Practical Laboratory Medicine 3 (2015) 1–7

Contents lists available at ScienceDirect

Practical Laboratory Medicine

journal homepage: www.elsevier.com/locate/plabm

Assessment of liver function tests on Piccolo Xpress point of care chemistry analyzer in a pediatric hospital

Neval Akbas [a,b], Graciela Gonzalez [b], Rachel Edwards [b], Sridevi Devaraj [a,b,*]

[a] Department of Pathology & Immunology, Baylor College of Medicine, 6621 Fannin Street, Houston, Tx 77030, USA
[b] Texas Children's Hospital, 6621 Fannin Street, Houston, Tx 77030, USA

ARTICLE INFO

Article history:
Received 2 June 2015
Received in revised form
25 September 2015
Accepted 28 September 2015
Available online 3 October 2015

Keywords:
Point of care testing
Analytical performance
Liver function tests
Precision
Method comparison
Interference

ABSTRACT

Objectives: Point of care testing (POCT) contributes to diagnosis and monitoring with fast testing time and easily performed assays. We evaluated the Abaxis Piccolo Xpress point of care chemistry analyzer using the Liver Panel Plus discs for our pediatric patient population at Texas Children's Hospital.
Design and methods: Analytical performance was evaluated for precision and linearity using quality control materials and commercially available verification samples. Comparison studies were performed between Piccolo Xpress analyzer and Vitros 5600 analyzer using patient samples. Interference studies were carried out using nine different patient pool sera. Lipemia interference was removed using LipoClear for severely lipemic sample pools.
Results: Precision of all tests was excellent (CVs < 5% for all measured analytes except TBIL). All assays were linear and accurate within the allowable total error. Comparison studies showed that three analytes (amylase, GGT and TBIL) had statistically significant bias. Interference study results did not exceed the total allowable error for hemoglobin (< 150 mg/dL), bilirubin (< 15 mg/dL) and lipemia (< 400 mg/dL except ALT, GGT and TP). LipoClear treatment removed lipemia interference for all analytes except total protein.
Conclusions: The Piccolo Xpress chemistry analyzer showed an acceptable analytical performance for precision, linearity and interference from common substances. Increased bias for three analytes in comparison studies could be due to different methodologies.

1. Introduction

Point of care tests (POCT) are gaining attention and popularity due to their simplicity of use and rapid turnaround time of results [1]. The need for more specialized and efficient support systems for neonatal and pediatric patients, in remote health centers and for infectious diseases such as viral hemorrhagic fever mandated the need for simplified equipment for POC liver function tests [2]. Recently, the Piccolo Xpress POC chemistry analyzer has been launched which includes a Liver Panel [2,3]. We have procured this instrumentation in our pediatric facility to assist physicians taking care of patients with viral hemorrhagic fever. As clinical laboratorians, one of our major focuses is to validate such POC instruments against the CAP-certified clinical laboratory methods used in the main laboratory to ensure the appropriate transferability and accuracy of

* Corresponding author at: Department of Pathology & Immunology, Baylor College of Medicine, 6621 Fannin Street, Houston, TX 77030, USA. Fax: +1 832 825 3400.
E-mail address: devaraj@bcm.edu (S. Devaraj).

http://dx.doi.org/10.1016/j.plabm.2015.09.002

such POC results for diagnosis and management of patients.

The aim of this study was to evaluate the performance of the Abaxis Piccolo Xpress point of care chemistry analyzer Liver Panel Plus discs assays in the pediatric setting. In this report, we provide data on precision, linearity, comparison with the central laboratory analyzer and on interference studies using the Liver Panel discs on the Piccolo Xpress POC analyzer. Various performance characteristics (e.g. accuracy, precision, specimen stability, consistency etc.) of the Piccolo Xpress analyzer have been investigated in adult and neonatal intensive care unit populations [4–7]. Our study adds to the literature by providing additional comprehensive evaluation in the pediatric population and interference studies using the Liver Panel Plus discs.

2. Materials and methods

We evaluated the Piccolo Xpress chemistry analyzer for the Liver Panel assays for our pediatric patient population at Texas Children's Hospital using the NCCLS (National Committee for Clinical Laboratory Standards) criteria [8,9]. Evaluations were performed for precision, linearity, method comparison and interferences from common substances using two different lots of discs with minimal variability between lots. The panel includes the following eight tests: alanine aminotransferase (ALT), albumin (ALB), alkaline phosphatase (ALP), amylase (AMY), aspartate aminotransferase (AST), Gamma glutamyltransferase (GGT), total bilirubin (TBIL) and total protein (TP). The Piccolo instrument uses dry and liquid reagents with various testing principles (e.g. dye-binding bromocresol purple technique for albumin assay, enzymatic bilirubin oxidase method for total bilirubin assay) using absorption detection to give quantitative results [3]. Testing of eight analytes is performed on a single-use Liver Panel disposable disc. Briefly working principle of instrument includes loading the sample into a disc up to the designated mark. Once the disc is placed into the Piccolo analyzer, sample and diluent are measured for the volume requirements. As first step, instrument spins down the sample to separate the plasma. Then, sample and diluent are pushed into the mixing chamber where they are mixed before diluted samples flow into the reaction cuvettes for reaction and measurement. Since it is a centrifugal device manufacturer states that lithium heparinized plasma or serum samples are also acceptable sample types. The instrument requires only 100 μL lithium heparinized whole blood, lithium heparinized plasma or serum for measurement.

We used randomly selected de-identified patient samples, under an IRB approved protocol, for the entire study. The pediatric patient samples received in the main laboratory at Texas Children's Hospital were used in this study.

2.1. Precision and linearity studies

Precision studies were performed using commercially available quality control materials (Liquid Assayed Chemistry Control from Bioresearch Technology Inc.). Intra-assay precision was conducted on two levels of control (Control Level 1 and Control Level 2) as 10 replicates. Inter-assay precision was determined using two levels of control as 10 replicates over a period of 32 days.

Linearity studies were performed using commercially available verification samples (Verification Samples from Bioresearch Technology Inc.) which are human liquid serum samples at three concentration levels. Each concentration level was run as 5 replicates and the average concentration obtained was compared to the assigned values.

2.2. Comparison studies

Comparison studies were performed using lithium heparinized whole blood samples. Twenty samples run on Piccolo Xpress chemistry analyzer in duplicates and simultaneously run on Vitros 5600 analyzer (main laboratory chemistry instrument). Whole blood samples were centrifuged at 4400*g* for 3 min and plasma separated from the cells before they were run on Vitros 5600 analyzer for comparison. All analyses were conducted within 1–2 h of collection.

2.3. Interference studies

Interference studies were performed for hemoglobin, icterus and lipemia using lithium heparin plasma sample pools. Total of nine plasma pools (three sample pools for each interferent) were used for the interference studies. Increasing concentrations of commercially available hemolysate (INT-01 Routine Interference ASSURANCE™ Interference Test Kit by Sun Diagnostics®, LLC) was added into each sample pool to obtain final concentrations of 75 mg/dL, 150 mg/dL and 300 mg/dL hemoglobin. These samples were then analyzed on Piccolo chemistry analyzer.

Icteric samples were prepared by addition of commercial conjugated bilirubin (INT-01 Routine Interference ASSURANCE™ Interference Test Kit by Sun Diagnostics®, LLC) into separate plasma sample pools ($n=3$) to yield final concentrations of 7.5 mg/dL and 15 mg/dL. All samples were prepared in dark room and protected from light exposure until analysis to prevent possible photodegradation of bilirubin. Then interference from icterus was determined by analyzing these samples within 60 min of preparation.

Aliquots of commercial triglycerides from Sun Diagnostics (INT-01 Routine Interference ASSURANCE™ Interference Test Kit by Sun Diagnostics®, LLC) were added into pooled plasma samples to obtain final concentrations of 400 mg/dL, 1000 mg/