

## Comparison of Impact of Original Reagents vs Third Party Hematology Reagents on Patient Reports

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**Abstract:** Analysis of patient's blood samples and providing accurate result is very important for a medical laboratory. It has been observed that now a day's many third-party reagent manufacturers have started providing reagents in competition with original equipment manufacturer. This study is meant to evaluate third party reagents in terms of quality and impact on patient results and impact on analyzer in comparison to reagents supplied by Original Equipment Manufacturers. This study is conducted on the ABX Micros 60 analyzer from HORIBA Medical, Japan at Jain's diagnostic laboratory, New Delhi. Third party reagents of different companies who claim the compatible reagents for ABX Micros 60 were analyzed in comparison to HORIBA original reagents. The comparison was made on patient blood samples for Complete Blood Count (CBC) parameters and microbiology tests. The study depicts that third-party reagents are inferior because they show bacterial and fungal contamination, leads to false flags and alarms and substandard patient CBC parameter reporting. Although the cost of the third-party reagents is lesser than the original certified reagents of the company leading to cost saving for the clinical laboratory but results in compromise in quality of patient report as well as long term damage to instruments and increased maintenance cost. We advise laboratory to use reagents of Original Equipment Manufacturer (OEM) to ensure better and consistent quality.

**Keywords:** blood, laboratory, manufacturer, Equipment.

## INTRODUCTION

Hematology analysis is very important analysis in a pathology laboratory [1]. Original equipment manufacturers provide chemical reagents for their instruments which are suitable and technically tested for the technology and mechanical parts of instrument. Being the price sensitive market, various third party manufacturers and vendors offer chemical reagents for the hematology instruments with lucrative price to customers to buy reagents from them and not from Original Equipment Manufacturer (OEM). These third party manufactures claim that reagents manufactured by them are suitable and profit maximizer for instrument's owner These offers have increased the negotiation power of the small and mid-size laboratories and it is becoming difficult to make them understand that authenticity and reliability of patient results is becoming compromised due to these unregulated and unorganized third party manufacturers

## MATERIALS AND METHODS

ABX Micros 60 is a three-part hematology analyzer from HORIBA Medical. This instrument gives 19 parameters for hematology analysis of patient sample.

Two instruments were used for the study. Out of two instruments (Instrument 1, Instrument 2) one is installed with three original reagents (ABX Minidil LMG, ABX Cleaner, ABX Lysebio) from HORIBA Medical. Second instrument (Instrument 2) was installed with all three reagents supplied by third-party reagent vendors

80 patient's samples were analyzed. These samples were analyzed with proper calibration and quality control of the instruments as per the standard operating procedure of original equipment manufacturer [2]. It is interesting to note here that no calibrators and quality controls were available with the third-party reagent manufacturer/vendors.

Hematology reagents of HORIBA Medical and third- party company were streaked for fungal (Fungal culture on SDA (Sabouraud Dextrose Agar Media) and bacterial culture (Bacteria culture on R2A Media) on petri dishes. These petri dishes were kept for the observation under the laminar air flow.

**RESULTS AND DISCUSSION**

Analysis of this study is categorized in two sections. First section has the analysis and result of microbiology testing. In Second section Complete Blood Count (CBC) parameters were analyzed. Patient samples were run simultaneously on both the instruments where one instrument was loaded with original reagents and second instrument with third-party reagents. Results of CBC parameters were analyzed with the regression and correlation analysis between both the analyzers.

**Microbiology testing**

We have conducted microbiology testing at HORIBA manufacturing unit at Haridwar, India which

is ISO certified facility. This testing was to check the contamination of bacterial and fungal in reagents. Testing was important because these contaminations may affect the results of the patient samples and may affect the mechanics of instrument. Hematology analyzers are meant to count the blood cells but if the reagents are contaminated with some other cells (Fungi, Bacterial) the chances of spurious results are high.

**Bacterial tests**

Third- party diluent, third- party Lysing reagents, third- party Cleaner are streaked on R2A (Reasoner's 2A agar) media for bacterial culture for 5 days in Laminar air flow. We have kept also the ABX Cleaner, ABX Lysebio and ABX Minidil LMG on R2A media for bacterial culture for 5 days. Figure 1. reveals the bacterial colonies are clearly visible on third- party reagents while HORIBA reagents (Original reagents) do not show any growth on Petri dishes.

**Bacterial Tests**



**Fig-1: Bacteria growth analysis on third- party and HORIBA original reagent in R2A culture medium**

Fungal Test: third- party diluent, third- party Lysing reagents, third- party Cleaner are streaked on SDA (Sabouraud Dextrose Agar) Medium for fungal culture for 5 days in Laminar air flow. We have streaked also ABX Cleaner, ABX Lysebio and ABX Minidil LMG on SDA (Sabouraud Dextrose Agar)

Medium for fungal culture for 5 days. Fig 2 reveals the fungal colony in third- party reagents while HORIBA medical reagents do not show growth of fungal growth on Petri dishes.

**Fungal Tests**

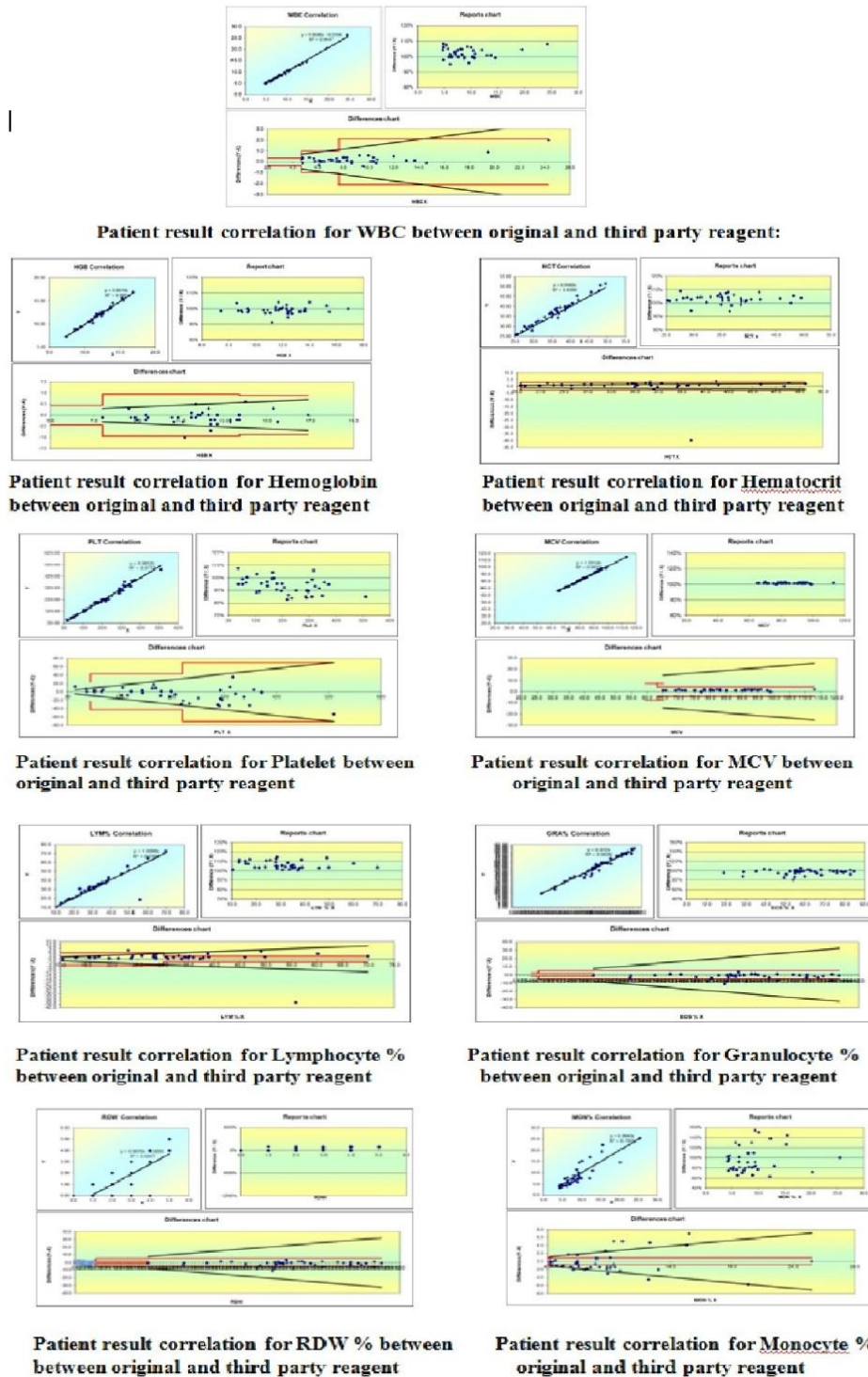


**Fig-2: Fungal growth analysis on third- party and HORIBA original reagent in SDA culture medium**

**PATIENT RESULT ANALYSIS**

Patient samples were analyzed on both the analyzers simultaneously within 2 hour of drawing the blood from patients. We have analyzed all 19

parameters produced by the analyzers. 10 parameters WBC, RBC, HGB, HCT, PLT, MCV, LYM%, MON %, GRA % and RDW were compared within two analyzers. (Fig 3).



**Fig-3**

It was interesting to see that WBC results correlation was acceptable because of no outlier however the other important parameters RBC, HGB,

HCT were in “To verify” category because the outliers results were less or equal than 2 in numbers. Very important parameters like LYM%, MON%, GRA% and

RDW were rejected because the results were more than 2 in numbers. 3 part hematology analyzers are known to deliver differentiation for WBC population of human blood.

Since flags and alarms of hematology analyzers are very important to understand. We have analyzed the pattern and quality of flags and alarms of both the instruments. It has been observed from below table (Table 1) that there is a significant difference between both the analyzers.

**Table-1: Correlation Study between the Both Analyzers**

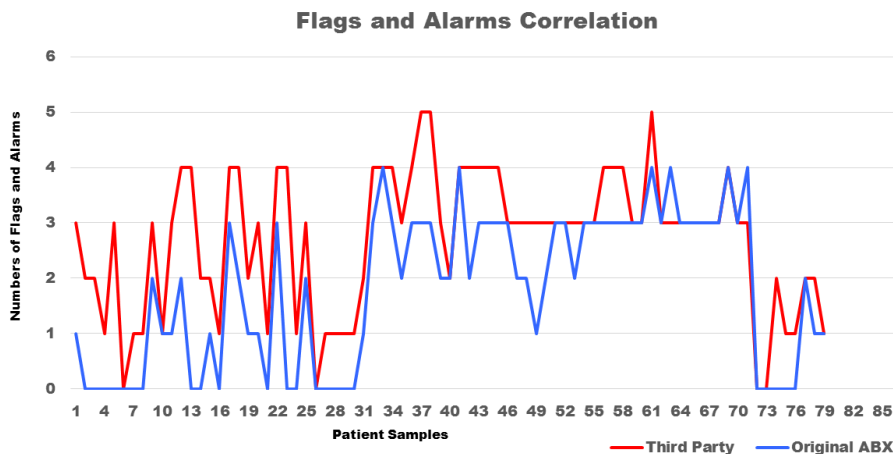
Parameter	Number (N)	Comparison interval	Linear regression	Discordant monitoring limits	Outliers vs Tea	Status
WBC	80	4.7 - 24.3	$y = 1.06x - 0.32$	0.00	0.00	Accepted
RBC	80	6.36 - 2.71	$y = 1.02x - 0.05$	1.00	10.00	To verify
HGB	80	7.4 - 16.9	$y = 1.01x - 0.19$	1.00	4.00	To verify
HCT	80	25.3 - 49.5	$y = 0.92x + 2.88$	2.00	18.00	To verify
PLT	80	35 - 530	$y = 0.93x + 10.88$	0.00	1.00	Accepted
MCV	80	65 - 113	$y = 1.01x + 0.61$	0.00	0.00	Accepted
LYM%	80	5.9 - 69.8	$y = 0.90x + 3.98$	3.00	3.00	Rejected
MON%	80	4.2 - 25.5	$y = 1.05x - 0.58$	25.00	11.00	Rejected
GRA%	80	20.7 - 86.7	$y = 1.00x - 1.80$	6.00	0.00	Rejected
RDW	80	12.9 - 23.6	$y = 0.94x + 1.29$	4.00	7.00	Rejected

Decision criterion / Status  
 0 Outlier Accepted  
 1-2 Outliers To be checked  
 >2 Outliers Rejected

**Flags and Alarms correlation**

Interestingly, Flags and alarms are more when patient samples were run on third-party reagents in comparison to original reagents. As evident in Figure 4,

false flags and alarms were more with third party reagents in comparison to original manufacturer reagents.



**Fig-4**

**CONCLUSION**

The study depicts that third-party reagents are inferior because they show bacterial and fungal contamination, leads to false flags and alarms and substandard patient CBC parameter reporting. Moreover, authenticity and traceability of manufacturer of third party is missing. The study shows that although the cost of the third-party reagents is lesser than the original certified reagents of the company which leads to saving of money for the clinical laboratory but leads to compromise in quality of patient results as well as long term damage to instruments and increased

maintenance cost. We advise laboratory to use reagents of Original Equipment Manufacturer (OEM) to ensure better and consistent quality.

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