



# 2019-nCOV Ab Test (Colloidal Gold)

## Clinical Test Report



# Clinical Report

## 1. Objective

To evaluate the quality performance and clinical application value of 2019-nCoV AbTest (Colloidal Gold). Clinical research was conducted in 5 institutions.

## 2. Sample amount and type

In this clinical study, the total sample amount was 517. (1) Confirmed cases: Both Clinical and PCR confirmed cases (212 cases in all). (2) Excluded cases: Both Clinical and PCR excluded cases (305 cases in all).

## 3. Test Sensitivity and specificity analysis of assessment reagents

### 3.1 IgM Results for all samples

Table 1: IgM Results for All Samples

		PCR Results		total
		Positive	Negative	
2019-nCOV Ab Test--IgM Result	Positive	(A) 151	(B) 5	(A+B)156
	Negative	(C) 61	(D) 300	(C+D) 361
Total		(A+C) 212	(B+D) 305	(A+B+C+D) 517

PPA (Positive percentage agreement)=A / (A+C)	71.23%	95%CI	64.80% -76.90%
NPA (Negative percentage agreement)= D/ (B+D)	98.36%	95%CI	96.22%-99.30%
Overall agreement	87.23%	95%CI	84.08% -89.84%

**Conclusion** : The IgM PPA is 71.23%, and the IgM NPA is 98.36%, the IgM overall agreement is 87.23%.



### 3.2 IgG results for all samples

Table 2: IgG Results for All Samples

		PCR Results		total
		Positive	Negative	
2019-nCOV Ab Test-IgG Result	Positive	(A) 184	(B) 1	(A+B) 185
	Negative	(C) 28	(D) 304	(C+D) 332
Total		212	(A+C) 305	(B+D) 517

PPA (Positive percentage agreement)=A / (A+C)	86.79%	95%CI	81.57% -90.70%
NPA (Negative percentage agreement)= D/ (B+D)	99.67%	95%CI	98.17% -99.94%
Overall agreement	94.39%	95%CI	92.06% -96.07%

**Conclusion :** The IgG PPA is 86.79%, and the IgG NPA is 99.67%, the IgG overall agreement is 94.39%.

### 3.3 Overall Clinical Study Results for all samples

Table 3: Overall Clinical Study Results for All Samples

			PCR		Total
			Positive	Negative	
2019-nCOV Ab Test Result	Positive	IgG+/IgM+	141	0	141
		IgG-/IgM+	10	5	15
		IgG+/IgM-	43	1	44
	Negative	IgG-/IgM-	18	299	317
Total			212	305	517

PPA (Positive percentage agreement)	91.51%	95%CI	86.98% -94.56%
NPA (Negative percentage agreement)	98.03%	95%CI	95.78% -99.10%
Overall agreement	95.36%	95%CI	93.19% -96.86%



#### 4. Clinical Study Results by Days Post Hospital Admission

##### 4.1 IgM Results for 163 samples by days post hospital admission

Table 4: IgM Results for 163 Samples by Days Post Hospital Admission

By days since to the hospital	PCR	IgM		
	Positive at any time	Positive	PPA	95%CI
≤7 days	107	84	78.50%	69.81% -85.23%
8-14 days	26	20	76.92%	57.95% -88.97 %
>15 days	30	15	50%	33.15% -66.85%

##### 4.2 IgG Results for 163 samples by days post hospital admission

Table 5: IgG Results for 163 Samples by Days Post Hospital Admission

By days since to the hospital	PCR	IgG		
	Positive at any time	Positive	PPA	95%CI
≤7 days	107	88	82.24%	73.7% -88.2%
8-14 days	26	24	92.31%	75.86% -97.87%
>15 days	30	30	100%	88.65% -100%

##### 4.3 Overall Clinical Study Results for 163 samples by days post hospital admission

Table 6: Overall Clinical Study Results by Days Post Hospital Admission

By days since to the hospital	PCR	IgM or IgG		
	Positive at any time	Positive	PPA	95%CI
≤7 days	107	94	87.85%	80.32% -92.76%
8-14 days	26	25	96.15%	81.11% -99.32%
>15 days	30	30	100%	88.65% -100%



**KBMO**

DIAGNOSTICS

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