

论著

国产全自动血液病毒核酸筛查系统的建立和应用研究

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摘要:

[摘要] 目的建立适合我国供血者全自动核酸检测的方法(国产), 探讨在我国血液筛查中引进全自动核酸筛查的可行性。方法在酶联免疫吸附试验筛查血液基础上, 采用全自动核酸提取仪进行血样汇集(8人份), 提取样本核酸, 应用聚合酶链反应(实时荧光PCR)在ABI 7300上进行扩增和检测, 并用国际标准核酸质控品考评检出限量, 对阳性供血者追踪检测。结果经考评及常规应用,该系统全自动汇集及全自动核酸提取、扩增、检测95%的检出限量, 乙型肝炎病毒(HBV) DNA、丙型肝炎病毒(HCV) RNA和人免疫缺陷病毒(HIV) 1 RNA分别为35.9 IU/mL、147.7 IU/mL、66.1 IU/mL, 95%可信区间分别为[21.9~124.8]、[93.3~386.4]和[38.8~235.3]。对60 112份样本共7 514汇集池进行检测分析, HBV DNA阳性12份, 阳性比例为1:5 009, 其中6份为抗HBc阳性; HCV RNA阳性1份, 比例为1:60 112; 未检出HIV 1 RNA阳性。对7例HBV DNA阳性者进行追踪, 发现4例发生了血清转换现象。结论我国全自动血液核酸筛查系统可应用于血液HBV DNA、HCV RNA和HIV RNA的筛查工作。

关键词: 血液筛查; 输血传播病毒; 核酸扩增技术; 供血者; 输血安全

Establishment and application of domestic entirely automatic system of nucleic acid amplification testing in blood screening

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Abstract:

Objective To establish domestic entirely automatic nucleic acid testing (NAT) assay for blood screening, and to study the feasibility of domestic NAT. Methods On the basis of enzyme linked immunosorbant assay for blood screen, blood samples were pooled and extracted nucleic acid with entirely automatic nucleic acid apparators, then the extracted nucleic acid was amplified and detected with real time polymerase chain reaction, sensitivity and efficacy was evaluated, NAT positive donors were traced. Results The 95% detection limits of HBV DNA, HCV RNA and HIV 1 RNA tested by automatic system were 35.9 IU/mL, 147.7 IU/mL and 66.1 IU/mL, respectively, 95% confidence intervals were [21.9, 124.8], [93.3, 386.4] and [38.8, 235.3] respectively. Twelve of 60 112 samples were HBV DNA positive, DNA positive ratio was 1:5 009, 6 of which were anti HBc positive; one sample was HCV RNA positive, RNA positive ratio was 1:60 112; no HIV 1 RNA positive was detected among all samples. Seven HBV DNA donors were followed up, 4 of whom had seroconverted. Conclusion The domestic entirely automatic system can be applied in blood HBV DNA, HCV RNA and HIV RNA screening.

Keywords: blood screen blood transmitted virus nucleic acid amplification techniques; donor; safety blood transfusion

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