Field evaluation of automatic new diagnostic CellCheck® in comparison to standard microscopy for detection of malaria from clinical suspected cases in Lampung Province, Indonesia.

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Introduction

Direct visual finding of malarial parasites in the blood remains the most relevant detection method. However, microscopic examination with Giemsa staining is subjective and requires relatively long roundabout time. Digitalization of the parasite image or byproduct is developed to overcome this issue. CellsCheck® (Biosynex, France) deploys fluorescence-based principle for automated identification of parasites. It developed plastic cartridge and patented sample preparation to create homogenous "thin blood smear." Cutting-edge computer vision technology algorithm system is utilized for detection, speciation, and quantification of the malaria parasites.

This study aims to compare this novel technology with standard microscopy.

Figure 1. CellsCheck® diagnostic system

Materials & Methods

Finger-pricked blood samples were collected from clinical suspected patients during September 2019-January 2020 in Lampung province, Indonesia. On-site testing was performed by CellsCheck®, whereas microscopic examination was done independently by expert in Jakarta.

Figure 2. On-site test by the study team

Real-Time PCR targeting 18S rRNA was performed for diagnostic verification of the discrepant results

Result

293 specimens were collected and examined by CellsCheck® and microscopy. CellsCheck® detected 40 (13.6%) malaria infections, compared to 38 (13.0%) by microscopy. 24 discordant results were found between CellsCheck® and microscopy

Table 1. CellsCheck® result in comparison with microscopy

CellsCheck®	Microscopy				Total
	P. falciparum	*P. vivax*	*Pf & Pv*	**Negative**	
P. falciparum	1	19	0	3	23
P. vivax	0	16	0	0	16
Pf & Pv	0	1	0	0	1
Negative	0	1	0	252	253
Total	1	37	0	255	293

Table 2. PCR verification of discordant result

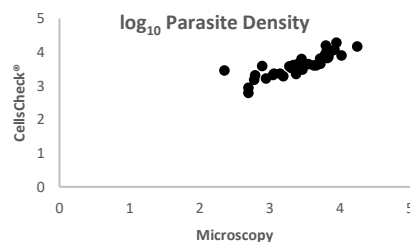| No. samples	CellsCheck®	Microscopy	PCR
19	*P. falciparum*	*P. vivax*	*P. vivax*
3	*P. falciparum*	Negative	*P. vivax*
1	*Pf & Pv*	*P. vivax*	*P. vivax*
1	Negative	*P. vivax*	*Pf & Pv*

Figure 3. Density plot of CellsCheck® against microscopy

Parasitemia quantification between CellsCheck® and microscopy demonstrated strong correlation

Sensitivity for non-specific malaria was 97.6%, whereas it was only 42% for *P. vivax.*

Table 3. Sensitivity, specificity, PPV, and NPV after PCR verification

Diagnosis*	p-value	Sensitivity	Specificity	PPV	NPV
All malaria	1,000	97,6%	100%	100%	99,6%
P. vivax	<0,001	42%	100%	100%	92%

*Evaluation for *P. falciparum* cannot be made as only one sample was found

Conclusion

Further improvement is required for speciation of CellsCheck® although its performance to detect malaria positivity is comparable to the standard microscopic examination.