TIMHUTI
MEDICAL SUPPLY

COVID-19
ANTIBODY INSTANT TEST KIT

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Antibody tests detect our body's natural defense against a foreign pathogen. That means they can tell whether someone has ever been infected with Covid-19 - even if that person wasn't able to get tested initially. They can also give researchers a picture of how much the virus has spread within a population.

Scientists use two basic measures to determine the accuracy of an antibody test: sensitivity and specificity. Sensitivity refers to how well a test detects antibodies when they're actually present (i.e. a true positive). Specificity refers to a test's ability to produce a true negative result.

Some antibody tests had 100% sensitivity, meaning all positive results should be accurate. Others had average sensitivity rates as low as 17%, according to raw data reviewed by Business Insider. A handful of individual tests showed 0% specificity, meaning any positive was false.

The rapid test from Healgen was one of the few tests with 100% sensitivity and 100% specificity - but those results were only for IgM antibodies.

Coronavirus antibody tests target three types of antibodies: immunoglobulin M (IgM), immunoglobulin G (IgG), and immunoglobulin A. Our bodies typically make IgM first in response to a viral infection, so these antibody levels tend to peak earlier than the rest. IgG is the most common antibody found in blood and usually a better indicator of long-term immunity. Most coronavirus antibody tests focus on these two antibodies as opposed to IgA, which is found mainly in the respiratory and digestive tracts.

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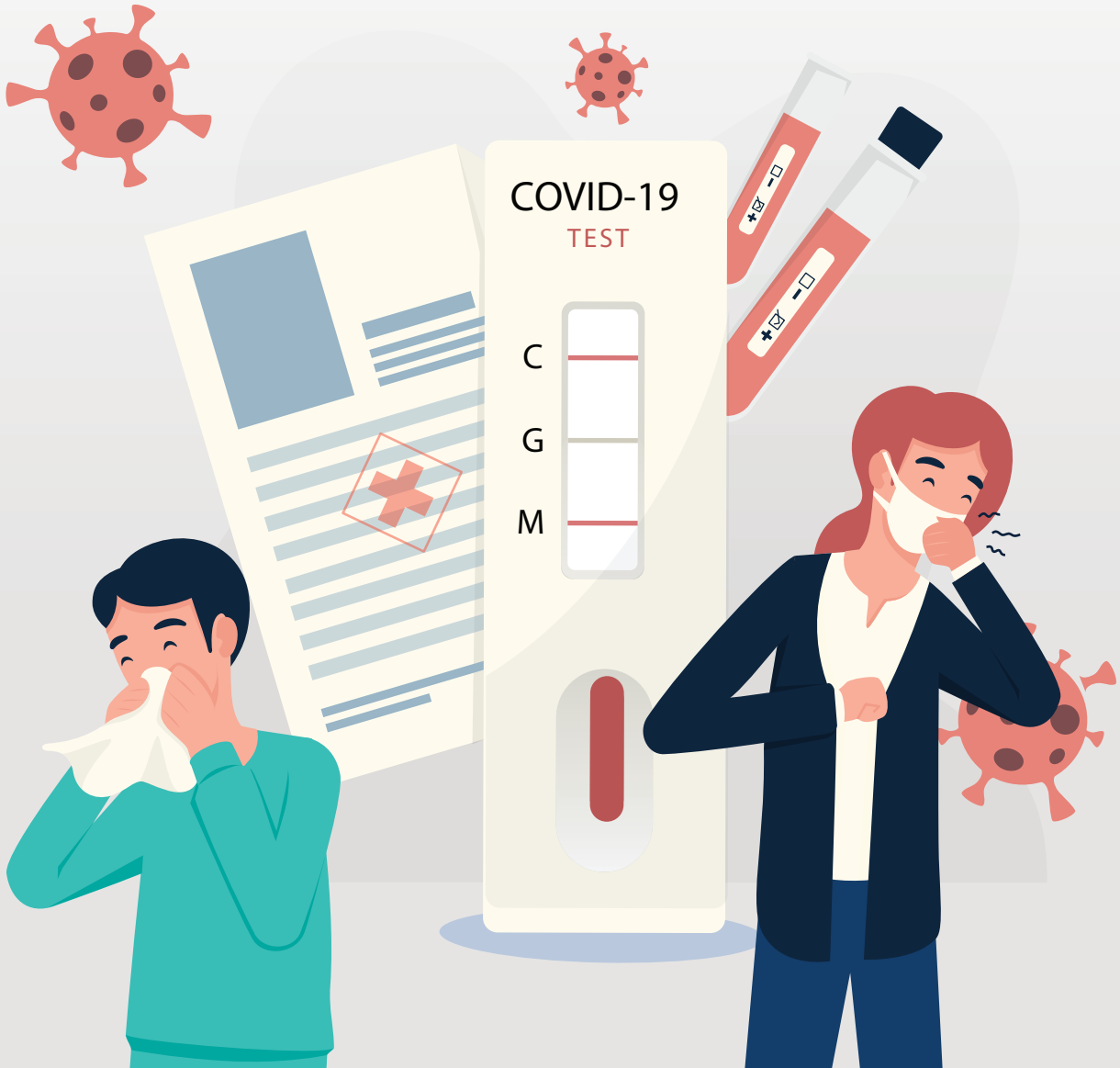

CLINICAL EVALUATION RESULTS:

The clinical evaluation was carried out during February 2020 across 10 hospitals and reported on March 12, 2020. Further clinical evaluations are ongoing and any further information needed can be granted at request.

Test Reagent	Reference Reagent		Total
	Positive	Negative	
Positive	245	4	249
Negative	16	439	455
Total	261	443	704

The results from the Healgen Scientific LLC tests show that the testing reagent and reference reagent have equivalent effectiveness in detecting COVID-19 when tested in the same clinical specimens. Compared with the reference reagent, the positive agreement was 93.87% (95%CI:90.24%~96.46%), the negative agreement was 99.10% (95%CI:97.70%~99.75%) and total agreement was 97.19% (95%CI:95.65%~98.26%). The kappa value of the consistency analysis was 0.94 (95%CI:95.65%~98.26%). The results of the clinical evaluation show that the two reagents (methods) have a high degree of consistency and equivalent sensitivity and specificity in detecting COVID-19.

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The COVID-19 IgG/IgM (Whole Blood/Serum/Plasma) Rapid Test Device utilizes lateral flow technology for the qualitative, differential detection of both anti-SARS-CoV-2 IgM and IgG antibodies. In general, antibodies can be detected 1-3 weeks after infection. This test is intended to screen patients for COVID-19. Combining RNA and Antibody tests can significantly raise the sensitivity for detecting COVID-19 in infected individuals.

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals and birds that cause respiratory, enteric, hepatic and neurologic diseases. Four viruses - 229E, OC43, NL63 and HKU1 are prevalent and typically cause common cold symptoms in immunocompromised individuals. Three other strains SARS-CoV, MERS-CoV and SARS-CoV-2 (COVID-19) can be transmitted from between non-human vertebrates to humans.

FEATURES

* Detection Window (IgM): 3-5 days after incubation
* Dual band results for simple interpretation
* Multivariable analysis of immunoglobin IgG & IgM
* Room temperature storage or refrigerated (2-30^{0}C / 36-86^{0}F)
* Procedural internal control included
* Buffer included

SPECIFICATIONS

Clinical Evaluation

* Positive Percent Agreement (PPA): IgG 96.7%; IgM 86.7%; ...Overall 96.7%
* Negative Percent Agreement (NPA): IgG 98.0%; IgM 99.0%; ...Overall 97.0%

Clinical Agreement with Characterized Samples

* Sensitivity: IgG 96.7%; IgM 100%; Combined 100%
* Specificity: IgG 97.5%; IgM 100%; Combined 97.5%

* Specimen: Whole Blood, Serum, Plasma
* Time to Results: 10 minutes
* Shelf Life: 24 months from the date of manufacture

HOW THE RAPID TEST WORKS

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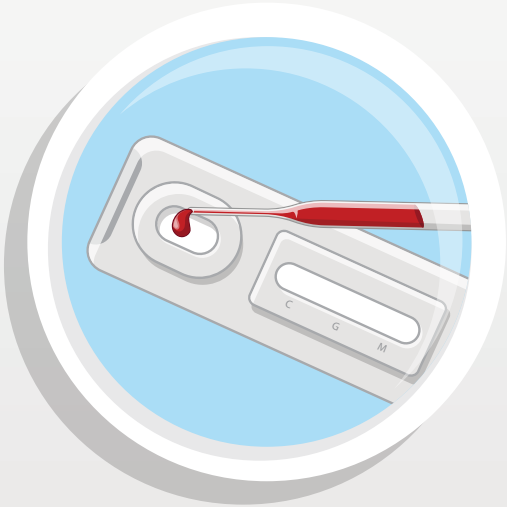
COLLECT SAMPLE

Remove the test cassette from the sealed foil pouch and use it as soon as possible.
Lay device on flat surface and add specimen.



ADDING OF SAMPLE

For Serum or Plasma Specimen: With the plastic dropper provided, draw serum/plasma specimen to exceed the specimen line. Hold the dropper vertically and transfer drawn serum/plasma specimen into the sample well.

DROPPING OF SAMPLE BUFFER

Immediately add 2 drops (about 80 µL) of sample buffer to the buffer well (B) ensuring that buffer vial tip does not touch the sample. Avoid air bubbles.

READING TEST RESULT

The results should be read in 10 minutes. Do not interpret the result after 15 minutes.

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