

## **Clinical evaluation of SD CHECK GOLD as point-of-care glucose meter**

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**Background:** Self-monitoring devices for blood glucose are widely used as a point-of-care testing (POCT) in the management of diabetic patients. In the present study, we evaluated the performance of SD CHECK GOLD Blood Glucose Testing System (SD diagnostic, Yongin, ROK) using electrochemical detection technique.

**Methods:** SD CHECK GOLD was tested for linearity, precision and comparison of method. Other glucometers including ACCU CHEK ACTIVE (Roche Diagnostics Ltd., Mannheim, Germany) and ONE TOUCH ULTRA (Lifescan Inc., Milpitas, CA, USA) were compared for the same categories according to the Clinical And Laboratory Standards Institute (CLSI) guidelines.

**Results:** SD CHECK GOLD revealed good linearity in glucose concentration ranging from 50 mg/dL to 550 mg/dL ( $r^2=0.9931$ ). In the precision study, within-run precision and total-run precision (CV)s were within 10%. Excellent correlation was found between SD CHECK GOLD and Toshiba 200FR (Toshiba, Japan) ( $y=0.9212x$ ,  $r=0.9756$ ).

**Conclusions:** SD CHECK GOLD showed good linearity, precision, and correlation with the reference method. No significant effect of testing procedure or operator was found. SD CHECK GOLD provided rapid and reliable results for blood glucose and seemed to be appropriate for the clinical useful in the management of diabetic patients.

**Key words:** SD CHECK GOLD, Blood glucose, Diabetes mellitus, Self monitoring, Point-of-care Testing

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## INTRODUCTION

Diabetes is a chronic illness, which occurs when pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces and requires continuing medical care and patient self-management education [1]. In domestic, 7.79% of the population (male 8.6%, female 7.1%) is reported to have diabetes with the reference of 126mg/dL of fasting plasma glucose value and the rate of patients with diabetic complication and death rate is increasingly going up.[2]. Diabetes is serious not because of itself but diabetic complication, so the purpose of diabetes care is to prevent and delay the complication by managing blood glucose. With this requirement, the self-monitoring of blood glucose have been used for patients with diabetes for a long time.[3,4]

Recently, as the accuracy of SMBG was improved than in the past, it plays a useful role in patients with diabetes as well as Point-of-care-testing (POCT). However, most domestic hospitals and people with diabetes are mainly using foreign glucometers, which are also evaluated with higher faith than domestic glucometers.[5-8]. Even though there are still differences in brand awareness and production capacity, many development and study are being carried more and more in domestic.[9,10]

According to this, we evaluated linearity, precision, and correlation with the reference method for ACCU CHEK ACTIVE (Roche Diagnostics Ltd., Mannheim, Germany), ONE TOUCH ULTRA (Lifescan Inc. Milpitas, CA, USA) and SD CHECK GOLD( Standard Diagnostics, Inc , Yong-in, Korea), glucometer using electro-chemical method which was launched recently in domestic

## SUBJECT AND METHODS

### 1. Subject

Blood samples were obtained from 208 patients, who requested blood glucose test to endocrinology of Korea hospital in Ansan, during 3 months, from 1 March to 1 June 2008. We collected about 3 mL of venous sample with Vacutainer EDTA(BD, Fanklin Lakes, NJ, USA) and 10  $\mu$ L of capillary blood by using lancet at the same time. All participants were over 18 years old and all procedure was proceeding by approval of (Institutional Review Board, IRB). The capillary whole bloods among all samples, which were used for comparison between methods, were used for SMBG while venous plasma samples were used for Toshiba 200FR(Toshiba, Tokyo, Japan), reference equipment. All patients consented to participate in this study.

### 2. Method

#### 1) Materials and principle

SD CHECK GOLD use electrochemical method, which measure the electrical signal by glucose concentration and ONE TOUCH ULTRA use the same method as well. In case of ACCU CHEK ACTIVE, it is photometry method measuring the color change.

#### 2) Linearity

Based on the result from Toshiba 200FR using Hexokinase method, we determined high and low level of glucose sample, and evaluated by measuring 5 kind of diluted samples 5 times, which were manufactured with 4:0, 3:1, 2:2, 1:3, 0:4 ratio by Clinical And Laboratory Standards Institute(CLSI) EP6-P[11].

### 3) Precision

With Glucose control solution (SD, INC, Yong-in, Korea), we measured each 2 kinds of quality control materials, which have high and low concentration, twice at once, twice a day during 5 days and it was carried out by one pathologist.

### 4) Effect of sample volume

With heparinized venous whole blood, we prepared low, medium, and high level of glucose sample having 0.5, 1, 1.5, 2, 4, 8, 10, 20, 40, and 80  $\mu$ L of blood volume and measured each of them 5 times. Each glucometer have different sample volume needed ; SD CHECK GOLD : 0.9  $\mu$ L , ONE TOUCH ULTRA : 1  $\mu$ L, ACCU CHECK ACTIVE : 2  $\mu$ L. For assessment of the result by sample volume, SD CHECK GOLD, ONE TOUCH ULTRA use 1  $\mu$ L while ACCU CHECK ACTIVE use 2  $\mu$ L as reference sample volume. Experiments were made 5 times at each condition.

### 5) Effects of different hematocrit value

The blood was pooled and then spun down to separate the erythrocyte from plasma. Separated erythrocytes and plasma was reconstituted to achieve the desired target hematocrit levels of 25%, 40%, 55%. Each hematocrit level had 3 target glucose concentrations (90, 200, 400 mg/dL). Each of them were measured 5 times and compared with reference of 40 % of hematocrit.

### 6). Data analysis

We use Microsoft Excel 2002 (Microsoft Corporation, New York, USA) for data analysis.

## RESULTS

### 1. Characteristics of subject

We did comparison test between 3 glucometers and

laboratory equipment with total 208 of patients. The number of male was 92, female was 116. Distribution of age was the same as following ; over than 81 : 2% , 71~81 : 13% , 61~70 : 20% , 51~60 : 28% , 41~50 : 24% , 31~40 : 9% , 21~30 : 3% , less than 20 : 1%. The range of glucose concentration was 74 to 567mg/dL.

### 2. Linearity

According to the information provided by manufacturer, the measuring range of the meter was 10 to 600 mg/dL and range of glucose concentration, which keeps linearity, was a little different between each meter, but all 3 glucometers including SD CHECK GOLD revealed good linearity in glucose concentration ranging from 10 to 600 mg/dL. ( $R^2 = 0.995 \sim 0.998$ ) (Fig.1)

### 3. Precision

We evaluated precision by measuring twice each time, twice a day during 5 days with glucose control solution (SD, INC, Yong-in, Korea) by CLSI EP5-A2[12] and we also did this experiment with 3 lots at each manufacturer to determine the deviation between lots and it was carried out by one pathologist to exclude the deviation resulting from different tester. As a result of performing this experiment with 3 glucose control solutions having different concentration, within-run precision and total-run precision (CV)s were shown in table 1. CV for 3 different glucose concentration materials and total-run CV were 3.1~5.5%. In case of SD CHECK GOLD, it revealed excellent precision showing below 5.0% of CV.(Table 1.)

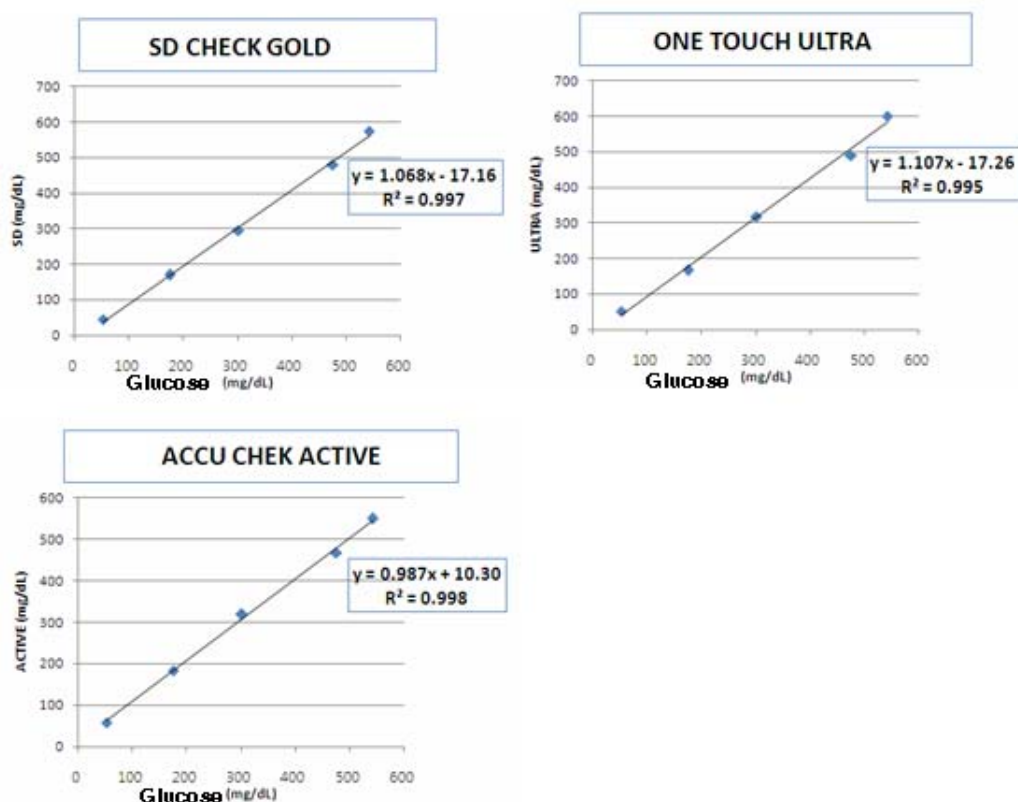


Fig. 1. Linearity of glucose concentrations measured by the 3 glucometers (SD CHECK GOLD, ONE TOUCH ULTRA and ACCU CHEK ACTIVE).

Abbreviations: SD, SD CHECK GOLD; ULTRA, ONE TOUCH ULTRA; ACTIVE, ACCU CHEK ACTIVE

Table 1. Precision of 3 glucometers including 3 different strip lot numbers at 3 glucose concentrations

		SD CHECK GOLD				ONE TOUCH ULTRA				ACCU CHEK ACTIVE			
Glucose Level		A	B	C	Total	A	B	C	Total	A	B	C	Total
112	Mean	107	102	107	105	91	82	87	86	91	94	90	92
	CV(%)	2.2	2.2	2.9	3.4	2.8	2.8	3.3	5.5	3.4	3.9	2.5	3.8
190	Mean	194	187	187	189	174	165	169	169	158	161	149	156
	CV(%)	2.0	2.7	3.2	3.1	2.2	1.3	2.6	3.1	3.1	6.7	2.6	5.5
281	Mean	298	293	282	291	278	260	265	268	238	248	240	242
	CV(%)	2.0	2.2	2.3	3.2	2.3	0.9	2.5	3.5	3.2	4.5	2.7	4.0

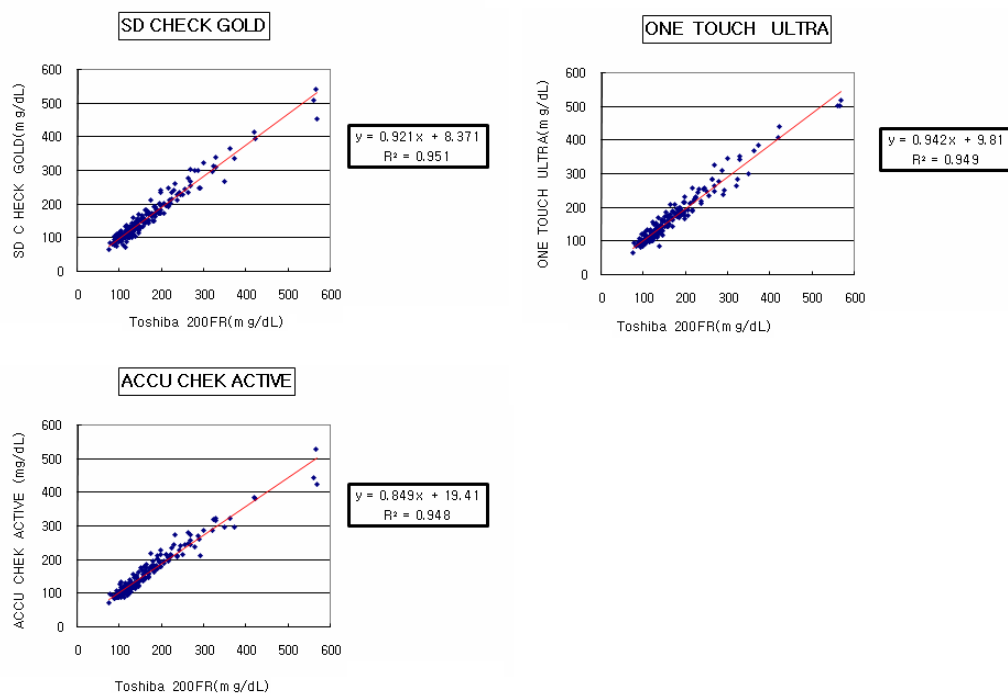


Fig. 2. Correlation of glucose concentrations measured by Toshiba 200FR vs. the 3 glucometers (SD CHECK GOLD, ONE TOUCH ULTRA and ACCU CHEK ACTIVE). Abbreviations: See Fig 1.

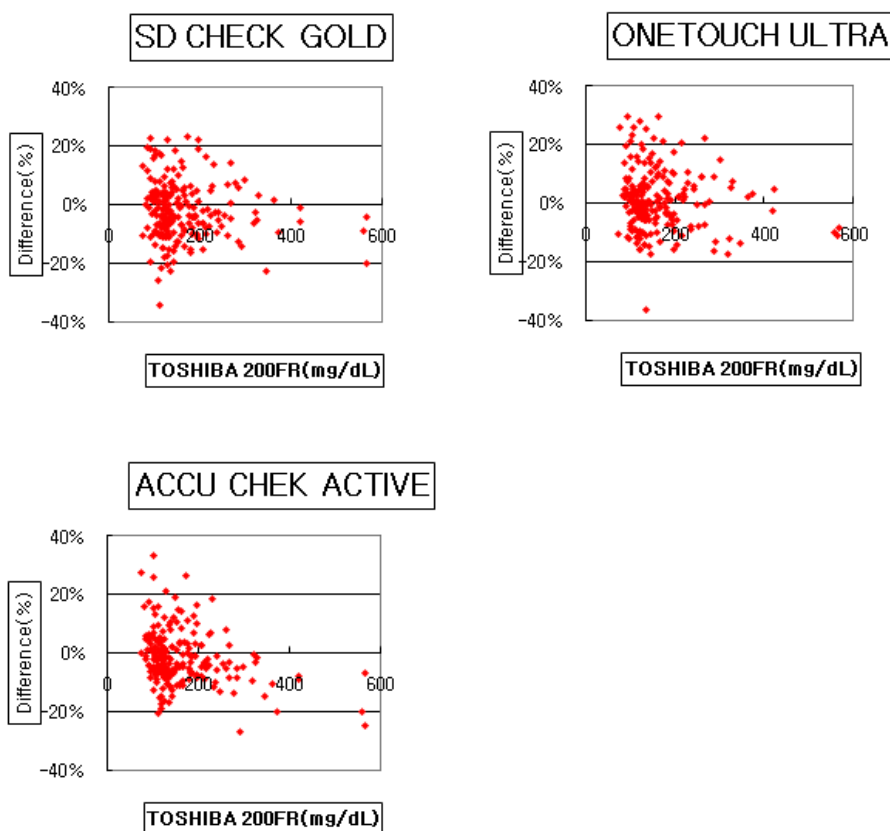


Figure 3. Bland-Altman plot of % glucose differences measured by Toshiba 200FR vs. the 3 glucometers

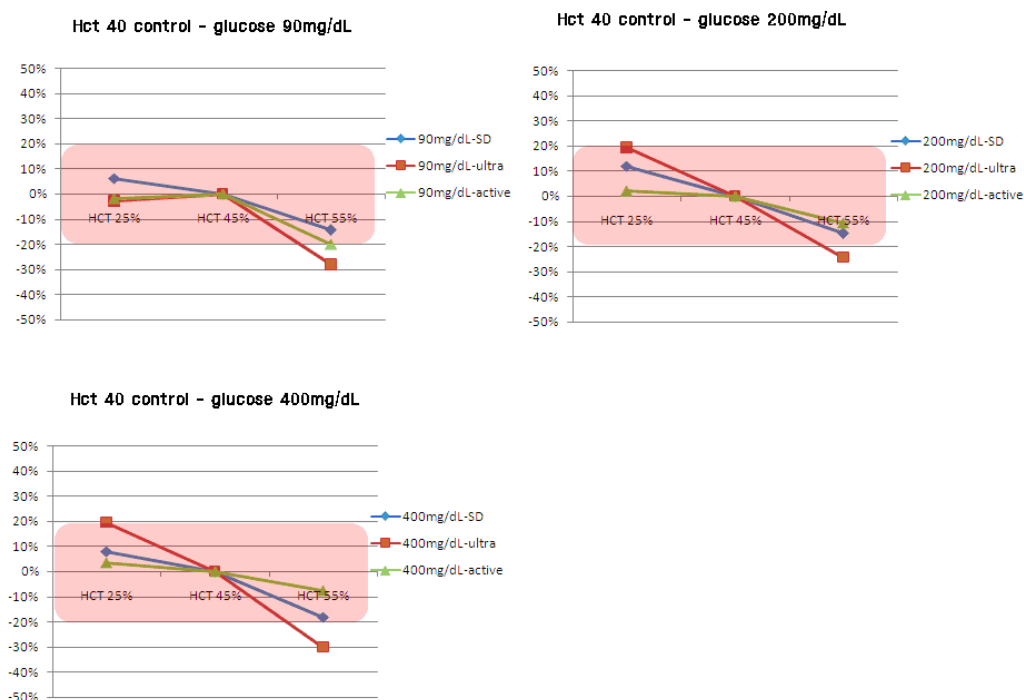


Fig 4. Effect of hematocrit on glucose measurements by the 3 glucometers (SD CHECK GOLD, ONE TOUCH ULTRA and ACCU CHEK ACTIVE).

Abbreviations See Fig 1.

#### 4. Comparison between methods

In method comparison test between 3 glucometers using capillary blood and laboratory equipment using venous blood targeting total 208 patients by CLSI EP9-P[7], excellent correlation( $r=0.97$ ) was found in 3 glucometers.(Fig.2). Bland-Altman plot of % glucose difference measured by Toshiba 200FR vs the 3 glucometers was same as shown in Fig.3. Totally, all 3 glucometers showed excellent correlation with laboratory equipment.

#### 5. Effect of sample volume

As a result of testing in 3 different glucose concentrations, it was valid to use reference sample volume in SD CHECK GOLD and ACCU CHEK

ACTIVE, but there were several errors in ONE TOUCH ULTRA when using less 1  $\mu$ L so we changed comparison reference as 1.5  $\mu$ L. In all sample volume, all 3 glucometers indicated little difference showing below 8% except the case that error message was displayed due to lack of sample volume.

#### 6. Effects of different hematocrit value

When we compared the difference of glucose level between whole blood with 20, 40, 55% of hematocrit and whole blood with 40% of hematocrit as reference, SD CHECK GOLD and ACCU CHEK ACTIVE showed within 20% of difference in all ranges while ONE TOUCH ULTRA showed maximum 30% of difference.(Fig. 4)

## CONSIDERATION

Diabetes is a chronic illness, requires continuing medical care and patient self-management education. Strict glycemic control must, therefore, be accompanied with proven therapies to reduce diabetic complication. SMBG is recommended to patients using multiple insulin or insulin pump therapy and allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved.[3,4]. Every point-of-care-testing should be assessed by quality reference applied to laboratory equipment regardless of equipment form or measuring principle and assure the quality of testing. For assessment of point-of-care-testing, it's important to include procedure problems such as type of sample, sample volume, sample vaccination method and effects by procedure environment as assessment subjects. Therefore, we compared the linearity, precision, method comparison, sample volume, and effect of different hematocrit value on SD CHECK GOLD. For comparison and assessment of SMBG, it's ideal to collect and analyze both whole blood and venous blood at the same time, but so far domestic study have assessed quality of SMBG by mainly using venous blood due to practical difficulty. In this study, we applied measuring method for point-of-care-testing to all subjects.

For correlation assessment with Toshiba 200FR chemistry analyzer, laboratory equipment, we collected venous blood and capillary blood for glucose measurement with SMBG at the same time. International Organization for Standardization, ISO, and CLSI apply different acceptance criteria according to glucose concentration. In case of less than 75 mg/dL, 95% of all differences in glucose values should be within  $\pm 15$ mg/dL of reference

value and while 95% of all differences in glucose values should be within  $\pm 20$ % of reference value when greater than 75mg/dL of glucose is used as sample.[14,15]. The difference of glucose result between SMBG and reference method was supposed by difference of accuracy according to type of sample. The fact that capillary whole blood's glucose value is 4-30% higher venous blood's one and plasma glucose is higher than 10-15% whole blood's one. However, 3 glucometers showed good correlation in this study.

SD CHECK GOLD provide test result in 5 seconds so that patients can achieve their glucose value very fast and it's quite useful for medical activity because of the fact that glucose measurement can be done beside patients not in laboratory. Furthermore, it's minimum sample volume is 1.0  $\mu$ L so user can collect enough blood sample without pricking deeply, which is suitable for patient who is sensitive to pain. We expect that this can reduce the strip consumption when lay person cannot collect enough capillary whole blood so testing is not made properly. However, actual user have to measure blood glucose with over than minimum sample volume demand provided by manufacturer for achieving accurate and reliable test result, otherwise glucose measurement cannot be done by SMBG or the test result is invalid.

In this study, SD CHECK GOLD showed good linearity, precision and performance in comparison of method, sample volume, effects of different hematocrit value compared with existing SMBG. Additionally, it's portable and easy to use due to small size and sample volume. SD CHECK GOLD provide rapid result and simple operation and seemed to be appropriate for emergency room or intensive care unit(ICU).

In conclusion, there is no difference in precision, measuring range, correlation with other method between SD CHECK GOLD and foreign glucometers and also there seemed to be benefit in terms of economic as SD CHECK GOLD is made in Korea so it can support laboratory operation for the future.

## SUMMARY

**Background:** Self-monitoring devices for blood glucose are widely used as a point-of-care testing (POCT) in the management of diabetic patients. In the present study, we evaluated the performance of SD CHECK GOLD Blood Glucose Testing System (SD diagnostic, Yongin, ROK) using electrochemical detection technique.

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