

Clinical Evaluation Report

Product name: Rapid COVID-19 Antigen Test (Colloidal Gold)

Company name: InTec PRODUCTS, INC.

Duration of experiment: October 12, 2020 to February 05, 2021

Objective

InTec PRODUCTS, INC. intends to introduce Rapid COVID-19 Antigen Test (Colloidal Gold) into the market. The objective of this study was designed to evaluate the user performance of COVID-19 Antigen Colloidal Gold Test.

The test results of samples from clinical cases were compared with PCR results of cases to verify the clinical performance of the test reagent.

1. Background information for clinical evaluation

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary for patient management.

2. Materials and Equipment

- (1) Rapid COVID-19 Antigen Test (Colloidal Gold)
Lot: S20200910 (X1), S20200911 (X 2), S20200912 (X3)
Manufacturer: InTec PRODUCTS, INC.
- (2) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV
Lot: S1572054
Manufacturer: BGI Genomics Co, Ltd.
- (3) Real time fluorescence quantitative PCR
Type: ABI 7500
Manufacturer: Applied Biosystems
- (4) Clinical specimens

3. Evaluation Sites

- (1) POC in Guangzhou, China
- (2) POC in Xiamen, China
- (3) POC in Beijing, China

The above POC are the designated laboratory for COVID-19 testing, and each POC is operated by 3-5 professionals.

4. Number of clinical specimens

Tab1 Number of clinical specimens

Group	PCR result (Nasopharyngeal swab)	Sample type	Number	Collection Day
1	Positive	Nasopharyngeal swab	At least 100 cases	2020/10/12 to 2021/2/1
		Saliva	At least 100 cases	
2	Negative	Nasopharyngeal swab	At least 200 cases	2020/10/12 to 2021/2/1
		Saliva	At least 200 cases	

5. Criteria for Participant

- (1) Gender: Male or female.
- (2) Age: no restriction, the neonatal excluded.
- (3) Days from Symptom Onset

Days from Symptom Onset	0-3 days	4-7 days	>7 days
Percentage	40%	40%	20%

- (4) Test within 48 hours after sample collection.

6. Clinical specimens storage

- (1) Applicable clinical specimens type: Nasopharyngeal swab specimen, Saliva specimen
- (2) Storage: Samples should be tested as soon as possible after collection. Processed samples (add Extraction Solution) are stable for up to 24-hours at room temperature or 2° to 8°C and cannot be frozen.
- (3) The specimens must be balanced to room temperature before testing.

7. Operation

- (1) Specimens collection and information record

The main researchers of the clinical institutions designate special personnel to select the eligible cases according to the enrollment criteria, and collect the clinical information of the enrolled specimens, including: age, gender, clinical symptoms, clinical classification(mild or moderate), sample collection time and other information. The specimens are numbered according to the sequence before and after grouping, i.e. Specimens number.

- (2) Specimens blinding

The main researchers of the clinical institution designated the person to randomly number the specimens in the group with the random number generating tool, record the random number of the specimens and the corresponding specimens number, and the person arranged the specimens according to the sequence of the random number, and handed them to the test operator for testing according to this sequence, noting that the person and the test operator cannot be the same person.

- (3) Testing

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The test operator shall test the specimens and operate according to the instructions. PCR test is used for in vitro qualitative detection of novel coronavirus (2019-nCoV) ORF1ab, N gene and E gene in nasopharyngeal swab, oropharyngeal swab, sputum, and alveolar lavage fluid samples.

(4) Unblinding

At the end of the test, according to the corresponding relationship between random number and specimens number, record the test results.

(5) Result determination

The test results should be statistically analyzed with clinical diagnosis to evaluate the clinical application performance of the product.

8. Control method

(1) Before the start of clinical research, the enterprise shall train the researchers to make them familiar with and master the operation method and technical performance of the product, so as to minimize the test error.

(2) Researchers should strictly follow the product's operation specifications and related requirements for testing to ensure that the testing error can be minimized.

(3) The supervisors shall check the relevant activities and documents of the clinical trial, whether the trial is conducted in accordance with the test scheme, standard operating procedures and relevant regulations, and whether the test data is recorded in a timely, clear, accurate and complete manner.

9. Data management

(1) Traceability of data, filling and transfer of case report form

Ensure the traceability of clinical trial data. According to the original observation records of the subjects, the researchers recorded the data in the case report form in a timely, complete, accurate and clear manner. The supervisor shall monitor whether the trial is carried out in accordance with the plan, confirm that the case report form is filled in correctly and completely, and is consistent with the original data. In case of any mistake or omission, the researcher shall be required to correct it in time. The original record shall be kept clear and visible during modification, and the correction shall be signed and dated by the researcher.

(2) Data entry and modification

In order to ensure the accuracy of data, two data entry personnel are responsible for independent entry and proofreading. During the data analysis, for the questions in the case report form, the researcher should answer and return them as soon as possible, and the statistician should modify, confirm and input them according to the researcher's answers.

(3) Lock of database

At the end of the test, after data entry, the researcher and the sponsor check the data, and lock the data after confirming that the data is correct, and then lock the data for statistical analysis.

10. Results and Statistical Analysis

10.1 Results for Nasopharyngeal swab specimen

(1) Results analysis table

Tab2 Analysis table of clinical specimens results (Nasopharyngeal Swab)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	94(a)	0(b)	94(a+b)
Antigen Test(Colloidal	Negative	7(c)	299(d)	306(c+d)
Gold) result	Total	101(a+c)	299(b+d)	400(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab3 Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	93.1%	86.4%~96.6%
Clinical specificity	100%	98.7%~100%
Total coincidence rate	98.3%	96.4%~99.2%

10.2 Results for Saliva specimen

(1) Results analysis table

Tab4 Analysis table of clinical specimens results (Saliva)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	92(a)	2(b)	94(a+b)
Antigen Test(Colloidal	Negative	9(c)	297(d)	306(c+d)
Gold) result	Total	101(a+c)	299(b+d)	400(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab5 Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	91.1%	83.9%~95.2%
Clinical specificity	99.3%	97.6%~99.8%
Total coincidence rate	97.3%	95.1%~98.5%

10.3 Results for Total specimen

(1) Results analysis table

Tab6 Analysis table of clinical specimens results

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	186(a)	2(b)	188(a+b)
Antigen Test(Colloidal	Negative	16(c)	596(d)	612(c+d)
Gold) result	Total	202(a+c)	598(b+d)	800(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab7 Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	92.1%	87.5%~95.1%
Clinical specificity	99.7%	98.8%~99.9%
Total coincidence rate	97.8%	96.5%~98.6%

(3) Statistical Analysis

Kappa value(K) calculation

K=0.939>0.75 indicates that the high consistency of two methods and equivalence of two such systems.

11. Conclusion

11.1 800 samples were tested in this clinical trial, included 400 Nasopharyngeal swabs and 400 saliva specimens.

11.2 Among them, there were 782 cases with product test results consistent with PCR result in this clinical trial, included 186 cases were positive, 596 cases were negative.

11.3 There were 18 cases of product test results inconsistent with PCR result in this clinical trial.

PCR result	Product result	Number
-	S(+)	2
+	N(-),S(-)	4
+	N(-)	3
+	S(-)	5

* Nasopharyngeal swab: N, Saliva: S

11.4 The sensitivity of product testing and PCR result are 93.1% (for Nasopharyngeal swab) and 91.1%(for Saliva) respectively. The specificity of product testing and PCR result are 100% (for Nasopharyngeal swab) and 99.7% (for Saliva) respectively. The total coincidence rate of product testing and PCR result are 97.8%.

11.5 Among 800 samples clinical trial, K=0.939>0.75 indicates that the high consistency of two methods and equivalence of two such systems.