Journal of Clinical and Experimental Pathology

Deori et al., J Clin Exp Pathol 2020, 10:4

Short Communication Open Access

Significant Cost-cutting in Internal Quality Controls for Urinalysis

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Received date: May 13, 2020; **Accepted date:** May 29, 2020; **Published date:** June 06, 2020

Abstract

Point of Care Testing (POCT) urinalysis involves performing tests nearer to patients -point of care using reagent strips which allow measurements of the following in urine: bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity and urobilinogen. It is one of the most common tests carried out in medical practice. Internal Quality Control (IQC) strip is mandatory to ensure the quality of urinalysis and for accreditation of the test.

Methods: In a secondary care centre we validated the use of two level IQC for Siemens Chek-Stix® Combo Pak for a week without any deterioration in the readings of any of the ten parameters, by increasing the contact time of the IQC strip with distilled water from thirty minutes to two hours.

Conclusion: This in-house validation of IQC for urinalysis helped to reduce cost of laboratory two level IQC substantially. This simple procedure can be easily emulated in small laboratories and for POCT urinalysis.

Keywords: Urinalysis; Internal quality controls; Dipstick

Introduction

A semi-automatic urine analyzer is used in small laboratories and also small clinics as a point of care test (POCT). It is essentially a dry chemistry strip reader which works through the use of a reflectance photometer to read and interpret the dipsticks. As per the regulations outlined by the Clinical Laboratory Improvement Amendments (CLIA). Per CLIA 42 CFR section 493.1256-Standard: Control Procedures use of internal quality control IQC is the law according to which for each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process [1]. Due to the high cost involved many small laboratories with limited workload either use a single level control daily or infrequently run IQC.

Siemens Chek-Stix® Combo Pak is the internal quality control for Urine analyzer containing 25 positive control (PC) and equal number of negative control strips (NC) which is stored at 15-30° Celsius and away from sunlight. The composition of NC strip is Potassium Phosphate Monobasic and dibasic, Sodium Chloride and Urea. PC strip contains-Bovine serum albumin, Glucose, sodium, Methyl acetoacetate, Crystalline Bilirubin, Bovine Hemoglobin and Sodium Nitrite,5-(4-Sulfobutoxy)-2-Methyllindole Sodium salt and protease. Normal shelf life 11 months from manufacture and as per the manufacturer's instructions is meant for single use.

Methods

Two sterile 15 ml sterile Tarson Tubes are taken and filled with 12 ml distilled water after which the NC and PC strips are immersed one in two different tubes and labelled. The tubes are allowed to stand for two hours at room temperature (22-25° Celsius) against a recommended time of thirty minutes in the product insert. Then invert six-eight times after which the strips are discarded and the two tubes were kept in the refrigerator (2-8° Celsius). Then on seven consecutive days the control solutions are tested as if they are routine urine samples after allowing them to come to room temperature using Siemens Multistix® 10 SG on a Siemens Clinitek Status+semi-automated urine analyzer for a month and results documented.

Results

The stored distilled water containing dissolved contents of NC and PC were found to be stable for seven days on refrigeration (2-8° Celsius) for all 10 parameters for both NC and PC. The PC strip showed deterioration for proteins which became negative on day 8.

Discussion

Running daily IQC for urinalysis is mandatory to validate instrument performance and ensure accurate patient diagnosis because Dipstick tests can be unreliable as a study found Most commonly used dipsticks in Croatia showed low level of agreement between each other. Moreover, their repeatability varies among manufacturers and their accuracy for glucose and proteins is poor [2]. POCT urinalysis is probably the commonest test and as per NHS data of 2013-2014 annual use of the test in Imperial College Healthcare Trust NHS, itself exceeded 300,000 [3]. Two-level IQC for urinalysis is a mandatory for laboratories seeking National Accreditation Board for Testing and Calibration Laboratories (NABL) in India [4]. Indian labs can use this modification of IQC for urinalysis after validation of the same.

Conclusion

The shelf life of IQC for urinalysis using two level IQC for Siemens Chek-Stix® Combo Pak could be extended for a week by immersing the

PC and NC strips for two hours resulting in significant cost reduction and making it affordable for all in resource poor settings.

Funding

The work was funded by Managing Director of Baptist Christian Hospital.

Conflict of Interest

Neither of the authors have any personal or financial relationship which could lead to bias.

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