

Analytical Performance

Limit of Detection

1 Main product

COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)

LOT 1: COA20G1001A LOT 2:COA20G1002A LOT 3:COA20G1001A

2 Purpose

The following study was done to assess the limit of detection of the COVID-19 Antigen Rapid Detection Kit (Colloidal Gold).

3 Method

Use the reference materials and virus culture to assess the limit of detection of the COVID-19 Antigen Rapid Detection Kit (Colloidal Gold).

Reference materials were diluted to 5mg/ml ,2.5ng/mL, 1ng/ml, 0.5ng/mL, 0.1ng/mL, 0.05ng/mL.

Virus culture were diluted to 1.088×10^5 , 5.44×10^4 , 2.72×10^4 , 1.36×10^4 , 6.8×10^3 , 3.4×10^3 , 1.7×10^3 , 8.5×10^2 , 4.25×10^2 , 2.12×10^2 TCID₅₀/mL.

Every specimen was tested for three times.

4 Interpretation of results

- Negative:There is only a red line appears in the quality control area (C), and no line appears in the test area (T).
- Positive:There are two red lines appear. One is in the test area (T) and the other is in the quality control area (C).
- Invalid:There is no red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged. Repeat the test with a new kit. If the problem persists, stop using this lot number immediately and contact your local supplier.

5 Limit of Detection of the kit

The minimum concentration detected by the kit was the LOD of the kit.

6 Results

materials	Lot1	Lot2	Lot3
5mg/ml	+ (3/3)	+ (3/3)	+ (3/3)
2.5ng/mL	+ (3/3)	+ (3/3)	+ (3/3)
1ng/ml	+ (3/3)	+ (3/3)	+ (3/3)
0.5ng/mL	+ (3/3)	+ (3/3)	+ (3/3)
0.1ng/mL	- (3/3)	- (3/3)	- (3/3)
0.05ng/mL	- (3/3)	- (3/3)	- (3/3)

1.088x10 ⁵	+ (3/3)	+ (3/3)	+ (3/3)
5.44x10 ⁴	+ (3/3)	+ (3/3)	+ (3/3)
2.72x10 ⁴	+ (3/3)	+ (3/3)	+ (3/3)
1.36x10 ⁴	+ (3/3)	+ (3/3)	+ (3/3)
6.8x10 ³	+ (3/3)	+ (3/3)	+ (3/3)
3.4x10 ³	+ (3/3)	+ (3/3)	+ (3/3)
8.5x10 ²	+ (3/3)	+ (3/3)	+ (3/3)
4.25x10 ²	- (3/3)	- (3/3)	- (3/3)
2.12x10 ²	- (3/3)	- (3/3)	- (3/3)

The kit test the Reference materials .The content more than 0.5ng/mL should be positive and content less than 0.5ng/mL should be negative. LoD of the kit is 8.5x10²TCID₅₀/mL.