

capsid (N) protein is considered the major diagnostic antigen. WO2005/118813 discloses a variant of SARS-CoV-1-related S protein and the detection of its presence, or the presence of antibodies binding to it, in samples. US2006/0188519 discloses peptides for the diagnosis of a SARS-CoV-1 infection. Hsueh *et al.* reported that IgG could be detected as early as four days after the onset of a SARS-CoV-1 infection, simultaneously as or one day *earlier* than IgM and IgA (Hsue, P. R., Huang, L. M., Chen, P. J., Kao, C. L., and Yang P. C. (2004) Chronological evolution of IgM, IgA, IgG and neutralization antibodies after infection with SARS-associated coronavirus, Clinical Microbiology and Infection, 10(12), 1062-1066). Reusken et al. disclose the specific, but not necessarily sensitive detection of antibodies to a SARS-CoV-2 spike protein fragment (Specific serology for emerging human coronaviruses by protein microarray. Euro Surveill. 2013;18(14). Yu *et al.* (2020) Measures for diagnosing and treating infections by a novel coronavirus responsible for a pneumonia outbreak originating in Wuh, China, Microbes and Infection 22 (2020), 74-79 disclose, without pointing to specific antigens, that immunological methods may be used for detecting a SARS-CoV-2 infection, but are associated with poor sensitivity and specificity.

The above-discussed problems are solved by the present invention, as described in the present specification and in the claims.

Summary

In one aspect, the present disclosure provides a method for diagnosing a SARS-CoV-2 infection comprising the step of detecting the presence or absence of an antibody to SEQ ID NO1, preferably IgA class antibody, in a sample from a subject. In another aspect, the present disclosure provides a method for the differential diagnosis of a coronavirus infection, preferably for distinguishing between a SARS-CoV; preferably SARS-CoV-2; MERS, NL63, 229E, OC43 and HKU1 infection, comprising the step of detecting the presence or absence of an antibody to SEQ ID NO1 in a sample from a subject, preferably an IgA and/or IgG class antibody, more preferably an IgA class antibody.

In yet another aspect, the present disclosure provides a use of an antibody to SEQ ID NO1, preferably IgA class antibody, for diagnosing a SARS-CoV-2 infection or for the differential diagnosis of a coronavirus infection, preferably for distinguishing between a SARS-CoV, preferably SARS-CoV-2, MERS and NL63, 229E, OC43 and HKU1 infection.

In a further aspect, the present disclosure provides a kit comprising a polypeptide comprising SEQ ID NO1 or a variant thereof, preferably coated to a diagnostically useful carrier and one or more, preferably all reagents from the group comprising an antibody to SEQ ID NO1, a washing buffer, a means for detecting the presence of antibody to SEQ ID NO1, preferably an IgA class antibody, preferably a secondary antibody binding specifically to IgA class antibodies, preferably comprising a detectable label, and a dilution buffer.

In yet another aspect, the present disclosure provides a use of a polypeptide comprising SEQ ID NO1 or a variant thereof or an antibody to SEQ ID NO1, preferably an IgA class antibody, for the manufacture of a diagnostic kit. In yet another aspect, the present disclosure provides a use of a recombinant

antibody binding to SEQ ID NO1 which is preferably recognized by a secondary antibody binding to IgA class antibodies as a calibrator for the early diagnosis of a SARS-CoV-2 infection.

Detailed Description

5 In a first aspect, the invention provides a method for diagnosing a SARS-CoV-2 infection, comprising the step of detecting the presence or absence of an antibody to SEQ ID NO:1, preferably IgM, IgG and/or IgA class antibody, more preferably IgA class antibody, in a sample from a subject. Whenever reference to a SEQ ID NO is made throughout this specification and the SEQ ID NO denotes an amino acid sequence, it is intended to denote a polypeptide comprising said corresponding amino acid string even if in that connection the term "polypeptide" is not specifically mentioned. The term "com-

10 comprising" has two meanings in connection with this invention, namely "containing" and "consisting of." In a second aspect, the invention provides a method for the differential diagnosis of a coronavirus infection, preferably for distinguishing between a SARS-CoV; preferably SARS-CoV-2; MERS, NL63, 229E, OC43 and HKU1 infection, comprising the step of detecting the presence or absence of an antibody to SEQ ID NO: 1 in a sample from a subject, preferably an IgA and/or IgG class antibody, more preferably an IgA class antibody.

15 In a preferred embodiment, the presence of an IgG and/or IgM class antibody to SEQ ID NO: 1 is detected in addition to an IgA class antibody to SEQ ID NO: 1.

In accordance with the present invention, the "subject", or interchangeably referred to herein as "patient", refers to a mammal, preferably a human, but may alternatively also refer to a different mammal, such as a non-human primate or other mammalian animal or even a non-mammalian animal capable of producing an antibody to SEQ ID NO: 1 or variant thereof.

20 In accordance with the present invention, the term "sample" from a subject may be a sample of any bodily fluid or tissue of said subject that may comprise an antibody. Exemplary bodily fluids include for example blood, saliva, nasal mucus or lymph fluid. In a preferred embodiment, the sample is a blood sample, preferably selected from the group comprising whole blood, serum, plasma, capillary blood, arterial blood, venous blood or any mixture thereof. The capillary blood is preferably in the form of a