

Dose Hook Effect Study Report of COVID-19 Antigen Rapid Test

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Dose Hook Effect Study Report of COVID-19 Antigen Rapid Test

1. Purpose

To determine if there is a remaining risk of false negative results identified due to a high dose hook effect.

2. Material

ICOV-502 Lot1: COV20060001-T
 Lot2: COV20060002-T
 Lot3: COV20060003-T

3. Test methods

A recombinant COVID-19 protein was diluted with dilution to 100ug/ml, 10ug/ml, 1ug/ml, 100ng/ml, 10ng/ml, 1ng/ml, 100pg/ml, 50pg/ml and 1pg/ml and tested according to the package insert in replicates of three. The results were rated at 15 minutes. Results were presented in Table below.

4. Acceptance Criteria

There is no dose hook effect.

5. Result

Table: Dose Hook Study Results

| Specimens | ICOV-502 | | | | | | | | |
|-----------|---------------|---|---|---------------|---|---|---------------|---|---|
| | COV20060001-T | | | COV20060002-T | | | COV20060003-T | | |
| | 15min | | | 15min | | | 15min | | |
| 100ug/ml | + | + | + | + | + | + | + | + | + |
| 10ug/ml | + | + | + | + | + | + | + | + | + |
| 1ug/ml | + | + | + | + | + | + | + | + | + |
| 100ng/ml | + | + | + | + | + | + | + | + | + |
| 10ng/ml | + | + | + | + | + | + | + | + | + |
| 1ng/ml | + | + | + | + | + | + | + | + | + |
| 100pg/ml | + | + | + | + | + | + | + | + | + |
| 50pg/ml | - | - | - | + | - | - | - | - | - |
| 1pg/ml | - | - | - | - | - | - | - | - | - |
| Dilution | - | - | - | - | - | - | - | - | - |

Note: "+" mean positive result, "-" mean negative result.

When different samples were tested, 100ug/ml, 10ug/ml, 1ug/ml, 100ng/ml, 10ng/ml, 1ng/ml, 100pg/ml test results were all positive, 50pg/ml test results were partly positive and partly negative, 1pg/ml and Dilution test results were all negative. That is, with the increase of concentration, the positive sample test results were still positive, so Hook effect was not found in the range of 0-100ug/ml.

6. Conclusion

Test results showed that there was no dose hook effect of the 3 lots of COVID-19 products.