

CLAIMS

1. A method for determining hand-foot-and-mouth disease (HFMD), the method
5 comprising detecting in a saliva sample the presence and/or amount of at least one protein
biomarker selected from the group defined in Table 1, wherein the presence and/or an
amount of the protein biomarker in the saliva sample is indicative of HFMD.
2. The method according to claim 1, wherein the at least one protein biomarker is
10 selected from the group consisting of PRX-IV, legumain, SIL1 and CREG1, and detecting the
presence and/or amount of either one or any combination of said biomarkers in the saliva
sample is indicative of HFMD.
3. The method according to any one of claims 1 or 2, wherein the step of detecting the
15 presence and/or amount of the at least one protein biomarker is performed using a binding
agent capable of binding to the at least one protein biomarker to form a bound complex.
4. The method according to claim 3, wherein the binding agent is an antibody or a
fragment thereof.
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5. The method according to any one of claims 3 or 4, wherein the binding agent is
labelled with a detectable moiety.
6. The method according to claim 5, wherein the detectable moiety is selected from the
25 group consisting of: a fluorescent moiety, a luminescent moiety, a chemiluminescent moiety,
a radioactive moiety, and an enzymatic moiety.
7. The method according to any one of the preceding claims, wherein the step of
30 detecting the presence and/or amount of the at least one protein biomarker is performed
using a lateral flow assay.

8. The method according to any one of the preceding claims, wherein the amount of the at least one protein biomarker present in the range of between 0.1ug to 1mg indicates a HFMD infection.
- 5 9. A method for diagnosing in a patient with HFMD, the method comprising detecting the presence of at least one protein biomarker selected from the group defined in Table 1 in a saliva sample, wherein the presence of the protein biomarker in the saliva sample is indicative of HFMD.
- 10 10. Use of one or more protein biomarkers selected from the group defined in Table 1 as a biomarker for determining HFMD in an individual.
11. A kit for diagnosing HFMD in an individual, the kit comprising an assay for detecting the presence of at least one protein biomarker in a saliva sample.
- 15 12. The kit according to claim 9, further comprising a binding agent capable of binding to at least one protein biomarker selected from the group defined in Table 1.