

# Clinical Validation Report

**Product name:** Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit

**Manufacturer:** Jiangsu Biopertectus Technologies Co., Ltd.

**Specification:** 50 tests/kit

**Clinical Trial Institution(seal):** The Fifth Hospital of Da Qing City

**Responsible Person:** Jianqi Tong

**Applicant Institution:** Jiangsu Biopertectus Technologies Co., Ltd.

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**Contact:** Jiafa Xu

**Report Date:** April 4, 2021

## **Abstract**

To evaluate the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit manufactured by Jiangsu Bioperfectus Technologies Co., Ltd. for clinical application in qualitative detection of SARS-CoV-2 antigen in clinical samples. A total of 989 nasal swab samples were enrolled in the clinical trial, including 170 positive samples and 819 negative samples whose results were confirmed by diagnosis and treatment protocol. COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) manufactured by Jiangsu Bioperfectus Technologies Co., Ltd. was used as the reference kit. Based on the test results of the COVID-19 Coronavirus Real Time PCR Kit, the samples were random divided into different groups. Then, the samples were tested with the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit, and the test results of the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and the COVID-19 Coronavirus Real Time PCR Kit were compared and statistically analyzed. The results showed that the Positive Percent Agreement, Negative Percent Agreement, Overall Percent Agreement, Positive Predictive Value and Negative Predictive Value between the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and the COVID-19 Coronavirus Real Time PCR Kit all were greater than 90%, indicating that the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit is in good consistency with the COVID-19 Coronavirus Real Time PCR Kit, and suitable for clinical diagnosis.

## **1. Overview**

### **1.1. Introduction**

#### **1.1.1. Background information**

Coronavirus (CoV) belongs to the family Coronaviridae and is divided into three genera:  $\alpha$ ,  $\beta$  and  $\gamma$ . The  $\alpha$  and  $\beta$  genus are only pathogenic to mammals, while the  $\gamma$  genus mainly causes infection in birds. CoV is mainly transmitted through direct contact with secretions, by aerosols and droplets, and by the fecal-oral route. CoV infections generally manifest as upper respiratory tract infections and/or with gastrointestinal symptoms, and severe cases are more common in infants, the elderly, and people with low immune function. Up to now, there have been six strains of CoV (CoV-229E, CoV-OC43, CoV-NL63, CoV-HKU1, SARS-CoV and MERS-CoV) causing human respiratory diseases. The recent epidemic of SARS-CoV-2 showed very efficient transmission with clinical manifestations that range from asymptomatic to flu-like symptoms, high fever, cough, dyspnea, to rapid progress to pneumonia and respiratory failure, acute respiratory distress syndrome, which could be life-threatening. Most infected individuals experience also gastrointestinal symptoms such as vomit or diarrhea. Although detection of SARS-CoV-2 RNA by real-time RT-PCR test has become the standard method for diagnosis, these many limitations, particularly for rapid screenings. Therefore, there is an urgent need for an accurate and rapid test method to quickly identify large number of infected patients and asymptomatic carriers to prevent virus transmission and assure timely treatment of patients.

#### **1.1.2. Testing principle**

The Ag rapid test performed here is based on an immunochromatographic technology to detect the presence of the viral antigen. The detection area of the strip has a test line (T line) and a control line (C line). Novel corona virus (SARS-CoV-2) antibody is coated on the T line and recombinant streptococcal protein G (r-SPG) is coated on the C line. An antibody against the SARS-CoV-2 virion is gold-labeled and mixed with the test sample. When starting the test, the sample mixed with the gold-labelled antibody will be added to the sample well on the cassette. The sample will then flow onto the nitrocellulose membrane by capillarity. If the (SARS-CoV-2 antigen is present in the sample, the antigen will form a complex with the colloidal gold-labeled antibody. The complex will be captured by the antibody coated in the T line area. In this case, a visible T line will appear on the detection area as the presence of SARS-CoV-2 antigen. The colloidal gold-labeled antibody will also be captured by the r-SPG in the C line area, resulting a colored C line as the indication of a valid test. If the SARS-CoV-2 antigen is not present in the sample or antigen concentration is lower than the detection limit of this method, only a C line will be visible.

#### **1.1.3. Intended use**

The Bioperfectus Technologies Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens, nasopharyngeal swab specimens or oropharyngeal swab specimens from individuals who are suspected of COVID-19.

## **2. Main objective**

The main objective of this study is to independently evaluate the performance of Bioperfectus Technologies Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit manufactured by Jiangsu Bioperfectus Technologies Co., Ltd. for the direct detection of SARS-CoV-2 nucleocapsid

antigens in comparison to RT-PCR method. Swab specimens are prospectively or retrospectively collected from asymptomatic or symptomatic individuals.

### **3. Test Management**

#### **3.1. Management structure**

The clinical trial was conducted by the clinical trialing agency (The Fifth Hospital Of Da Qing City). As the applicant, Jiangsu Bioperfectus Technologies Co., Ltd. was responsible for communication and contact during the clinical trial.

#### **3.2. Quality control in the laboratory**

1) All researchers participating in this clinical trial shall have passed the qualification examination and had professional background and capacity related to clinical trial. Before the clinical trial, all researchers had a full understanding of the specific contents about the clinical trial protocol and all indexes through training.

2) The quality control of the laboratory shall meet the requirements of quality control of clinical laboratory to ensure the standardization of test procedure.

3) Quality control before the analysis: Sample collection and preparation was checked for compliance with the requirements and, sample number and other information were checked for correctness.

4) The execution and completion of clinical trial was inspected regularly. The completeness and precision of clinical sample information was checked and the test results were verified.

#### **3.3. Statistics and data management**

1) All selected cases were filled in the clinical outcome summary sheet, including sample number, age, gender, etc. The operators are responsible for recording the test results of the reference kit and the Test Kit in the clinical outcome summary sheet.

2) After finishing data entry, the main researchers, testers and applicant jointly reviewed the data and locked the data when they had no doubt.

3) The clinical outcome summary sheet was then sent to analysts for statistics and analysis. The obtained statics and analysis results were incorporated into corresponding parts of the clinical report.

#### **3.4. Data preservation**

The testing agency and the applicant each keeps a copy of clinical trial documents. The documents including the following contents: Clinical Trial Agreement, Clinical Test Protocol, Ethics Committee Instructions, Clinical Test Report (testing agency's report), General Report on Clinical Trial, and Clinical Outcome Summary Sheet.

### **4. Study design**

#### **4.1. Description of overall test design and protocol**

The clinical trial protocol was reference to the Guideline of Clinical Study on *In Vitro* Diagnostic Reagents. The appropriate study objects are selected. COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) manufactured by Jiangsu Bioperfectus Technologies Co., Ltd. which have approved by NMPA was used as the reference kit. The trial was conducted in a blind mode. At least 900 nasal swab samples should be enrolled as the study objects in the trial. Samples were random divided into different groups according

to the test results of reference kit. Then, the samples were tested with the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit, and the test results of the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and the COVID-19 Coronavirus Real Time PCR Kit were compared and statistically analyzed. Positive Percent Agreement, Negative Percent Agreement, Overall Percent Agreement, Positive Predictive Value and Negative Predictive Value between the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and the COVID-19 Coronavirus Real Time PCR Kit was calculated to judge the clinical suitability and accuracy of the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit, and whether the test result of the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit was consistent with that of the PCR method.

## 4.2. Research method

### 1) Sample collection, storage, transportation

Swabs were placed in dry and clean tubes and store at 2~8°C for no more than 24 hours after been collected.

### 2) Sample Selection and Exclusion Criteria

Inclusion:

- a) Recently confirmed or suspect COVID-19
- b) Understands and signs the consent form
- c) Agrees to provide medical history and Nasal swab specimens
- d) Completed data and information

Exclusion:

- a) Recently have an inoculation
- b) Incomplete information
- c) Specimens were not stored or transported as requested
- d) Operate miss
- e) Specimens were contaminated

### 3) Determination of method for comparison

COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) manufactured by Jiangsu Bioperfectus Technologies Co., Ltd. was approved for marketing by NMPA and was widely used in clinical and obtained the consistent high praise. Therefore, the COVID-19 Coronavirus Real Time PCR Kit is selected as a reference kit in the clinical study.

### 4) Names, specifications, sources, lot number, expiry dates and preservation conditions of the products for clinical study

Product name for clinical study is SARS-CoV-2 Antigen Rapid Test Kit, and the specification is 50 tests/kit. The product is manufactured and provided by Jiangsu Bioperfectus Technologies Co., Ltd. The lot number is 20201101, and its shelf-life is 12 months. The storage condition is 4°C-30°C. The reference kit is COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) manufactured by Jiangsu Bioperfectus Technologies Co., Ltd., the specification is 50 tests/kit, its shelf-life is 12 months and the storage condition is dark place with -20°C±5°C.

### 5) Quality control method

- 1) The person in charge of the clinical investigation institution and the person in charge of

the implementation of the clinical investigation program are delegated to discuss, modify and confirm the program; to train participate in clinical investigations;

- 2) Strictly in accordance with the clinical investigation program;
- 3) The same batch of reagent and the same type of instrument are used for testing. Every test is conducted with quality control and related information is kept;
- 4) The experiment is carried out in strict accordance with the operating instructions of the kit to ensure the accuracy of the test data;
- 5) Preserve the complete clinical investigation original record;
- 6) During the clinical investigation, the manufacturer should supervise the main investigators of the medical institution, check the progress of the project in charge of the clinical investigation, record and solve the main problems, and check whether the test records are complete, whether the obtained data is authentic or traceable, and whether there are potential data modifications, etc.;
- 7) Each case must have a uniform number;
- 8) Clinical data and test results are filled in unified forms;
- 9) All clinical data and test results should be signed by designated persons.

#### 6) Clinical trial method

All test samples were simultaneously tested with the COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) and the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit, and the test results of the two methods were compared. When all clinical samples were tested, the recorded test results of the antigen test kit and the reference kit were statistically analyzed, to calculate the Positive Percent Agreement, Negative Percent Agreement, Overall Percent Agreement, Positive Predictive Value and Negative Predictive Value and then evaluate whether they were equivalent according to these statistical indexes.

#### 7) Statistical analysis methods for clinical study data

Tested reagent	Reference reagent		Total
	Positive	Negative	
Positive	A	B	A+B
Negative	C	D	C+D
Total	A+C	B+D	N(A+B+C+D)

(1) Positive Percent Agreement:  $A / (A+C)$

(2) Negative Percent Agreement:  $D / (B+D)$

(3) Overall Percent Agreement:  $(A+D) / (A+B+C+D)$

(4) Positive Predictive Value:  $A / (A+B)$

(5) Negative Predictive Value:  $(D) / (C+D)$

### 5. Statistical analysis

A total of 508 samples were enrolled and tested.

The detailed cases are summarized in the form of four-fold table. The agreement between the RT-PCR test and Bioperfectus Ag Rapid tests were calculated with all the valid results, as indicated.

<b>Ag Rapid Test Results</b>	<b>PCR results</b>		
	<b>Positive</b>	<b>Negative</b>	<b>Total</b>
<b>Positive</b>	165	7	172
<b>Negative</b>	5	812	817
<b>Total</b>	170	819	989

PPA(Positive Percent Agreement): 97.06%, 95%CI: 93.30%~98.74%

NPA(Negative Percent Agreement): 99.15%, 95%CI: 98.25%~99.59%

OPA(Overall Percent Agreement): 98.79%, 95%CI: 97.89%~99.30%

PPV(Positive Predictive Value): 95.93%, 95%CI: 91.84%~98.01%

NPV(Negative Predictive Value): 99.39%, 95%CI: 98.58%~99.74%

As illustrated in the table, 170 samples were confirmed positive by the COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) and 165 of which were tested as positive by the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit. 819 samples were confirmed negative by the COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384) and 812 of which were tested as negative by the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit. The results show that the negative coincidence rate, positive coincidence rate and total coincidence rate all are greater than 95%, indicating that they are in good consistency with those of the reference kit.

## **6. Discussion and Conclusion**

The Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit manufactured by Jiangsu Bioperfectus Technologies Co., Ltd. is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from individuals who are suspected of COVID-19.

The sensitivity and specificity of the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit are both greater than 95% compared to that of RT-PCR results, suggesting the good consistency between the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and COVID-19 Coronavirus Real Time PCR Kit (GXZZ 20203400384), indicating that the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit can effectively detect the SARS-CoV-2 antigens.

## Annex I Clinical Trial Data

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
1	Negative	Negative	31	Positive	Positive	61	Negative	Negative
2	Negative	Negative	32	Negative	Negative	62	Negative	Negative
3	Positive	Positive	33	Negative	Negative	63	Negative	Negative
4	Negative	Negative	34	Negative	Negative	64	Negative	Negative
5	Negative	Negative	35	Negative	Negative	65	Negative	Negative
6	Positive	Positive	36	Positive	Positive	66	Negative	Negative
7	Negative	Negative	37	Negative	Negative	67	Negative	Negative
8	Negative	Negative	38	Negative	Negative	68	<b>Negative</b>	Positive
9	Negative	Negative	39	Negative	Negative	69	Positive	Positive
10	Negative	Negative	40	Negative	Negative	70	Negative	Negative
11	Negative	Negative	41	Negative	Negative	71	Negative	Negative
12	Negative	Negative	42	Negative	Negative	72	Negative	Negative
13	Negative	Negative	43	Negative	Negative	73	Negative	Negative
14	Negative	Negative	44	<b>Positive</b>	Negative	74	Positive	Positive
15	Negative	Negative	45	Negative	Negative	75	Negative	Negative
16	Positive	Positive	46	Positive	Positive	76	Negative	Negative
17	Negative	Negative	47	Negative	Negative	77	Negative	Negative
18	Negative	Negative	48	Negative	Negative	78	Negative	Negative
19	Negative	Negative	49	Negative	Negative	79	Positive	Positive
20	Negative	Negative	50	Negative	Negative	80	Negative	Negative
21	Negative	Negative	51	Negative	Negative	81	Positive	Positive
22	Positive	Positive	52	Negative	Negative	82	Negative	Negative
23	Negative	Negative	53	Negative	Negative	83	Negative	Negative
24	Negative	Negative	54	Positive	Positive	84	Positive	Positive
25	Negative	Negative	55	Negative	Negative	85	Negative	Negative
26	Negative	Negative	56	Positive	Positive	86	Positive	Positive
27	Negative	Negative	57	Negative	Negative	87	Negative	Negative
28	Positive	Positive	58	Negative	Negative	88	Positive	Positive
29	Negative	Negative	59	Negative	Negative	89	Negative	Negative
30	Negative	Negative	60	Negative	Negative	90	Negative	Negative



Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
91	Negative	Negative	121	Positive	Positive	151	Negative	Negative
92	Negative	Negative	122	Negative	Negative	152	Negative	Negative
93	Negative	Negative	123	Negative	Negative	153	Negative	Negative
94	Negative	Negative	124	Negative	Negative	154	Positive	Positive
95	Negative	Negative	125	Negative	Negative	155	Negative	Negative
96	Negative	Negative	126	Positive	Positive	156	Negative	Negative
97	Negative	Negative	127	Negative	Negative	157	Positive	Positive
98	Negative	Negative	128	Negative	Negative	158	Negative	Negative
99	Positive	Positive	129	Negative	Negative	159	Positive	Positive
100	Positive	Positive	130	Negative	Negative	160	Negative	Negative
101	Positive	Positive	131	Negative	Negative	161	Negative	Negative
102	Negative	Negative	132	Positive	Positive	162	Negative	Negative
103	Negative	Negative	133	Negative	Negative	163	Positive	Positive
104	Negative	Negative	134	Negative	Negative	164	<b>Positive</b>	Negative
105	Positive	Positive	135	Positive	Positive	165	Negative	Negative
106	Negative	Negative	136	Negative	Negative	166	Negative	Negative
107	Negative	Negative	137	Negative	Negative	167	Negative	Negative
108	Negative	Negative	138	Negative	Negative	168	Negative	Negative
109	Negative	Negative	139	Negative	Negative	169	Negative	Negative
110	Positive	Positive	140	Negative	Negative	170	Negative	Negative
111	Negative	Negative	141	Positive	Positive	171	Negative	Negative
112	Positive	Positive	142	Negative	Negative	172	Positive	Positive
113	Negative	Negative	143	Negative	Negative	173	Negative	Negative
114	Positive	Positive	144	Negative	Negative	174	Negative	Negative
115	Positive	Positive	145	Negative	Negative	175	Negative	Negative
116	Positive	Positive	146	<b>Negative</b>	Positive	176	Negative	Negative
117	Negative	Negative	147	Negative	Negative	177	Positive	Positive
118	Negative	Negative	148	Negative	Negative	178	Negative	Negative
119	Negative	Negative	149	Negative	Negative	179	Negative	Negative
120	Positive	Positive	150	Negative	Negative	180	Negative	Negative

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
181	Negative	Negative	211	Negative	Negative	241	Negative	Negative
182	Negative	Negative	212	Negative	Negative	242	Negative	Negative
183	Positive	Positive	213	Negative	Negative	243	Negative	Negative
184	Negative	Negative	214	Negative	Negative	244	Negative	Negative
185	Negative	Negative	215	Negative	Negative	245	Negative	Negative
186	Negative	Negative	216	Positive	Positive	246	Positive	Positive
187	Negative	Negative	217	Negative	Negative	247	Negative	Negative
188	Negative	Negative	218	Negative	Negative	248	Negative	Negative
189	Negative	Negative	219	Negative	Negative	249	Negative	Negative
190	Negative	Negative	220	Negative	Negative	250	Negative	Negative
191	Negative	Negative	221	Positive	Positive	251	Negative	Negative
192	Negative	Negative	222	Negative	Negative	252	Negative	Negative
193	Positive	Positive	223	<b>Positive</b>	Negative	253	Negative	Negative
194	Negative	Negative	224	Positive	Positive	254	Negative	Negative
195	Negative	Negative	225	Negative	Negative	255	Negative	Negative
196	Negative	Negative	226	Positive	Positive	256	Negative	Negative
197	Negative	Negative	227	Negative	Negative	257	Negative	Negative
198	Negative	Negative	228	Positive	Positive	258	Positive	Positive
199	Positive	Positive	229	Positive	Positive	259	Negative	Negative
200	Positive	Positive	230	Positive	Positive	260	Negative	Negative
201	Negative	Negative	231	Negative	Negative	261	Negative	Negative
202	Negative	Negative	232	Negative	Negative	262	<b>Positive</b>	Negative
203	Positive	Positive	233	Negative	Negative	263	Negative	Negative
204	Positive	Positive	234	Negative	Negative	264	Negative	Negative
205	Positive	Positive	235	Negative	Negative	265	Negative	Negative
206	Positive	Positive	236	Negative	Negative	266	Negative	Negative
207	Negative	Negative	237	Negative	Negative	267	Positive	Positive
208	Negative	Negative	238	Negative	Negative	268	Negative	Negative
209	Negative	Negative	239	Negative	Negative	269	Positive	Positive
210	Negative	Negative	240	Positive	Positive	270	Negative	Negative

<b>Code</b>	<b>Test result of Evaluated Reagent</b>	<b>Test result of Contrast Reagent</b>	<b>Code</b>	<b>Test result of Evaluated Reagent</b>	<b>Test result of Contrast Reagent</b>	<b>Code</b>	<b>Test result of Evaluated Reagent</b>	<b>Test result of Contrast Reagent</b>
271	Negative	Negative	301	Negative	Negative	331	Negative	Negative
272	Negative	Negative	302	Negative	Negative	332	Positive	Positive
273	Negative	Negative	303	Negative	Negative	333	Negative	Negative
274	Negative	Negative	304	Negative	Negative	334	Negative	Negative
275	Negative	Negative	305	Negative	Negative	335	Negative	Negative
276	Negative	Negative	306	Negative	Negative	336	Negative	Negative
277	Negative	Negative	307	Negative	Negative	337	Negative	Negative
278	Negative	Negative	308	Positive	Positive	338	Negative	Negative
279	Negative	Negative	309	Negative	Negative	339	Negative	Negative
280	Positive	Positive	310	Negative	Negative	340	Negative	Negative
281	Negative	Negative	311	Negative	Negative	341	Negative	Negative
282	Positive	Positive	312	Negative	Negative	342	Negative	Negative
283	Negative	Negative	313	Negative	Negative	343	Negative	Negative
284	Negative	Negative	314	Negative	Negative	344	Negative	Negative
285	Negative	Negative	315	Positive	Positive	345	Positive	Positive
286	Negative	Negative	316	Positive	Positive	346	Positive	Positive
287	Positive	Positive	317	Negative	Negative	347	Negative	Negative
288	Negative	Negative	318	Positive	Positive	348	Negative	Negative
289	Negative	Negative	319	Negative	Negative	349	Negative	Negative
290	Negative	Negative	320	Negative	Negative	350	Negative	Negative
291	Negative	Negative	321	Negative	Negative	351	Negative	Negative
292	Negative	Negative	322	Negative	Negative	352	Negative	Negative
293	Negative	Negative	323	Negative	Negative	353	Negative	Negative
294	Negative	Negative	324	Negative	Negative	354	Negative	Negative
295	Positive	Positive	325	Negative	Negative	355	Negative	Negative
296	Positive	Positive	326	Positive	Positive	356	Positive	Positive
297	Negative	Negative	327	Negative	Negative	357	Negative	Negative
298	Negative	Negative	328	Negative	Negative	358	Positive	Positive
299	Positive	Positive	329	Positive	Positive	359	Negative	Negative
300	Negative	Negative	330	Negative	Negative	360	Negative	Negative

<b>Code</b>	<b>Test result of Evaluated Reagent</b>	<b>Test result of Contrast Reagent</b>	<b>Code</b>	<b>Test result of Evaluated Reagent</b>	<b>Test result of Contrast Reagent</b>	<b>Code</b>	<b>Test result of Evaluated Reagent</b>	<b>Test result of Contrast Reagent</b>
361	Negative	Negative	391	Negative	Negative	421	Negative	Negative
362	Negative	Negative	392	Positive	Positive	422	Negative	Negative
363	Negative	Negative	393	Negative	Negative	423	Negative	Negative
364	Negative	Negative	394	Negative	Negative	424	Negative	Negative
365	Negative	Negative	395	Positive	Positive	425	Positive	Positive
366	Negative	Negative	396	Negative	Negative	426	Negative	Negative
367	Negative	Negative	397	Negative	Negative	427	Negative	Negative
368	Negative	Negative	398	Negative	Negative	428	Negative	Negative
369	Negative	Negative	399	Negative	Negative	429	Negative	Negative
370	Negative	Negative	400	Negative	Negative	430	Negative	Negative
371	Negative	Negative	401	Negative	Negative	431	Negative	Negative
372	Positive	Positive	402	Negative	Negative	432	Negative	Negative
373	Positive	Positive	403	Negative	Negative	433	Positive	Positive
374	Negative	Negative	404	Negative	Negative	434	Negative	Negative
375	Positive	Positive	405	Negative	Negative	435	Negative	Negative
376	Negative	Negative	406	Negative	Negative	436	Negative	Negative
377	Positive	Positive	407	Negative	Negative	437	Negative	Negative
378	Negative	Negative	408	Positive	Positive	438	Negative	Negative
379	Negative	Negative	409	Negative	Negative	439	Negative	Negative
380	Negative	Negative	410	Negative	Negative	440	Negative	Negative
381	Negative	Negative	411	Negative	Negative	441	Negative	Negative
382	Negative	Negative	412	Negative	Negative	442	Negative	Negative
383	Negative	Negative	413	Negative	Negative	443	Negative	Negative
384	Negative	Negative	414	Negative	Negative	444	Positive	Positive
385	Positive	Positive	415	Negative	Negative	445	Positive	Positive
386	Positive	Positive	416	Negative	Negative	446	Negative	Negative
387	Negative	Negative	417	Negative	Negative	447	Positive	Positive
388	Negative	Negative	418	Negative	Negative	448	Negative	Negative
389	Positive	Positive	419	Negative	Negative	449	Negative	Negative
390	Positive	Positive	420	Positive	Positive	450	Negative	Negative

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
451	Positive	Positive	481	Negative	Negative	511	Negative	Negative
452	Positive	Positive	482	Negative	Negative	512	Negative	Negative
453	Positive	Positive	483	Positive	Positive	513	Negative	Negative
454	Negative	Negative	484	Negative	Negative	514	Negative	Negative
455	Positive	Negative	485	<b>Positive</b>	Negative	515	Positive	Positive
456	Negative	Negative	486	Negative	Negative	516	Negative	Negative
457	Negative	Negative	487	Positive	Positive	517	Negative	Negative
458	Negative	Positive	488	Negative	Negative	518	Negative	Negative
459	Negative	Negative	489	Negative	Negative	519	Negative	Negative
460	Negative	Negative	490	Negative	Negative	520	Negative	Negative
461	Negative	Negative	491	Negative	Negative	521	Negative	Negative
462	Negative	Negative	492	Negative	Negative	522	Negative	Negative
463	Negative	Negative	493	Negative	Negative	523	Negative	Negative
464	Negative	Negative	494	Negative	Negative	524	Negative	Negative
465	Negative	Negative	495	Negative	Negative	525	Negative	Negative
466	Negative	Negative	496	Positive	Positive	526	Negative	Negative
467	Positive	Positive	497	Negative	Negative	527	Negative	Negative
468	Negative	Negative	498	Negative	Negative	528	Positive	Positive
469	Negative	Negative	499	Positive	Positive	529	Negative	Negative
470	Negative	Negative	500	Negative	Negative	530	Negative	Negative
471	Negative	Negative	501	Negative	Negative	531	Negative	Negative
472	Negative	Negative	502	Negative	Negative	532	Negative	Negative
473	Negative	Negative	503	Negative	Negative	533	Negative	Negative
474	Negative	Negative	504	Positive	Positive	534	Positive	Positive
475	Negative	Negative	505	Negative	Negative	535	Negative	Negative
476	Positive	Negative	506	Negative	Negative	536	Negative	Negative
477	Positive	Positive	507	Negative	Negative	537	Negative	Negative
478	Positive	Positive	508	Positive	Positive	538	Negative	Negative
479	Negative	Positive	509	Negative	Negative	539	Negative	Negative
480	Negative	Negative	510	Positive	Positive	540	Negative	Negative

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
541	Negative	Negative	571	Negative	Negative	601	Negative	Negative
542	Negative	Negative	572	Negative	Negative	602	Negative	Negative
543	Negative	Negative	573	Positive	Positive	603	Negative	Negative
544	Negative	Negative	574	Negative	Negative	604	Negative	Negative
545	Negative	Negative	575	Negative	Negative	605	Negative	Negative
546	Negative	Negative	576	Negative	Negative	606	Negative	Negative
547	Negative	Negative	577	Negative	Negative	607	Negative	Negative
548	Negative	Negative	578	Negative	Negative	608	Negative	Negative
549	Negative	Negative	579	Negative	Negative	609	Negative	Negative
550	Positive	Positive	580	Negative	Negative	610	Negative	Negative
551	Negative	Negative	581	Negative	Negative	611	Negative	Negative
552	Negative	Negative	582	Negative	Negative	612	Negative	Negative
553	Negative	Negative	583	Negative	Negative	613	Negative	Negative
554	Negative	Negative	584	Negative	Negative	614	Positive	Positive
555	Negative	Negative	585	Negative	Negative	615	Negative	Negative
556	Negative	Negative	586	Negative	Negative	616	Negative	Negative
557	Negative	Negative	587	Negative	Negative	617	Positive	Positive
558	Negative	Negative	588	Negative	Negative	618	Negative	Negative
559	Negative	Negative	589	Positive	Positive	619	Positive	Positive
560	Negative	Negative	590	Negative	Negative	620	Negative	Negative
561	Positive	Positive	591	Negative	Negative	621	Negative	Negative
562	Negative	Negative	592	Negative	Negative	622	Negative	Negative
563	Negative	Negative	593	Negative	Negative	623	Negative	Negative
564	Negative	Negative	594	Negative	Negative	624	Negative	Negative
565	Negative	Negative	595	Negative	Negative	625	Negative	Negative
566	Negative	Negative	596	Negative	Negative	626	Positive	Positive
567	Negative	Negative	597	Negative	Negative	627	Negative	Negative
568	Negative	Negative	598	Negative	Negative	628	Positive	Positive
569	Negative	Negative	599	Positive	Positive	629	Negative	Negative
570	Negative	Negative	600	Negative	Negative	630	Negative	Negative

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
631	Negative	Negative	661	Negative	Negative	691	Positive	Positive
632	Negative	Negative	662	Negative	Negative	692	Negative	Negative
633	Negative	Negative	663	Positive	Positive	693	Positive	Positive
634	Positive	Positive	664	Negative	Negative	694	Negative	Negative
635	Positive	Positive	665	Negative	Negative	695	Negative	Negative
636	Negative	Negative	666	Positive	Positive	696	Negative	Negative
637	Negative	Negative	667	Negative	Negative	697	Negative	Negative
638	Negative	Negative	668	Positive	Positive	698	Negative	Negative
639	Negative	Negative	669	Negative	Negative	699	Negative	Negative
640	Negative	Negative	670	Negative	Negative	700	Negative	Negative
641	Negative	Negative	671	Negative	Negative	701	Negative	Negative
642	Negative	Negative	672	Positive	Positive	702	Negative	Negative
643	Negative	Negative	673	Negative	Negative	703	Negative	Negative
644	Negative	Negative	674	Negative	Negative	704	Negative	Negative
645	Negative	Negative	675	Negative	Negative	705	Negative	Negative
646	Negative	Negative	676	Negative	Negative	706	Negative	Negative
647	Negative	Negative	677	Negative	Negative	707	Negative	Negative
648	Negative	Negative	678	Negative	Negative	708	Negative	Negative
649	Negative	Negative	679	Negative	Negative	709	Negative	Negative
650	Negative	Negative	680	Negative	Negative	710	Negative	Negative
651	Negative	Negative	681	Negative	Negative	711	Negative	Negative
652	Negative	Negative	682	Negative	Negative	712	Negative	Negative
653	Negative	Negative	683	Negative	Negative	713	Negative	Negative
654	Negative	Negative	684	Negative	Negative	714	Negative	Negative
655	Negative	Negative	685	Positive	Positive	715	Negative	Negative
656	Negative	Negative	686	Negative	Negative	716	Negative	Negative
657	Negative	Negative	687	Positive	Positive	717	Negative	Negative
658	Positive	Positive	688	Negative	Negative	718	Negative	Negative
659	Negative	Negative	689	Negative	Negative	719	Negative	Negative
660	Negative	Negative	690	Negative	Negative	720	Negative	Negative

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
721	Negative	Negative	751	Positive	Positive	781	Negative	Negative
722	Negative	Negative	752	Negative	Negative	782	Negative	Negative
723	Negative	Negative	753	Negative	Negative	783	Negative	Negative
724	Negative	Negative	754	Negative	Negative	784	Negative	Negative
725	Negative	Negative	755	Negative	Negative	785	Negative	Negative
726	Negative	Negative	756	Negative	Negative	786	Negative	Negative
727	Positive	Positive	757	Positive	Positive	787	Negative	Negative
728	Positive	Positive	758	Negative	Negative	788	Negative	Negative
729	Negative	Negative	759	Negative	Negative	789	Negative	Negative
730	Negative	Negative	760	Negative	Negative	790	Negative	Negative
731	Negative	Negative	761	Negative	Negative	791	Negative	Negative
732	Negative	Negative	762	Positive	Positive	792	Negative	Negative
733	Negative	Negative	763	Negative	Negative	793	Negative	Negative
734	Negative	Negative	764	Negative	Negative	794	Negative	Negative
735	Negative	Negative	765	Negative	Negative	795	Negative	Negative
736	Negative	Negative	766	Negative	Negative	796	Negative	Negative
737	Negative	Negative	767	Negative	Negative	797	Negative	Negative
738	Positive	Positive	768	Negative	Negative	798	Negative	Negative
739	Negative	Negative	769	Negative	Negative	799	Positive	Positive
740	Negative	Negative	770	Negative	Negative	800	Negative	Negative
741	Negative	Negative	771	Negative	Negative	801	Negative	Negative
742	Negative	Negative	772	Negative	Negative	802	Negative	Negative
743	Negative	Negative	773	Negative	Negative	803	Negative	Negative
744	Positive	Positive	774	Positive	Positive	804	Positive	Positive
745	Negative	Positive	775	Negative	Negative	805	Positive	Positive
746	Negative	Negative	776	Negative	Negative	806	Negative	Negative
747	Negative	Negative	777	Negative	Negative	807	Negative	Negative
748	Negative	Negative	778	Negative	Negative	808	Positive	Positive
749	Negative	Negative	779	Negative	Negative	809	Positive	Positive
750	Negative	Negative	780	Negative	Negative	810	Negative	Negative



Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
811	Negative	Negative	841	Negative	Negative	871	Negative	Negative
812	Negative	Negative	842	Negative	Negative	872	Positive	Positive
813	Negative	Negative	843	Negative	Negative	873	Negative	Negative
814	Positive	Positive	844	Negative	Negative	874	Negative	Negative
815	Negative	Negative	845	Negative	Negative	875	Negative	Negative
816	Negative	Negative	846	Negative	Negative	876	Negative	Negative
817	Negative	Negative	847	Negative	Negative	877	Negative	Negative
818	Negative	Negative	848	Negative	Negative	878	Negative	Negative
819	Negative	Negative	849	Positive	Positive	879	Negative	Negative
820	Negative	Negative	850	Negative	Negative	880	Negative	Negative
821	Negative	Negative	851	Negative	Negative	881	Positive	Positive
822	Negative	Negative	852	Negative	Negative	882	Negative	Negative
823	Negative	Negative	853	Negative	Negative	883	Negative	Negative
824	Negative	Negative	854	Negative	Negative	884	Negative	Negative
825	Negative	Negative	855	Negative	Negative	885	Negative	Negative
826	Negative	Negative	856	Negative	Negative	886	Negative	Negative
827	Negative	Negative	857	Negative	Negative	887	Negative	Negative
828	Negative	Negative	858	Negative	Negative	888	Negative	Negative
829	Negative	Negative	859	Negative	Negative	889	Negative	Negative
830	Positive	Positive	860	Negative	Negative	890	Negative	Negative
831	Negative	Negative	861	Negative	Negative	891	Negative	Negative
832	Negative	Negative	862	Negative	Negative	892	Positive	Positive
833	Positive	Positive	863	Positive	Positive	893	Negative	Negative
834	Negative	Negative	864	Negative	Negative	894	Negative	Negative
835	Negative	Negative	865	Negative	Negative	895	Negative	Negative
836	Negative	Negative	866	Negative	Negative	896	Negative	Negative
837	Positive	Positive	867	Negative	Negative	897	Negative	Negative
838	Negative	Negative	868	Negative	Negative	898	Negative	Negative
839	Negative	Negative	869	Negative	Negative	899	Negative	Negative
840	Negative	Negative	870	Negative	Negative	900	Negative	Negative

Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent	Code	Test result of Evaluated Reagent	Test result of Contrast Reagent
901	Negative	Negative	931	Negative	Negative	961	Negative	Negative
902	Negative	Negative	932	Negative	Negative	962	Negative	Negative
903	Negative	Negative	933	Negative	Negative	963	Negative	Negative
904	Negative	Negative	934	Negative	Negative	964	Positive	Positive
905	Positive	Positive	935	Positive	Positive	965	Negative	Negative
906	Negative	Negative	936	Negative	Negative	966	Negative	Negative
907	Negative	Negative	937	Negative	Negative	967	Negative	Negative
908	Positive	Positive	938	Negative	Negative	968	Negative	Negative
909	Negative	Negative	939	Negative	Negative	969	Negative	Negative
910	Negative	Negative	940	Negative	Negative	970	Positive	Positive
911	Negative	Negative	941	Negative	Negative	971	Negative	Negative
912	Negative	Negative	942	Negative	Negative	972	Negative	Negative
913	Negative	Negative	943	Negative	Negative	973	Negative	Negative
914	Negative	Negative	944	Positive	Positive	974	Negative	Negative
915	Negative	Negative	945	Negative	Negative	975	Negative	Negative
916	Negative	Negative	946	Negative	Negative	976	Negative	Negative
917	Negative	Negative	947	Positive	Positive	977	Negative	Negative
918	Negative	Negative	948	Negative	Negative	978	Negative	Negative
919	Positive	Positive	949	Negative	Negative	979	Negative	Negative
920	Negative	Negative	950	Positive	Positive	980	Negative	Negative
921	Negative	Negative	951	Negative	Negative	981	Negative	Negative
922	Negative	Negative	952	Negative	Negative	982	Negative	Negative
923	Negative	Negative	953	Positive	Positive	983	Positive	Positive
924	Positive	Positive	954	Negative	Negative	984	Negative	Negative
925	Negative	Negative	955	Negative	Negative	985	Negative	Negative
926	Negative	Negative	956	Negative	Negative	986	Positive	Positive
927	Negative	Negative	957	Negative	Negative	987	Negative	Negative
928	Negative	Negative	958	Negative	Negative	988	Negative	Negative
929	Positive	Positive	959	Negative	Negative	989	Negative	Negative
930	Negative	Negative	960	Negative	Negative			