

CLAIMS

1. An *in vitro* or *ex vivo* method of distinguishing diarrhoea predominant irritable bowel syndrome (D-IBS) from both inflammatory bowel disease (IBD) and celiac disease comprising:

5 providing a biological sample from a subject desiring a diagnosis to distinguish D-IBS from both IBD and celiac disease, in which the biological sample is whole blood, blood plasma or blood serum;

detecting in the biological sample, levels of anti-vinculin and anti-CdtB (cytolethal distending toxin B) antibodies; and

10 making a diagnosis that the subject has D-IBS but does not have IBD and does not have celiac disease if the level of anti-vinculin antibodies is significantly higher than an established control level of anti-vinculin antibodies, the level of anti-CdtB antibodies is significantly higher than an established control level of anti-CdtB antibodies, or both levels of anti-vinculin antibodies and anti-CdtB antibodies are significantly higher than
15 the established control levels of anti-vinculin antibodies and anti-CdtB antibodies;

in which the established control level of anti-vinculin antibodies is a level of anti-vinculin antibodies from healthy subjects without IBS, IBD, Celiac disease or combinations thereof; and

20 in which the established control level of anti-CdtB antibodies is a level of anti-CdtB antibodies from healthy subjects without IBS, IBD, Celiac disease or combinations thereof.

2. A method according to Claim 1, in which detecting in the biological sample comprises using enzyme-linked immunosorbent assay (ELISA).

3. A method according to Claim 1, in which detecting in the biological sample comprises
25 using immunohistochemistry, flow cytometry, fluorescence *in situ* hybridization (FISH), radioimmuno assays, or affinity purification.

4. A method according to Claim 1, in which the anti-vinculin antibodies are capable of binding specifically to an epitope on vinculin or SEQ ID NO: 7.

5. A method according to Claim 1, in which the anti-CdtB antibodies are capable of binding specifically to an epitope on CdtB of *Campylobacter jejuni* or SEQ ID NO: 5.
6. A method according to Claim 1, in which the diagnosis of D-IBS is made if the level of anti-vinculin antibodies is significantly higher than the established control level of anti-
5 vinculin antibodies.
7. A method according to Claim 1, in which the diagnosis of D-IBS is made if the level of anti-CdtB antibodies is significantly higher than the established control level of anti-CdtB antibodies.
8. A method according to Claim 1, in which the diagnosis of D-IBS is made if both levels
10 of anti-vinculin antibodies and anti-CdtB antibodies are significantly higher than the established control levels of anti-vinculin antibodies and anti-CdtB antibodies.
9. A method according to Claim 1, in which the established control level of anti-vinculin antibodies, anti-CdtB antibodies, or both is an optical density measurement.
10. An *in vitro* or *ex vivo* method of selecting a treatment for diarrhoea predominant irritable
15 bowel syndrome (D-IBS) comprising:
 - providing a biological sample from a subject desiring a diagnosis to distinguish D-IBS from both IBD and celiac disease, in which the biological sample is whole blood, blood plasma or blood serum;
 - detecting in the biological sample, levels of anti-vinculin and anti-CdtB (cytolethal
20 distending toxin B) antibodies;
 - making a diagnosis that the subject has D-IBS but does not have IBD and does not have celiac disease if the level of anti-vinculin antibodies is significantly higher than an established control level of anti-vinculin antibodies, the level of anti-CdtB antibodies is significantly higher than an established control level of anti-CdtB antibodies, or both
25 levels of anti-vinculin antibodies and anti-CdtB antibodies are significantly higher than the established control levels of anti-vinculin antibodies and anti-CdtB antibodies;
 - in which the established control level of anti-vinculin antibodies is a level of anti-vinculin antibodies from healthy subjects without IBS, IBD, Celiac disease or combinations thereof;

in which the established control level of anti-CdtB antibodies is a level of anti-CdtB antibodies from healthy subjects without IBS, IBD, Celiac disease or combinations thereof; and

selecting an D-IBS treatment for the subject if D-IBS and not IBD or celiac disease is diagnosed.

11. A method according to Claim 10, in which detecting in the biological sample comprises using enzyme-linked immunosorbent assay (ELISA).

12. A method according to Claim 10, in which detecting in the biological sample comprises using immunohistochemistry, flow cytometry, fluorescence *in situ* hybridization (FISH), radioimmuno assays, or affinity purification.

13. A method according to Claim 10, in which the anti-vinculin antibodies are capable of binding specifically to an epitope on vinculin or SEQ ID NO: 7.

14. A method according to Claim 10, in which the anti-CdtB antibodies are capable of binding specifically to an epitope on CdtB of *Campylobacter jejuni* or SEQ ID NO: 5.

15. A method according to Claim 10, in which the established control level of anti-vinculin antibodies, anti-CdtB antibodies, or both is an optical density measurement.

16. A method according to Claim 10, in which the diagnosis of D-IBS is made if the level of anti-vinculin antibodies is significantly higher than the established control level of anti-vinculin antibodies.

17. A method according to Claim 10, in which the diagnosis of D-IBS is made if the level of anti-CdtB antibodies is significantly higher than the established control level of anti-CdtB antibodies.

18. A method according to Claim 10, in which the diagnosis of D-IBS is made if both levels of anti-vinculin antibodies and anti-CdtB antibodies are significantly higher than the established control levels of anti-vinculin antibodies and anti-CdtB antibodies.