

试剂盒医疗器械注册/临床试验/CE认证

产品名称	试剂盒医疗器械注册/临床试验/CE认证
公司名称	全球法规注册CRO-国瑞IVDEAR
价格	.00/个
规格参数	
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产品详情

[摘要]详细介绍了10种(SARS CoV-2)核酸测试剂盒的特点和相关技术指标，从样本制备、检测靶点和阈值判断3个方面总结了不同生产厂家的SARS-CoV-2核酸测试剂盒产品的设计差异和不足。得出了检测限水平差并是此类产品重要的风险评估指标,提出了使用核酸评价物质衡量试剂盒产品检测限的必要性，以期SARS-CoV-2核酸测试剂盒产品的评价提供参考。

[关键词] SARS-CoV-2;荧光定量PCR法;核酸检测;检测靶点;产品评价

Analysis and evaluation of SARS-CoV-2 nucleic acid testing reagent kit

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(1. Beijing Institute of Medical Testing, Beijing 101111, China; 2. Beijing Key Laboratory of Medical Device Testing and Safety Evaluation, Beijing 101111, China) Abstract The characteristics and related technical specifications of 10 novel coronavirus (SARS - CoV -2) nucleic acid detection kits were introduced in detail, and the design differences and shortcomings of SARS-CoV-2 nucleic acid detection kits from different manufacturers are summarized in terms of sample preparation, detection targets and threshold judgment. It was concluded that the difference in detection limit level was an important risk assessment index of these kits, and the necessity of using nucleic acid evaluation substances to measure the detection limit of the kits was proposed as a reference for the evaluation of SARS-CoV - 2 nucleic acid test kits.

Key words SARS-CoV-2; fluorescence quantitative PCR; nucleic acid detection; detection target; product evaluation