

O326

2-hour Oral Session

Still thriving at the host's expense: parasitic infection

CellsCheck® automated malaria diagnosis: A new tool in the fight against malaria

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Background: Malaria is a major infectious disease in tropical areas. Accurate diagnosis and treatment are necessary, since the disease could be lethal without antimalarial treatment. Accurate diagnosis depends on the observation of parasites by microscopy of stained thin smear or thick film which allows for the identification of the species of parasite and evaluation of the parasitaemia. However, microscopic diagnosis is difficult, time consuming, and requires materials and expertise of trained professionals. ALLDIAG, a medical device company, has developed a platform, for diagnosing blood diseases using computer vision technology. The detection technology combines cutting edge applications from the fields of computer hardware, software and biology to deliver a diagnosis. The product, CellsCheck®, identifies, enumerates and speciates malaria. We conducted a validation on samples from clinically imported cases with microscopy as reference method.

Material/methods: Blood samples received in the laboratory of parasitology for diagnosis of malaria, or in the Malaria National French Reference Center, in Bichat hospital were included in the study. Reference diagnosis of malaria was performed by microscopy of thin/thick Giemsa stained smears. The samples were then analyzed on the CellsCheck® device following the manufacturer's instructions. For all non-*falciparum* samples, PCR (Fast Track, Launch Diagnostics) was used to confirm diagnosis. In cases of discordance between CellsCheck® and microscopy results, smears were blindly read again and PCR was performed on the sample. For the final result, microscopy was considered the reference.

Results: During the study, between September 2014 and August 2015, 916 samples were included which were scanned by the CellsCheck® device. Among the 237 negative samples, the CellsCheck® device reported negative on 224 for a specificity of 94.5% (IC 95%: 91.6-97.4). The PCR performed on discordant samples was negative. From the 679 positive samples of all species, 653 were found positive with the CellsCheck®, yielding a sensitivity of 96.2% (IC 95%: 94.6-97.6). Among 637 samples with a parasitaemia above 100p/μl, 631 (99.1%; IC 95%: 98.3-99.48) were found positive by CellsCheck®.

The species identification as *P. falciparum* with the CellsCheck® was correct for 555 of the 575 *Pf* confirmed samples (96.5%; IC 95%: 95-98). Among the samples with non *falciparum* malaria, 68 of 78 samples (87.2%; IC 95%: 79.8-94.6) were correctly classified as non *falciparum*. The correlation between parasitaemia determined by microscopy and by the Cellscheck device parasitaemia was accurate ($R^2=0.77$).

Conclusions: Performances of CellsCheck compared to microscopy were good and the evaluation of parasitaemia is a superiority. The species diagnosis is limited to *falciparum* and non-*falciparum*

however large data collections are underway to increase the possibility of complete speciation. This device could be a major advance in the fight against malaria through the provision of reliable, accurate and quickly diagnosis without the constraints of the technician laboratory qualification.