

SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method) Clinical evaluation report

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Clinical evaluation organization (seal): The First Affiliated Hospital of Anhui Medical University, Clinical Laboratory



Research Institute: Biohit Healthcare (Hefei) Co., Ltd.



S ARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)

Clinical evaluation report

Abstract

Target Evaluation of the performance and clinical application value of the SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)

Method The research method is retrospective study. 226 samples were tested in the First Affiliated Hospital of Anhui Medical University. Of these, 78 cases were other respiratory infection samples, 108 cases were normal samples and 40 cases were samples of patients with COVID-19. In this study, the clinical diagnosis results of the patients corresponding to these samples were taken as the reference standard. All samples were also tested for SARS-CoV-2 IgM and IgG antibody presence. The antibody test kit results were compared to the clinical diagnosis results for clinical performance evaluations using the clinical diagnosis results as gold standard. Kappa test was used for statistical analysis of test results and clinical diagnosis results.

Result The clinical sensitivity of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, total antibody (IgM and IgG) were 97.5% (39/40), 97.5% (39/40), and 97.5% (39/40) respectively. The clinical specificity was 99.5% (185/186), 100% (186/186), and 99.5% (185/186) respectively. The overall accuracy of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, and total antibody (IgM and IgG) was 99.1% (224/226), 99.6% (225/226), and 99.1% (224/226) respectively. The PPV of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, and total antibody (IgM and IgG) was 97.5% (39/40), 100% (39/39), and 97.5% (39/40) respectively. The NPV of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, and total antibody (IgM and IgG) was 99.5% (185/186), 99.5% (185/186), and 99.5% (185/186) respectively. Among the 226 samples used for the validation, 78 cases were for other respiratory infection samples. All these samples were negative for both IgM/IgG antibody testing and the clinical diagnosis, suggesting that there is

no cross-reactivity as the result of IgM/IgG antibody testing is exempt from other respiratory infections. Kappa analysis was performed on the test results and clinical diagnosis results. The kappa coefficient of SARS-CoV-2 IgM is 0.970, SARS-CoV-2 IgG is 0.985, and the total antibody (IgM and IgG) is 0.970.

Conclusion SARS-CoV-2 IgM and IgG antibody test kits can effectively screen for SARS-CoV-2 IgM and IgG antibody. It plays an important role in a variety of scenarios and is applied to medical and health institutions at all levels.

1 Overview

On March 4, 2020, the National Health Commission issued the "Diagnosis and Treatment Program for New Coronavirus Pneumonia (Trial version 7)"¹¹. It is pointed out that "serological test" should be added as a supplemental screening kit to the original nucleic acid test to test for the presence of SARS-CoV-2 antibodies.

Specific IgM antibody is produced early in the body after infection, suggesting initial infection or re-infection. IgG antibody is the main antibody produced by the body's re-immune response, suggesting that the disease enters the recovery period or the infection period is long. IgM antibody can be detected on the 7th day after infection of the SARS-CoV-2 or on the 3rd day of symptoms. The combined detection of IgM and IgG antibodies can help medical professions

2 Method

2.1 Sample

Serial number	Results of clinical diagnosis	Sample
1	Other respiratory infection samples	78 cases
2	Normal samples	108 cases
3	Covid-19 confirmed samples	40 cases

2.2 Reagent

The SARS-CoV-2 IgM/IgG antibody test kit (colloidal gold method) produced by Biohit Healthcare (Hefei) Co., Ltd. Kit lot: NCOV20200306.

2.3 Method

The SARS-CoV-2 IgM/IgG antibody test kit (colloidal gold method) was used according to the instructions. After adding the sample, count the time and read the result within 15 minutes. Results interpretation should follow the following interpretation principles: if quality control line C is not observed, the test results are

invalid regardless of whether there is a test line, and the test should be carried out again. The SARS-CoV-2 IgM antibody was detected if the quality control line C and the detection line M appeared, and the result was IgM antibody positive. The novel coronavirus IgG antibody was detected if the quality control line C and the detection line G appeared, and the result was IgG antibody positive.

2.4 Statistical analysis

Statistical method	Statistical software used
Sensitivity and specificity analysis	Excel
Kappa test analysis	SPSS

3 Result

Table I sample test results

Sample type	Number	Sample number	IgM	IgG	clinical diagnosis
Other respiratory infection sample	1	0224 -3501	negative	negative	negative
Other respiratory infection sample	2	0224-3502	negative	negative	negative
Other respiratory infection sample	3	0224-3503	negative	negative	negative
Other respiratory infection sample	4	0224-3507	negative	negative	negative
Other respiratory infection sample	5	0224-3508	negative	negative	negative
Other respiratory infection sample	6	0224-3509	negative	negative	negative
Other respiratory infection sample	7	0224-3510	negative	negative	negative
Other respiratory infection sample	8	0224-3511	negative	negative	negative
Other respiratory infection sample	9	0224-3512	negative	negative	negative
Other respiratory infection sample	10	0224-3513	negative	negative	negative
Other respiratory infection sample	11	0224-3514	negative	negative	negative
Other respiratory infection sample	12	0224-3517	negative	negative	negative
Other respiratory	13	0224-3520	Negative	negative	negative

infection sample					
Other respiratory infection sample	14	0224-3522	negative	negative	negative
Other respiratory infection sample	15	0227-3502	negative	negative	negative
Other respiratory infection sample	16	0227-3503	negative	negative	negative
Other respiratory infection sample	17	0227-3504	Negative	negative	negative
Other respiratory infection sample	18	0227-3505	negative	negative	negative
Other respiratory infection sample	19	0227-3506	Negative	negative	negative
Other respiratory infection sample	20	0227-3507	Negative	negative	negative
Other respiratory infection sample	21	0227-3508	Negative	negative	negative
Other respiratory infection sample	22	0227-3023	Negative	negative	negative
Other respiratory infection sample	23	0217-3501	Negative	negative	negative
Other respiratory infection sample	24	0217-3502	Negative	negative	negative
Other respiratory infection sample	25	0217-3503	Negative	negative	negative
Other respiratory infection sample	26	0217-3504	Negative	negative	negative
Other respiratory infection sample	27	0217-3505	Negative	negative	negative
Other respiratory infection sample	28	0217-3506	Negative	negative	negative
Other respiratory infection sample	29	0217-3507	Negative	negative	negative
Other respiratory infection sample	30	0217-3508	Negative	negative	negative
Other respiratory infection sample	31	0217-3509	Negative	negative	negative
Other respiratory infection sample	32	0217-3510	Negative	negative	negative
Other respiratory infection sample	33	0219-3501	Negative	negative	negative
Other respiratory infection sample	34	0219-3502	Negative	negative	negative

Other respiratory infection sample	35	0219-3503	negative	negative	negative
Other respiratory infection sample	36	0219-3504	negative	negative	negative
Other respiratory infection sample	37	0219-3505	negative	negative	negative
Other respiratory infection sample	38	0219-3506	negative	negative	negative
Other respiratory infection sample	39	0219-3507	negative	negative	negative
Other respiratory infection sample	40	0219-3508	Negative	negative	negative
Other respiratory infection sample	41	0219-3509	Negative	negative	negative
Other respiratory infection sample	42	0219-3510	Negative	negative	negative
Other respiratory infection sample	43	0305-3501	Negative	negative	negative
Other respiratory infection sample	44	0305-3502	Negative	negative	negative
Other respiratory infection sample	45	0305-3503	Negative	negative	negative
Other respiratory infection sample	46	0305-3504	Negative	negative	negative
Other respiratory infection sample	47	0305-3505	Negative	negative	negative
Other respiratory infection sample	48	0305-3506	Negative	negative	negative
Other respiratory infection sample	49	0305-3507	Negative	negative	negative
Other respiratory infection sample	50	0305-3508	Negative	negative	negative
Other respiratory infection sample	51	0305-3509	Negative	negative	negative
Other respiratory infection sample	52	0305-3510	Negative	negative	negative
Other respiratory infection sample	53	0307-3501	Negative	negative	negative
Other respiratory infection sample	54	0307-3502	Negative	negative	negative
Other respiratory infection sample	55	0307-3503	Negative	negative	negative
Other respiratory infection sample	56	0307-3504	Negative	negative	negative

infection sample					
Other respiratory infection sample	57	0307-3505	negative	negative	negative
Other respiratory infection sample	58	0307-3506	negative	negative	negative
Other respiratory infection sample	59	0307-3507	negative	negative	negative
Other respiratory infection sample	60	0307-3508	negative	negative	negative
Other respiratory infection sample	61	0307-3509	Negative	negative	negative
Other respiratory infection sample	62	0307-3510	Negative	negative	negative
Other respiratory infection sample	63	0307-3511	Negative	negative	negative
Other respiratory infection sample	64	0307-3512	Negative	negative	negative
Other respiratory infection sample	65	0313-3502	Negative	negative	negative
Other respiratory infection sample	66	0313-3503	Negative	negative	negative
Other respiratory infection sample	67	0313-3504	Positive	negative	negative
Other respiratory infection sample	68	0313-3505	Negative	negative	negative
Other respiratory infection sample	69	0313-3506	Negative	negative	negative
Other respiratory infection sample	70	0313-3507	Negative	negative	negative
Other respiratory infection sample	71	0313-3508	Negative	negative	negative
Other respiratory infection sample	72	0313-3509	Negative	negative	negative
Other respiratory infection sample	73	0313-3510	Negative	negative	negative
Other respiratory infection sample	74	0313-3511	Negative	negative	negative
Other respiratory infection sample	75	0313-4101	Negative	negative	negative
Other respiratory infection sample	76	0313-4102	Negative	negative	negative
Other respiratory infection sample	77	0313-4103	Negative	negative	negative

Other respiratory infection sample	78	0313-4104	negative	negative	negative
Normal sample	79	ZJY (12.25)	negative	negative	negative
Normal sample	80	HIZ (12.27)	negative	negative	negative
Normal sample	81	ZYX (11.28)	negative	negative	negative
Normal sample	82	CC (12.25)	negative	negative	negative
Normal sample	83	FLX (12.27)	negative	negative	negative
Normal sample	84	ZZJ (12.27)	negative	negative	negative
Normal sample	85	HJZ (12.25)	negative	negative	negative
Normal sample	86	WQF (12.26)	negative	negative	negative
Normal sample	87	XB (12.28)	negative	negative	negative
Normal sample	88	QZM (12.28)	negative	negative	negative
Normal sample	89	HHM (12.20)	negative	negative	negative
Normal sample	90	DBR (12.25)	negative	negative	negative
Normal sample	91	RJL(12.28)	negative	negative	negative
Normal sample	92	ZGJ (12.28)	negative	negative	negative
Normal sample	93	LML(12.26)	negative	negative	negative
Normal sample	94	YHQ (12.26)	negative	negative	negative
Normal sample	95	WYM (5.31)	negative	negative	negative
Normal sample	96	XJY (6.11)	negative	negative	negative
Normal sample	97	WFY (6.12)	negative	negative	negative
Normal sample	98	KXA(6.9)	negative	negative	negative
Normal sample	99	0227-01	negative	negative	negative
Normal sample	J00	0227-02	negative	negative	negative
Normal sample	101	0227-03	negative	negative	negative
Normal sample	102	0227-04	negative	negative	negative
Normal sample	103	0227-05	negative	negative	negative
Normal sample	104	0227-09	negative	negative	negative
Normal sample	105	0227-10	negative	negative	negative
Normal sample	106	0227-11	negative	negative	negative
Normal sample	107	0227-15	negative	negative	negative
Normal sample	108	0227-17	negative	negative	negative
Normal sample	109	0313-02	negative	negative	negative
Normal sample	110	0313-03	negative	negative	negative
Normal sample	111	0313-05	negative	negative	negative
Normal sample	112	0313-06	negative	negative	negative
Normal sample	113	0313-07	negative	negative	negative
Normal sample	114	0313-08	negative	negative	negative
Normal sample	115	0313-09	negative	negative	negative
Normal sample	116	0313-10	negative	negative	negative
Normal sample	117	0313-11	negative	negative	negative
Normal sample	118	0313-12	negative	negative	negative

Normal sample	119	0313-13	negative	negative	negative
Normal sample	120	0313-14	negative	negative	negative
Normal sample	121	0313-15	negative	negative	negative
Normal sample	122	0313-16	negative	negative	negative
Normal sample	123	0313-17	negative	negative	negative
Normal sample	124	0313-18	negative	negative	negative
Normal sample	125	0313-19	negative	negative	negative
Normal sample	126	0313-20	negative	negative	negative
Normal sample	127	0313-21	negative	negative	negative
Normal sample	128	0313-22	negative	negative	negative
Normal sample	129	0313-23	negative	negative	negative
Normal sample	130	0313-24	negative	negative	negative
Normal sample	131	0313-25	negative	negative	negative
Normal sample	132	0313-26	negative	negative	negative
Normal sample	133	0313-27	negative	negative	negative
Normal sample	134	0313-28	negative	negative	negative
Normal sample	135	0313-29	negative	negative	negative
Normal sample	136	0313-30	negative	negative	negative
Normal sample	137	0313-31	negative	negative	negative
Normal sample	138	0313-32	negative	negative	negative
Normal sample	139	0313-33	negative	negative	negative
Normal sample	140	0313-34	negative	negative	negative
Normal sample	141	0313-35	negative	negative	negative
Normal sample	142	0313-36	negative	negative	negative
Normal sample	143	0313-37	negative	negative	negative
Normal sample	144	0313-38	negative	negative	negative
Normal sample	145	0313-39	negative	negative	negative
Normal sample	146	0313-40	negative	negative	negative
Normal sample	147	0313-41	negative	negative	negative
Normal sample	148	0313-42	negative	negative	negative
Normal sample	149	0313-43	negative	negative	negative
Normal sample	150	0313-44	negative	negative	negative
Normal sample	151	0313-45	negative	negative	negative
Normal sample	152	0313-46	negative	negative	negative
Normal sample	153	0313-47	negative	negative	negative
Normal sample	154	0313-48	negative	negative	negative
Normal sample	155	0313-49	negative	negative	negative
Normal sample	156	0313-50	negative	negative	negative
Normal sample	157	0313-51	negative	negative	negative
Normal sample	158	0313-52	negative	negative	negative
Normal sample	159	0313-53	negative	negative	negative
Normal sample	160	0313-54	negative	negative	negative

Normal sample	161	0313-55	negative	negative	negative
Normal sample	162	0313-56	negative	negative	negative
Normal sample	163	0313-57	negative	negative	negative
Normal sample	164	0313-58	negative	negative	negative
Normal sample	165	0313-59	negative	negative	negative
Normal sample	166	0313-60	negative	negative	negative
Normal sample	167	0313-61	negative	negative	negative
Normal sample	168	0313-62	negative	negative	negative
Normal sample	169	0313-63	negative	negative	negative
Normal sample	170	0313-64	negative	negative	negative
Normal sample	171	0313-65	negative	negative	negative
Normal sample	172	0313-66	negative	negative	negative
Normal sample	173	0313-67	negative	negative	negative
Normal sample	174	0313-68	negative	negative	negative
Normal sample	175	0313-69	negative	negative	negative
Normal sample	176	0313-70	negative	negative	negative
Normal sample	177	0313-71	negative	negative	negative
Normal sample	178	0313-72	negative	negative	negative
Normal sample	179	0313-73	negative	negative	negative
Normal sample	180	0313-74	negative	negative	negative
Normal sample	181	0313-75	negative	negative	negative
Normal sample	182	0313-76	negative	negative	negative
Normal sample	183	0313-77	negative	negative	negative
Normal sample	184	0313-78	negative	negative	negative
Normal sample	185	0313-79	negative	negative	negative
Normal sample	186	0313-80	negative	negative	negative
COVID-19 confirmed Sample	187	01	positive	positive	positive
COVID-19 confirmed Sample	188	02	positive	positive	positive
COVID-19 confirmed Sample	189	03	positive	positive	positive
COVID-19 confirmed Sample	190	04	positive	positive	positive
COVID-19 confirmed Sample	191	05	positive	positive	positive
COVID-19 confirmed Sample	192	06	positive	positive	positive
COVID-19 confirmed Sample	193	07	positive	positive	positive
COVID-19 confirmed Sample	194	08	positive	positive	positive
COVID-19 confirmed	195	09	positive	positive	positive

sample					
COIVD-19 confirmed sample	196	10	positive	positive	positive
COIVD-19 confirmed sample	197	11	positive	positive	positive
COIVD-19 confirmed sample	198	12	positive	positive	positive
COIVD-19 confirmed sample	199	13	positive	positive	positive
COIVD-19 confirmed sample	200	14	positive	positive	positive
COIVD-19 confirmed sample	201	15	positive	positive	positive
COIVD-19 confirmed sample	202	16	positive	positive	positive
COIVD-19 confirmed sample	203	17	positive	positive	positive
COIVD-19 confirmed sample	204	18	positive	positive	positive
COIVD-19 confirmed sample	205	19	positive	positive	positive
COIVD-19 confirmed sample	206	20	positive	positive	positive
COIVD-19 confirmed sample	207	21	positive	positive	positive
COIVD-19 confirmed sample	208	22	positive	positive	positive
COIVD-19 confirmed sample	209	23	positive	positive	positive
COIVD-19 confirmed sample	210	24	positive	positive	positive
COIVD-19 confirmed sample	211	25	positive	positive	positive
COIVD-19 confirmed sample	212	26	positive	positive	positive
COIVD-19 confirmed sample	213	27	positive	positive	positive
COIVD-19 confirmed sample	214	28	positive	positive	positive
COIVD-19 confirmed sample	215	29	positive	positive	positive
COIVD-19 confirmed sample	216	30	positive	positive	positive

COIVD-19 confirmed sample	217	31	positive	positive	positive
COIVD-19 confirmed sample	218	32	positive	positive	positive
COIVD-19 confirmed sample	219	33	positive	positive	positive
COIVD- I9 confirmed sample	220	34	positive	positive	positive
COIVD-19 confirmed Sample	221	35	positive	positive	positive
COIVD-19 confirmed Sample	222	36	positive	positive	positive
COIVD-19 confirmed Sample	223	37	positive	positive	positive
COIVD-19 confirmed Sample	224	38	positive	positive	positive
COIVD-19 confirmed Samples	225	39	positive	positive	positive
COIVD-19 confirmed Sample	226	40	negative	negative	positive

4 Result analysis

4.1 Sensitivity and specificity analysis

(I) Sensitivity and specificity analysis of IgM

Table 2 Statistics of IgM results

Examination Reagent	Reference result		Total (case)
	Positive (case)	Negative (case)	
Positive (case)	39	1	40
Negative (case)	1	185	186
Total (case)	40	186	226

IgM sensitivity= $100\% \times 39/40 = 97.5\%$.

IgM specificity= $100\% \times 185/186=99.5\%$.

The total coincidence rate of IgM = $100\% \times 224/226 = 99.1\%$.

(2) Sensitivity and specificity analysis of IgG

Table 3 Statistics of IgG results

Examination	Reference result	Total (case)
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Reagent	Positive (case)	Negative (case)	
Positive (case)	39	0	39
Negative (case)	1	186	187
Total (case)	40	186	226

IgG sensitivity = $100\% \times 39/40 = 97.5\%$. IgG

specificity = $100\% \times 186/186 = 100\%$.

The total coincidence rate of IgG = $100\% \times 225/226 = 99.6\%$.

(3) Sensitivity and specificity analysis of total antibody

Table 4 statistical table of total antibody results

Examination Reagent	Reference result		Total (case)
	Positive (case)	Negative (case)	
Positive (case)	39	1	40
Negative (case)	1	185	186
Total (case)	40	186	226

Total antibody sensitivity = $100\% \times 39/40 = 97.5\%$.

Total antibody specificity = $100\% \times 185/186 = 99.5\%$.

The total coincidence rate of total antibody = $100\% \times 224/226 = 99.1\%$.

4.2 Consistency analysis: kappa test analysis

(1) IgM kappa analysis

Symmetry measure					
		value	Progressive standard error a	Approximate value Tb	Approximate value sig
Consistency measurement	Kappa	.970	.021	14.577	.000
N in valid cases		226			

a. Zero hypothesis is not assumed.

b. The assumption of zero is used.

(2) IgG kappa analysis

Symmetry measure					
		value	Progressive standard errorTOr a	Approximate value Tb	Approximate value sig

Consistency measurement	Kappa	.985	.015	14.804	.000
N in valid cases		226			

- a. Zero hypothesis is not assumed.
- b. The assumption of zero is used.

(3) Kappa analysis of total antibody

Symmetry measure

		value	Progressive standard error a	Approximate value Tb	Approximate value sig
Consistency measurement	Kappa	.970	.021	14.577	.000
N in valid cases		226			

- a. Zero hypothesis is not assumed.
- b. The assumption of zero is used.

5 Discussion

The novel coronavirus, also known as severe acute respiratory syndrome coronavirus -2 (SARS-CoV-2), causes respiratory inflammation, which leads to severe immune system disorder, which in turn leads to severe pneumonia. Secondary infection (nosocomial infection) is prone to occur during treatment, and severe cases can lead to severe injuries and deaths. It is a very serious health threats to people's lives and health and the seventh known coronavirus that can infect human Its genome is linear single strand positive RNA. The etiological basis for clinical diagnosis is either by positive the nucleic acid test results or the sequencing results showing that the disease gene sequence was highly homologous with SARS-CoV-2. A Diagnosis and

Treatment Program for New Coronavirus Pneumonia (Trial version 7) released by the National Health Committee in March 4, 2020 clearly stated that the uses of the serological antibody screening kits as a supplement to the nucleic acid testing should be increased to enhance the efficacy of the fight against COVID-19.

The key to SARS-CoV-2 IgM/IgG antibody test (colloidal gold method) is sensitivity and specificity. Therefore, it is necessary to verify the clinical sensitivity and clinical specificity of SARS-CoV-2 laboratory serological methodology. In this study, the clinical diagnosis results of the patients corresponding to the sample were taken as the reference standard. The results showed that the clinical sensitivity of SARS-CoV-2 IgM, SARS-CoV-2 IgG and SARS-CoV-2 total antibody were 97.5% (39/40), 97.5% (39/40) and 97.5% (39/40), and the clinical specificity were 99.5% (185/186), 100% (186/186) and 99.5% (185/186). The overall accuracy of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, and total antibody (IgM and IgG) was 99.1% (224/226), 99.6% (225/226), and 99.1% (224/226) respectively. The PPV of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, and total antibody (IgM and IgG) was 97.5% (39/40), 100% (39/39), and 97.5% (39/40) respectively. The NPV of the test for SARS-CoV-2 IgM antibody, SARS-CoV-2 IgG antibody, and total antibody (IgM and IgG) was 99.5% (185/186), 99.5% (185/186), and 99.5% (185/186) respectively. Among the 226 samples used for the validation, 78 cases were for other respiratory infection samples. All these samples were negative for both IgM/IgG antibody testing and the clinical diagnosis, suggesting that there is no cross-reactivity as the result of IgM/IgG antibody testing is exempt from other respiratory infections. The kappa consistency coefficient SARS-CoV-2 IgM was 0.970, that of SARS-CoV-2 IgG was 0.985, and that of SARS-CoV-2 total antibody was 0.970. The SARS-CoV-2 IgM/IgG antibody test (colloidal gold method) can meet the needs of clinical examination and can be used for screening of new coronavirus infection. The applicable sources of antibody serology test are serum, plasma or whole blood samples. The collection of blood samples is a standardized

operation. The samples are easy to preserve, and the antibody can exist stably in the blood samples, which ensures the sensitivity and repeatability of the test results. At the same time, there is no virus nucleic acid detected in the blood samples, hence greatly reducing the risk of infection and providing a safer working environment for medical and healthcare professionals. Colloidal gold reagent can be used for easy sampling with small sample consumption. Because of room temperature storage, low cost and convenient operation, it can realize rapid and large-scale detection, break through the limitations of nucleic acid testing on lab space, equipment, and operators, and play an important role in a variety of scenarios. Therefore, colloidal gold antibody detection kit has obvious advantages in laboratory test and preventive screening, which can be widely used in all levels of medical and health institutions.

Literature

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