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### SDBIOLINE恶性疟原虫/间日疟原虫抗原快速检测试剂盒现场应用效果评价

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### Field Evaluation of SDBIOLINE Malaria Antigen Plasmodium falciparum/Plasmodium vivax Rapid Test Kit

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**摘要** 2011年6月至12月在云南中缅边境, 采用双盲法对475例48 h内有发热史的门诊患者进行疟原虫检测。结果表明, 使用SDBIOLINE恶性疟原虫/间日疟原虫抗原快速检测试剂盒共检出疟原虫阳性202例, 其中恶性疟原虫98例, 间日疟原虫104例。镜检结果显示, 疟原虫阳性共206例, 其中恶性疟99例, 间日疟107例。以镜检法为金标准, SDBIOLINE试剂盒检测疟原虫总体敏感性为98.1% (202/206), 特异性为97.8% (263/269), 与镜检符合率为97.9% (465/475); 检测恶性疟原虫的敏感性和特异性分别为99.0% (98/99)和97.8% (263/269), 与镜检符合率为98.1% (361/368); 检测间日疟原虫的敏感性和特异性分别为97.2% (104/107)和100% (269/269), 与镜检符合率为99.2% (373/376)。提示SDBIOLINE疟疾快速诊断盒检测结果的特异性和敏感性较高, 并可区分虫种。

**关键词:** SD<sup>BIOLINE</sup>试剂盒 恶性疟原虫 间日疟原虫

**Abstract:** Four hundred and seventy-five patients with fever within 48 h were detected for Plasmodium using double blind field trials in China-Myanmar border from June to December 2011. The result showed that 202 of 475 were positive by SDBIOLINE kits, with 98 positive of Plasmodium falciparum and 104 positive of Plasmodium vivax. By microscope examination, 206 were positive. Taking the result of microscope examination as the reference standard, the general sensitivity and specificity were 98.1% (202/206) and 97.8% (263/269) respectively, and the general coincidence rate of SDBIOLINE kits with microscopy was 97.9% (465/475). The sensitivity and specificity of P. falciparum were 99.0% (98/99) and 97.8% (263/269) respectively, and the coincidence rate of SDBIOLINE with microscopy was 98.1% (361/368). The sensitivity and specificity of P. vivax were 97.2% (104/107) and 100% (269/269), and the coincidence rate of SDBIOLINE with microscopy was 99.2% (373/376). Therefore, the test results of SDBIOLINE are stable with a high specificity and sensitivity.

**Keywords:** SD<sup>BIOLINE</sup> kit Plasmodium falciparum Plasmodium vivax

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