

# Automated Screening for Malaria parasites on Mindray BC-6800 hematology analyzer: a follow-up report

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## Introduction

Malaria is a globally spread vector borne disease that continues to be a major cause of high morbidity & mortality. In spite of their availability, Immunochromatographic based rapid diagnostic tests (RDT) have not gained popularity due to their high cost. That leaves the microscopic examination of malaria parasites in patient's blood, as the Reference method. Unfortunately, the 'Reference method' is labor intensive, requiring high level of expertise to scan thick blood film for detecting presence of malaria parasites and examination of thin blood film to differentiate the type of malaria.

Given that automated blood counts are extensively requested when investigating febrile patients; hematology analyzers equipped with a dedicated flag that alerts the user to the possible presence of malaria parasites can be a great boon to today's busy diagnostic labs. BC-6800 (Mindray, Shenzhen, China) hematology analyzer was first-in-its class to offer a dedicated Research use only (RUO) flag named "infected RBC?" that reflects the number of infected red blood cells in the patient sample. The Flag is generated without help of any special reagents.

In May 2012, in the ISLH Congress at Nice-France, we had reported<sup>1</sup> high efficiency of BC-6800 to screen for presence malaria parasites in patient blood.

## Objectives

This follow-up study was set up at Dr. Bhide's Laboratory, Mumbai-India, to re-confirm our earlier findings that supported use of BC-6800 as a tool to prospectively screen for malaria parasites among patient samples.

The study was carried out during the waning monsoon season when mosquito infestation – and consequently incidence of malaria - is high in the city.

## Methods

A total of 948 patients – having symptoms suggestive of malaria infection & referred to rule out / or confirm the possibility - were included in the present study.

All patient samples were tested by (A) the Reference method to rule out presence of at least one of the three forms of malaria parasites i.e. trophozoites, schizonts and/or gametocytes of *P. vivax* and/or *P. falciparum*, (B) RDT and also (C) Mindray BC-6800 analyzer; to look for the "infected RBC?" flag. The flagging was evaluated for its sensitivity, specificity & predictive value in screening for malaria parasites.

BC-6800 hematology analyzer was operated as per manufacturer's recommendations using proprietary reagents, calibrator & quality control material. Analyzer performance was monitored daily using 02 levels of QC material.

Results of analyzer were not known to the expert microscopist at the time of thick and thin blood film examination.

## Results

- Malaria parasite present = in 52 out of 948 blood samples (using both, Reference method & RDT).
  - P. vivax* type was detected in 39 out of 52 +ve cases
  - P. falciparum* type was detected in 13 out of 52 +ve cases
  - 896 samples did not show presence of malaria parasites
- All 948 patient samples were analyzed on BC-6800 in CDRN mode

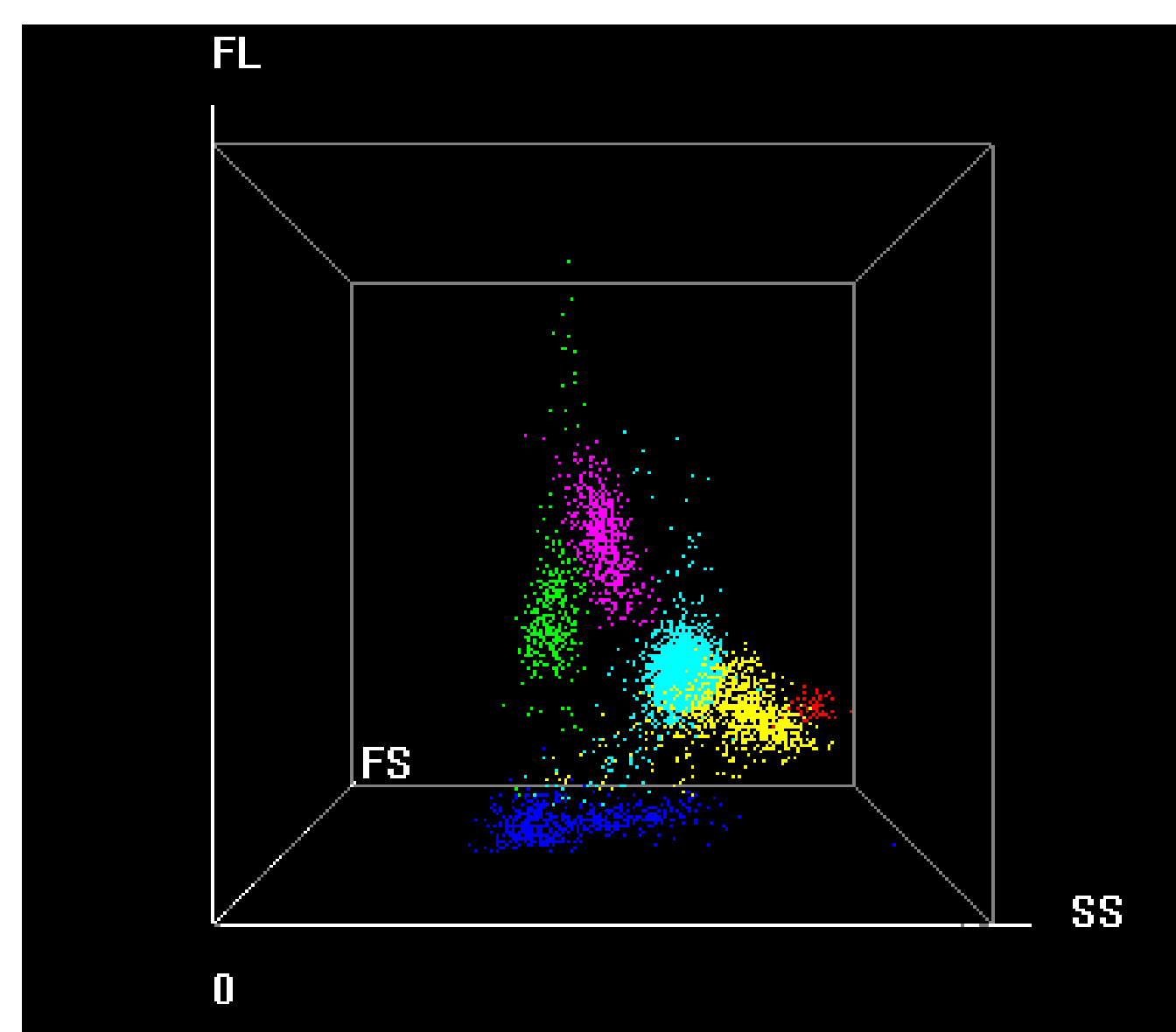


Fig. 1 WBC Diff Screen shot

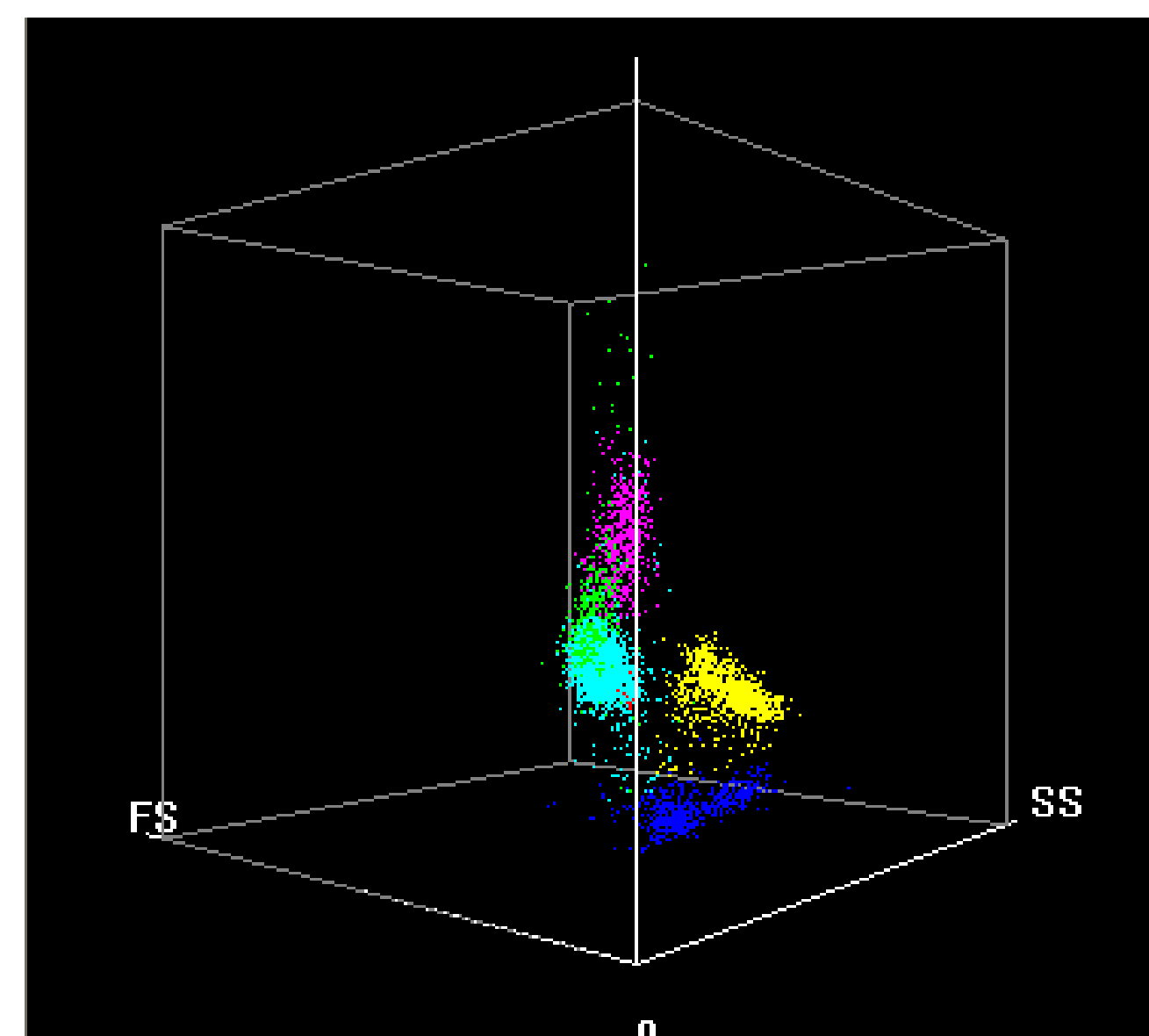


Fig. 2 SF Cube Screen shot

## Results - Continued

<u>Only P. vivax</u> Parasites types	REFERENCE METHOD (Microscopy)	
	SEEN	NOT SEEN
"Infected RBC?" Flag <b>PRESENT</b>	<b>TP</b> 36	<b>FP</b> 0
"Infected RBC?" Flag <b>ABSENT</b>	<b>FN</b> 03	<b>TN</b> 896
<b>TOTAL CASES</b>	<b>39</b>	<b>896</b>
<b>Sensitivity</b>	<b>92.3% (95% CL: 79.1 ~ 98.3%)</b>	
<b>Specificity</b>	<b>100.0% (95% CL: 99.6 ~ 100%)</b>	
<b>PPV = 100% &amp; NPV = 99.7%</b>		

Table-1: with data of only P. vivax cases

<u>Both Parasite types</u>	REFERENCE METHOD (Microscopy)	
	SEEN	NOT SEEN
"Infected RBC?" Flag <b>PRESENT</b>	<b>TP</b> 41	<b>FP</b> 0
"Infected RBC?" Flag <b>ABSENT</b>	<b>FN</b> 11	<b>TN</b> 896
<b>TOTAL CASES</b>	<b>52</b>	<b>896</b>
<b>Sensitivity</b>	<b>78.9% (95% CL: 65.3 ~ 88.9%)</b>	
<b>Specificity</b>	<b>100.0% (95% CL: 99.6 ~ 100%)</b>	
<b>PPV = 100% &amp; NPV = 98.8%</b>		

Table-2: with data of all cases

## Discussion

Compared with our earlier experience in 2011-12, when 248 of total 497 patients tested positive for malaria i.e. ~50% +ve rate, in the present study the incidence of malaria was much lower at just 5.5% +ve rate.

This is attributable to several factors like effective measures to control mosquito proliferation and vigorous malaria awareness campaigns adopted by the Mumbai municipality. Besides, the study was conducted during out-going 'malaria season' (so called lean period) of September-October. However, this proved to be an opportunity to test the advantage of a dedicated flag on BC-6800 at 'routine level' when the degree of suspicion is rather low and/or not anticipated.

## Conclusion

- Our earlier reported findings<sup>1</sup> on utility of "infected RBC?" are reconfirmed
- In present study, "Infected RBC?" flag demonstrated excellent sensitivity, specificity to help analyzer user screen for presence of *P. vivax* parasites.
- Since the "infected RBC?" is a standard feature on BC-6800 not requiring special reagents for its generation, in resource constrained busy labs, it could adopt easily a cost efficient screening tool to look for *P. vivax* parasites.
- In our opinion, excellent NPV of "Infected RBC?" flag provides safety from missing malaria cases, in regions relatively free from malaria.

## References

- Screening for Malaria – using Mindray BC-6800 automated hematology analyzer, poster presented by Bhide M. & Parekh V. at ISLH Congress 2012