



## Statement on the validity of SARS-CoV-2

### Antigen Rapid Test Kit

For the newly discovered new coronavirus mutant strain Omicron (B.1.1.529), our company conducts the sequence comparison analysis of its 32 mutation sites. All mutation sites are outside the epitope region recognized by the new crown paired monoclonal antibody selected by our company. Therefore, according to known academic opinions, the effective production strain for Omicron (B.1.1.529) can still be detected by our product "SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)".

Next, our company will continue to follow up on the mutation of Covid-19, perform sequence alignment analysis in time, and evaluate and verify the detection ability of key mutation sites to ensure the sensitivity and specificity of the kit.

北京乐普诊断科技股份有限公司

Beijing Lepu Medical Technology Co., Ltd.

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## 新冠病毒变异毒株检测有效性声明

针对近期新发现的新型冠状病毒变异株 Omicron(B.1.1.529) 我司对其 32 个突变位点进行序列比对分析，所有突变位点均在我司选择的新冠配对单抗识别的表位区域之外，因此根据已知学术观点，针对 Omicron(B.1.1.529) 变异株我司产品“新型冠状病毒(SARS-CoV-2) 抗原检测试剂盒（胶体金免疫层析法）” 仍能有效检出。

后续，我司将持续跟进新冠病毒的变异情况，及时进行序列比对分析，并对关键突变位点进行检测能力的评价和验证，以确保检测试剂盒的灵敏度和特异性。

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