Product Verification And Validation

The performance characteristics of the VivaChek Ino X Blood Glucose Monitoring System were evaluated by performing the following studies: measurement repeatability, intermediate measurement precision, linearity, interference testing, packed cell volume, altitude, sample volume, low battery, temperature effect evaluation for blood & control solution and humidity effect.

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1. Measurement Repeatability

The measurement repeatability of the VivaChek Ino X Blood Glucose Monitoring System was evaluated according to EN ISO 15197:2015 / ISO 15197:2013(E), Section 6.2.3 Measurement Repeatability, with three test strip lots using blood samples at 42% hematocrit level prepared at five glucose concentrations as specified in EN ISO 15197:2015, Section 6.2.3.2, Table 1. Actual glucose concentrations were determined using YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer, which was selected as the reference laboratory method for this study. Each blood sample was tested with ten test strips on each meter (totally ten meters were used) at each glucose concentration for each of the three test strip lots. The measurement repeatability results show ≤5% CV when blood glucose concentration is greater than or equal to 100 mg/dL and ≤5.0 mg/dL SD when blood glucose concentration is less than 100 mg/dL.

2. Intermediate Measurement Precision

The intermediate measurement precision of the VivaChek Ino X Blood Glucose Monitoring System was evaluated according to EN ISO 15197:2015, Section 6.2.4 Intermediate measurement precision, with three test strip lots using control solution at three control solution glucose concentration levels. The three levels of control solutions were prepared from control material as specified in EN ISO 15197:2015, Section 6.2.4.2, Table 2. Each control solution sample was tested using one test strip on each meter (totally ten meters were used) on the first day, and then repeated nine more times for a total of over at least ten days for each of the three test strip lots. The intermediate measurement precision results show ≤5% CV when glucose concentration is greater than or equal to 100 mg/dL and ≤5.0 mg/dL SD when glucose concentration is less than 100 mg/dL.

VivaChek Biotech (Hangzhou) Co., Ltd
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
Tel: +86-571-89182700 Fax: +86-571-89182733 Email: info@vivachek.com www.vivachek.com

3. Linearity

The linearity of the VivaChek Ino X Blood Glucose Monitoring System was evaluated according to CLSI/NCCLS EP-6A across the measuring range of the meter. Three test strip lots using blood samples at five glucose concentration levels prepared from venous blood samples at 42% hematocrit level were used for the study. The linearity was assessed as the correlation between strip readings vs. YSI Plasma Values yielding slope values of 1.0313 to 1.0612 which meets acceptance criteria of within 0.90 to 1.10, and R values of 0.9985 to 0.9991 for each of the three strip lots tested. Furthermore, the average %bias obtained by the VivaChek Ino X Blood Glucose Monitoring System when glucose concentrations is ≥100 mg/dL were from -2.0% to 8.6% of values measured by the YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer, while average bias when glucose concentrations <100 mg/dL is -5.8 mg/dL to -0.3 mg/dL. In conclusion, the study demonstrates that the VivaChek Ino X Blood Glucose Monitoring System has excellent linearity across the measuring range of the meter.

4. Interference testing

The interference testing of the VivaChek Ino X Blood Glucose Monitoring System was evaluated using guidelines from CLSI EP7-A2 with three test strip lots using venous blood samples at three glucose concentrations containing approximately 40–60 mg/dL, 80–120 mg/dL and 300- 400 mg/dL. Each blood sample was prepared containing the interfering substance at low and high test concentrations using venous blood samples containing heparin anticoagulant at 42%±2% hematocrit level. Other preservatives were prepared and evaluated as part of the study. Ten test strips were tested for each test pool and control pool for each test strip lot.

The performance study for interfering substances effect was conducted, which included the interference effect evaluation of Acetaminophen, Ascorbic acid (Vitamin C), Bilirubin, Cholesterol, Creatinine, Dopamine, EDTA, Galactose, Gentisic Acid, Glutathione, Haemoglobin, Heparin, Ibuprofen, Icodextrin, L-DOPA, Maltose, Methyl DOPA, Salicylate, Tolbutamide, Tolazamide, Triglycerides, Uric acid, Xylose, Lactose, Tetracycline. The results show that there is no significant interference effect for these substances on VivaChek Ino X Blood Glucose Monitoring System test except at abnormally high concentration for Ascorbic acid (Vitamin C>3mg/dL). The test strip insert and user's manual for VivaChek Ino X Blood Glucose Monitoring System indicate that abnormally high level of Ascorbic acid (Vitamin C>3mg/dL) will produce falsely high blood glucose measurement results.

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5. Clinical Data Summary:

The clinical performance data were performed and summarized below.

5.1 System Accuracy Evaluation for Fingertip, Palm, and Forearm Testing

The clinical trials for the products have been conducted based on system accuracy evaluation in EN ISO 15197:2015. The clinical study for system accuracy was evaluated with 106 subjects. Individual measurements from the VivaChek Ino X Blood Glucose Monitoring System were compared to reference glucose concentration values ranging from 39.1 to 570.1 mg/dL for fingertip testing, palm and forearm testing determined by the YSI Glucose Analyzer (reference measurement method). The results showed that more than 95% of data points of three strips for fingertip, palm and forearm sites were within15 mg/dL for glucose concentration <100mg/dL and15% for glucose concentration ≥100mg/dL.

It also showed that more than 99% of data points of combination 3 reagent lots for fingertip site were in Zones A and B of Consensus Error Grid (CEG).

Taken together, the system accuracy evaluation results demonstrate that the VivaChek Ino X Blood Glucose Monitoring System meets the system accuracy criteria per EN ISO 15197:2015, Section 6.3 for fingertip, palm and forearm sample sites

5.2 User Performance Evaluation (Fingertip, Palm and Forearm)

The user performance evaluation was performed to validate whether the VivaChek Ino X Blood Glucose Monitoring System can meet the design requirements and exhibit functionality when placed in the hands of inexperienced, non-professional laypersons as well as by trained technicians in accordance to EN ISO 15197:2015, Section 8.0, User performance evaluation. For this study, 106 lay persons participated. Capillary blood samples from fingertip, palm, and forearm were collected from the subjects and tested on the studied system by both layperson and technician using 1 reagent lot. Glucose values from whole blood calibrated to plasma value were also obtained using YSI Glucose Analyzer for comparison with the studied system.

The study evaluating glucose values from fingertip capillary blood samples obtained by 106 lay persons showed the following results:

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China

Tel: +86-571-89182700 Fax: +86-571-89182733 Email: info@vivachek.com www.vivachek.com

100% within ±15 mg/dL (±0.83 mmol/L) of the plasma YSI values at glucose concentration below 100 mg/dL (5.55 mmol/L), and 100% within ±15% of the plasma YSI values at glucose concentration s at or above 100 mg/dL (5.55 mmol/L).

The study evaluating glucose values from palm capillary blood samples obtained by 106 lay persons showed the following results:
100% within ±15 mg/dL (±0.83 mmol/L) of the plasma YSI values at glucose concentration below 100 mg/dL (5.55 mmol/L), and 100% within ±15% of the plasma YSI values at glucose concentration s at or above 100 mg/dL (5.55 mmol/L).

The study evaluating glucose values from forearm capillary blood samples obtained by 106 lay persons showed the following results:
100% within ±15 mg/dL (±0.83 mmol/L) of the plasma YSI values at glucose concentration below 100 mg/dL (5.55 mmol/L), and 100% within ±15% of the plasma YSI values at glucose concentration s at or above 100 mg/dL (5.55 mmol/L).

In summary, the user performance evaluation results demonstrates that lay users can perform testing and obtain accurate results for the VivaChek Ino X Blood Monitoring System.

6. Stability Testing

Stability is determined according to the procedures and requirements listed in EN ISO 15197:2015 Stability testing of in vitro diagnostic reagents.

6.1 Test Strip

The real time stability study evaluation for the VivaChek Ino X Blood Glucose Test Strip was evaluated at 2℃、25℃、30℃ for 24 months. The test strips were assayed using glucose-spiked heparinized venous whole blood prepared at approximately 40-60, 80-120, 250-300 and 450-550 mg/dL with 42% hematocrit level. The results show that the acceptance criteria are met for the real time stability study for the three strip lots: Average %Bias (vs. Plasma YSI) is ≤±10% (when glucose concentration is ≥100 mg/dL), Average Bias vs. (Plasma YSI) is ≤±10mg/dL (when glucose concentration is <100 mg/dL); The test results show the projection of at least 24 month stability for the test strip of VivaChek Ino X Blood Glucose Monitoring System.

VivaChek Biotech (Hangzhou) Co., Ltd
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
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6.2 Control Solution

The real time stability study for shelf life evaluation for the VivaChek Ino X Blood Glucose Control Solution was evaluated at 2℃、25℃、30℃、35℃ for 24 months.. Three levels of glucose control solutions at 40-60, 96-144 and 280-420 mg/dL were assayed and the results indicate that the acceptance criteria are met and that the shelf life of the control solution is projected for greater than 24 months when stored properly in unopened control solution dropper bottle.

The results show that the acceptance criteria are met for the real time stability study for three levels of the three control solution lots tested on one strip lot: 95% of control solution test result shall fall within the assigned control solution range at each control solution level.
The test results show the projection of at least 24 month stability for the control solutions of VivaChek Ino X Blood Glucose Monitoring System.

7. Real time use life

Real time use life is determined according to the procedures and requirements listed in ISO 15197:2013(E), real time use life testing of in vitro diagnostic reagents.

7.1 Test Strip

The test strips were expose respectively in a temperature&humidity controller at five different temperature&humidity conditions(5℃&10% RH, 5℃&90% RH, 21℃&45% RH, 45℃&10% RH, 45℃&90% RH) for 50 minutes, then placed in an oven at 30 ℃ for a time period of 6 months. The test strips were assayed using glucose-spiked heparinized venous whole blood prepared at approximately 40-60, 80-120, 250-300 and 450-550 mg/dL with 42% hematocrit level. The results show that the acceptance criteria are met for the real time stability study for the three strip lots: Average %Bias (vs. Plasma YSI) is ≤±10% (when glucose concentration is ≥100 mg/dL), Average Bias vs. (Plasma YSI) is ≤±10mg/dL (when glucose concentration is <100 mg/dL); The test results show the projection of at least 6 month use life after first openning of vial for the test strip of VivaChek Ino X Blood Glucose Monitoring System.

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7.2 Control Solution

The control solution were expose respectively in a temperature&humidity controller at five different temperature&humidity conditions(10℃&10% RH, 10℃&90% RH, 21℃&45% RH, 40℃&10% RH, 40℃&90% RH) for 50 minutes, then placed in an oven at 30 ℃ for a time period of 6 months. Three levels of glucose control solutions at 31-50, 95-144 and 281-419 mg/dL were assayed and the results indicate that the acceptance criteria are met and that the real time use life of the control solution is projected for greater than 6 months after first opening of vial

The results show that the acceptance criteria are met for the real time stability study for three levels of the three control solution lots tested on one strip lot: more than 95% of control solution test result shall fall within the assigned control solution range at each control solution level.
The test results show the projection of at least 6 month use life after first opening the bottle for for the control solutions of VivaChek Ino X Blood Glucose Monitoring System.

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