

XXVII. Balkan Clinical Laboratory Federation Meeting and XXX. National Congress of the Turkish Biochemical Society

Antalya, 27-31 October 2019

Evaluation of Roche Accu-Chek Inform II Glucose test strip system in the hospital setting

Settar KOSOVA, PhD

Zonguldak Çaycuma Devlet Hastanesi, Turkey

PROFESSIONAL GLUCOMETERS

- **Glucometers**: widely used in hospital wards
- Accurate glucose results are of paramount importance



OBJECTIVES

- To Evaluate Roche Accu-Chek Inform II in the hospital setting
- Modified ISO 15197 2013 protocol (venous instead of capillary whole blood was used)

ISO 15197 2013 CRITERIA

a) Accuracy criteria ISO 15197 2013

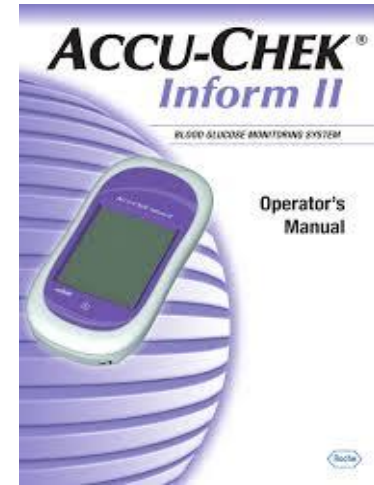
- ≥ 100 mg/dl $\pm 15\%$
- ≤ 99 mg/dl ± 15 mg/dl

b) $\geq 99\%$ results within **CEG** zones **A + B**

CEG: *Consensus Error Grid*

DEVICE COMPARISON STUDY

- **Glucometers:** Roche Accu-Chek Inform II (for Professional use)
- **Laboratory Glucose** method: Roche Cobas 6000 (c501), Hexokinase
(Reference method)



QUALITY ASSURANCE



- a) Weekly comparison of venous blood glucose by Glucometer and Laboratory
- b) Weekly two levels internal qc



*Note: Glucometer measurements performed by **Nurses***

STUDY DESIGN

Venous blood → for Glucometer *instantly*



Serum → for Laboratory Glucose measurements



- *BD SST I gel serum tubes are centrifugated within 30 min after sampling (10 min 2000 g at 20-25 °C)*

STUDY DESIGN

- **18 months** data retrospectively reviewed (01-2018 -- 06-2019)



- **7 wards**



- **13 different** strip lot codes



MATERIALS and METHODS

- 246 patients' **venous blood** glucose results (Laboratory and Glucometer) were analyzed.
- Performance evaluated, according to:
 - a) **ISO 15197 2013** standard (**modified-venous**),
 - b) **New consensus error grid**

RESULTS

Roche c501 serum Glucose, mg/dl Median (Range)	Roche Accu-chek Inform II blood Glucose, mg/dl Median (Range)	p (Wilcoxon)
134,5 (71 - 441)	136,5 (75 – 461)	0,0061

- Higher Glucose results with Glucometer

RESULTS

- 91,1 % (224 / 246) of glucometer glucose results were within allowed limits according to ISO 15197 2013
- Standard requirement is ≥ 95 %
- This item didn't fulfill the first ISO requirement

RESULTS

- Of 22 patients's glucose outside the ISO limits:
 - 19 zone a consensus error grid
 - 3 zone b consensus error grid
- Fulfils Standard's 2nd necessity at a rate of 100% (at least 99% required).

IMPROVEMENT-EDUCATION AND AUDITING

- Using wrong Strip Code
- Open left strip containers



SUMMARY

- Roche Accu-Chek Inform II glucometer system is clinically useful for professional use in health care institutions.

References

- 1. Freckmann G, Schmid C, Baumstark A, Rutschmann M, Haug C, and Heinemann L. Analytical Performance Requirements for System for Self-Monitoring of Blood Glucose With Focus on System Accuracy: Relevant Differences Among ISO 15197:2003, ISO 15197:2013, and Current FDA Recommendation. J Diab Science and Technol 2015, vol 9(4) 885-894**
- 2. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the Clinical significance of inaccuracies in the measurements of blood glucose. Diabetes care. 2000; 23(8): 1143-8**

Thank You!
setkos@yahoo.com
www.settarkosova.com

