of the prior art, leads to less false positive and less false negative results, particularly in population-based approaches. A further problem underlying the present invention was to provide means for carrying out such methods and such assays, respectively. A still further problem underlying the present invention was the provision of a biomarker for H. pylori infected patients, whereby the biomarker preferably does not show any cross-reactivity with other bacteria and any proteins, peptides or nucleic acid molecules coding for such proteins and peptides in particular.

Summary

These and other problems underlying the present invention are solved by the subject matter of the attached independent claims. Preferred embodiments may be taken from the attached dependent claims. In one aspect, the present invention refers to a method for detecting *H. pylori* infection in a subject, wherein the method comprises detecting in a sample from the subject an immune response against FliD, wherein the immune response comprises an anti-FliD antibody, and wherein the method comprises reacting the sample with FliD or a fragment thereof. In another aspect, the present invention refers to the use of a kit comprising FliD or a fragment thereof and at least one further constituent, in a method of the present invention, wherein the at least one further constituent is selected from the group consisting of a buffer, a solid phase and an instruction leaflet. In yet another aspect, the present invention refers to a kit suitable for use in a method of the present invention, said kit comprising full-length FliD or a fragment thereof and at least one further constituent, wherein the fragment is a fragment the amino acid sequence of which is shorter than the amino acid sequence of full-length FliD, whereby the fragment is still active as a virulence factor, and wherein the at least one further constituent is selected from the group consisting of a buffer, a solid phase and an instruction leaflet.

Detailed description of the invention

These and other problems underlying the present invention are also solved by the following embodiments.

Embodiment 1: A method for detecting Helicobacter infection and more preferably an H. pylori infection in a subject, wherein the method comprises detecting in a sample from the subject an immune response against FliD.

Embodiment 2: The method of Embodiment 1, wherein if an immune response against FliD is detected in the sample from the subject, the subject is suffering from a Helicobacter infection, preferably an H. pylori infection, or the subject has undergone a Helicobacter infection, preferably an H. pylori infection, in the past.

Embodiment 3: The method of any one of Embodiments 1 to 2, wherein if no immune response against FliD is detected in the sample from the subject, the subject is not suffering from a Helicobacter infection, preferably an H. pylori infection.

Embodiment 4: The method of any one of Embodiments 1 to 2, wherein if no immune response against FliD is detected in the sample from the subject, the subject has undergone a Helicobacter infection, preferably an H. pylori infection, in the past.

Claims

1. A method for detecting *H. pylori* infection in a subject, wherein the method comprises detecting in a sample from the subject an immune response against FliD, wherein the immune response comprises an anti-FliD antibody, and wherein the method comprises reacting the sample with FliD or a fragment thereof.

2. The method of claim 1, wherein the anti-FliD antibody is an IgG antibody and/or an IgA antibody.

3. The method of any one of claims 1 to 2, wherein the detection occurs by means of an ELISA, a lateral flow assay or a line assay.

4. The method of any one of claims 1 to 3, wherein the method further comprises detecting one or more antigens of *Helicobacter*, preferably of *H. pylori*, wherein the one or more antigens is/are selected from the group consisting of CagA, VacA, GroEL, Hp 0231, JHp 0940 and HtrA.

5. The method of any one of claims 1 to 4, wherein the sample is selected from the group consisting of blood serum, blood plasma, whole blood and stool.

6. Use of a kit comprising FliD or a fragment thereof and at least one further constituent, in a method of any one of claims 1 to 5, wherein the at least one further constituent is selected from the group consisting of a buffer, a solid phase and an instruction leaflet.

7. A kit suitable for use in a method of any one of claims 1 to 5, said kit comprising full-length FliD or a fragment thereof and at least one further constituent, wherein the fragment is a fragment the amino acid sequence of which is shorter than the amino acid sequence of full-length FliD, whereby the fragment is still active as a virulence factor, and wherein the at least one further constituent is selected from the group consisting of a buffer, a solid phase and an instruction leaflet.

Claims

1. A method for detecting H. pylori infection in a subject, wherein the method comprises detecting in a sample from the subject an immune response against FliD, wherein the immune response comprises an anti-FliD antibody.

2. The method of claim 2, wherein the anti-FliD antibody is an IgG antibody and/or an IgA antibody.

3. The method of any one of claims 1 to 2, wherein the detection occurs by means of an ELISA, a lateral flow assay or a line assay.

4. Use of an immune response against FliD in a subject as a biomarker, wherein the biomarker is a biomarker for infection of the subject with H. pylori and wherein the immune response against FliD comprises an anti-FliD antibody.

5. Use of a kit comprising FliD or a fragment thereof and at least one further constituent, in a method of any one of claims 1 to 3.

6. A method for detecting H. pylori infection in a subject, wherein the method comprises detecting FliD or a fragment thereof in a sample from the subject.

7. The method of claim 6, wherein the detection occurs by means of an ELISA, a line immunoassay, a lateral flow assay or mass spectrometry.

8. Use of FliD as a biomarker, wherein the biomarker is a biomarker for infection of a subject with H. pylori.

9. Use of a kit comprising an interacting agent capable of interacting with FliD or a fragment thereof and at least one further constituent, in a method according to any one of claims 6 to 7.

10. A method for detecting H. pylori infection in a subject, wherein the method comprises detecting in a sample from the subject a nucleic acid coding for FliD or a fragment thereof.

11. The method according to claim 10, wherein the nucleic acid molecule coding for FliD is detected by means of mass spectroscopy, a hybridization assay or PCR.

12. Use of a nucleic acid coding for FliD as a biomarker, wherein the biomarker is a biomarker for infection of a subject with H. pylori.

13. Use of a kit comprising an interacting agent capable of interacting with a nucleic acid coding for FliD or a fragment thereof and at least one further constituent, in a method of any one of claims 10 to 11.

14. The method of any one of claims 1 to 3, 6 to 7 and 10 to 11, wherein the method further comprises detecting one or more antigens of Helicobacter, preferably of H. pylori, wherein the one or more antigens is/are selected from the group comprising CagA, VacA, GroEL, Hp 0231, JHp 0940 and HtrA.

15. The method of any one of claims 1 to 3, 6 to 7, 10 to 11 and 14, wherein the sample is selected from the group consisting of blood serum, blood plasma, whole blood and stool.