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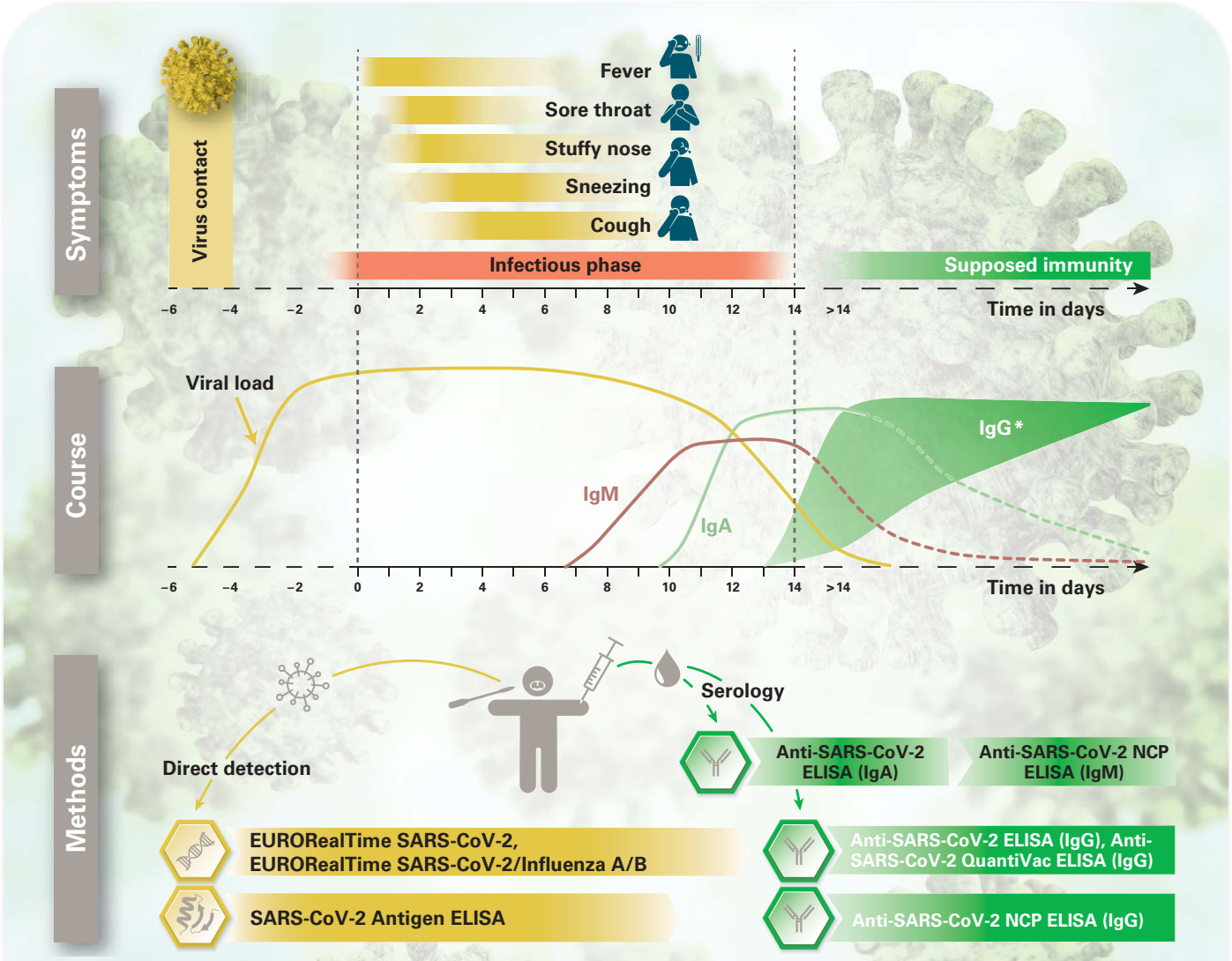
Application of EUROIMMUN tests for COVID-19 diagnostics



** IgG seroconversion may take place at different time points after contact with the pathogen (Wölfel R, et al. Nature 581(7809):465-469 (2020) and Okba NMA, et al. Emerg Infect Dis 26(7):1478–1488 (2020)).* In individual cases, antibodies are only detectable more than four weeks after the onset of symptoms or not at all due to a generally delayed or absent antibody secretion.

Correct application of our tests

- Identification of an acute infection by direct pathogen detection using PCR and antigen ELISA: **EURORealTime SARS-CoV-2, EURORealTime SARS-CoV-2/Influenza A/B** as well as **SARS-CoV-2 Antigen ELISA**
- Further monitoring of patients with acute infection (confirmed by positive PCR): Antibody detection using the **Anti-SARS-CoV-2 ELISA (IgA)** and **Anti-SARS-CoV-2 NCP ELISA (IgM)**
- Detection of a past contact with the pathogen (from 2 to 4 weeks after infection): Antibody detection using the **Anti-SARS-CoV-2 ELISA (IgG)** or **Anti-SARS-CoV-2 QuantiVac ELISA (IgG)** and **Anti-SARS-CoV-2 NCP ELISA (IgG)**

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Areas of application of EUROIMMUN SARS-CoV-2 tests

	PCR	Antigen ELISA	IgA ELISA	IgM ELISA	IgG ELISA
Detection of acute infections	✓	✓	✗	✗	✗
Screening for detection of acute infections	✓	✓	✗	✗	✗
Detection of a pathogen contact (up to day 10)	✓	✓	✗/✓	✗/✓	✗
Detection of a pathogen contact (from week 2 to 4)	✗	✗	✗	✗	✓
Further monitoring after acute infection (confirmed by direct detection)	✓	✓	✓	✓	✓
Detection of past infections	✗	✗	✗	✗	✓

Interpretation of SARS-CoV-2 test results

	PCR	Antigen ELISA	IgA ELISA	IgM ELISA	IgG ELISA
Early phase of acute infection (up to day 10)	+	+	+/−	+/−	− (+)
Late phase of acute infection (from day 10)	− (+)	−	+/−	+/−	+ (−)
Past infection	−	−	+/−	−	+
No statement possible (follow-up sample recommended)	−	−	+	+	−

PCR: *EURORealTime SARS-CoV-2, EURORealTime SARS-CoV-2/Influenza A/B;* ***antigen ELISA:*** *SARS-CoV-2 Antigen ELISA;* ***IgA ELISA:*** *Anti-SARS-CoV-2 ELISA (IgA);* ***IgM ELISA:*** *Anti-SARS-CoV-2 NCP ELISA (IgM);* ***IgG ELISA:*** *Anti-SARS-CoV-2 ELISA (IgG), Anti-SARS-CoV-2 QuantiVac ELISA (IgG), Anti-SARS-CoV-2 NCP ELISA (IgG)*

Characteristics of EUROIMMUN SARS-CoV-2 tests

- **EURORealTime SARS-CoV-2:** High sensitivity and reliability due to simultaneous detection of two target sequences of SARS-CoV-2; only one reaction per sample
- **EURORealTime SARS-CoV-2/Influenza A/B:** For direct detection of SARS-CoV-2 and influenza viruses (types A and B); for differential diagnostic clarification of symptoms that can be associated with COVID-19 as well as influenza
- **Anti-SARS-CoV-2 ELISA (IgG):** High specificity of 99.6% due to the use of the spike protein domain S1 including the immunologically relevant receptor binding domain (RBD) – the main target antigen for virus-neutralising antibodies
- **Anti-SARS-CoV-2 QuantiVac ELISA (IgG):** Quantitative determination of Anti-SARS-CoV-2 S1/RBD antibodies in standardised units based on the "First WHO International Standard for anti-SARS-CoV-2 immunoglobulin" (NIBSC code: 20/136); excellent correlation with neutralisation tests; supports the detection and assessment of the immune response following infection or vaccination
- **Anti-SARS-CoV-2 NCP ELISA (IgM or IgG):** High specificity of the ELISAs of 98.6% (IgM) and 99.8% (IgG), due to the use of a modified nucleocapsid protein (NCP) containing exclusively diagnostically relevant epitopes
- **Anti-SARS-CoV-2 ELISA (IgA):** Use of the S1 domain of the spike protein as the antigen; for supportive analysis of follow-up samples after infection confirmed by PCR; indicates a beginning immune reaction

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