新冠流感A/B检测试剂临床试验,新冠流感A+B三联检临床试验

产品名称	新冠流感A/B检测试剂临床试验,新冠流感A+B 三联检临床试验
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产品详情

新冠、流感联合检测试剂盒获批上市

9月7日,澳大利亚治疗用品管理局(TGA)批准了首个COVID-19和流感自检组合试剂盒上市销售。

本次获得TGA批准的试剂盒,是由TouchBio和Fanttest制造:

TouchBio SARS-CoV-2 & FLU A/B 抗原组合测试(鼻)

Fanttest COVID-19 / 甲型和乙型流感抗原检测试剂盒。

可以在15分钟内同时检测使用者新冠,病毒和流感的感染情况。TGA预计供应商将让消费者在药店、超市或网上进行购买。

TGA表示,新的快速检测试剂盒可以快速指导澳大利亚人获得适当的治疗。所批准这类检测试剂的机构 ,已审查证明其满足新冠和流感自检zui低性能标准的临床和分析数据。

新冠、流感"双疫"风险

20世纪以来人类至少经历了5次传染病大流行,给生命健康和社会经济造成了灾难性的伤害。前4次主要是由甲型流感病毒造成,分别是1918年的H1N1、1957年的H2N2、1968年的H3N2、2009年的H1N1流感病毒,以及2019年12月由冠状病毒(SARS-CoV-2)引发的新冠疫情。

目前,IVDEAR团队已与多家欧洲临床试验机构达成合作,可承接新冠+流感A/B检测试剂的临床试验,由于拥有多家临床试验机构渠道资源,IVDEAR团队克服了流感A/B样本稀缺的棘手难题,能为IVD企业提供全流程的临床试验研究解决方案服务。

New Corona and Influenza Joint Test Kit was approved for marketing

On September 7, the Australian Treatment Supplies Authority (TGA) approved the first COVID-19 and flu self inspection combination kit for marketing.

The kit approved by TGA this time is manufactured by TouchBio and Fantest:

TouchBio SARS-CoV-2&FLU A/B antigen combination test (nose)

Fantest COVID-19/influenza A and B antigen detection kit.

The new coronavirus and influenza infection of users can be detected simultaneously within 15 minutes. TGA anticipates that suppliers will allow consumers to purchase in pharmacies, supermarkets or online.

TGA said that the new rapid detection kit can quickly guide Australians to obtain appropriate treatment. The organization that has approved this type of testing reagent has reviewed the clinical and analytical data proving that it meets the minimum performance standards of the new crown and flu self inspection.

Risk of "Double Epidemic" of New Crown and Influenza

Since the 20th century, human beings have experienced at least five pandemics of infectious diseases, which have caused catastrophic damage to life, health and social economy. The first four were mainly caused by influenza A virus, namely H1N1 in 1918, H2N2 in 1957, H3N2 in 1968, H1N1 in 2009, and the new coronal epidemic caused by coronavirus (SARS CoV-2) in December 2019.