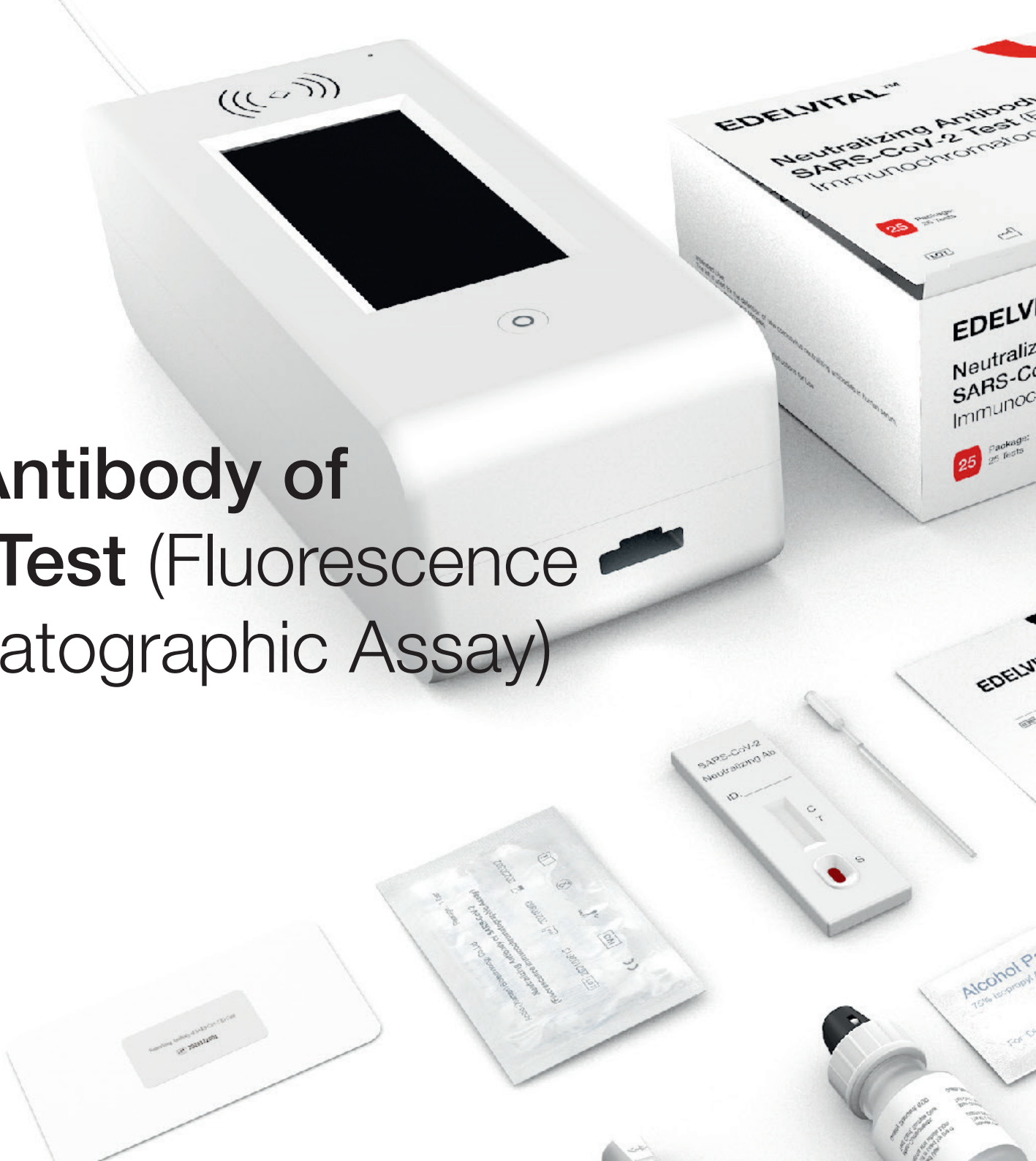
EDELVITAL™

Neutralizing Antibody of SARS-CoV-2 Test (Fluorescence Immunochromatographic Assay)



Advanced quantitative
gold standard testing.

EDELVITAL™

Edelvital is the trademark for a medically registered Austrian company specialising in unique medical diagnostic solutions. Together with their partner laboratories and in co-operation with the Medical University in Vienna Austria, they conduct clinical trials and evaluation assessments, on those products that they believe worthy, of being brought to the attention of the medical profession.

With this new Point-of-Care Neutralizing Antibody Fluorescence, Immunochromatographic Assay test, Edelvital, offers for the first time, the unique opportunity, for patients that have either previously contracted the SARS CoV-2 virus, or have been vaccinated, **to finally have a quantitative status of their immunogenicity, in relation to this disease and their subsequent ability to fight the infection**.

This ground breaking test, provides a result that would normally require a laboratory PRNT test, conducted in a laboratory setting over a minimum two day period. With the Edelvital test the patient can have a test administered anywhere, with a result available within 15 minutes. Saving time and allowing the patient's general practitioner to act quickly and address the patient's status. This vital information, used together with our proprietary software can aid institutions looking for a passport solution, for access and travel control. It can also inform on quarantine periods and provide a far more accurate reflection of community Infectivity status, than inoculation alone.

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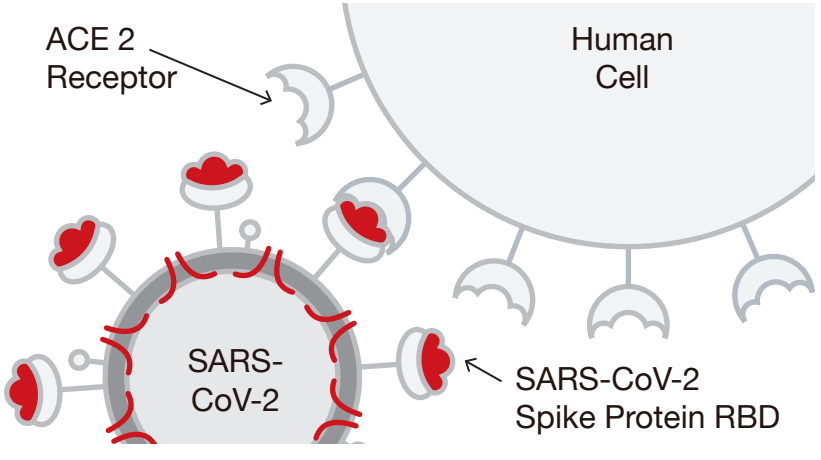
What is a SARS-CoV-2 Neutralizing Antibody?

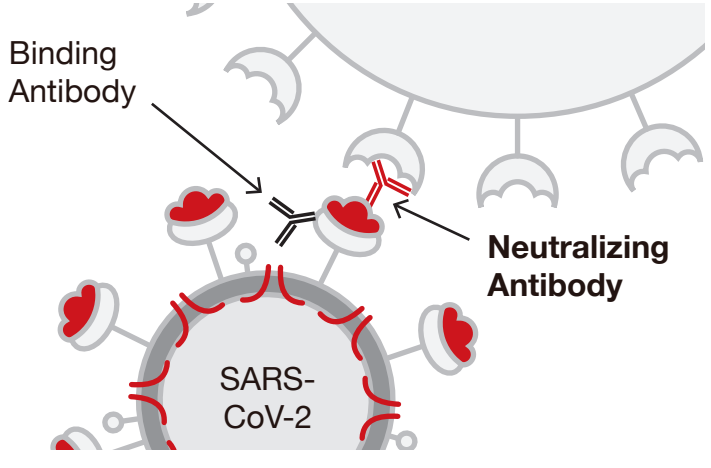
The SARS-CoV-2 Neutralization Antibody

The SARS-CoV-2 Neutralizing Anitbody is a special type of antibody produced in a particular part of the body with a unique function. Additionally known as an inhibitive or BLOCKING antibody, the quantity of SARS-CoV-2 Neutralizing antibodies in the blood stream is directly linked to the ability to fight an infection of the disease.



Why and how are people infected by the SARS-CoV-2 virus?

Patients become infected when the RBD (receptor binding domain of the glycoprotein viral spike) interacts with the ACE 2 cell surface receptor of the patient's lung, directly initiating an infection.



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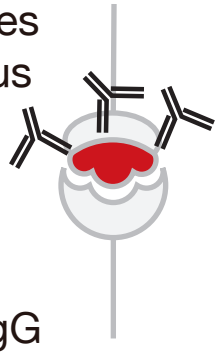
The difference between Neutralizing Antibodies (NAb) and Binding antibodies (BAU)

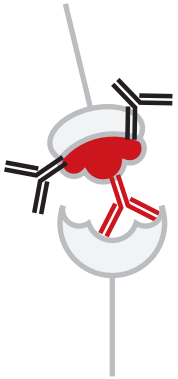
It is well understood that there are a number of antibodies created by the body in response to the SARS CoV-2 virus which has been the cause of the recent international pandemic. Included in that cohort are so called ”binding” Antibodies that adhere to the receptor binding domain of the protein spike of the virus in an attempt to bind and cover it and are identified as IgM, IgG and IgA.



Binding antibodies

RBD can still successfully dock to the ACE2 receptor

As demonstrated by a study carried out on behalf of the Austrian Government in 2020 www.meduniwien.ac.at/. Binding antibodies have a high incidence of false positive results. Recent studies in Hong Kong have revealed, that when only binding antibodies are monitored there is a high case in reinfection rates with severe symptoms. Giving no indication of transmissibility in a community.



Neutralizing antibodies

RBD successfully blocked from docking to the ACE2 receptor

The difference between Neutralizing Antibodies (NAb) and Binding antibodies (BAU)

It is scientifically recognised that the target of the virus is the patient's lung. In addition, when the RBD of the viral spike has successfully docked onto the ACE 2 receptor cell of the lung, that infection has been initiated (Yan et al., 2020 Wrapp et al., Tai et al., 2019).

Only Neutralizing antibodies or BLOCKING antibodies, therefore, that operate differently from binding antibodies and cover the small ACE 2 entrance receptors of the lung cells, prevent the virus from entering the lung and are important when making an assessment of infectivity.

The Edelvital Neutralizing antibody test was designed following a clinical trial of 3350 people utilising the gold standard PRNT test the results for which, the machine is calibrated. The only test of its kind currently being used for further investigations by healthcare professionals. Including a study at the AKH in collaboration with AGIS and the Medical University of Vienna. It is the best point of care test, to assist healthcare professionals in making that assessment.

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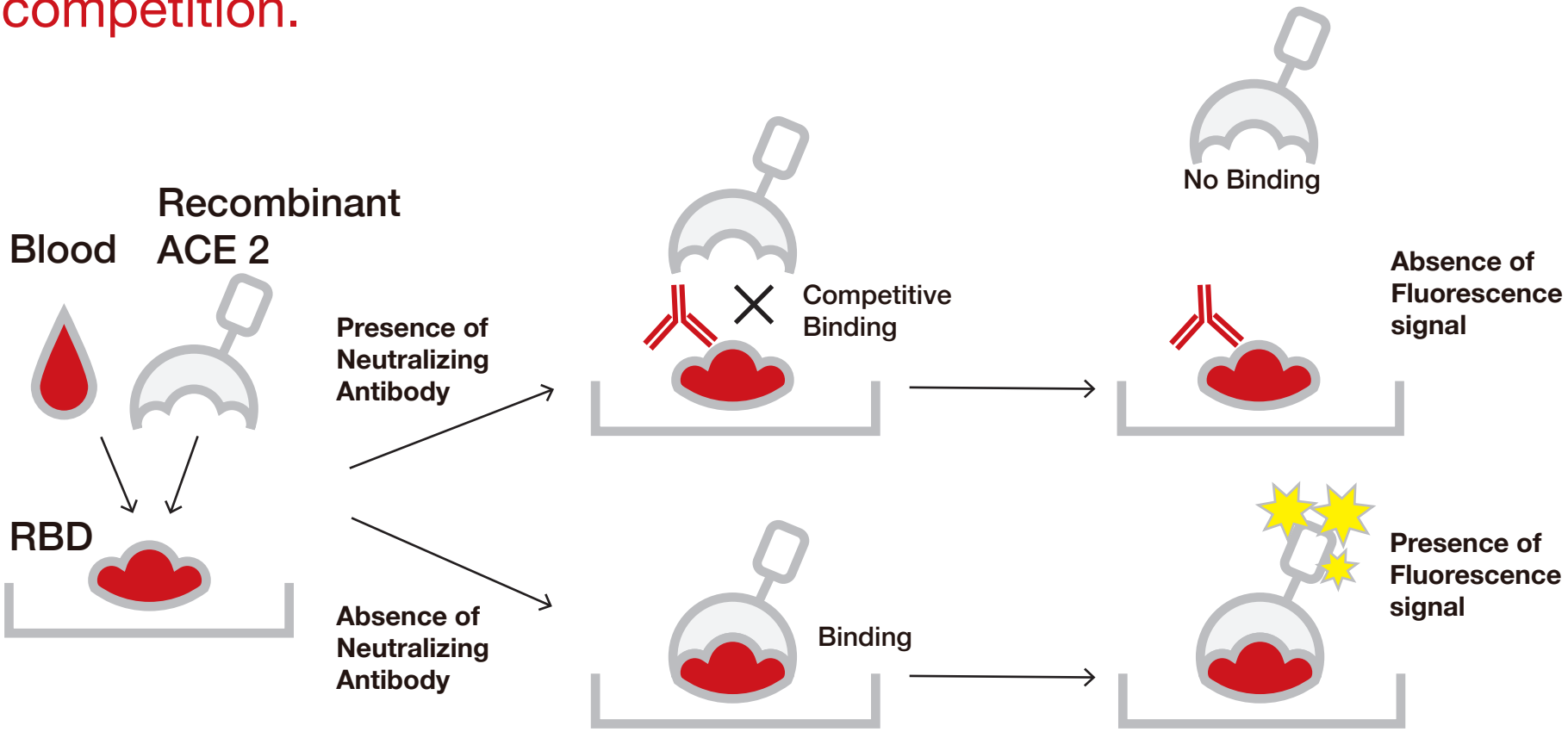
Principle - EDELVITAL™ Fluorescence Immunochromatographic Assay

The basic principle utilized in the test is immunochromatographic competition.



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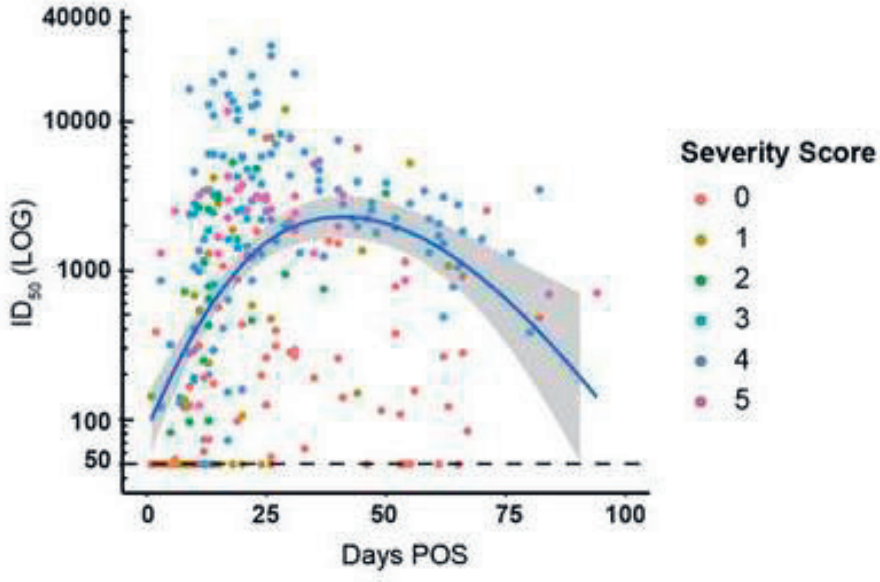
Why do we need quantitative testing for Neutralizing Antibodies?

- Different brands and types of vaccines produce different titers of neutralizing antibodies

- Only quantitative testing can give an accurate analysis of vaccine efficacy.

- As neutralizing antibodies decrease over time, only testing in this way will indicate the need for a booster or further monoclonal antibody treatment.

- Any real time investigation into the potential for herd immunity, will require quantitative analysis as opposed to the qualitative results of a positive or negative provided by vaccines.



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Application

- Monitoring of herd immunity in the community
- A screening test used prior to vaccination
- Monitoring serological results after vaccination
- For use in risk assessment to predict secondary infections
- In the evaluation of the efficacy of monoclonal antibody treatments

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Advantages in comparison to ELISA and Colloidal Gold tests
POCT (Point-of-Care trained)

Methods	ELISA kit	EDELVITAL Neutralizing Antibodies test kit	Colloidal Gold test kit
Principle	Only competetive neutralizing antibodies are detected	Only competetive neutralizing antibodies are detected	Sandwich RBD total antibodies
Testing Time	>90mins	15mins	15mins
Used by	Professionals only	POCT, non-professionals	POCT, non-professionals
Cost	Cost intensive	Non cost intensive	Non cost intensive
Laboratory	Necessary	Unnecessary	Unnecessary
Storage & logistics	Cold chain	Room temperature	Room temperature
Quantitative	Yes	Yes	No

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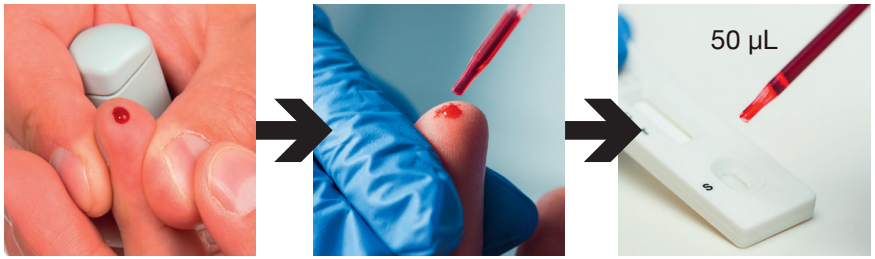
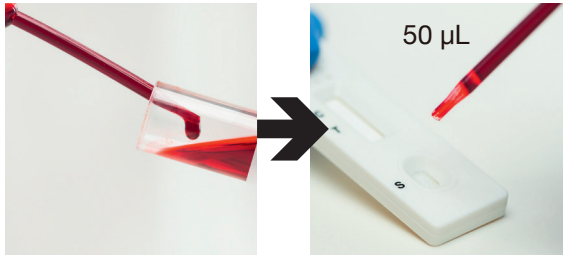
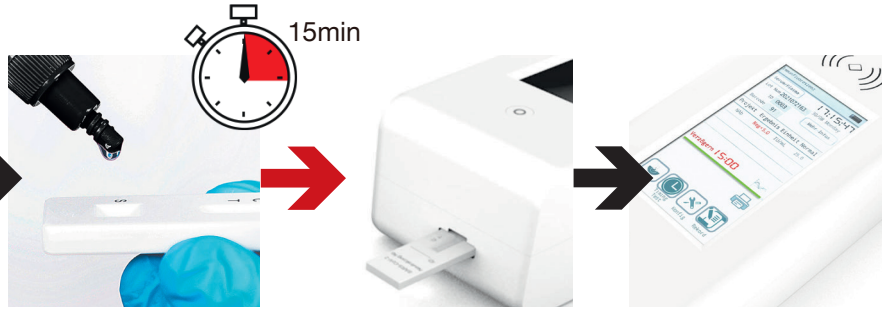
Test kit function

Finger tip draw



Whole blood



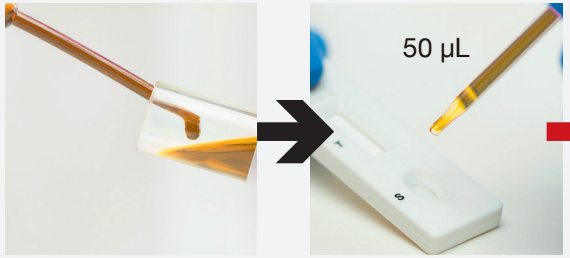


One drop of dilutant

5 sec

Result

Serum / plasma



No need for dilutant

5 sec

Result

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Clear visible results
available for data processing

Lot Num 2021072163	30/08 Monday		
ID 0003	Mehr Infos		
Barcode 91			
Projekt	**Ergebnis**	**Einheit**	**Normal**
NAb	14.0	IU/mL	25.0

Reading value = 14 IU/ml

< 25 = Negative

Lot Num 2021072163	30/08 Monday		
ID 0003	Mehr Infos		
Barcode 91			
Projekt	**Ergebnis**	**Einheit**	**Normal**
NAb	39.0	IU/mL	25.0

Reading value = 39 IU/ml

> 25 = Positive

Calibrated in accordance with the
WHO International Standards for SARS-CoV-2 antibody (human)
NiBSC Code: 20/136 in IU/mL.

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Clinical analysis in comparison to *PRNT test results

Clinical trial
sample size 3350

***PRNT:** Plaque Reduction Neutralization Test

PRNT result		Positive	Negative	Total
EDELVITAL test kit result	Positive	94 (=a)	0(=b)	94(=a+b)
	Negative	1(=c)	87(=d)	88(=c+d)
	Total	95(=a+c)	87(=b+d)	*182(=a+b+c+d)

Sensitivity
= a/(a+c) x 100% = 94/95 x 100% = **98,95%**

Specificity
= d/(b+d) x 100% = 87/87 x 100% = **100%**

Total coincidence rate
= (a+c)/(a+b+c+d) x 100% = (94+87)/(94+0+1+87) x 100% = **99,45%**

*182 cases: included 53 previously infected people, 50 vaccinated people and 79 healthy people.

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Clinical analysis in comparison to ELISA test results (Vaccinated)

cPass™ (ELISA) result		Positive	Negative	Total
EDELVITAL test kit result	Positive	652 (=a)	2(=b)	654(=a+b)
	Negative	1(=c)	8(=d)	9(=c+d)
	Total	653(=a+c)	10(=b+d)	663(=a+b+c+d)

Total coincidence rate

= (a+c)/(a+b+c+d) x 100% = (652+8)/(652+2+1+8) x 100% = **99,55%**

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Clinical analysis in comparison to ELISA test results
(Previously infected)

cPass™ (ELISA) result		Positive	Negative	Total
EDELVITAL test kit result	Positive	1642 (=a)	6(=b)	1648(=a+b)
	Negative	7(=c)	21(=d)	28(=c+d)
	Total	1649(=a+c)	27(=b+d)	1676(=a+b+c+d)

Total coincidence rate
= (a+c)/(a+b+c+d) x 100% = (1642+21)/(1642+6+7+21) x 100% = **99,22%**

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Clinical analysis in comparison to ELISA test results
(Uninfected, Unvaccinated)

cPass™ (ELISA) result		Positive	Negative	Total
EDELVITAL test kit result	Positive	2(=a)	3(=b)	5(=a+b)
	Negative	4(=c)	918(=d)	922(=c+d)
	Total	6(=a+c)	921(=b+d)	927(=a+b+c+d)

Total coincidence rate
= (a+c)/(a+b+c+d) x 100% = (2+918)/(2+3+4+918) x 100% = **99,24%**

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Clinical analysis in comparison to ELISA test results
(Previously infected, Vaccinated, Uninfected & Unvaccinated)

cPass™ (ELISA) result		Positive	Negative	Total
EDELVITAL test kit result	Positive	2296(=a)	11(=b)	2307(=a+b)
	Negative	12(=c)	947(=d)	959(=c+d)
	Total	2308(=a+c)	958(=b+d)	*3226(=a+b+c+d)

Sensitivity
= a/(a+c) x 100% = 2296/2308 x 100% = **99,48%**

Specificity
= d/(b+d) x 100% = 947/958x 100% = **98,85%**

*3266 cases included:
1676 Previously infected people
663 Vaccinated people
927 Not infected & not vaccinated people

Total coincidence rate
= (a+c)/(a+b+c+d) x 100% = (2296+947)/(2296+11+12+947) x 100% = **99,30%**

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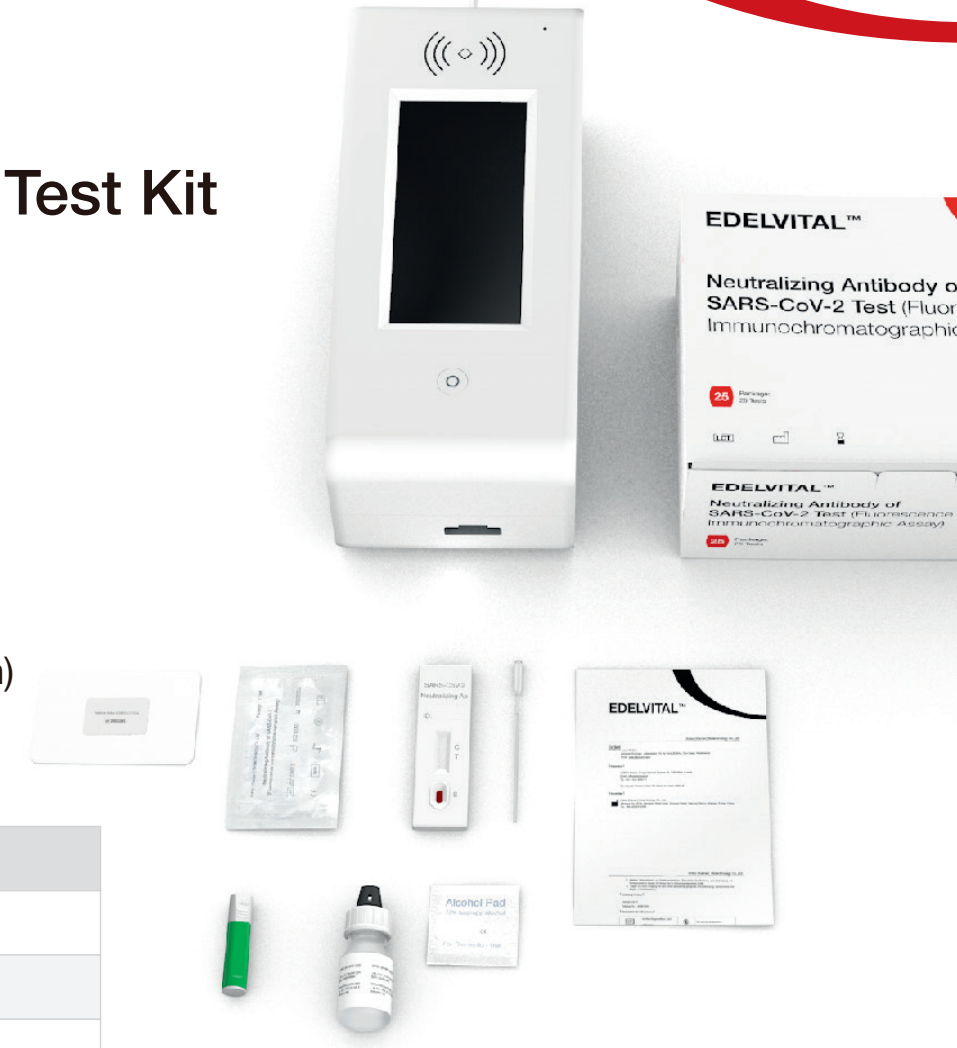
Neutralizing Antibody of SARS-CoV-2 Test Kit
Product information

- Registration certificate: CE
- Specification: 25 tests / kit
- Specimen type: serum / plasma / whole blood (50μL)
- Storage and shelf life: 2-30°C for 18 months
- To be used with Immunofluorescence Analyzer
- EMC tested: IEC 61326-1:2012, IEC 61326:2012
- Calibrated in accordance with the
  WHO International Standards for SARS-CoV-2 antibody (human)
  NiBSC Code: 20/136 in IU/mL.
- Test kit inclusive of below components:

Contents	25 tests / kit
Test cards	25
Dilutant	1 bottle
Drops	25
Instruction for use	1
IC card	1
Record sheet	1



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Neutralizing Antibody of SARS-CoV-2 Test Kit Packaging

Name	Kit size	Kit weight	Carton size	Kits per carton	Gross weight per carton
Neutralizing Antibody of SARS-CoV-2 Test (Fluoroscence Immunochromatographic Assay)	18*14*7.5cm	0.35kg	72*38*40cm	50	20kg

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Thank you for your kind attention!

Contact us:

DIST

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Available as:

25 **Large Package:** 25 Tests

or

1 **Single Package:** 1Test