实验研究

快速诊断疟疾胶体金免疫层析试条方法的建立与评价

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目的 建立一种能区分恶性疟的快速、简便诊断疟疾的胶体金免疫层析试条方法,并对其进行评价。 方法 筛选基于恶性疟原虫乳酸脱氢酶制备的单克隆抗体对,采用柠檬酸三钠还原法制备胶体金颗粒,标记筛选 到的单克隆抗体F4H12、G4C9和D8F7,并将其吸附于样品垫;将单克隆抗体B2G10(针对恶性疟原虫 与间日疟原虫)和D6A7(只针对恶性疟原虫)分别划线包被于同一硝酸纤维素膜适当位置,制成免疫层 析检测试条。用该试条检测疫区非疟疾发热病人血样(107份)和内脏利什曼病患者血样(17份)以评 价其特异性,检测确诊的疟疾患者血样(间日疟110份, 恶性疟54份)以评价其敏感性。均用单盲法检 测。 结果 检测107份疫区非疟疾发热病人血样和17份内脏利什曼病患者血样,有119份显示为阴性, 特异性约为96.0%; 其中17份内脏利什曼病患者血样全部为阴性。检测164份疟疾患者血样,阳性153 份, 敏感性为93.3%, 其中间日疟柃出率为92.7%(102/110), 恶性疟柃出率为94.4% (51/54)。 结论 研制出的快速诊断疟疾胶体金免疫层析试条敏感性、特异性均较高。

疟疾 免疫层析试条 诊断 关键词

分类号

Establishment and evaluation of Colloid Gold Labeled Immunochromatographic Strip Test for Rapid Diagnosis of Malaria

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Abstract

Objective To establish and evaluate a gold immunochromatographic strip test for detection and differentiation of *Plasmodium vivax* and *P.falciporum*. Methods monoclonal antibodies, F4H12, G4C9 and D8F7, were conjugated with colloid gold as detecting reagent; monoclonal antibody B2G10 (against P.vivax/ P.faciporum) and D6A7 (only against *P.falciporum*) were immobilized on nitrocellulose in proper position. Blood samples from 107 febrile patients from endemic area of malaria and 17 patients with visceral leishmaniasis were used for evaluating the specificity. Blood samples of malaria patients (110 with *P.vivax* and 54 with *P.falciparum*) were used for evaluating the sensitivity. Results 5 samples out of 107 febrile patients and 17 patients with visceral leishmaniasis showed false positive reaction with a specificity of 96.0% (119/124), all the 17 samples from patients with visceral leishmaniasis were negative. 164 blood samples of malaria patients showed a sensitivity of 92.3% (153/164), 92.7% (102/110) and 94.4% (51/54) for patients infected with *P. vivax* or *P.falciporum*, respectively. Conclusion The immunochromatographic strip test based on antigen-capturing is a sensitive, specific, simple and rapid assay for malaria diagnosis.

Key words Malaria Immunochromatographic strip Diagnosis.

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