingertip sample correlate well with EKF test result.

6. Problems existed and suggestions for improvement

No suggestions.

7. List of study sites for multi-center study

Single-center clinical performance study.

8. List of operators participated

Researcher	Responsibility	Title	Research center
Yibing Lu	Principal Investigator	Chief physician	Device clinical performance study institution, The Second Affiliated Hospital of Nanjing Medical University
Jinjing Liang	Investigator	Supervisor Nurse	Device clinical performance study institution, The Second Affiliated Hospital of Nanjing Medical University
Yan Tang	Investigator	Supervisor Nurse	Device clinical performance study institution, The Second Affiliated Hospital of Nanjing Medical University
Ting Li	Investigator	Nurse	Device clinical performance study institution, The Second Affiliated Hospital of Nanjing Medical University

9. Abbreviated terms and definitions

NA.

10. Ethics

During the implementation of the clinical performance study, the protocol, informed consent form, case report form, and other test documents have not been revised. The implementation version number of the protocol is V1.0, and the version date is April 11, 2023.

11. Investigators and administrative structure of the study

Coordinating investigator	**Signature** Yibing Lu **Date** 2023.07.17
Leading study site	**Stamp** 南京医科大学第二附属医院 医疗器械临床试验机构 **Date** 2023.07.17
Sponsor	**Stamp** 江苏硕世生物科技有限公司 3211811101615 **Date**

12.Annexes to the report

12.1 Clinical performance study summary of each site (including attachments)

Single-center clinical performance study.

12.2 IFU of the comparator or reference measurement

Reference to Annex I EKF user manual.

12.3 List of principal investigators, their qualifications or a copy of CV

Chief Physician, Professor, Medical Doctor, Doctoral Supervisor, Director of the Endocrinology Department of the Second Affiliated Hospital of Nanjing Medical University. Vice Chairman of diabetes Branch of Jiangsu Medical Association, Vice Chairman of diabetes Professional Committee of Jiangsu Medical Doctor Association, Vice Chairman of Endocrine Professional Committee of Jiangsu Association of Integrated Traditional and Western Medicine, Member of Endocrinology Branch of Jiangsu Medical Association, and Member of Bone Metabolism Group of Geriatrics Branch of Chinese Medical Association. Select and cultivate high-level talents for the "Six Talent Peaks" in Jiangsu Province. Visiting scholar of the Affiliated Hospital of the University of Munich, Germany, presided over more than 10 NSFC and other provincial and municipal projects, published more than 20 SCI articles as the lead author or corresponding author, and more than 70 papers in domestic core journals. I am currently an expert in the evaluation of the National Natural Science Foundation of China and a key research project evaluation expert of the Ministry of Science and Technology. He is good at diagnosis and treatment of diabetes and diabetes kidney disease, diabetes neuropathy, thyroid disease, obesity, osteoporosis.

12.4 List of names and contact details for CRO/SMO/CRC

CRO company is Nanjing STK Pharmaceutical Technology Co., Ltd., contact number +86 13305154069.

12.5 List of Monitors

Weining Yan, CRA, female, undergraduate, working at Nanjing Rayhu-Anong Pharmaceutical Technology Co., Ltd., contact number +86 15952046990.

12.6 CPSP deviations, all adverse events, adverse effects and device deficiencies

This clinical performance study did not deviate from CPSP, no adverse events and device

deficiencies occurred in the study.