THE THIRD AFFILIATED HOSPITAL,SUN YAT-SEN UNIVERSITY

Experimental Summary of SARS-CoV-2 Coronavirus Antigen Reagent Assay

1. Experimental Objective:

SARS-CoV-2 coronavirus antigen reagent (colloidal gold method) and nucleic acid detection of Shenzhen Green Spring Biotechnology Co., Ltd. is used to explore the equivalence of the reagent.

2. Experimental Time: January 19, 2021

3. Experimental Site: Clinical Laboratory of the Third Affiliated Hospital of Sun Yat-sen University

4. Intended Use, Principle and Testing Method of the Reagent

Intended Use: for qualitative detection of COVID-19 (2019-nCoV) antigen in nasal anterior end swab sample in vitro, mainly for screening of COVID-19 pneumonia.

Principle: this kit adopts colloidal gold immunochromatography. The detection card contains: 1) colloidal gold labeled mouse-derived COVID-19 antibody α; 2) fixed with nitrocellulose membrane of a detection line (T line) and a quality control line (C line). T line is fixed with mouse-derived COVID-19 antibody β, used to detect COVID-19 antigen, C line is fixed with quality control antibody. When an appropriate amount of the sample is added to the sample hole of the card, the sample will move forward along the card under capillary action. If the sample contains a COVID-19 antigen, the antigen will be captured by α, colloidal gold labeled mouse-derived COVID-19 antibody, which binds the membrane-fixed mouse-derived COVID-19 antibody β to form a purplish red T line, showing the COVID-19 antigen positive. The test card also contains a quality control line C. Regardless of whether there is a test line, purplish red quality control line C should always appear.

5. Experimental Design:

5.1 Experimental Materials

Evaluation of the Reagent: COVID-19 (2019-nCoV) antigen reagent (immune chromatography) of Shenzhen Green Spring Biotechnology Co., Ltd. Type of samples: nasal anterior end swab sample

5.2 Test Methods

The experimental procedure is as follows:

1. Read the instructions carefully before testing. The specimen, reagents and other materials need to be balanced to room temperature.

2. Open along the aluminum foil bag and remove the reagent card.

3. Add 2-3 drops (about 80-100 microliter) of nasal anterior end swab sample diluent to the sample hole (hole) of the test card.

4. The results of 15 min observation showed no clinical significance after 20 minutes observation.

5. Data statistics and analysis.

6. Selection, Number and Collection of Clinical Samples

(1) Inclusion criteria for clinical samples:

According to the diagnosis and treatment program for COVID-19 pneumonia (trial sixth edition), the patient's nasal anterior end swab sample is confirmed, sex and age are unlimited.

The nasal anterior end swab samples that meet the selection criteria are randomly selected for clinical research.

(2) Number of Samples

There are 275 samples in the experiment in total, with the reagent to be evaluated and the methods of single assay.

(3) Methods of sample collection

In principle, sample collection shall be conducted by professionals of the clinical unit according to the technical specifications of nasal front-end swab sample collection (except for special requirements of testing items).

7. Data Processing and Record Keeping

The experimenter shall accurately and completely record the data and results related to the experiment.

No.	1	2	3	4	5	6	7	8	9	10
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	11	12	13	14	15	16	17	18	19	20
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	21	22	23	24	25	26	27	28	29	30
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	31	32	33	34	35	36	37	38	39	40
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	41	42	43	44	45	46	47	48	49	50
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	51	52	53	54	55	56	57	58	59	60
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	61	62	63	64	65	66	67	68	69	70
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	71	72	73	74	75	76	77	78	79	80
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	81	82	83	84	85	86	87	88	89	90
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	91	92	93	94	95	96	97	98	99	100
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	101	102	103	104	105	106	107	108	109	110
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	111	112	113	114	115	116	117	118	119	120
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	121	122	123	124	125	126	127	128	129	130
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	131	132	133	134	135	136	137	138	139	140
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	141	142	143	144	145	146	147	148	149	150
	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
No.	151	152	153	154	155	156	157	158	159	160
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	161	162	163	164	165	166	167	168	169	170
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	171	172	173	174	175	176	177	178	179	180
	Positive	Positive	Negative	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	181	182	183	184	185	186	187	188	189	190
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	191	192	193	194	195	196	197	198	199	200
	Positive	Positive	Positive	Positive	Negative	Positive	Positive	Positive	Positive	Positive
No.	201	202	203	204	205	206	207	208	209	210

	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	211	212	213	214	215	216	217	218	219	220
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	221	222	223	224	225	226	227	228	229	230
	Positive	Positive	Positive	Positive	Positive	Positive	Negative	Positive	Positive	Positive
No.	231	232	233	234	235	236	237	238	239	240
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	241	242	243	244	245	246	247	248	249	250
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	251	252	253	254	255	256	257	258	259	260
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	261	262	263	264	265	266	267	268	269	270
	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
No.	271	272	273	274	275	/	/	/	/	/
	Positive	Positive	Positive	Positive	Negative	/	/	/	/	/

Conclusion:

No. 1-12 are coronavirusIIKU1> coronavirus0C43, coronavirusNL63, coronavirus229E, HPIV-K HPIV-2, HPIV-3, HPIV-4, HRV, HAV, HRSV, mycoplasma pneumoniae virus culture medium, with negative results.

No. 12-150 (excluding COVID-19 patients) are 100% coincidence with negative specimens.

No .151-275 are from the newly diagnosed COVID-19 patients, and the results from Green Spring are 121 positive samples, with 96.8% coincidence.

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Operator: 操作人

Auditor: 审核人

Special Seal for Clinical Laboratory, Third Affiliated Hospital of Sun Yat-sen University