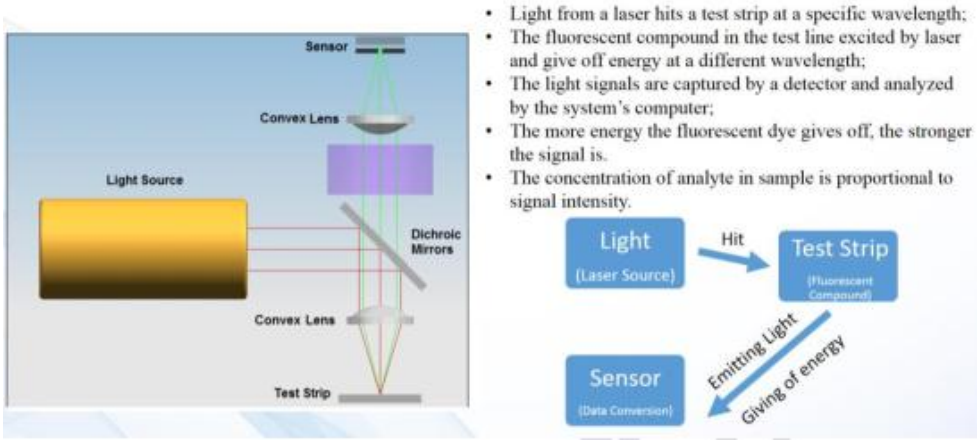
1. Q: How does the machine work with the laser?

A: 1) Principle of Optical System



The detection element scans the binding area and converts the optical signal to electrical signal. The voltage variation between test line and background has a linear relationship with the analyte concentration which can be used to calculate the concentration.

2) Test Principle (Neu.Ab for example)

Getein SARS-CoV-2 Neu.Ab Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunochromatographic assay by double-antigen sandwich for the detection of SARS-CoV-2 neutralizing antibodies in human serum, plasma, venous whole blood or fingertip blood. The rapid test membrane is pre-coated with recombinant SARS-CoV-2 S-RBD antigen on the test line region and utilizes a separate control line to assure assay flow and performance. Another recombinant SARS-CoV-2 S-RBD antigen conjugated with the fluorescence latex labeled on the sample pad. After the sample has been applied to the test strip, the fluorescence latex-labelled SARS-CoV-2 S-RBD antigen binds with SARS-COV-2 neutralizing antibodies in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by another SARS-CoV-2 S-RBD antigen coated on the test line of nitrocellulose membrane, forming a double-antigen complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of SARS-COV-2 neutralizing antibody in sample.

2. Q: What's the maximum time to do the test?

A: For Neu.Ab test, the recommended reaction time is 15 min after adding sample mixture to the test card. No more than 20 min, otherwise the result will be inaccurate.

3. Q: What's in the buffer solution?

A: The main components of Neu.Ab sample diluent are phosphate buffered saline, protein stabilizer and surfactant.

4. Q: Does it make difference with the amount of blood you take?

A: The standard sample volume of serum/plasma/whole blood/ fingertip blood for neu.Ab is 40 µL. And the standard volume of sample diluent is 400 µL. For this kind of reagent with a small dilution ratio (1:10), the influence of little change of sample volume will be significant. So we should try our best to ensure the accuracy of the sample volume.

5. Q: What's the accuracy of the machine percentage wise?

A: According to the clinical agreement study of Getein SARS-CoV-2 Neu.Ab test kit and Roche Elecsys Anti-SARS-

CoV-2 S electro-chemiluminescence immunoassay (ECLIA), the positive percent agreement was 99.34%, the 95% confidence interval of the positive percent agreement was [96.37%,99.88%], the negative percent agreement was 99.61%, the 95% confidence interval of the negative percent agreement was [97.83%,99.93%], the total percent agreement is 99.51%, the 95% confidence interval of the total percent agreement was [98.23%,99.87%].

Details refer to the Appendix 1: Clinical Agreement Study for SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay).

6. Q: What's minimum amount of antibody to be considered protected?

A: Data from a randomized efficacy trial of the AZD1222 vaccine reveals that higher levels of immune biomarkers is associated with a reduced risk of infection. (Feng, et al. Correlations between SARS-CoV-2 neutralizing antibody level and immune protection against SARS-CoV-2 infection)

Table 2 | Outputs from generalized additive models, with immune marker values associated with 50%, 60%, 70%, 80%, and 90% VE against symptomatic infection

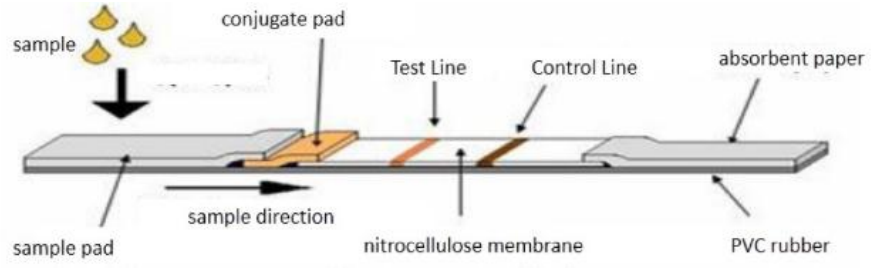
Assay units	*P* value $_{\text{immune marker}}$	*P* value $_{\text{baseline risk score}}$	No. cases	No. noncase	50% VE (95% CI)	60% VE (95% CI)	70% VE (95% CI)	80% VE (95% CI)	90% VE (95% CI)
Anti-spike IgG									
AU/ml	0.003	<0.001	52	1155	4446 (NC, 12822)	8413 (NC, 22232)	17538 (NC, 37929)	40923 (16748, 125017)	139306 (57276, NC)
BAU/ml					29 (NC, 83)	54 (NC, 143)	113 (NC, 245)	264 (108, 806)	899 (369, NC)
Anti-RBD IgG									
AU/ml	0.018	<0.001	52	1155	2193 (NC, 13614)	6266 (NC, 29105)	20700 (NC, 56620)	63383 (16903, NC)	295781 (90567, NC)
BAU/ml					17 (NC, 109)	50 (NC, 232)	165 (NC, 452)	506 (135, NC)	2360 (723, NC)
Normalized live-virus neutralization assay									
NF_{50}	<0.001	<0.001	36	412	68 (NC, 129)	91 (NC, 175)	135 (48, 267)	247 (101, NC)	938 (294, NC)
Pseudovirus neutralization assay									
ID_{50}	0.005	<0.001	47	828	NC	22 (NC, 76)	57 (NC, 183)	185 (NC, NC)	982 (303, NC)
IU/ml					NC	3 (NC, 11)	8 (NC, 26)	26 (NC, NC)	140 (43, NC)

ID_{50}: neutralization dilution for 50% virus inhibition; NC: not computed; AU/ml: arbitrary units per mL; BAU/ml: binding antibody units per ml (WHO international standard 20/136), IU/ml: international units per ml (WHO international standard 20/136). Where CIs were outside the range of values of the assay the limits are reported as NC. VE estimates and CIs are those shown in Fig. 4, at every 10% increment in the *y* axis. The two-sided *P* value for each immune marker (column 2) is from the generalized additive models in Fig. 1, showing the strength of the relationship between the antibody value and infection. The *P* values were not adjusted for multiple comparisons.

Details refer to Appendix 2: Correlations between SARS-CoV-2 neutralizing antibody level and immune protection against SARS-CoV-2 infection

7. Q: What's the material of the test cards?

A: 1) Test card constitution:



Sample Pad

(1) Avoid excessive sample impregnation; Remove particle impurities and cells of samples; Can be infiltrated by chemical substances, modify the sample to reduce the difference; Add the best place for sealing agent

(2) It is made of inert materials that can be wetted, such as cellulose, glass microfiber, polyester film, textile polymer.

(3) Our company's sample pad material is mainly glass microfiber.

Conjugate Pad

(1) Adsorb of a certain amount of gold standard binding material particles and continuously move the sample to the reaction membrane, guarantee the gold standard binding material stable, so that the dry binding material is not damaged

(2) The suitable materials are mainly fiberglass;

(3) Most of our company's products have abandoned the conjugate pad, and the gold standard combination or latex are directly put in the reaction membrane

Nitrocellulose Membrane

(1) Test Line and Control Line are coated with antibodies; The immune reaction accurs here

(2) Our company's products mainly use the cellulose nitrate film (NC membrane), the competition method generally uses the capillary rise rate of 180 s/4 cm NC membrane, and the double-antibody method uses 135 s/4 cm NC membrane.

(3) The combination of protein and nitric acid cellulose mainly depends on electrostatic action and hydrophobic action.

Absorbent Paper

(1) Control the flow rate of the sample and promote siphoning

(2) Our company's product absorption pad material is mainly absorbent filter paper

2) For Neu.Ab test card:

A plastic shell and a test strip which is composed of a sample pad, a fluorescence latex labeled pad (coated with recombinant SARS-CoV-2 S-RBD antigen), nitrocellulose membrane with test line (T line coated with another recombinant S-RBD antigen), the control line (coated with anti-recombinant protein tag protein) and absorbent paper.

8. Q: Why can’t the machine have the battery?

A: Getein1100 is designed with lithium battery, and it can be used in the ambulance or the situation power failure. But for Lithium battery transportation, we need provide special appraisal report. And for some logistics companies, they don’t agree to transport lithium battery even if we provide the appraisal report. Normally, for foreign market, we don’t provide the analyzer with battery.

For some customers who really need the battery, we can provide the battery parameters, and they adapt the battery by themselves in the local market.