mediagnost®
Gesellschaft für Forschung und Herstellung von Diagnostika GmbH

Available immediately!

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anti-SARS-CoV-2 ANTIBODY TEST

CE IVD REF E111-IVD

Detection of IgG

Reliable detection of anti-SARS-CoV-2 IgG antibodies in human serum or plasma

Specificity

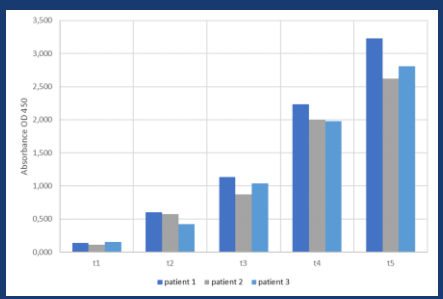
No cross reactivity with antibodies directed against other viruses i.e. beta corona virus HUK-1 detectable

Sensitivity

Detection of even low levels of antibody concentrations at the onset of an immune response

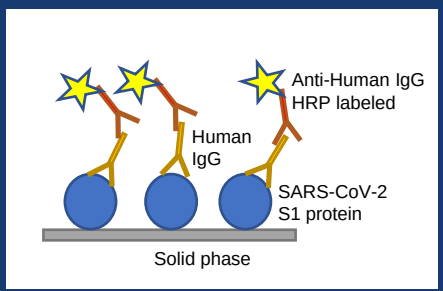
FAST IDENTIFICATION OF IMMUNE RESPONSE

- Antibody detection approx. day 10 after onset of COVID-19 symptoms



Time course of antibody development (IgG to S1 (RBD) protein) of 3 clinically ill patients. Blood samples were drawn at 10-13, 17-20, 22-25, 30-33 and 37-40 days after onset of symptoms.

- Reliable assay principle



Reliable results with the Mediagnost anti-SARS-CoV-2 enzyme immuno assay can be obtained in every laboratory with standard equipment.
35 years of ELISA experience lead to a superior product.
Quality - made in Germany!

- E111-IVD Manual & Specifications

Mediagnost anti-SARS-CoV-2 ANTIBODY TEST E111

ASSAY PROCEDURE

Step 1	**Addition of controls and samples**
	Add 100 µL of each blank, Positive Control (PC), Negative Control (NC) and samples (diluted 1:200 in dilution buffer DIL). Blanks and samples in double determination Positive and Negative Controls in triple determination
Step 2	**Incubation**
	Cover the plate with sealing tape and incubate for 2 h at 37°C
Step 3	**Washing**
	Remove the sealing tape from the plate and aspirate the contents of the wells. Wash 3 x with 300 µL Washing Buffer WP per well
Step 4	**Addition of Conjugate and Incubation**
	Add 100 µL Conjugate HRP labeled anti-human IgG DET to each well, cover the plate with sealing tape and incubate for 30 min at 37°C
Step 5	**Washing**
	Remove the sealing tape from the plate and aspirate the contents of the wells. Wash 3 x with 300 µL Washing Buffer WP per well
Step 6	**Addition of Substrate and Incubation**
	Add 100 µL of Substrate Solution S to each well and incubate 10 min at 20-25°C in the dark
Step 7	**Addition of Stop Solution**
	Add 100 µL Stop Solution SL to each well
Step 8	**Measurement**
	Measure the absorbance within 30 min at 450 nm (reference filter ≥ 590 nm)
Step 9	**Evaluation of results**
	The test is valid if a P/N ratio of >5 is achieved
Step 10	**Cut-off determination**
	The cut-off is calculated 3 x and 5 x mean values of negative controls.
Step 11	**Interpretation of results**
	Values under 3 x cut-off are negative, Values above 5 x cut-off are positive Values in between both cut-offs are borderline.

Analytical Specificity

Up to now no serologically unique strains of SARS-CoV-2 have been described relative to the originally isolated virus.

Cross-reactivity of non SARS-CoV-2 specific antibodies against SARS-CoV-2 S1 RBD protein in Anti-SARS-CoV-2 ELISA E111 was examined using sera with known antibodies against confirmed past infections.

Antibody positive sera	n	Anti-SARS-CoV-2 ELISA E111
Beta Corona HKU1*	1	Negative
VCV	4	Negative
HCV	5	Negative
HAV	4	Negative
HBV	3	Negative
EBV	4	Negative
CMV	5	Negative
HSV	5	Negative

*The patient was tested PCR positive for Beta Corona HKU1 and PCR negative for SARS-CoV-2. Four weeks after PCR testing a serum sample was drawn from the patient and found to be negative in the Anti-SARS-CoV-2 ELISA E111.

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