# Clinical Validation Report on IVD Reagents

Product name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

Model and specification: 25 tests/kit, each test strip packaged separately

**Type of clinical trial:** Clinical validation

**Completion date:** August 21, 2020

**Testing agency: IPE Center for Clinical Laboratory**

# Abstract

To evaluate the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) (the "Test Kit" for short) produced by Beijing Lepu Medical Technology Co., Ltd. ("the Company" for short) for clinical application in qualitative detection of the content of SARS-CoV-2 antigen in clinical samples (nasal swab samples), IPE Center for Clinical Laboratory conducted a clinical study on the test strip therein. A total of 210 nasal swab samples were selected as the study objects, including 75 positive samples and 135 negative samples confirmed by COVID-19 diagnosis and treatment protocol. The kits used for diagnosis was 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd. was used as the reference kit. Based on the test result of the reference kit, the study objects were divided into 2019-nCoV antigen positive group and 2019-nCoV antigen negative group. At the same time, these samples were tested with the Test Kit, and the test results of the Test Kit and the reference kit were compared and statistically analyzed. The results showed that the negative coincidence rate, positive coincidence rate and total coincidence rate between the Test Kit and the reference kit all were greater than 90%, indicating that the Test Kit is in good consistency with the reference kit, and suitable for clinical auxiliary diagnosis.

# I. Introduction

As a large virus family, 2019-nCoV is a single strand plus RNA virus with an envelope. It can cause major diseases such as colds, Middle East Respiratory Syndrome (MERS), and severe acute respiratory syndrome (SARS). SARS-CoV-2 was officially named by the World Health Organization on January 12, 2020. The core protein of SARS-CoV-2 is N protein (Nucleocapsid) inside. It is relatively conserved among β-coronaviruses and is often used for the diagnosis of coronaviruses. As the key recipient for SARS-CoV-2 to enter the cells, ACE2 is of great significance to study the viral infection mechanism.

The research and development work of the Test Kit produced by the Company has been completed. Clinical validation work has been started in order to validate the suitability and accuracy of the test strip in clinical application. Entrusted by the Company, IPE Center for Clinical Laboratory undertook the clinical trial on 210 test samples with the Test Kit produced hereby in the clinical study.

# II. Purpose

The clinical performance of the Test Kit produced by the Company will be systematically studied in order to validate its suitability and accuracy in clinical application.

The purpose of this clinical trial is to conduct the comparative experimental study for the same clinical sample with the Test Kit "SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)" produced by the Company and the reference kit "2019-nCoV PCR Kit (fluorescent PCR method)" (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd.. Statistical analysis was carried out on the test results to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate. According to the results of statistical analysis, it was validated that the Test Kit is equivalent to the reference kit, so as to validate the suitability and accuracy of the Test Kit for clinical auxiliary diagnosis.

The results of this clinical trial are an important basis for evaluating the efficacy and safety of the Test Kit.

# III. Test Management

1. Introduction to management structure

The clinical trial was conducted by the clinical trialing agency IPE Center for Clinical Laboratory. As the applicant, the Company was responsible for communication and contact during the clinical trial.

2. Quality control in the laboratory

1) All researchers participating in this clinical trial 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 met the requirements of quality control of clinical laboratory to ensure the standardization of test procedure.

3) Quality control before the analysis: Sample collection and treatment 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. Statistics and data management

1) All selected cases were filled in the clinical outcome summary sheet, including the subjects' sample number, age, gender, and so on. The testers filled 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.

4. Data preservation

The testing agency and the applicant kept one copy of clinical trial data respectively, 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.

5. Problems found in the study and treatment measures

In clinical trials, when a small number of samples are tested, the results of control samples and test samples are inconsistent. In this case, the clinical quantitative data of these samples or other common clinical strips produced with the same principle are used for re-test.

## IV. Test Design

1. Description of overall test design and protocol

With reference to the *Guideline of Clinical Study on In Vitro Diagnostic Reagents*, the appropriate study objects are selected and the 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) that was approved for marketing was used as the reference kit to conduct blinding simultaneous comparison, for analyzing the negative coincidence rate, positive coincidence rate and total coincidence rate of the Test Kit and the reference kit.

The trial protocol was to select 210 nasal swab samples as the study objects. Samples were divided into positive group and negative group according to the test results of reference kit. At the same time, the samples were tested with qualitative test strip and reference agent, the test results of the Test Kit and the reference agent were compared and statistically analyzed to

calculate the negative coincidence rate, positive coincidence rate and total coincidence rate, so as to judge the clinical suitability and accuracy of the Test Kit, and whether the test result of the Test Kit was consistent with that of the reference kit.

2. Research method

1) Sample collection, storage, transportation

After the samples were collected, they were placed in the sample treatment solution, stored at 2-8℃ and tested within 24 h. The samples should not be stored for a long time at room temperature.

2) Determination of method for comparison

Since the 2019-nCoV PCR Kit (fluorescent PCR method) produced by Beijing Applied Biological Technologies Co., Ltd. (GXZZ 20203400179) is a 2019-nCoV PCR Kit approved for marketing in China earlier, it is 2019-nCoV antigen test kit just like the Test Kit produced by the Company, both of which are new coronavirus detection products and widely used in clinical practice and generally considered to be of good quality. The purpose and scope of clinical use of this product are the same as the Test Kit. The product is therefore selected as a reference kit for clinical study.

The samples with inconsistent test results in the test group and the control group can be compared and checked by clinical quantitative results and clinical diagnosis results.

3) 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 (Colloidal Gold Immunochromatography), and the specification is 25 tests/kit. The product is provided by the Company. The lot number is 20CG2701X, and its shelf-life is 12 months. The storage condition is 4℃- 30°C.

The reference kit is 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd., the specification is 48 tests/kit, its shelf-life is 6 months and the storage condition is dark place with -20℃±5℃.

4) Quality control method

The execution and completion of clinical trial is inspected on a regular basis. The completeness and precision of clinical sample information is checked and the test results are verified.

5) Clinical trial method

All test samples were simultaneously tested with the control test strip and the Test Kit, and the test results of the two were compared. When all clinical samples were tested, the recorded test results of the Test Kit and the reference kit were statistically analyzed, to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate and then evaluate whether they were equivalent according to these statistical indexes.

6) Statistical analysis methods for clinical study data

Calculate the negative coincidence rate, positive coincidence rate and total coincidence rate of the test results of the Test Kit and the reference kit. Determine whether each index meets the

clinical evaluation criteria to validate the accuracy and suitability of the product in clinic. Test the Test Kit with different types of samples and statistically analyze the test results. At the same time, test different types of samples of subjects simultaneously with the Test Kit, and compare the test results. When all clinical samples are tested, the recorded test results are statistically analyzed to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate. And then evaluate whether they are equivalent according to these statistical indexes.

7) Clinical evaluation criteria

Compare the Test Kit with the marketed reference kit to calculate coincidence rate. Product performance shall meet the following requirements.

1) Negative coincidence rate: the proportion of samples whose test results obtained with the Test Kit and the reference kit are negative in the samples whose test results obtained with the reference kit are negative. The negative coincidence rate shall be greater than 90%.

2) Negative coincidence rate: the proportion of samples whose test results obtained with the Test Kit and the reference kit are positive in the samples whose test results obtained with the reference kit are positive. The positive coincidence rate shall be greater than 90%.

3) Total coincidence rate: the proportion of samples whose test results obtained with the Test Kit and the reference kit are the same in the total number of samples. Total coincidence rate shall be larger than 90%.

| | | Control system | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Test system | Positive | a | b | a+b |
| | Negative | c | d | c+d |
| Total | | a+c | b+d | a+b+c+d |

Generally, formulas of positive coincidence rate and negative coincidence rate are as follows:

Positive coincidence rate = a/ (a+c) * 100%

Negative coincidence rate = d/ (b+d) * 100%

Total coincidence rate = (a+d)/(a+c+b+d) * 100%

If the positive coincidence rate and negative coincidence rate meet the clinical requirements, the two methods or products are considered to be equivalent; if the difference between the positive coincidence rate and negative coincidence rate is too large, the clinical protocol shall be redesigned.

8) Modification of the protocol during the study

No modification.

## V. Results and Analysis of Clinical Trial

A total of 210 samples were selected. All selected samples were tested.

Make consistency statistics on the test results of Test Kit (test product) produced by the Company and the 2019-nCoV PCR Kit, analyze their diagnostic sensitivity and specificity, and list them in the form of four-fold table.

| | Test result of reference kit | | Total |
|---|---|---|---|
| Test Kit | Positive | Negative | |
| Positive | True positive (A) | False positive (B) | A+B |
| Negative | False negative (C) | True positive (D) | C+D |
| Total | A+ C | B+D | A+B +C+D |

Generally, formulas of diagnostic sensitivity and specificity are as follows:

Diagnostic sensitivity = A/ (A+C) × 100%

Diagnostic specificity = D/ (B+D) × 100%

Total coincidence rate= (A+D)/ (A+B+C+D) × 100%

Table 1: Statistics of Test Results of Test Kit and Reference Kit

| | Positive result of reference kit | Negative result of reference kit | Total |
|---|---|---|---|
| Positive result of Test Kit | 69 | 1 | 70 |
| Negative result of Test Kit | 6 | 134 | 140 |
| Total | 75 | 135 | 210 |

| **Item** | **Formula** | **Results** | 95% CI |
|---|---|---|---|
| Diagnostic sensitivity (%) | A/(A+C)*100% | 92.00% | 83.63%~96.28% |

| | | | |
|---|---|---|---|
| Diagnostic specificity (%) | D/(B+D)*100% | 99.26% | 95.92%~99.87% |
| Total coincidence rate (%) | (a+d)/(a+b+c+d)*100% | 96.67% | |

It can be seen from Table 1 that among the 75 samples in the positive group tested with the Test Kit, 69 cases are positive and 6 cases are negative. Among the 135 samples in the negative group tested with the Test Kit, 134 cases are negative and 1 cases are positive. The results show that the negative coincidence rate, positive coincidence rate and total coincidence rate all are greater than 90%, indicating that they are in good consistency with those of the reference kit.

## VI. Discussion and Conclusion

(I) Discussion

The SARS-CoV-2 antigen rapid test strip produced by the Company contains SARS-CoV-2 N protein monoclonal antibody labeled by colloidal gold that is pre-coated on the colloidal gold labeled pad, SARS-CoV-2 N protein monoclonal antibody fixed in the test area and the corresponding antigen in the quality control area (C). The rapid test of SARS-CoV-2 antibodies in nasal swab samples is used clinically for auxiliary screening of COVID-19 patients. The purpose of the clinical trial is to evaluate the clinical performance of the product. The test conditions are presented as follows:

Comparative analysis results of the Test Kit and 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd.:

Test results of the Test Kit and the reference kit: The diagnostic sensitivity and specificity are greater than 90%, indicating that they are in good consistency with those of the reference kit.

(II) Test conclusion

After validation, the negative coincidence rate, positive coincidence rate and total coincidence rate between the test results of the Test Kit and 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd. are relatively high, and the results of the statistical analysis also show that there is no significant difference between the test results of the Test Kit and the reference kit, the two methods have good diagnosis consistency and are equivalent. At the same time, the diagnostic sensitivity and specificity of the Test Kit and the nucleic acid test results are both greater than 90%, indicating that they are in good consistency with those of the reference kit.

## VI. Description of Special Circumstances on Clinical Studies

There is no special circumstance to be explained in this clinical study.

# Annex I Instruction for Use of All Diagnostic Reagents Used in Clinical Trials

## Instruction for Use of the Test Kit

LEPU MEDICAL

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**SARS-CoV-2 Antigen Rapid Test Kit**
**(Colloidal Gold Immunochromatography)**

【Product name】

SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold Immunochromatography)

【Model】

1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 30 tests/kit.

【Intended Use】

The product is intended for the qualitative detection of antigen against SARS-CoV-2 in clinical samples (nasal swab).

【Summary】

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (Nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

【Principle】

The current test card is based on the specific antibody-antigen reaction and immunoanalysis technology. The test card contains colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area (T) and corresponding antibody in the quality control area (C). During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad. The conjugates migrate upward under capillary effect, and subsequently captured by the N protein monoclonal antibody immobilized in the Test area (T). The higher the contents of N protein in the sample, the more the conjugates captures and the darker the color in the test area is. If there is no virus in the sample or the virus content is lower than the detection limit, then there is no color demonstrated in the test area (T). Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area (C). The purple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

【Components】

The product consists of test cards, Instructions for use, sample treatment solution. And in each test card bag, it includes one SARS-CoV-2 antigen detection card and one package of desiccant.

| Model | Test card | Instructions for use | Sample treatment solution |
|---|---|---|---|
| 1 test/kit | 1 test | 1 | 1ml×1 |
| 5 tests/kit | 5 tests | 1 | 1ml×1 |
| 10tests/kit | 10 tests | 1 | 2ml×1 |
| 25 tests/kit | 25 tests | 1 | 3ml×2 |
| 30 tests/kit | 30 tests | 1 | 5ml×2 |

For each test card bag, it contains one test card and one package of desiccant.

The test card consists of gold standard mat (coated with colloidal gold labelled SARS-CoV-2 N protein monoclonal antibody), sample mat, nitrocellulose membrane (Test area (T) is coated with an SARS-CoV-2 N protein monoclonal antibody; the quality control area (C) is coated with goat anti-mouse antibody), absorbing paper, and hydrophobic stiff card.

【Storage and Stability】

It should be stored at 4 ~ 30℃, be kept dry and away from sunlight. The shelf life is 12 months.
For per test card, it should be used within 1 hour after unsealing.
Production Date and Expiration date are shown in the package label.

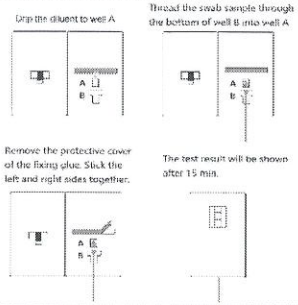
【Sample Requirements】

The product is used to test the human nasal swab sample.
Sample collection: During the collection procedures for samples, take care to make proper protection, and avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken.

Nasal swab sample: gently and slowly insert the swab into the nasopharynx through the nasal cavity. When resistance is encountered, the swab will arrive at the posterior nasopharynx. After a few seconds of suction, gently rotate the swab, then take out the swab to obtain the nasal swab sample.
Sample preservation: after sample collection, please complete the test within 1 hour.
The sample should come to room temperature before testing.

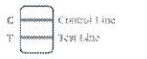
【Test Method】

Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and sample to room temperature.
1. Remove the test card from the test card bag and use it within 1 hour, especially in the environment with room temperature higher than 30 °C or in high humidity.
2. Place the test card on a clean platform. Drip 6 drops of the sample treatment solution to well A.
3. Thread the swab head through the bottom of well B into well A and rotate it two rounds clockwise and counterclockwise respectively in the sample treatment solution.
4. Remove the protective cover of the fixing glue. Stick the left and right sides together and start timing. Wait until the purple band appears. The test result should be read within 15-20 minutes.



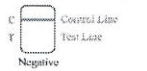

【The Explanation of the Testing Results】

• Positive (+). There appear purple stripes in both quality control area (C) and either test area (T).



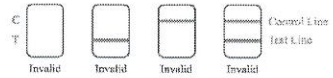
Positive

• Negative (-). There is only one purple stripe in the quality control area (C), and without purple stripe in either test area (T).



Negative

• Invalid: There is no purple stripe in the quality control area (C), or there is blue stripe in the quality control area (C), indicating incorrect operating procedures or the test card has already deteriorated. Under this condition, it must read the instruction for use again carefully, and then use the new test card to test again. If the problem still exists, stop using the products with same lot number and contact the local suppliers immediately.



Invalid Invalid Invalid Invalid

【Limitation of Procedure】

1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to test the SARS-CoV-2 antigen of the clinical sample.

【Product Performance Index】

1 Physical Property
1.1 Appearance

The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly adhered; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.
1.2 Liquid migration speed
The liquid migration speed should be no less than 10mm/min.
1.3 Membrane Strip Width
The membrane strip width of the testing card should be≥2.5mm.
1.4 The preparation quantity of the diluent for the samples
The volume of the diluents for the sample is no less than the indicated value.
2 Detection Limit
For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.
3 Negative reference products compliance rate
For the detection of negative reference material, the negative detection rate should be 100%.
4 Positive reference products compliance rate
For the detection of positive reference material, the positive detection rate should be 100%.
5 Repeatability
For the detection of enterprise reference material P2 and P4, the results should be positive and the color rendering should be uniform.
6 Cross-reactivity
Cross-reactivity: This test device has no cross reactivity with endemicity human coronavirus OC43, influenza a virus, influenza B virus, respiratory syncytial virus, adenovirus, EB virus, measles virus, cytomegalovirus, rotavirus, Norovirus, mumps virus, varicella zoster virus, mycoplasma pneumoniae, Human metapneumovirus.

【Precautions】

1. The test is only suitable for professionals to use in vitro auxiliary diagnosis. Do not use expired products.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15-30 °C and the humidity should be below 70%.
4. The test card bag contains desiccant, and it should not be taking orally.
5. When testing, please wear protective clothing, medical mask, gloves and goggles.
6. Do not use the test card with broken single packaging, unclear marks, and past the expiration date.
7. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.

【Explanation of Symbols】

| | | | |
|---|---|---|---|
| | DO NOT USE IF PACKAGE IS DAMAGED | | CONSULT INSTRUCTIONS FOR USE |
| | DO NOT REUSE | | USE-BY DATE |
| | TEMPERATURE LIMIT | | DATE OF MANUFACTURE |
| | MANUFACTURER | LOT | BATCH CODE |
| | KEEP AWAY FROM SUNLIGHT | | KEEP DRY |
| IVD | IN VITRO DIAGNOSTIC MEDICAL DEVICE | CE | CE MARK |
| EC REP | AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY | | |

【Basic Information】

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【Approval Date and Revision Date of the Instruction】

Approved on 2nd, Sept., 2020.
Version number: CR-InCG27 REV.01

## Annex II Clinical Trial Data

| Sample number | Test result of Product tested | Test result of reference product |
|---|---|---|
| 1 | positive | positive |
| 2 | negative | negative |
| 3 | positive | positive |
| 4 | negative | negative |
| 5 | negative | negative |
| 6 | negative | negative |
| 7 | positive | positive |
| 8 | positive | positive |
| 9 | positive | positive |
| 10 | negative | negative |
| 11 | negative | negative |
| 12 | negative | negative |
| 13 | positive | positive |
| 14 | positive | positive |
| 15 | positive | positive |
| 16 | negative | negative |
| 17 | negative | negative |
| 18 | positive | negative |
| 19 | positive | positive |
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| 37 | positive | positive |
| 38 | negative | negative |
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| 40 | negative | negative |
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| 42 | negative | negative |
| 43 | negative | negative |
| 44 | negative | negative |
| 45 | negative | negative |
| 46 | negative | negative |

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| 47 | positive | positive |
| 48 | negative | positive |
| 49 | negative | negative |
| 50 | positive | positive |
| 51 | negative | negative |
| 52 | negative | negative |
| 53 | positive | positive |
| 54 | positive | positive |
| 55 | negative | positive |
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| 95 | positive | positive |
| 96 | negative | negative |

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| 103 | positive | positive |
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| 140 | negative | negative |
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| 142 | negative | negative |
| 143 | negative | negative |
| 144 | negative | negative |
| 145 | negative | negative |
| 146 | positive | positive |

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|---|---|---|
| 147 | negative | negative |
| 148 | positive | positive |
| 149 | negative | negative |
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| 189 | negative | negative |
| 190 | negative | negative |
| 191 | negative | negative |
| 192 | positive | positive |
| 193 | negative | negative |
| 194 | negative | negative |
| 195 | positive | positive |
| 196 | negative | negative |

| | | |
|---|---|---|
| 197 | positive | positive |
| 198 | negative | negative |
| 199 | positive | positive |
| 200 | negative | negative |
| 201 | negative | negative |
| 202 | negative | negative |
| 203 | negative | negative |
| 204 | positive | positive |
| 205 | positive | positive |
| 206 | negative | negative |
| 207 | negative | negative |
| 208 | negative | negative |
| 209 | positive | positive |
| 210 | negative | negative |