Malaria screening in the Haematology laboratory - QBC or gold standard?

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Introduction

Malaria is an infection caused by Plasmodium (P.) parasites transmitted by Anopheles mosquitoes. Five species are known to infect humans: *P. falciparum, P. vivax, P. ovale, P. malariae* and *P. knowlesi* [1]. Early diagnosis is crucial for positive outcomes, so laboratories need to use methodologies that are fast and reliable, with high sensitivity and specificity [2].

In the Haematology Laboratory at the Royal Free Hospital, Quantitative Buffy Coat is used instead of the examination of stained thick films. The objective of this study is to ascertain if the QBC Dry Haematology kit can replace the QBC Malaria kit and compare their performance against that of the Thick and Thin blood films and BinaxNow Rapid Diagnostic Test. The performance of the Sysmex DI60 Digital Morphology System was also assessed, even though it has not been validated for this purpose.

Methods

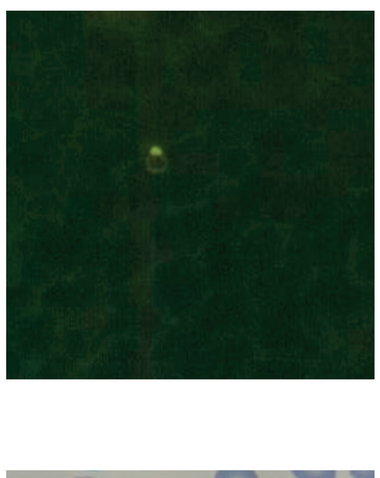
To compare the performance of the different methods, the following was established:

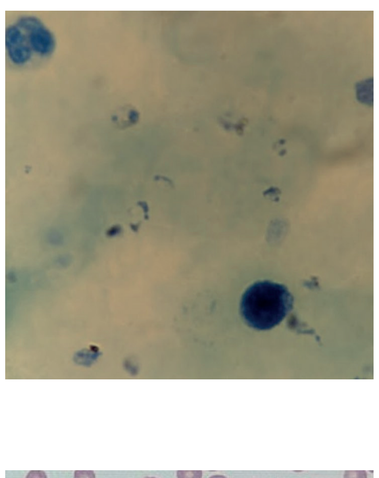
- Sensitivity, specificity and accuracy;
- Positive and Negative Predictive Values;
- Minimum detection levels

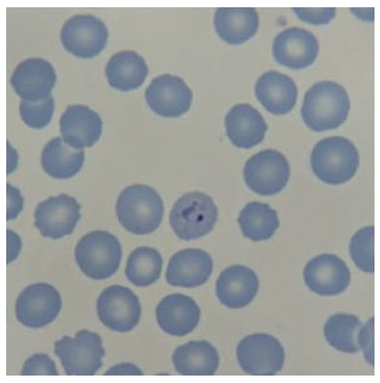
Subsequently, blood slides were prepared for scanning and assessing using the Sysmex DI60 Digital Morphology System. To ensure that results obtained from each test were valid, each of the methods was assured by a quality control (QC) step.

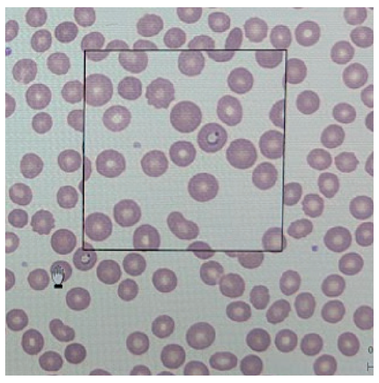
Results

- A total of 104 samples with were sourced for testing as part of this study.
- A total of 74 samples were reported negative and thirty were reported positive. These were the consensus results for QBC Malaria Kit, QBC Dry Haematology kit Malaria Reference Laboratory.
- False negative results were reported using Thin and Thick films, BinaxNow and Sysmex DI60.
- The BinaxNow was the only method producing false positive results.









Images 1, 2, 3 & 4
Examples of positive results on QBC, Thick Film, Thin Film and Sysmex DI60

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
QBC Malaria	100	100	100	100	100
QBC Dry Haematology	100	100	100	100	100
Thick Film	97	100	100	99	99
Thin Film	97	100	100	99	99
RDT BinaxNOW	97	99	97	99	98
Sysmex DI60	67	99	100	95	95

Thick Film	Thin Film	QBC Malaria Kit	QBC Dry Haematology Kit	ICT RDT BinaxNow	Sysmex DI60	Species	Parasitaemia (%)	MRL Result (thick and thin film)
Positive	Positive	Positive	Positive	Negative	Positive	*P.ovale*	n/a	Positive
Negative	Negative	Negative	Negative	Positive	Negative	n/a	n/a	Negative
Negative	Negative	Positive	Positive	Positive	Insufficient	*P.falciparum*	<0.01%	Positive
Poor Stain	Positive	Positive	Positive	Positive	Positive	*P.falciparum*	<0.01%	Positive
Positive	Positive	Positive	Positive	Positive	Negative	*P.falciparum*	<0.01%	Positive
Positive	Positive	Positive	Positive	Positive	Negative	*P.falciparum*	<0.01%	Positive
Positive	Positive	Positive	Positive	Positive	Negative	*P.falciparum*	<0.01%	Positive
Positive	Positive	Positive	Positive	Positive	Negative	*P.falciparum*	<0.1%	Positive

Conclusion

It was found that the QBC Dry Haematology and QBC Malaria Kits allowed the laboratory to obtain more reliable results than those from examination of thick and thin films. When asked, staff stated that QBC was preferred when compared to examination of thick films, which are still considered by WHO as the field standard for malarial diagnosis [3].

False negative results were observed when parasitaemia was low: <0.1% for the Sysmex DI 60 and <0.01% for Thick and thin films. The BinaxNow was the only test with false positive results, and it showed poor performance when assessing non-falciparum species (false negative result on a case of ***P. ovale***).

Future Work

Advances in Nucleic-acid detection methods and digital morphology software could significantly improve the speed, cost-effectiveness, and accuracy of malaria parasite screening. This could redefine the new gold standard. Further research is needed, particularly around use of digital morphology with integrated Artificial Intelligence.

References

1. World Health Organization, (2024). Malaria. https://www.who.int/news-room/fact-sheets/detail/malaria
2. National Institute for Health and Care Excellence, (2024). Malaria: What is the Prognosis? https://cks.nice.org.uk/topics/malaria/background-information/prognosis/
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