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Evaluation of a new point of care automated complete blood count (CBC) analyzer in various clinical settings

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Abstract

Background: WBC counts and differentials are currently performed on complex analyzers in either central or satellite laboratories. Rapid and easy to use point of care (POC) CBC testing can benefit certain outpatient clinical settings, where the greatest clinical need has been demonstrated.
Methods: We evaluated a new POC CBC analyzer Chempaq XBC (Chempaq A/S, Denmark) for hemoglobin, leukocyte counts and 3-part differentials and compared the results with established laboratory based Beckman Coulter LH750 analyzers. The performance of these POC analyzers was tested at multiple clinic locations as a part of regular care on both venous and finger stick blood samples.
Results: Method validation parameters including precision, accuracy and linearity studies are within the acceptable limits between POC and lab based analyzers. Method comparison studies at various locations showed good correlation at various clinical settings including ER, primary care, Ob/Gyn, ICU, Pedi clinic, Hematology–Oncology clinics, and in-patient ward's in venous blood samples. In addition, at the hematology–oncology clinic, the comparisons of venous as well as finger stick blood sample analyses showed good correlation.
Conclusion: The Chempaq XBC analyzer provides accurate hematologic results that can facilitate rapid quantitative assessment of CBC parameters and thus is clinically relevant, especially in outreach clinic settings and in critically ill patients.

Keywords: Point of care; CBC; WBC differentials; leukocytes; evaluation; hemoglobin

1. Introduction

The complete blood count (CBC) is a very common test which provides important information about the types and numbers of cells in blood. Currently the CBC is performed with complex and expensive hematology analyzers located in central and or satellite laboratories, which require trained and accredited professionals to operate. Point of care (POC) analyses of CBCs could reduce turn around times for STAT CBC and increase the likelihood that medical decisions in remote sites could be made at the time of the patient visit [1]. The greatest clinical need and benefit for POC CBC can be demonstrated in the outpatient settings of hematology–oncology clinics, ER, ICU, Ob/Gyn patients and remote office practices.

Currently there are no POC devices available capable of measuring WBC counts and differentials. These devices are limited to bench top analyzers placed in locations near patient care or handheld instruments that can be easily transported within the health care facility. Although many well known instrument manufacturers produce hematology analyzers, only a few make systems portable enough to be used in near patient test settings (I-STAT, HemoCue etc). Moreover, they are restricted to only hemoglobin and hematocrit measurements and do not include WBC and differentials. Clinicians routinely use WBC and differentials as biomarkers for acute infection/

Abbreviations: WBC, White Blood Cells; HGB, Hemoglobin; LYM, Lymphocytes; GRN, Granulocytes; MON, Monocytes; ER, Emergency Room; ICU, Intensive Care Unit; OB/GYN, Obstetrics and Gynecology; heme–onc, Hematology–Oncology; Pedi, Pediatrics.

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inflammation in various clinical settings from primary to critical care. An elevated WBC count occurs in infection, allergy, systemic illness, inflammation, tissue injury, and leukemia. A low WBC count may occur in viral infections, immunodeficiency states, and bone marrow failure, post chemotherapy, acute leukemia. The differential will reveal which WBC types are affected the most. Under these settings, WBC values may facilitate early and rapid diagnosis of neutropenia and systemic infection. Leukocytosis is a prognostic marker of patients who are at a higher risk of hospital mortality [2] and identifies patients at increased risk for excessive bleeding [3]. Galloway et al. [4] following an evaluation of waiting times in a hematology–oncology clinic before and after the introduction of POC testing and concluded that the introduction of POCT significantly expedited the clinical decision process.

Chempaq XBC (eXpress Blood Counter) is a new point of care hematology analyzer [5]. It is intended for measurements of hemoglobin concentration, leukocyte counts and a 3-part differential (lymphocytes, monocytes and granulocytes, concentrations and % of total). In the present study we compared the results obtained with Chempaq XBC point of care hematology analyzer with results from an established laboratory based instrument (Beckman Coulter LH 750). Furthermore, we evaluated the performance of this new hematology analyzer in different clinical settings (ER, primary care, Ob/Gyn offices, ICU, Pedi clinic, heme–onc clinics and in-patient's) in comparison to the CBC results obtained in the existing central lab analyzer on both venous and finger stick CBC specimens.

2. Materials and methods

2.1. Chempaq XBC analyzer

The Chempaq CBC analyzer is a point of care system consisting of a Reader and a small disposable cassette called a PAQ (particle analyzer and quantifier). All reagents are self contained in the PAQ and require no external handling and storage of reagent bottles etc. A finger stick or a drop of blood from an EDTA venous sample is applied directly to the cassette, and inserted into the Reader. The user then simply follows the visual prompts on the instrument. The results (WBC, WBC differentials and HGB) are available in approximately 3 min. The Chempaq XBC has been designed to meet CLIA '88 waiver requirements and can be operated by inexperienced users. The basic principle employed is impedance measurement (the Coulter principle), and a photometry measurement, which is used to assess the hemoglobin content. In Chempaq XBC, each sample is analyzed in a disposable cassette. Leukocytes, lymphocytes, monocytes and granulocytes are counted in an impedance cell. Hemoglobin is measured photometrically at 2 wavelengths.

A number of functions, important for the performance of the Chempaq XBC, are monitored during measurements. When problems are detected the Chempaq XBC will flag the results with an Error Code. Chempaq XBC anticipates white cells to be detected inside a certain size range. In the case, where cells are detected outside this range, Chempaq XBC will mark the WBC, LYM, MON and GRN parameters with "*", indicating an abnormal blood sample (odd distribution of cells).

2.2. Beckman Coulter LH 750

The Beckman Coulter LH750 measures the WBC RBC, HGB, MCV, MPV, RDW, platelet counts and calculates HCT, MCH, MCHC [6,7]. A five part differential includes percent and absolute number of total neutrophils, total lymphoid cells, monocytes, eosinophils, and basophils. The Beckman Coulter LH750 employs electric impedance technology to enumerate WBC, RBC, and platelet counts. It can also determine RBC and platelet volume. Hemoglobin is determined by CN-methemoglobin photometry. The 5-part differential (lymphocytes, neutrophils, monocytes, eosinophils, basophils) is generated by analyzing events in a flow cell with 3 different technologies: volumetric impedance using direct current (related to cell size or volume), conductivity using high frequency electromagnetic energy (signal related to internal cell complexity), and laser light scatter (related to both cell size and structure). Data are plotted in a 3-dimensional matrix (VCS), and clusters are identified as specific cell populations. If the populations are not in expected locations, or a significant number of events are detected outside of the population clusters, flags are generated. This indicates that abnormal cells may be present, and a manual slide review is needed.

3. Experimental protocol

3.1. Precision

Within-day and between-day precision for WBC count, WBC differentials and hemoglobin of Chempaq XBC analyzer was determined by testing 2 levels of control solutions (Labex, Sweden, provided by Chempaq) provided by the manufacturers, and on 2 levels of patient blood samples. Within-day precision was performed by taking 10 consecutive measurements at each level. Between-assay precision was determined by testing with control solutions for 10 consecutive days. Precision testing was performed on 2 analyzers. The mean, SD, and CVs were calculated.

3.2. Linearity and accuracy

Linearity performance of the Chempaq XBC analyzers for WBC count and hemoglobin were analyzed by diluting high patient blood samples.

3.3. Method comparison

WBC counts, differentials and hemoglobin values from both the Beckman Coulter LH750 and the Chempaq XBC were compared to blood specimens routinely submitted for CBC analysis in our main clinical laboratory. Measurements were done by using venous blood specimens obtained from approximately 60 in-patients from each of the different clinical services (ER, primary care, Ob/Gyn, ICU, Pedi clinic, Hematology–Oncology clinics, and in-patient ward's) for a total of 420 at UMass Memorial Medical Center at Worcester, MA as a part of regular care. This study followed guidelines and was approved by the human subjects committee. In the hematology–oncology clinic (57 patients), CBC parameters were measured simultaneously on both venous and finger stick samples. For granulocyte comparison, the total number of eosinophils, basophils and neutrophils from the Beckman Coulter LH750 (5-part differential) were added and compared to Chempaq XBC.

3.4. Statistical analyses

Precision, linearity, accuracy and method comparison data were analyzed using EP Evaluator, release 7.0 (D.G. Rhoades Associates, Inc, Kennett Square, PA).