



مركز الجودة للمختبرات الطبية
Center for Quality in Medical Laboratories



Use of EQAS data for Validation of Urine Dipstick Commercial Brands

Yumna Shehadah

Director, Center for Quality in Medical Laboratories

Department Of Medical Laboratory Sciences

Al Quds University

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Outline:

- Background
- Study design
- Results
- Conclusions

Verification:

“EuroLab cookbook”

- Standard methods need verification to ensure that the laboratory is capable of performing the stated activities. Verification is the demonstration that the laboratory is capable of replicating, with an acceptable level of performance, a standard method. Verification under conditions of use is demonstrated by meeting system suitability specifications established for the method, as well as a demonstration of accuracy and precision or other method parameters for the type of method

Validation:

- ISO/IEC 17025: 2017 – Clause 7.2.2.1: “The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. ... ”

ISO 15189:2012(E)

- 3.26 Validation:

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

- 3.27 Verification:

confirmation, through provision of objective evidence, that specified requirements have been fulfilled

Purpose:

“To evaluate the performance of available Urine Dipsticks bands”

“Validation??”

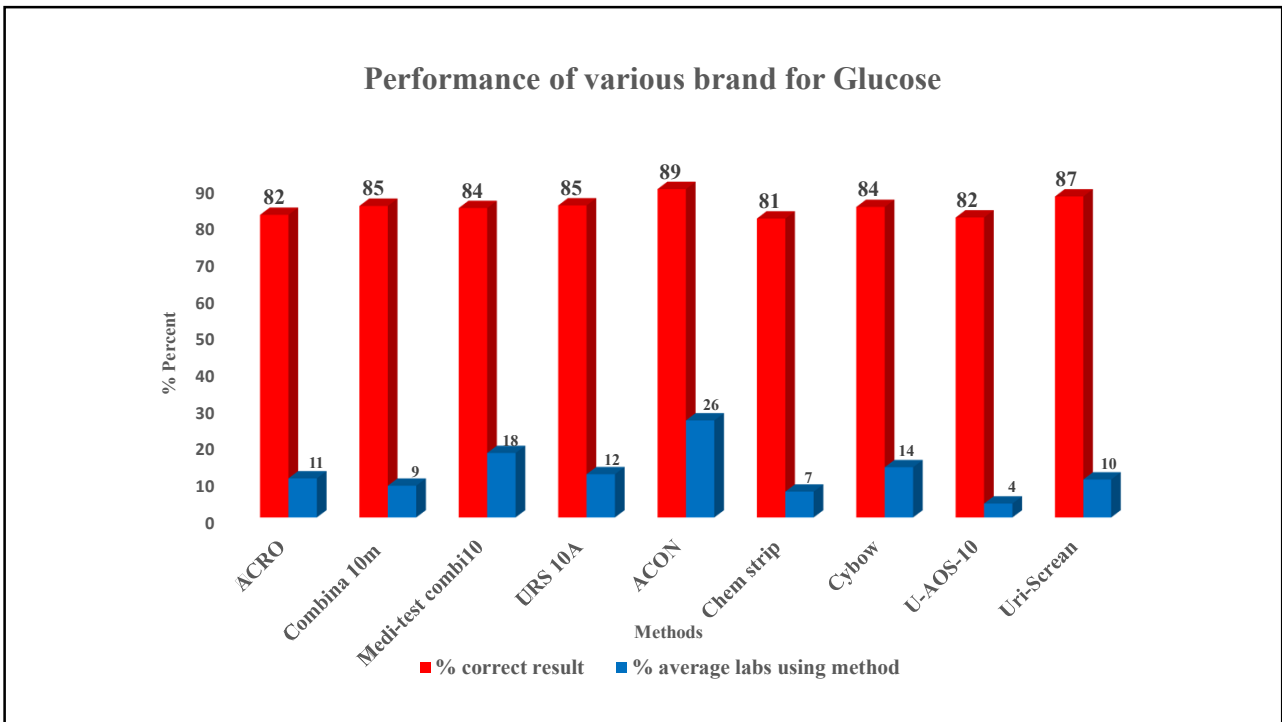
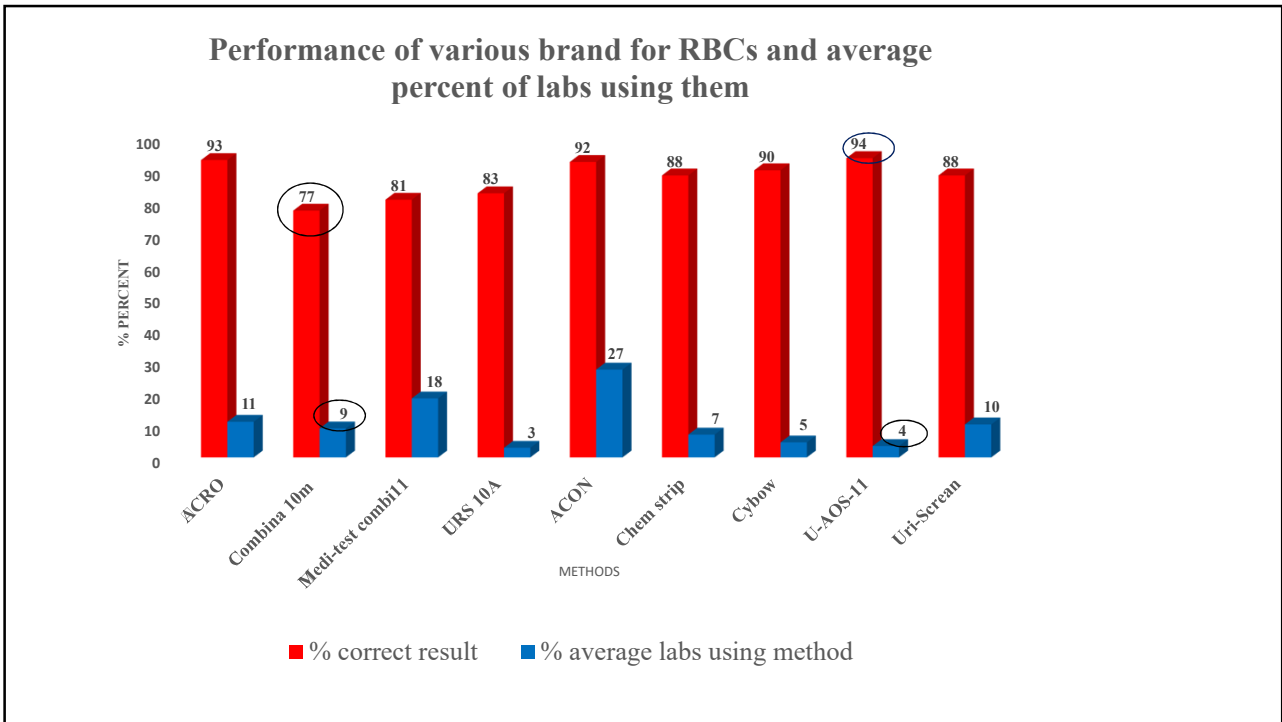
Indications:

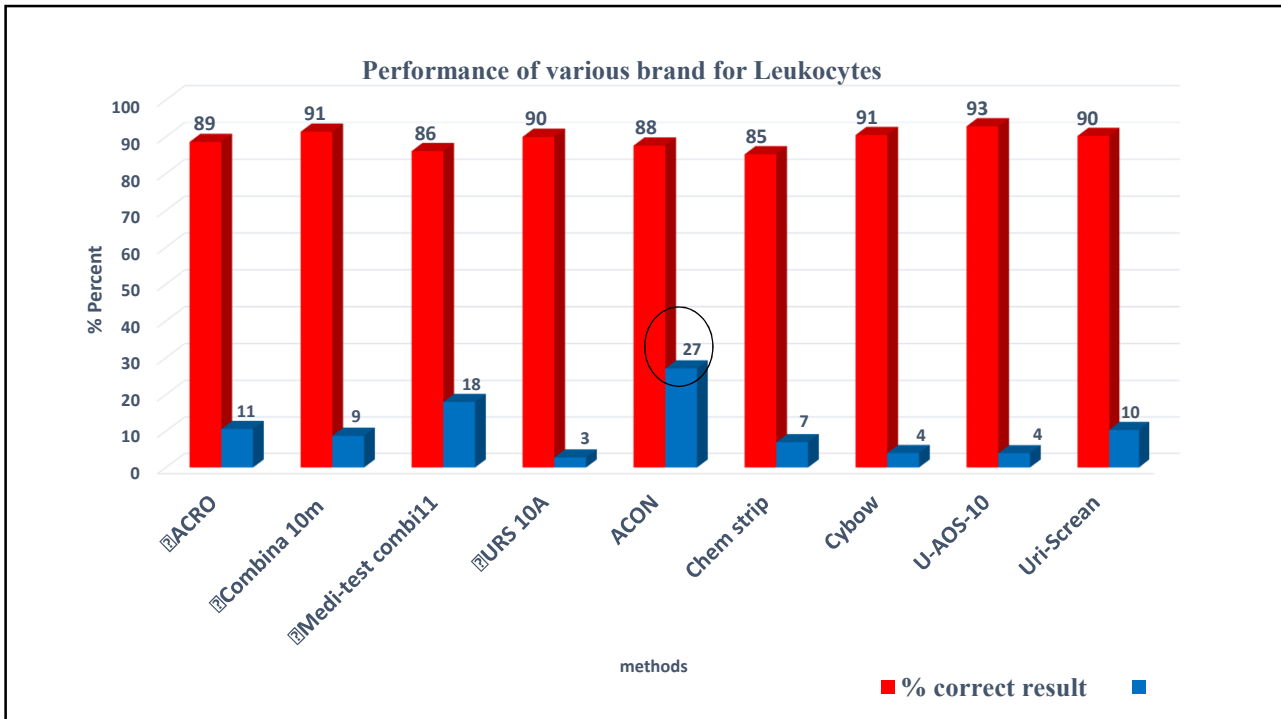
- Large Variability in results
- large number of commercial Urine Dipstick available
- Labs do not use internal controls for urine analysis
- Labs can't do verification in their labs
- No reference material available for Urine analysis
- they depend on QC data

Study Design

- Spiked stabilized liquid urine EQAS samples were used for assessment
- 8 samples during 2019
- Three parameters: RBCs, Leukocytes, Glucose were assessed
- 94% of the labs use these commercial urine dipsticks (9 brands)
(ACRO, Combina 10m, Medi-test combi10, URS 10A, ACON, Chem strip, Cybow, U-AOS-11, Uri-Screen)
- Performance is evaluated by calculating the average % correct response for brands

Results





Results

- All methods (brands) did not exceed 90% correct for glucose
- Leukocytes: the most commonly used commercial brand (27% of labs use it) did not exceed 88% average correct value
- RBC: The lowest average correct value for one commercial brand was 77% which being used by 9% of labs

Problems Faced by Center

- Labs are not committed: Response rate 50 – 63 %
- Do not indicate methods names (others: 7.5%)

Conclusion:

- There is no commercial brand that always give correct response.
- There are certain commercial brands that have bad performance, and should be removed from the market.

