

Comparison between Branded CBC Vials Versus Laboratories Made Vials

Muhammad Munir,¹ Ahmad Hameed,² Nisha Waqas,³ Samina Naeem,⁴ Humera Rafiq⁵
Ambareen Hameed⁶

Abstract

Introduction: Disposable items like CBC vials make an integral part of clinical laboratories. The study was carried out to determine the difference in results of four different types of vials.

Study Design: It was an observational comparative study.

Material and Method: Four hundred blood samples were included in the study. CBC was carried out within 4 hrs on all the four types of vials i.e. branded high quality and low quality vials and lab made vials with standard washing and routine washing. Instrument

used was Sysmex KX – 21.

Results: All the parameters measured and compared showed no difference between four types of vials. P-value was not significant.

Discussion: RBC count, WBC count, Platelet count, Hemoglobin, HCT, MCV, DLC percentage in all the four different types of vials showed no statistical difference in the results.

Conclusion: The Labs can make their own CBC vials. Washing practice at hematology dept KEMU is of international laboratory standards.

Key Words: CBC (complete blood count), CBC vacutainers or vials, EDTA anticoagulant.

Munir M.¹

Former Professor of Pathology
King Edward Medical University, Lahore

Hameed A.²

Assistant Professor of Pathology, KEMU, Lahore

Waqas N.³

PGR, Department of Pathology, KEMU, Lahore

Naeem S.⁴

Professor and HOD of Pathology, KEMU, Lahore.

Rafiq H.⁵

Assistant Professor of Pathology, KEMU, Lahore

Hameed A.⁶

Assistant Professor of Pathology, KEMU, Lahore

Introduction

Pathology laboratories make an integral part of national health services. Use of diagnostic laboratories has increased over the last decade implying the use of diagnostic tests for optimal patient care. Without reliable lab support patients are less likely to receive best possible care. Recognition of the role of lab by health authorities is essential, although paucity of funds is a problem in developing countries like Pakistan and funds that are available should be used judiciously.¹

Hemogram (CBC: Complete blood count, FBC: Full blood count, FBE: Full blood exam) is one of the common screening test requisitioned in adults and pediatrics patients for clinical pathology laboratories to determine certain types of blood disorders. CBC also provides valuable information about patients diag-

nosis, prognosis and response to treatment.² Hematology is also a specialty where technology has been advancing at rapid pace. Traditionally the blood counts were performed manually using the hemocytometer. The high workload experienced by many hematology laboratories coupled with the reduction in staff numbers lead to the introduction of automated hematology analyzers where it was not possible to screen each slide under the microscope. Approximately 10 – 20% of the samples are examined under the microscope. Cell counting with these instruments is rapid, objective, precise, accurate and statistically significant (800 or more cells are counted) and is not subjected to the distribution bias seen in manual counting. With automatic blood cell analyzers data not otherwise routinely available by visual procedures can be gathered also. They are also more efficient and cost effective than manual count. Some of the cell counters can process 120-150 samples per hour.^{3,4}

Sysmex KX – 21 is a discrete hematology analyzer designed for high volume testing in clinical laboratories. It is an automatic multiparameter blood cell counter for in vitro diagnostic use in clinical labs. It employs impedance technology for counting of RBC, WBC and platelet counts. It provides hemogram with 17 reportable parameters and three part WBC differential leukocyte count which includes absolute neutrophil and lymphocyte count. The results also include histogram for WBC, RBC and platelets. For the detection of hemoglobin it uses cyanide free method that does not pollute the environment.⁵

In order to get correct lab results for patient satisfaction and ultimate laboratory reputation it is pertinent that samples are collected and handled properly. Objective of blood sampling is to obtain a representative sample of the circulating blood with minimum of artifact weather produced by collection, procedure, container, anticoagulant or subsequent storage and handling. For CBC test, blood is collected through venipuncture by phlebotomist using hypodermic needle from median cubital, cephalic or basilic vein and transferred to lavender color EDTA anticoagulant containing vials. Blood is then mixed (not shaken) with the help of rotating mixer. Di or tri potassium salts of EDTA in a concentration of 1.5 mg/ml are used in vials. EDTA acts by stoichiometric chelation of calcium molecules in the blood. Advantage of this anticoagulant is that it preserves the morphology of RBC, WBC and also there no platelet clumping.⁶ The ICSH and CLSI have recommended dipotassium EDTA as anticoagulant of choice. It is important that blood even if it

taken in correct concentration of anticoagulant should be examined within 8 hours at room temperature otherwise HCT MCV MCHC and MPV are significantly altered. Material used for the containers is glass or polystyrene plastic and they have indication for the volume of blood to be added. For blood counting there is little to choose between glass and plastic and both could be used.^{7,8}

Majority of well – known clinical pathology laboratories use branded CBC vacutainers for blood sampling purposes. These vacutainers make an important part of the lab budget that goes into purchasing disposables items. The purpose of the study was to compare the results of CBC between branded i.e. BD (Becton Dickinson) vacutainers, Chinese vacutainers, lab made properly standardized and washed CBC vials and routine, ordinary washed CBC vials.

Aims and Objectives

To determine statistical difference in CBC results in four different types of EDTA anti-coagulated vials.

Materials and Methods

This study was conducted in the Pathology department of King Edward Medical University Lahore from 24th to 29th September 2012. It was an observational comparative study. Routine samples from medical and allied wards, surgical and allied wards and outdoors were received in four types of EDTA CBC collection vials and were analyzed within 4 hours. Whole procedure was explained to the patient and written consent was taken. 8.0 ml of blood was taken from the patients and equally distributed in the four vials. CBC was performed using Sysmex KX – 21 that was maintained and calibrated as recommended by the manufacturer to control analyzers drift. Quality control was maintained by running controls (E check) daily and maintaining LJ chart to check precision and reproducibility of the analyzer.

Test tubes / vacutainers can be cleaned in the following way.⁹

- 1) Put detergent in the dishpan containing moderate amount of warm water, rinse the tubes in tap water and then put them in the detergent solution for at least one hour.
- 2) Using cleaning brush thoroughly scrub the tubes.
- 3) Rinse tubes under running tap water, allow water

to run – in each tube, pour it out and repeat (7 – 10) times to remove the last traces of detergent. Rinse the outside of the tubes also.

- 4) Rinse inside and out with distilled water.
- 5) Tubes can be dried in hot air oven at 50 – 100°C or at room temperature in inverted position to ensure complete drainage of water as it dries.
- 6) Check the tubes for cleanliness by observing the water drainage. Dirty tubes will leave water droplets adhering to the wall of tubes.

Inclusion Criteria

Samples of patients which were properly collected and anti-coagulated in all four CBC vials were included in the study.

Exclusion Criteria

Low volume, high volume and clotted samples were excluded in the study.

Each of the blood cells parameters were analyzed for significant comparison and difference in the four CBC samples taken in four different types of vials. Blood cell parameter included are those that were measured by the instrument e.g. hemoglobin, RBC count, WBC count, Platelet count, and HCT, MCV, DLC. Parameters that were derived or calculated are not shown in the results. The data is presented as Tables, and figures (bar charts) of descriptive statistics.

Results

A total of 400 samples were received during study duration. Out of these, those samples which fulfilled the inclusion criteria were included in the study. Parameters measured by the analyzer showed no difference between four types of vials. P – Value (which shows that the groups under study differ or not) was not significant i.e. was more than 0.05 (significance < 0.05).

Discussion

The above mentioned results make it clear that since all the four types of vials showed no difference in the results the laboratories should try to make their own vials and save the financial resources of the lab. Some of the labs do follow this practice. In majority of the tertiary care public sector hospitals about 200 CBC samples are received daily. On average a good branded

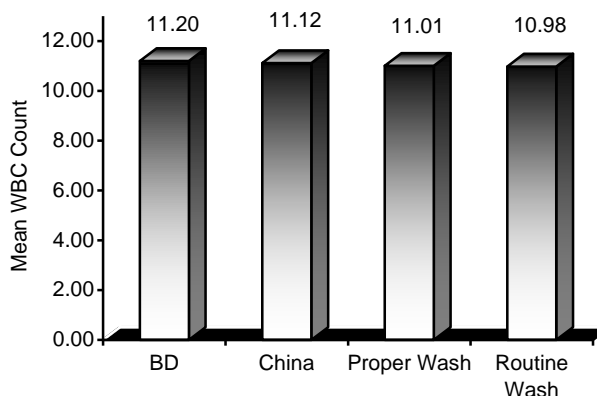


Figure 1: Type of Container.

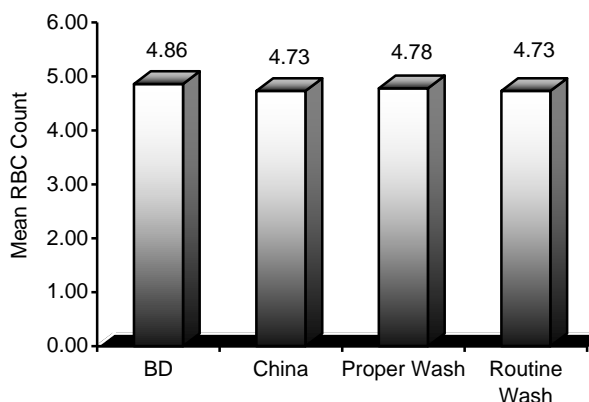


Figure 2: Type of Container.

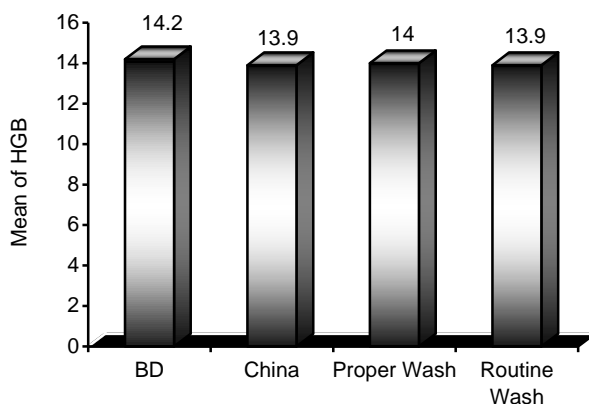


Figure 3: Type of Container.

CBC vial cost Rs10 and Chinese CBC vials costs Rs 05. If calculated this comes to about 0.2 – 0.4 million rupees annually which could be saved. With this saved money you could by other items like chemicals, kits

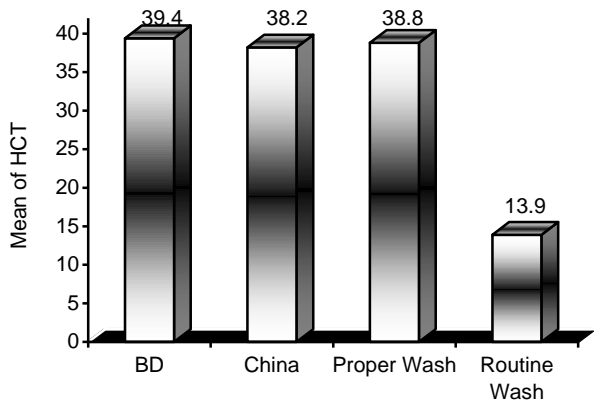


Figure 4: Type of Container.

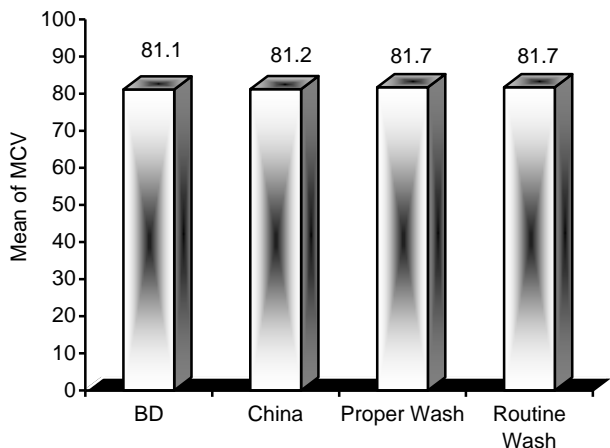


Figure 5: Type of Container.

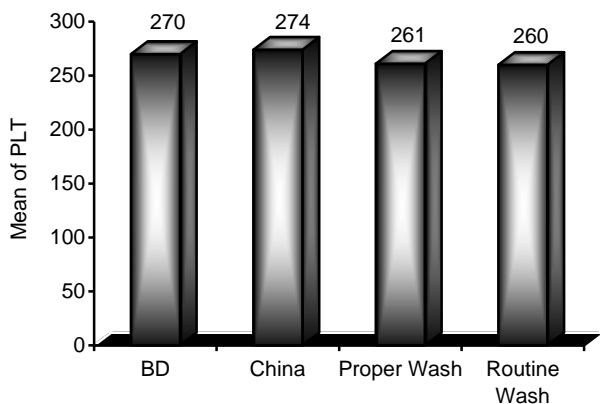


Figure 6: Type of Container.

and instruments or new jobs for lab staff could be created. It is also clear from the study that routine washing at the hematology section of pathology department

of KEMU is of high standard since the blood sample results received in routinely washed reused vials showed no difference with the other vials.

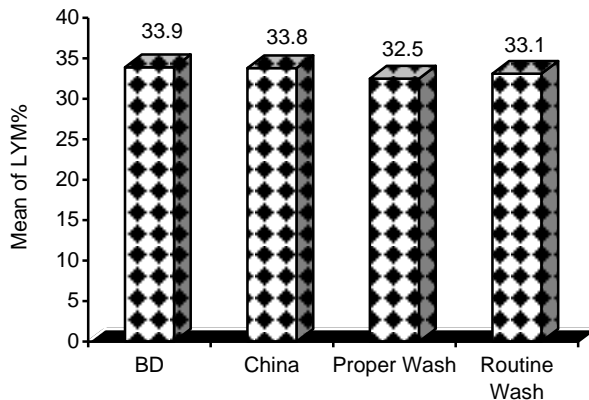


Figure 7: Type of Container.

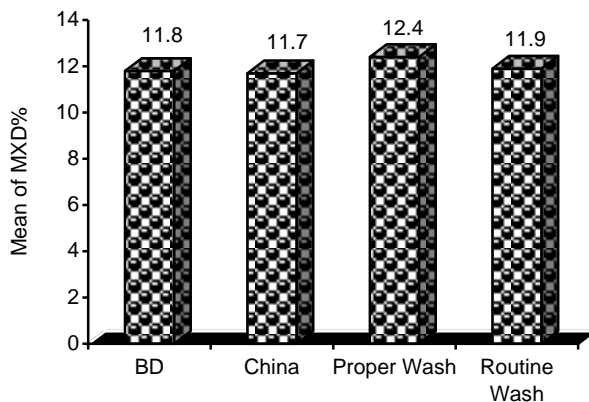


Figure 8: Type of Container.

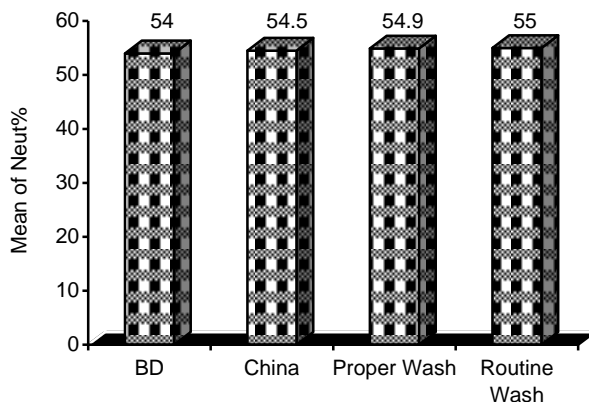


Figure 9: Type of Container.

Table 1: Descriptive Statistics

Parameters	Type of CBC Vials	No. of Samples	Mean	Standard Error	P-Value of Parameters
WBC COUNT	BD	100	11.1960	2.80646	1.000
	China	100	11.1210	2.81535	
	Proper wash	100	11.0140	2.87005	
	Routine wash	100	10.9760	2.86177	
	Total	400	11.0767	1.41393	
RBC COUNT	BD	100	4.8560	.08094	0.648
	China	100	4.7343	.07840	
	Proper wash	100	4.7834	.07839	
	Routine wash	100	4.7307	.07713	
	Total	400	4.7761	.03930	
HGB	BD	100	14.2240	.23436	0.669
	China	100	13.8730	.22784	
	Proper wash	100	13.9870	.23423	
	Routine wash	100	13.8680	.22784	
	Total	400	13.9880	.11534	
HCT	BD	100	39.4000	.61088	0.516
	China	100	38.2150	.58476	
	Proper wash	100	38.8440	.59887	
	Routine wash	100	38.4360	.59061	
	Total	400	38.7237	.29791	
MCV	BD	100	81.1190	.91553	0.926
	China	100	81.2100	.74379	
	Proper wash	100	81.6760	.74307	
	Routine wash	100	81.7230	.74462	
	Total	400	81.4320	.39387	
PLT	BD	100	269.51	10.863	0.741
	China	100	274.29	10.872	
	Proper wash	100	261.06	10.538	
	Routine wash	100	259.91	10.438	
	Total	400	266.19	5.328	
LYMP	BD	96	33.9344	.98528	0.696
	China	96	33.8146	.94168	
	Proper wash	96	32.5000	.96555	
	Routine wash	96	33.1188	.95370	
	Total	384	33.3419	.47987	

Parameters	Type of CBC Vials	No. of Samples	Mean	Standard Error	P-Value of Parameters
MXDP	BD	91	11.8011	.44806	0.912
	China	90	11.7078	.48205	
	Proper wash	31	12.3806	.98276	
	Routine wash	79	11.8709	.48668	
	Total	291	11.8529	.26383	
NEUP	BD	91	54.0000	1.04039	0.939
	China	90	54.3844	1.10845	
	Proper wash	31	54.8710	2.54957	
	Routine wash	79	54.9684	1.10168	
	Total	291	54.4746	.61844	

Conclusion

The labs can make their own CBC vials by reusing vacutainers. Washing practices at hematology dept KEMU is of international laboratory standards.

References

1. Monica Cheesborough. Medical laboratories manual for tropical countries. 2nd ed. Cambridgeshire: ELBS; 1987.
2. Sexena R, Tayagi S. Hemogram. In: Sexena R, Pati HP editors. Laboratory techniques in hematology. New Dehli: Jaypee Brothers Medical Publishers; 2012: p.5-37.
3. M. Aroon Kamath, MD. Automated blood cell analyzers. Can you count on them to count well? Available from <http://www.doctorslounge.com/index.php/blogs/page/17172>. accessed February 04 2012.
4. Ike SO, Nubila T, Ukaejiofo EO, Nubila IM, Shu EN and Ezema I. Comparison of hematological parameters determined by the Sysmex KX – 21N automated hematology analyzer and the manual counts. BMC Clinical Pathology 2010, 10:3doi:10.1186/1472-6890-10-3
5. Operators manual. Sysmex KX – 21, Japan 2000.
6. Juvy C, Nagai Y, Tatsumi N .Collection and handling of blood .In Bain BJ, Lewis SM, Bates I, Laffan MA, editors. Dacie and Lewis Practical Hematology. Philadelphia: Churchill Livingstone; 2012: page 6-7.
7. Clinical Lab Standards Institute (CLSI) USA, Evacuated tubes and additive for blood specimen collection 4th edition; Approved Standard .CLSI Documentation H₁ – A₄, dec.1996; Vol. 16: No. 13.
8. International Council for Standardization in hematology (ICSH). Expert panel on cytometry. Recommendation of the ICSH for the ethylenediaminetetraacetic acid anticoagulation for the blood cell counting and sizing. AM J Clin Pathol 1993; 100: 371-372.
9. Khan FA, Ahmad S, Ahmad TA, Khan DA, Hussain AB, Abbasi SA, Jamal S, Khadim TA, Ikram A, editors. Manual of laboratory medicine.4th ed. A Publication of Armed Forces Institute of Pathology Rawalpindi-Pakistan; 2012.