CLAIMS

1. A method to determine if a pregnant woman is at risk of infection-associated spontaneous pre-term birth (sPTB), the method comprising the steps of:

   a) testing a sample of vaginal fluid for the presence of the following bacteria:

      i) *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6;

      ii) *Gardnerella vaginalis*; and

      iii) *Lactobacillus iners*

   wherein the presence of the bacteria indicates that the subject is at risk of sPTB.

2. The method of claim 1 wherein the testing method also tests for the presence of *Fusobacterium nucleatum* and wherein ~~the presence of either:~~ if the testing for the presence of

   ~~- *Fusobacterium nucleatum* in the absence of *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6; or~~

   ~~-~~ *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6 of claim 1 provides a negative result, the presence of *Fusobacterium nucleatum* ~~, *Gardnerella vaginalis*, and *Lactobacillus iners*~~ indicates that the subject is at risk of a sPTB.

3. The method of claim 1 wherein the testing method is chosen from the list consisting of: nucleic acid amplification, fluorescence *in situ* hybridisation, bacterial culture, or immunological testing ~~qPCR~~.

4. The method of claim 1 wherein the testing is carried out at between 10 and 24 weeks' gestation.

5. The method of claim 1 wherein the testing also tests the sample of vaginal fluid for the presence of

   iv) a *Lactobacillus* species other than *L. iners*

   wherein if bacteria of species (iv) are present at more than 10,000 16S rRNA gene copies, the subject is not at risk of sPTB; and if bacteria of species (iv) are present at less than 10,000 16S rRNA gene copies and bacteria of species (i), (ii) and (iii) are present, the subject is at risk of sPTB.

6. The method of claim 5 wherein the *Lactobacillus* species other than *L. iners* is chosen from *Lactobacillus gasseri*, *Lactobacillus crispatus* and/or *Lactobacillus jensenii*.

75. A method to determine if a pregnant woman would benefit from treatment to prevent infection-associated spontaneous pre-term birth (sPTB), the method comprising the steps of:

a) testing a sample of vaginal fluid for the presence of the following bacteria:

i) *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6;

ii) *Gardnerella vaginalis*; and

iii) *Lactobacillus iners*

wherein the presence of the bacteria indicates that the subject is at risk of a sPTB and therefore would benefit from treatment to prevent sPTB.

~~6. A method to treat a pregnant woman at risk of infection-associated spontaneous pre-term birth (sPTB), comprising the steps of:~~

~~a) testing a sample of vaginal fluid for the presence of the following bacteria:~~

~~i) *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6;~~

~~ii) *Gardnerella vaginalis*; and~~

~~iii) *Lactobacillus iners*~~

~~b) if the bacteria are present, giving the pregnant woman antibiotic therapy to eliminate the bacteria.~~

~~7. A method of reducing the risk of a pregnant woman having a infection-associated spontaneous pre-term birth (sPTB), comprising the steps of:~~

~~a) testing a sample of vaginal fluid for the presence of the following bacteria:~~

~~i) *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6;~~

~~ii) *Gardnerella vaginalis*; and~~

~~iii) *Lactobacillus iners*~~

~~b) if the bacteria are present, giving the pregnant woman antibiotic therapy to eliminate the bacteria and therefore reduce the risk of sPTB.~~

8. A kit when used to determine if a pregnant woman is at risk of infection-associated spontaneous pre-term birth (sPTB), the kit comprising:

   a) a means for testing a sample of vaginal fluid for the presence of the following bacteria:

      i) *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6;

      ii) *Gardnerella vaginalis*; and

      iii) *Lactobacillus iners*

   b) instructions for use.

9. The method of ~~any one of~~ claim~~s 5 to~~ 7 or kit of claim 8 wherein the testing method also tests for the presence of *Fusobacterium nucleatum* and wherein ~~the presence of either:~~if the testing for the presence of

   ~~- *Fusobacterium nucleatum* in the absence of *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6; or~~

   ~~-~~ *Ureaplasma parvum* genotype SV3 and/or *Ureaplasma parvum* genotype SV6 of claim 1 provides a negative result, the presence of *Fusobacterium nucleatum*~~, *Gardnerella vaginalis*, and *Lactobacillus iners*~~

   indicates that the subject is at risk of a sPTB.

10. The method of ~~any one of~~ claim~~s 5 to~~ 7 or kit of claim 8 wherein the testing method is ~~qPCR~~chosen from the list consisting of: nucleic acid amplification, fluorescence *in situ* hybridisation, bacterial culture, or immunological testing.

11. The method of ~~any one of~~ claim~~s 5 to~~ 7 ~~or kit of claim 8~~ wherein the testing is carried out at between 10 and 24 weeks' gestation.

12. The kit of claim 8 wherein the instructions indicate that the testing is carried out at between 10 and 24 weeks' gestation.

13. The method of claim 7 or kit of claim 8 wherein the testing also tests the sample of vaginal fluid for the presence of

    iv) a *Lactobacillus* species other than *L. iners*

    wherein if bacteria of species (iv) are present at more than 10,000 16S rRNA gene copies, the subject is not at risk of sPTB; and if bacteria of species (iv) are present at less than

10,000 16S rRNA gene copies and bacteria of species (i), (ii) and (iii) are present, the subject is at risk of sPTB.

14. The method or kit of claim 13 wherein the *Lactobacillus* species other than *L. iners* is chosen from *Lactobacillus gasseri*, *Lactobacillus crispatus* and/or *Lactobacillus jensenii*.