

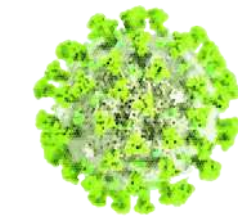
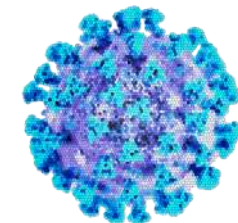
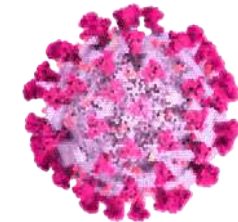
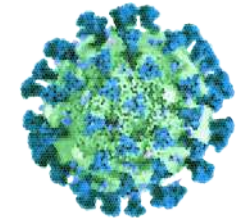
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Complete diagnostics program on COVID-19

Current clinical symptoms screening methods (cough and fever, etc) fail to find the viral infections during the incubation period. To fully combat COVID-19, LimingBio has developed complementarily two types of diagnostic tests:

- Strongstep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)
- Strongstep® SARS-CoV-2 IgM/IgG Antibody Rapid Test





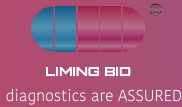
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Los diagnósticos están ASEGURADOS

Products List

Coronavirus Disease 2019

Cat.	Product	Model	Detection	Muestra	Specification
500190	StrongStep [®] Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)	96 Tests/Box	RNA	throat swab/ nasopharyngeal swab/ sputum	CE
502090	StrongStep [®] SARS-CoV-2 IgM/IgG Antibody Rapid Test	20 Tests/Box	Antibody	Whole Blood/ Serum/ Plasma	CE FDA



Strongstep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)

Product package



96 Tests
16×11×5.5CM



Specimen: throat swab nasopharyngeal swab sputum

Results come out in 2 hours, satisfactory performance done by clinical trials. room-temperature transportation and storage.

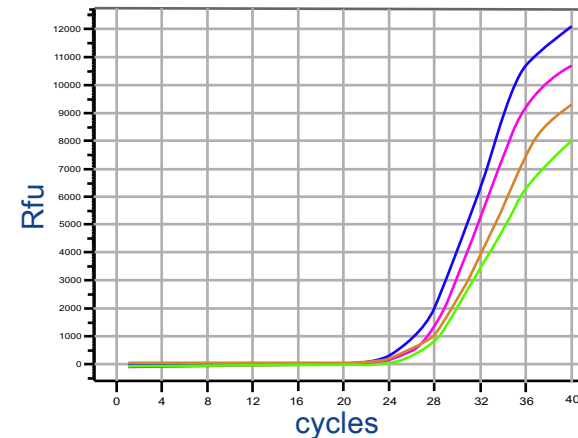
Kit Components

- Lyophilized qPCR reagents
- Positive control
- PCR CAP

Package

- 12x8-Strip Tubes (lyophilized)
- 1.5 mL Tube (lyophilized)
- 12x8-Strip Caps

Cat.	Product	Model	Detection	Muestra	Specification
500190	StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)	96 Tests/Box	RNA	throat swab/ nasopharyngeal swab/ sputum	



This kit provides multiplex detections of SARS-CoV-2's ORF1ab gene, S gene and N gene in a single tube. Reduce false negative caused by mutation, At least one of the three positives can be used to determine the presence of virus infection.

An internal Control (IC) amplifying human RNase P gene was used to evaluate extraction of RNA and detect PCR inhibition in PCR.

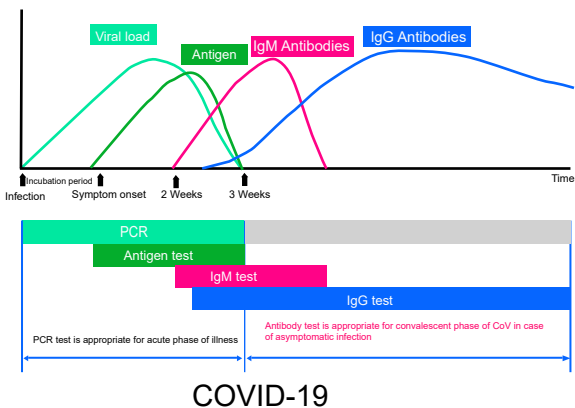
The kit is supplied as lyophilized PCR BEADS, which contains nucleic acid amplification enzyme, reaction buffer, specific primers and probes. The kit can be directly put into qPCR instrument after adding sample and water.



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StrongStep® SARS-CoV-2 IgM/IgG Antibody Rapid Test

Cat.	Product	Model	Detection	Muestra	Specification
502090	StrongStep® SARS-CoV-2 IgM/IgG Antibody Rapid Test	20 Tests/Box	Antibody	Whole Blood/ Serum/ Plasma	CE FDA



Interpretation of novel coronavirus related laboratory results

Nucleic acid test negative	IgM-	IgG-	No infection (most of them belong to this kind). Or infection incubation period, need to inquire contact history (14 days without exposure, can be excluded)
	IgM+	IgG-	False positive test results caused by interference Or infection acute stage, nucleic acid result false negative, union CT diagnosis
Nucleic acid test positive	IgM _{WEAK} +	IgG-	False positive test results caused by interference Or the initial infection load is very low and in the early stage, combined with CT diagnosis
	IgM-	IgG+	It is suggested that IgG can exist in vivo for a long time and can be eliminated with CT
	IgM+	IgG+	It is suggested that in the near future infection, the nucleic acid result is false negative, combined with CT diagnosis, or in the recovery period, IgM has not disappeared
	IgM-	IgG-	There is no antibody in the body during the "window period" of infection, or there is no antibody due to immunosuppressive therapy or immunodeficiency disease
Nucleic acid test positive	IgM+	IgG-	In the early stage of infection, IgM can begin to produce symptoms within 3-5 days.
	IgM-	IgG+	The infection is advanced and the virus has not been cleared
	IgM+	IgG+	Infection symptom stage, or infection active stage, or the second recurrence of infection

Performance

Test	Sensitivity	Specificity
IgM	71.9%	100%
IgG	93.3%	98.7%
Total	93.5%	98.7%

Use of these tests:

- 1) The first-visit suspected patients (no molecular results or molecular negative), if antibody positive, should be managed as confirmed case; if antibody negative, it suggests to do PCR again, and test antibody after one week.
- 2) The asymptomatic close contacts or investigation crowd, if antibody positive, no matter how the PCR result is, should be managed as carriers; if antibody negative, it suggests to do PCR firstly and follow up with antibody detection, it can be excluded from COVID infection if results negative again.
- 3) For asymptomatic quarantined-14-days people, if antibody positive, it suggests to do PCR again and be kept under observation.

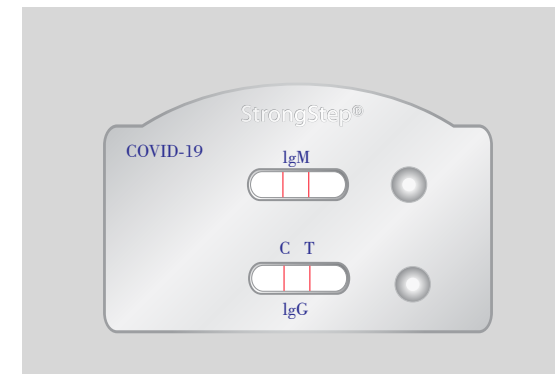
All test results need to be combined with the patient's clinical symptoms and signs, and the interpretation of the test results must follow the local diagnostic guidelines in each country.

Regence: Diagnosis and treatment plan for the novel coronavirus disease (COVID-19) <http://www.nhc.gov.cn/yzygj/s7652m/202003/a31191442e29474b98bfd5579d5af95.shtml>

Product package



22.5×18×6.5CM



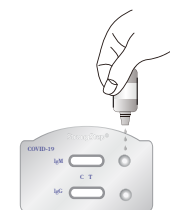
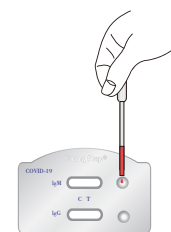
Individually Packed Test Devices: 20
Dilution Buffer: 1*5mL
Package insert: 1
Workstation: 1

Specimen: Whole Blood/ Serum/Plasma
Results come out in 15 minutes,
proven auxiliary to molecular tests

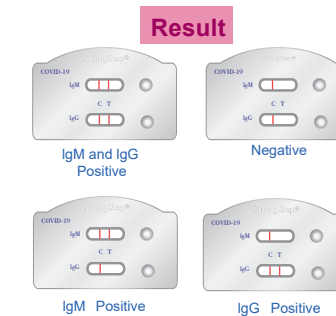
Method of operation of kit illustrated

Apply 10µL of serum, plasma or whole blood to the sample well.

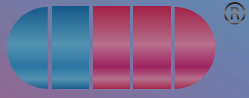
Add 2-3 drops of buffer to sample well



Waiting for 15 minutes reading result



Note: Control band fails to appear should be regarded as invalid results.



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Thanks!

