

To: (10)(2e) (10)(2e) (10)(2e) @minocw.nl; (10)(2e) (10)(2e) (MOCW); (10)(2e) @minocw.nl;
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Goedemorgen,

Hierbij de definitieve brief die VWS zojuist heeft verzonden. Teksten over onderwijs zijn keurig overgenomen, cultuur (en horeca) is nog wel een beetje omgegooid.

Groet (10)(2e)



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Sensitivity and specificity of multiple ELISA tests in clinical patients; version 2

At the end of 2019, SARS-CoV-2 emerged in the human population. The subsequent growing pandemic spread of the virus is accompanied by high morbidity and mortality, and has an enormous negative impact on societal and economic circumstances world-wide. In response to this outbreak ELISA tests are currently overflowing the diagnostic market. As at 15 May 2020, the FIND organization has listed 106 manual or automated assays in different stages of validation and regulation on its website. The added value of these ELISA tests for individual patient diagnostics and their usefulness for epidemiological studies and to direct mitigation strategies, urgently needs to be established. Here, we took a first look at the clinical sensitivity and specificity of eight ELISA kits.

Methods.

Eight ELISA kits for detection of SARS-CoV-2 antibodies were included in the study. Selection was partially based on pre-study dossier analysis of data provided by the manufacturers that included test-specifics (antigen used), validation data on sensitivity and specificity in relation to type of cohort used and reliability of the manufacturer. The following three kits were analyzed in this report:

RIVM

A. van Leeuwenhoeklaan 9
3721 MA Bilthoven
Postbus 1
3720 BA Bilthoven
www.rivm.nl

T 030 274 91 11
info@rivm.nl

Authors

(10)(2e) (10)(2e)
(10)(2e) (10)(2e) (10)(2e)
(10)(2e) (10)(2e)
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Test	Manufacturer	Certification	Antigen
Wantai SARS-CoV-2 Ab ELISA	Beijing Wantai Biological	CE-IVD	RBD
EUROIMMUN SARS-CoV-2 IgG	EUROIMMUN AG	CE-IVD	S1
EUROIMMUN SARS-CoV-2 IgA	EUROIMMUN AG	CE-IVD	S1
EDI™ Novel Coronavirus COVID-19 ELISA IgG	Epitope Diagnostics Inc	CE-IVD	COVID-19 recombinant protein
EDI™ Novel Coronavirus COVID-19 ELISA IgM	Epitope Diagnostics Inc	CE-IVD	COVID-19 recombinant protein
SARS-CoV-2 IgG ELISA kit	Creative Diagnostics	RUO	Whole virus lysate antigen
SARS-CoV-2 IgM ELISA kit	Creative Diagnostics	RUO	anti- μ chain monoclonal antibody
Platelia SARS-CoV-2 Total Ab	Bio-Rad Laboratories	CE-IVD	Nucleocapsid