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**The illumigene® Malaria and illumigene® Malaria Plus assays: new and highly effective screening tools for malaria in western laboratory settings**

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**Background:** Malaria can cause severe morbidity and mortality in travelers returning from the tropics . Early treatment can prevent severe complications but requires fast diagnosis. Routine microscopic diagnosis is demanding and requires highly skilled staff. Therefore, rapid diagnostic tests (RDT), e.g. the BinaxNOW, are increasingly used as screening tests. RDTs often perform well, but can lack sensitivity. Therefore better screening methods are needed.

We evaluated the newly developed illumigene Malaria® and illumigene Malaria PLUS® DNA amplification assays (Meridian) for rapid diagnosis of malaria in travelers returning from the tropics.

**Material/methods:** Of 205 patients suspected for malaria, 205 samples and results of microscopic examinations and BinaxNOW RDT prospectively were collected by eleven laboratories in The Netherlands and Belgium. Only samples taken before start of treatment were included. Microscopy was performed with thick and thin blood films. Blood samples of all patients were examined with quantitative real-time PCR and illumigene Malaria® - and illumigene Malaria Plus® assays at the AMC, Amsterdam. The gold standard of positivity for any species of *Plasmodium* was observation of asexual stages in thick and/or thin smears, and species confirmation by PCR. Patients were negative for malaria when both microscopy and PCR were negative.

**Results:** According to the gold standard 85 patients were positive - and 120 patients negative for malaria (table). All five human Plasmodium species, including two subspecies of *P. ovale*, were present (table). Sensitivity of the illumigene Malaria®, illumigene Malaria Plus® and BinaxNOW® were respectively 99%, 100% and 89% (table). Specificity of the illumigene Malaria®- and illumigene Malaria Plus® assay was 100% and of the BinaxNOW® 99% with respectively 120/120 and 119/120 samples correctly identified as negative.

| Positive cases according to Gold standard |                           | Results of methods under investigation |                     |                          |                |   |    |    |       |
|---|---------------------------|--|---------------------|--------------------------|----------------|---|----|----|-------|
|   |                           | Routine microscopy                     | illumigene Malaria® | illumigene Malaria PLUS® | Binax Now ICT® |   |    |    |       |
| No.                                       | (sub)species              | Detected cases                         | Detected cases      | Detected cases           | Detected cases | 0 | T1 | T2 | T1+T2 |
| 52  | <i>P. falciparum</i>      | 52                                     | 51                  | 52                       | 52             | 0 | 19 | 1  | 32    |
| 25  | <i>P. vivax</i>           | 25                                     | 25                  | 25                       | 20             | 5 | 0  | 20 | 0     |
| 3   | <i>P. ovale wallikeri</i> | 3                                      | 3                   | 3                        | 0              | 3 | 0  | 0  | 0     |
| 1   | <i>P. ovale curtisi</i>   | 1                                      | 1                   | 1                        | 0              | 1 | 0  | 0  | 0     |
| 1   | <i>P. knowlesi</i>        | 1                                      | 1                   | 1                        | 1              | 0 | 0  | 1  | 0     |

|                  |   |                  |                 |                  |                 |          |           |           |           |
|------------------|---|------------------|-----------------|------------------|-----------------|----------|-----------|-----------|-----------|
| 1                | <i>P. malariae</i>                                | 1                | 1               | 1                | 1               | 0        | 0         | 1         | 0         |
| 2                | <i>P. falciparum</i><br>and<br><i>P. malariae</i> | 2                | 2               | 2                | 2               | 0        | 0         | 2         | 0         |
| <b>Total: 85</b> |   | <b>85 (100%)</b> | <b>84 (99%)</b> | <b>85 (100%)</b> | <b>76 (89%)</b> | <b>9</b> | <b>19</b> | <b>25</b> | <b>32</b> |

**Conclusions:** The *illumigene*<sup>®</sup> Malaria and *illumigene*<sup>®</sup> Malaria Plus assays demonstrate excellent performances as screening tools for identification or exclusion of malaria in returning travellers in Western laboratory settings.