

**O0263 Evaluation of two new real-time PCR-based kits for the diagnosis of the five human-infecting *Plasmodium* species, including *Plasmodium knowlesi***

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**Background:** In 2017, there were an estimated 219 million cases and 435 000 malaria related deaths, according to the WHO. Even in settings in which malaria is not endemic, infections can be seen in individuals who have travelled to or emigrated from endemic malaria regions. Human infection is caused by five *Plasmodium* species (*P. falciparum*, *P. ovale*, *P. vivax*, *P. malariae* and *P. knowlesi*). Clinically, *Plasmodium* species are managed differently and it is important to identify the causal agent at species level.

The aim of this study was the evaluation of two real-time PCR based Kits (RealStar® Malaria PCR and RealStar® Malaria Screen&Type PCR, Altona Diagnostics) for detection and typing of human pathogenic *Plasmodium* species.

**Materials/methods:** A collection of 105 whole blood samples, previously characterized by a “in house” nested-multiplex PCR used as reference method in the Spanish Malaria Reference Laboratory, was included in the study. Each of the five human *Plasmodium* species was present in 15 samples. In addition, fifteen samples previously tested negative for *Plasmodium* species and fifteen samples previously tested positive for other human blood parasites (*Leishmania*, *Loa*, *Trypanosoma cruzi* and *Dirofilaria*) were used. All samples were tested by duplicate and repeated in case of discrepancies.

Limits of detection (LOD) were calculated for all *Plasmodium* species using serial dilution of infected samples with known parasitaemia.

**Results:** Both commercial kits show 100% concordance between them and only a sample showed discordant result with respect to the reference method. A discrepant sample was excluded due to the impossibility of repeating the techniques. Sensitivity and specificity values were 98.6% and 100% respectively, with a Kappa Index of 0.98.

The limit of detection for *P. falciparum* detected by RealStar® Malaria PCR was 0.068 parasites/μl and the limit for the rest of *Plasmodium* species were below 0.1 parasites/μl.

**Conclusions:** The results obtained with RealStar® Malaria PCR and RealStar® Malaria Screen&Type PCR were quite similar to the reference PCR, with high sensitivity and specificity for the detection of human *Plasmodium* species, showing that these kits can be good tools to be used in the malaria diagnosis.