Research report: Measurement precision research of COVID-19 Coronavirus Real Time PCR Kit

Research period: 2020.01-2020.02

Product lot examined: Lot1：20200104 (expire date: 2021.01.20)，Lot2：20200105 (expire date: 2021.01.20), Lot3：20200106 (expire date: 2021.01.20). Enzyme system, primers and probes used in those three kit lots were provided by Jiangsu Shuoying biotechnology co. Ltd from their three independent batches.

Instruction version: v1.0

Research institution/organization: R&D department, Jiangsu Bioperfectus Biotechnology co. Ltd.

Test location: on-site real-time test

Purpose

This study is to test the measurement precision of COVID-19 Coronavirus Real Time PCR Kit

Risk assessment

The risk caused by the detection precision of the kit is evaluated and summarized in risk assessment file where possible effects of measurement precision on accuracy of the kit has been analyzed.

Acceptance criteria

Coefficients of intra-/inter-lot variation, intra-/inter-day variation and intra-/inter-operator variation are less than 5% (%CV<5%).

Study design

Standards referred：

1. CLSI EP05-A3CLSI EP05-A3:Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition. [2014].
2. Diagnostic Assessment. Principles for Performance studies, TGS–3. Geneva: World Health Organization; 2016
3. GHTF/SG1/N68:2012 Essential Principles of Safety and Performance of Medical Devices
4. EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices

Reference panel* (VLP: virus-like particle)

Code	Composition	Property	Concentrations	Lot	Specification
J1	SARS-CoV-2(402125), RNaseP	VLP	10^8~10^6	20200101	1000 μL/tube
J2	SARS-CoV-2(402125), RNaseP	VLP	10^4	20200101	1000 μL/tube
N	Negative pharynx swab substance	sample	/	20200101	1000 μL/tube

*Limited by the inaccessibility of adequate positive samples of SARS-COV-2, we prepared the reference panel J1 J2 and N by using SARS-CoV-2 VLPs made by Tsinghua University and RNaseP VLPs， substance of negative pharynx swab sample, respectively, to mimic the real clinical

samples

Method

Two operators test the kit of three different lots on the identical instrument by using J1, J2 and N with the same method. The test was carried out for 20 successive days. Measurement precision was evaluated based on the all test results in those 20 days.

Results

Detailed results are provided by R&D department. The analysis results are as it follows.

Table 1. Intra-/inter-lot precision

Precision（CV，%）	J1		J2	
	ORF1ab	N	ORF1ab	N
Lot-to-lot precision	1.48%	1.77%	1.28%	1.28%
Within-lot precision	1.36%	1.45%	1.44%	1.09%

As illustrated in table 1, it shows that both the within-lot and lot-to-lot variation coefficients are less than 5% implying that there are no statistically significant variations among the results from separate runs within-lot or those with different kits.

Table 2. Intra-/inter-day precision

precision（CV，%）	J1		J2	
	ORF1ab	N	ORF1ab	N
Within-day precision	1.64%	1.20%	1.65%	1.19%
Day-to-day precision	1.29%	1.48%	1.38%	1.06%

As illustrated in table 2, it shows that both the within-day and day-to-day variation coefficients are less than 5% implying that there are no statistically significant variations among the results from separate runs within-days or those carried out on different days.

Table 3. Intra-/inter-operator precision

precision（CV，%）	J1		J2	
	ORF1ab	N	ORF1ab	N
within-operator precision	1.48%	1.19%	1.52%	0.37%
operator-to-operator precision	0.95%	1.02%	1.00%	0.76%

As illustrated in table 3, it shows that both the within-operator and operator-to-operator variation coefficients are less than 5% implying that there are no statistically significant variations among the results from separate runs carried out by the same operator or those carried out by two different operators.

Conclusion

Results from runs in the 20 successive days demonstrate that the coefficients of intra-/inter-lot variation, intra-/inter-day variation and intra-/inter-operator variation are all less than 5% (%CV<5%). It is concluded by the researchers that the measurement precision of the SARS-CoV-2 detection kit can ensure the reproducible and repeatable test therefore meet the requirement from the users.