3DMed SARS-CoV-2 RT-qPCR LoD validation results by National Institutes for Food And Drug control

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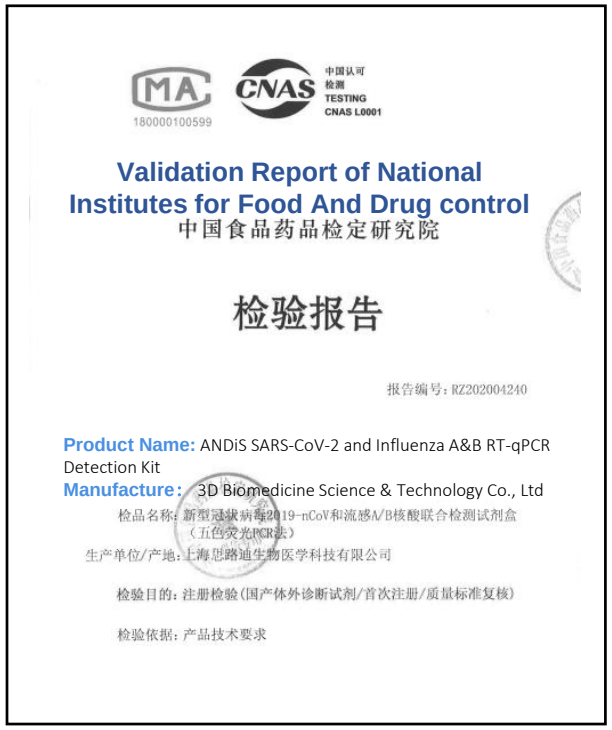
- **Samples and method for LoD validation:**
  The known concentration of National Reference (Cultured virus in National Reference Panel for 2019-nCoV Nucleic Acids Detection Kit) was diluted to 10^5copies/mL with Nuclease Free water.

  A serial dilution (S1-S10) of the stock solution of 10^5copies/mL was built as follows.
  3 replicates of each concentration were detected with our qRT-PCR kit.

- **Conclusion:**
  Based on the results of LoD validation, the limit of detection for **ANDiS SARS-CoV-2 and Influenza A&B RT-qPCR Detection Kit** is 50 RNA copies/mL

Samples and Titer Used for LoD Study

Target	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10
Dilution	1:9	1:27	1:81	1:243	1:729	1:2187	1:6561	1:19683	1:59049	1:177147
Concentration	1.1E+04	3.7E+03	1.2E+03	4.1E+02	1.4E+02	4.6E+01	1.5E+01	5.1E+00	1.7E+00	5.6E-01
Positive /Total	3/3	3/3	3/3	3/3	3/3	3/3	N	N	N	N



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Validation Report of National Institutes for Food And Drug control
中国食品药品检定研究院

检验报告

报告编号：RZ202004240

Product Name: ANDiS SARS-CoV-2 and Influenza A&B RT-qPCR Detection Kit
Manufacture: 3D Biomedicine Science & Technology Co., Ltd

检品名称：新型冠状病毒2019-nCoV和流感A/B核酸联合检测试剂盒（五色荧光PCR法）

生产单位/产地：上海思路迪生物医学科技有限公司

检验目的：注册检验（国产体外诊断试剂/首次注册/质量标准复核）

检验依据：产品技术要求

中国食品药品检定研究院检验报告

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Validation experiments	Specification	Results
2.3阴性参考品符合率	检测国家参考品，不在试剂盒检测范围内的病原体均不应检出，或检测企业阴性参考品N1-N8，结果均为阴性	符合规定
新型冠状病毒核酸检测试剂国家参考品	N1～N14、N20～N22应均为阴性	均为新型冠状病毒和流感病毒A/B型阴性
	N15、N16、N18、N19应均为流感病毒A型阳性	均为新型冠状病毒阴性，流感病毒A型阳性，流感病毒B型阴性
	N17应为流感病毒B型阳性	均为新型冠状病毒阴性，流感病毒B型阳性，流感病毒A型阴性
第二代甲/乙型流感病毒核酸检测试剂国家参考品	在试剂检测靶标范围内，结果应与预期病原体类型/型别一致	N1～N10均为流感病毒A/B型和新型冠状病毒阴性
	检测国家参考品，[illegible]考品L1-L5，结果均为阳性，S4～S10不作要求	S1～S3 应为阳性，S4～S10不作要求

Validate LoD with National SARS-CoV-2 Reference Standards

S1-S3 positive, S4-S10 no requirement

S1-S6 SARS-CoV-2 positive; S7-S10 SARS-CoV-2 Negative

National drug standard substance instruction manual
国家药品标准物质使用说明书

V1.0

【特性量值】灵敏度参考品 S 浓度（原液）为 3×10^5copies/mL，使用数字 PCR 方法联合定值。S 不可用于量值溯源。

3）灵敏度参考品：S 使用无 RNA/DNA 酶去离子水进行 1:3 倍比稀释（2 份水+1 份样本）后，将 1:9、1:27、1:81、1:243、1:729、1:2187、1:6561、1:19683、1:59049、1:177147 分别标记为 S1~S10，按照试剂盒说明书要求进行核酸提取后进行检测；

The concentration of LoD Reference S is 3×10^5 copies / mL. 3 times dilute S with nuclease free water first to make the stock solution. Then 1:9, 1:27, 1:81, 1:243, 1:729, 1:2187, 1:6561 and 1:19683 dilute the stock solution. Mark S1 to S9 with the diluted samples. Finally perform RT-qPCR detection with extracted RNA from S1-S9.