From: [redacted]
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Subject: EUROIMMUN SARS-CoV-2 ELISA (IgA en IgG) vanaf heden CE gelabeld
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EI_2606A_A_UK_C01.pdf
EI_2606G_A_UK_C01.pdf
Okba et al_SARS-CoV-2 ELISA EU_medRxiv_2020.pdf

Beste,

BIOGNOST houdt er zich aan u ook wetenschappelijke duiding te brengen bij onze SARS-CoV-2 antistof testen.

Onze anti-SARS-CoV-2 ELISA testen zijn volledig ontwikkeld en geproduceerd door **EUROIMMUN AG** (Lübeck, Duitsland) en **bevatten alle nodige *Ready-to-Use* reagentia voor uitvoering van de test**, inclusief controles. Deze ELISA testen zijn **tevens volautomatisch uitvoerbaar** op gangbare ELISA pipetteer robots.

In de bijlage kan u het artikel vinden van OKBA *et al*. De auteurs beschrijven de serologische respons van een SARS-CoV-2 infectie en de performantie van de anti-SARS-CoV-2 ELISA's van EUROIMMUN AG ten opzichte van referentietesten *oa* PRNT (Plaque Reduction Neutralization Test) in welomschreven cohortes. (https://www.medrxiv.org/content/10.1101/2020.03.18.20038059v1). Hiernaast zijn beide bijsluiters opgenomen in de bijlage.

Graag maken wij voor u een synthese van de belangrijkste conclusies van de auteurs:

- S1 is more specific than N or S (complete) protein as an antigen for SARS-CoV-2 serological diagnosis.
- **EUROIMMUN Anti-SARS-CoV-2 ELISAs (IgA and IgG) show 89-100 % sensitivity.**
- **The specificity of the EUROIMMUN Anti-SARS-CoV-2 ELISAs varies between 87.5 – 95.5 % for IgA and 83.5 – 97.5 % for IgG**, depending on the used sample panel.
- EUROIMMUN Anti-SARS-CoV-2 ELISAs (IgA and IgG) correlate strongly with PRNT.
- The detection of IgA antibodies can have an added value in diagnosing SARS-CoV-2 infection at the early phase of the disease.

Both test systems are therefore not only ideal for supporting the diagnosis of SARS-CoV-2 infection, but also for differentiating from infections with other pathogens causing similar symptoms.

NOTE: The results presented in this study were based on EUROIMMUN Anti-SARS-CoV-2 ELISAs (IgA and IgG) available for research use only purposes. EUROIMMUN was actively taking part in this study and had access to the results before this publication. Based on the collected data EUROIMMUN performed a redesign on the IgG Kits leading to an improved signal-to-noise ratio. This improved version of the EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) underwent the complete CE registration process. All CE marked lots are produced after the redesign.

Relevance of IgA/Why not IgM?
The Anti-SARS-CoV-2 ELISA (IgA) was designed in order to **reduce or even close a diagnostic gap between direct detection and serology**. According to MiQ (Mikrobiologisch-infektiologischer Qualitätsstandard), secretory antibodies of class IgA are an "essential carrier of the humoral immune response in the areas of mucous membranes and bodily fluids". Therefore, their detection has a diagnostic relevance for supporting diagnostics in suspected cases of respiratory infection. Like the IgG test, the Anti-SARS-CoV-2 ELISA (IgA) is based on recombinant S1 structural protein and hence enables a significantly more specific detection than would be possible by determination of IgM antibodies, which are mainly directed against the highly conserved (N)-protein. **Using the Anti-SARS-CoV-2 ELISA (IgA), the risk of detection of cross-reactive antibodies against other coronaviruses is significantly lower in comparison to IgM detection.**

Relevance of serological tests
Direct pathogen detection by means of nucleic acid amplification is the method of choice for detection of acute COVID-19 infections. However, when the adaptive immune response has started and therefore **the viral load is decreasing, the sensitivity of the direct detection decreases correspondingly**. After approx. 10-14 days, the pathogen is no longer reliably detectable (LIU *et al.* 2020), **which is why serological procedures can be applied from this phase on**.
The following areas of application have been described for serology:

- **Tracing of infection chains** in order to identify persisting or past infections and take corresponding measures (source: European Centres for Disease Control and Prevention (ECDC) – Technical Report - Novel coronavirus [SARS-CoV-2])
- **Decision aid** at the moment of releasing patients from medical care (source: European Centres for Disease Control and Prevention (ECDC) – Technical Report - Novel coronavirus [SARS-CoV-2])
- **Identification of the pathogen contact** or a past infection with SARS-COV-2 (source: Bao et al., Reinfection could not occur in SARS-CoV-2 infected rhesus macaques, bioRxiv 2020.03.13.990226 and Okba et al., SARS-CoV-2 specific antibody responses in COVID-19 patients, medRxiv 10.1101/2020.03.18.20038059).
- **Epidemiological** studies in the population. (source: Robert-Koch Institute [RKI] - SARS-CoV-2 / Characteristics of coronavirus disease 2019 [COVID-19])

Aarzel niet om ons te contacteren voor verder toelichting,

Met vriendelijke groet, [redacted]

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