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To Compare and Evaluate the Accuracy of Fully Automated Cell Counters Performing Standard Deviation Index (SDI) and check with External Quality Assurance (EQAS)

Authors
Dr B.Rajsekhar[1], Dr R.Sabitha Devi[2]
[1]Associate Professor, Department of Pathology, P.K.Das Medical College, Kerala
Email: *drrspath@gmail.com*
[2]Reader, Oral Pathology, SJDC, Eluru

Abstract
Most of the laboratories in India are not well equipped to perform the tests required on routine basis and cater the requirement for the patients and the doctors to arrive for concluding the diagnosis. In the present scenario, 20th century the government, public and private sectors are investing an enormous fund to help the humankind and poor to get rid of their diseases and get diagnosed at the earliest for treatment. For this to make successful there are governing bodies for all the diagnostics centers to perform and mandatory to follow guidelines. The present study was conducted to compare and evaluation the accuracy of the machines (Pentra) and efficiency of the technicians performing the quality check on fully automated cell counters on routine basis following the West Gard rules and also maintaining the quality management systems of ISO 9001:2008 and ISO 15189:2012.

Aims and Objectives
The present study was conducted to compare and evaluation the accuracy of the machines (Pentra) and efficiency of the technicians performing the quality check on fully automated cell counters on routine basis following the West Gard rules and also maintaining the quality management systems of ISO 9001:2008 and ISO 15189:2012.

Introduction

Quality depends on sum total of all the characteristics of a product/service bearing on which will satisfy the consumer i.e, acceptability, affordability, accessibility and appropriate.

The maintenance of a quality management system is crucial to a laboratory for providing the correct test results every time.

1. **Quality assurance**

Important elements of a quality management system include:

- Documentation
- Standard Operating Procedures (SOP's)
- Quality Control samples
- External Quality Assessment Scheme

2. **Quality control**

Are procedures used in each assay to assure a test run is valid and results are reliable:

Kit Controls

Quality Control Samples

3. **External quality assessment schemes (EQAS)**

Aims to analyse the accuracy of the entire testing process from receipt of sample and testing of sample to reporting of results (also known as proficiency testing)[1]

Comparison of performance to peer laboratories, external quality control, is a practical, if limited, yardstick of performance. Customer satisfaction and turn-around-time of tests are receiving more recent attention as quality measures[2]

The implementation of management systems in accordance with standards like ISO 9001:2008 (1,2) in the clinical laboratories has conferred and added value of reliability and therefore a very significant input to patient safety. As we know the ISO 9001:2008 (1) a certification standard, and ISO 15189:2012 (2) an accreditation standard[3]

In the leukocyte differential, morphological differential has been usually performed with chromatoaffinity of blood cells, but physical differential is recently performed with biophysicochemical characteristics of blood cells using an automated blood cell counter. The trend of the leukocyte differential has changed to physical differential (automated count method) from morphological differential (eye count method). In the automated count method, leukocytes are differentiated into neutrophils, lymphocytes, monocytes, eosinophils and basophils according to the predetermined region of each leukocyte population on the cytogram using an automated blood cell counter. An automated count method is very useful for the screening test in the laboratory because of its high precision and accuracy for the normal samples. However, it is not easy to identify abnormal cells such as leukemia cells by an automated count method. Therefore, an automated count method dealing with various suspect flags generated using an automated blood cell counter must be used for such abnormal samples. In case of absolutely few leukemia cells in the peripheral blood during complete remission, the automated count method cannot detect a leukemia cell[4]

The four main procedures for platelet counting are: manual phase contrast microscopy, impedance, optical light scatter/fluorescence and flow cytometry. Early methods to enumerate platelets were inaccurate and irreproducible. The manual count is still recognized as the gold standard or reference method, and until very recently the calibration of platelet counts by the manufacturers of automated cell counters and quality control material was performed by this method. However, it is time-consuming and results in high levels of imprecision. The introduction of automated full blood counters using impedance technology resulted in a dramatic improvement in precision. However, impedance counts still have limitations as cell size analysis cannot discriminate platelets from other similar-sized particles[5]. The pre-analytical, analytical and post-analytical evaluation should be done and collection of the sample and processing should be done precisely to minimize the errors[6].

Materials and Methods

Venous blood samples were collected from the patients approaching in 07 different laboratories' of which the Lab no.01 was central lab and all the other labs were situated in different locations and all the quality measures were taken to minimize the errors and also the turnaround time to perform the tests to diagnose and satisfy the patients.

Observations and Results

Five parameters were taken into consideration- Hb%, PCV, Erythrocyte count, Leukocyte count and Platelet count for all the patients who had given the venous blood samples. Samples were run in the fully automated cell counters (hematology analyzers) for all the laboratories. The standard deviation Index was calculated accordingly for a period of 03 months and compared and evaluated with other laboratories. Parallel the samples were sent to external quality assurance also.

Table no.01. Comparison of the various laboratory values

Lab Name	Parameter	SDI - Standard Deviation Index			
Lab Name	Parameter	April-16	May-16	June-16	Running Mean SDI
Lab 01	Hemoglobin	-0.8	-1	-1	-0.9
Lab 01	Hematocrit	1.2	-1	-1	-0.3
Lab 01	Erythrocyte count	-1.1	-1	-1.1	-1.1
Lab 01	Leukocyte count	-1.5	1	0.5	0.0
Lab 01	Platelet count	1.5	-0.2	0.4	0.6
Lab 02	Hemoglobin	-1.4	-1	-0.7	-1.0
Lab 02	Hematocrit	-0.8	-0.9	-0.4	-0.7
Lab 02	Erythrocyte count	-0.1	-0.2	-0.2	-0.2
Lab 02	Leukocyte count	1.2	0.5	0.3	0.7
Lab 02	Platelet count	-0.1	0.4	-0.5	-0.1
Lab 03	Hemoglobin	-0.3	-0.3	-0.4	-0.3
Lab 03	Hematocrit	-0.2	-0.5	-0.6	-0.4
Lab 03	Erythrocyte count	0.2	-0.4	-0.8	-0.3
Lab 03	Leukocyte count	0.1	0.5	0.2	0.3
Lab 03	Platelet count	-0.2	-0.7	0	-0.3
Lab 04	Hemoglobin	-0.5	-0.3	-0.5	-0.4
Lab 04	Hematocrit	-0.7	-1	-0.8	-0.8
Lab 04	Erythrocyte count	-0.4	-0.5	-1	-0.6
Lab 04	Leukocyte count	-0.2	-0.5	0.4	-0.1
Lab 04	Platelet count	0.2	1	0.2	0.5
Lab 05	Hemoglobin	0.2	0	0.2	0.1
Lab 05	Hematocrit	-0.4	-0.7	-0.7	-0.6
Lab 05	Erythrocyte count	0.1	-0.2	-0.4	-0.2
Lab 05	Leukocyte count	-0.4	-0.5	-0.1	-0.3
Lab 05	Platelet count	-0.1	0.6	0.5	0.3
Lab 06	Hemoglobin	-1.2	-1	0	-0.7
Lab 06	Hematocrit	0.6	0.9	1.2	0.9
Lab 06	Erythrocyte count	0	0.6	1	0.5
Lab 06	Leukocyte count	-0.9	-0.5	-0.5	-0.6
Lab 06	Platelet count	-0.1	0.1	-0.4	-0.1
Lab 07	Hemoglobin	-2.3	-1.7	7.4	1.1
Lab 07	Hematocrit	1	-0.2	4.3	1.7
Lab 07	Erythrocyte count	-1.8	-0.4	7.4	1.7
Lab 07	Leukocyte count	-0.2	0	4.1	1.3
Lab 07	Platelet count	2.1	0.3	-1.5	0.3

Table no.02-External quality interpretation

Parameters	No. of Participants	Group mean	Standard deviation (SD)	Uncertainty Of Assign values	Range (+/- 2SD)	Value	Standard deviation Index (SDI)
Hb%	163	16.6	1.0	0.1	14.6-18.6	16.2	-0.4
WBC $x10^3/\mu L$	152	21.56	1.68	0.2	18.2-25.0	22.0	0.2
RBC $x10^3/\mu L$	153	5.4	0.3	0.0	4.7-6.1	5.17	-0.8
PCV%	152	47.4	4.5	0.5	38.4-56.4	44.5	-0.6
Platelet $x10^3/\mu L$	154	491.5	49.9	1163.0	391.7-591.2	490	0.0

SDI-0.5-1.0-Good, 1.0-2.0-Acceptable

Discussion

Quality depends on sum total of all the characteristics of a product/service bearing on which will satisfy the consumer i.e, acceptability, affordability, accessibility and appropriate. Quality laboratory management system depends upon Quality assurance and Quality control measures. Customer satisfaction and turn-around-time of tests are receiving more recent attention as quality measures. Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting[2]

Conclusion

Laboratory Quality Management System (Lab QMS) for a medical testing and diagnostic laboratory in a holistic way and hopes to expand the horizon beyond quality control (QC) and quality assurance[7]. Customer satisfaction and turn-around-time of tests are receiving more recent attention as quality measures[2]

Take Home Message

"Precision depends on knowledge and skills. Never blame tools."

Interest of conflict: None

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