CLAIMS:

1. A method of assessing the infection status of a ~~breastfeeding mother and/or of an infant being breastfed by said mother, said method~~human subject comprising the steps of:

a) ~~analysing~~determining the ~~composition~~proportion of ~~immunological markers~~viable immune cells (ICs) in mature breastmilk ~~obtained~~ from said ~~breastfeeding mother~~subject using a marker found on all leucocytes; and

b) comparing said ~~composition with a reference,~~proportion of viable ICs with a reference, wherein said reference is the proportion of viable ICs in mature breastmilk from said same subject, determined using said same marker at a time when said subject did not have an infection as indicated by a proportion of viable ICs in said subject's breastmilk of less than 2%,

wherein ~~a difference~~an at least 3-fold increase in the ~~composition~~proportion of ~~immunological markers in~~ said ~~breastmilk~~viable ICs when compared to said reference ~~is indicative of a change in the~~ indicates that said subject has an infection ~~status~~.

2. A method of diagnosing an infection in a lactating human subject, comprising the steps of ~~said mother and/or~~

a) determining the proportion of viable immune cells (ICs) in mature breastmilk from said ~~infant.~~subject using a marker found on all human leucocytes; and

~~The method of claim 1~~b) comparing said proportion of viable ICs with a reference, wherein said reference is the ~~composition of immunological markers~~proportion of viable ICs in mature breastmilk ~~obtained~~ from ~~the~~said same ~~breastfeeding mother obtained~~subject, determined using said same marker at a time when said ~~mother was healthy~~subject did not have an infection as indicated by a proportion of viable ICs in said subject's breastmilk of less than 2%,

wherein an at least 3-fold increase in the proportion of said viable ICs when compared to said reference indicates that said subject has an infection

~~2.~~3. The method of claim 1 or claim 2, wherein said infection is selected from the group consisting of bacterial, viral and fungal infections.

~~3. The method of claim 1, wherein said reference is the composition of immunological markers in breastmilk obtained from a population of breastfeeding mothers obtained when said mothers were healthy.~~

4. ~~The method of any~~ one of ~~the preceding~~ claims 1 to 3, wherein ~~said immunological marker~~the infection is selected from ~~immune cells (IC), cytokines,~~the group consisting of systemic infections, infections of the breast, upper respiratory tract infections, ear infections, eye infections, gastrointestinal infections and ~~immunoglobulins~~vaginal infections.

~~5. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the proportion of immune cells (ICs) in said breastmilk and wherein an increase in the proportion of said ICs when compared to said reference indicates that said mother and/or said infant have an infection.~~

~~6. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the relative proportions of an immune cell (IC)-type within the total IC population in said breastmilk to establish an IC-type profile of said breastmilk and wherein a relative change in the IC-type profile when compared to said reference indicates that said mother and/or said infant have an infection.~~

5. The method of claim 3, wherein said systemic infection is an influenza infection.

6. The method of claim 3, wherein said upper respiratory tract infection is a common cold.

7. The method of claim 3, wherein said infection of the breast is mastitis.

~~7.~~8. The method of claim ~~5 or claim 6 wherein said ICs are leukocytes and~~3, wherein said ~~proportion of leukocytes within said reference is between 0 and 2 %.~~infection of the breast is subclinical mastitis.

~~8. The method of any one of claims 5 to 7~~claim 3, wherein said ~~increase the proportion of said ICs is an increase in leukocytes of up to about 94% leukocytes of total breastmilk cells.~~

~~9. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the cytokine level in said breastmilk.~~

10. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the relative cytokine proportions in said breastmilk to establish a cytokine profile of said breastmilk.

11. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the immunoglobulin level in said breastmilk.

12. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the relative immunoglobulin proportions in said breastmilk to establish an immunoglobulin profile of said breastmilk.

13. The method of any one of the preceding claims, wherein said difference is indicative of a change in the infection status of said mother and said infant.

14. The method of any one of claims 1 to 12, wherein said difference is indicative of a change in the infection status of said mother only.

15. The method of any one of claims 1 to 12, wherein said difference is indicative of a change in the infection status of said infant only.

16. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the proportion of immune cells (ICs) in breastmilk obtained from said breastfeeding mother; and

b) comparing said proportion of ICs with a reference,

wherein an increase in the proportion of said ICs when compared to said reference indicates that said mother and/or said infant have an infection.

17. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the relative proportions of an IC-type within the total IC population in breastmilk obtained from said breastfeeding mother to establish a IC-type profile of said breastmilk; and

b) comparing said IC-type profile with a reference,

~~wherein a relative change in the IC-type profile when compared to said reference indicates that said mother and/or said infant have an infection.~~

~~18. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:~~

~~a) determining the cytokine level in breastmilk obtained from said breastfeeding mother; and~~

~~b) comparing said cytokine level with a reference,~~

~~wherein a change in the cytokine level when compared to said reference indicates that said mother and/or said infant have an infection.~~

~~19. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:~~

~~a) determining the relative cytokine proportions in breastmilk obtained from said breastfeeding mother to establish a cytokine profile of said breastmilk; and~~

~~b) comparing said cytokine profile with a reference,~~

~~wherein a change in said cytokine profile when compared to said reference indicates that said mother and/or said infant have an infection.~~

~~20. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:~~

~~a) determining the immunoglobulin level in breastmilk obtained from said breastfeeding mother; and~~

~~b) comparing said immunoglobulin level with a reference,~~

~~wherein a change in the immunoglobulin level when compared to said reference indicates that said mother and/or said infant have an infection.~~

~~21. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:~~

a) determining the relative immunoglobulin proportions in breastmilk obtained from said breastfeeding mother to establish an immunoglobulin profile of said breastmilk; and

b) comparing said immunoglobulin profile with a reference,

wherein a change in said immunoglobulin profile when compared to said reference indicates that said mother and/or said infant have an infection.

22. A method of diagnosing an infection of the breast in a lactating human subject, comprising the steps of

a) determining the proportion of immune cells (ICs) in breastmilk obtained from said subject; and

b) comparing said proportion of ICs with a reference,

wherein said reference is the proportion of ICs in breastmilk from the same subject obtained when said subject was healthy, and wherein an increase in the proportion of said ICs when compared to said reference is indicative of an infection of the breast of said subject.

23. A method of diagnosing an infection of the breast in a lactating human subject, comprising the steps of

a) determining the proportion of immune cells (ICs) in breastmilk obtained from said subject; and

b) comparing said proportion of ICs with a reference,

24.9. wherein said reference is the proportion of ICs in breastmilk obtained from a population of lactating human subjects when said subjects were healthy, and wherein an increase in the proportion of said ICs when compared to said reference is indicative of an infection of the breast of said subjectis clinical mastitis.

WHAT IS CLAIMED IS:

1. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) analysing the composition of immunological markers in breastmilk obtained from said breastfeeding mother; and

b) comparing said composition with a reference,

wherein a difference in the composition of immunological markers in said breastmilk when compared to said reference is indicative of a change in the infection status of said mother and/or said infant.

2. The method of claim 1, wherein said reference is the composition of immunological markers in breastmilk obtained from the same breastfeeding mother obtained when said mother was healthy.

3. The method of claim 1, wherein said reference is the composition of immunological markers in breastmilk obtained from a population of breastfeeding mothers obtained when said mothers were healthy.

4. The method of any one of the preceding claims, wherein said immunological marker is selected from immune cells (IC), cytokines, and immunoglobulins.

5. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the proportion of immune cells (ICs) in said breastmilk and wherein an increase in the proportion of said ICs when compared to said reference indicates that said mother and/or said infant have an infection.

6. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the relative proportions of an immune cell (IC)-type within the total IC population in said breastmilk to establish an IC-type profile of said breastmilk and wherein a relative change in the IC-type profile when compared to said reference indicates that said mother and/or said infant have an infection.

7. The method of claim 5 or claim 6 wherein said ICs are leukocytes and wherein said proportion of leukocytes within said reference is between 0 and 2 %.

8. The method of any one of claims 5 to 7, wherein said increase the proportion of said ICs is an increase in leukocytes of up to about 94% leukocytes of total breastmilk cells.

9. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the cytokine level in said breastmilk.

10. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the relative cytokine proportions in said breastmilk to establish a cytokine profile of said breastmilk.

11. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the immunoglobulin level in said breastmilk.

12. The method of any one of the preceding claims, wherein analysing the composition of immunological markers comprises determining the relative immunoglobulin proportions in said breastmilk to establish an immunoglobulin profile of said breastmilk.

13. The method of any one of the preceding claims, wherein said difference is indicative of a change in the infection status of said mother and said infant.

14. The method of any one of claims 1 to 12, wherein said difference is indicative of a change in the infection status of said mother only.

15. The method of any one of claims 1 to 12, wherein said difference is indicative of a change in the infection status of said infant only.

16. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the proportion of immune cells (ICs) in breastmilk obtained from said breastfeeding mother; and

b) comparing said proportion of ICs with a reference,

wherein an increase in the proportion of said ICs when compared to said reference indicates that said mother and/or said infant have an infection.

17. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the relative proportions of an IC-type within the total IC population in breastmilk obtained from said breastfeeding mother to establish a IC-type profile of said breastmilk; and

b) comparing said IC-type profile with a reference,

wherein a relative change in the IC-type profile when compared to said reference indicates that said mother and/or said infant have an infection.

18. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the cytokine level in breastmilk obtained from said breastfeeding mother; and

b) comparing said cytokine level with a reference,

wherein a change in the cytokine level when compared to said reference indicates that said mother and/or said infant have an infection.

19. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the relative cytokine proportions in breastmilk obtained from said breastfeeding mother to establish a cytokine profile of said breastmilk; and

b) comparing said cytokine profile with a reference,

wherein a change in said cytokine profile when compared to said reference indicates that said mother and/or said infant have an infection.

20. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the immunoglobulin level in breastmilk obtained from said breastfeeding mother; and

b) comparing said immunoglobulin level with a reference,

wherein a change in the immunoglobulin level when compared to said reference indicates that said mother and/or said infant have an infection.

21. A method of assessing the infection status of a breastfeeding mother and/or of an infant being breastfed by said mother, said method comprising the steps of:

a) determining the relative immunoglobulin proportions in breastmilk obtained from said breastfeeding mother to establish an immunoglobulin profile of said breastmilk; and

b) comparing said immunoglobulin profile with a reference,

wherein a change in said immunoglobulin profile when compared to said reference indicates that said mother and/or said infant have an infection.

22. A method of diagnosing an infection of the breast in a lactating human subject, comprising the steps of

a) determining the proportion of immune cells (ICs) in breastmilk obtained from said subject; and

b) comparing said proportion of ICs with a reference,

wherein said reference is the proportion of ICs in breastmilk from the same subject obtained when said subject was healthy, and wherein an increase in the proportion of said ICs when compared to said reference is indicative of an infection of the breast of said subject.

23. A method of diagnosing an infection of the breast in a lactating human subject, comprising the steps of

a) determining the proportion of immune cells (ICs) in breastmilk obtained from said subject; and

b) comparing said proportion of ICs with a reference,

wherein said reference is the proportion of ICs in breastmilk obtained from a population of lactating human subjects when said subjects were healthy, and wherein an increase in the proportion of said ICs when compared to said reference is indicative of an infection of the breast of said subject.

CLAIMS

1. A method of assessing the infection status of a human subject comprising the steps of:

a) determining the proportion of viable immune cells (ICs) in mature breastmilk from said subject using a marker found on all leucocytes; and

b) comparing said proportion of viable ICs with a reference, wherein said reference is the proportion of viable ICs in mature breastmilk from said same subject, determined using said same marker at a time when said subject did not have an infection as indicated by a proportion of viable ICs in said subject's breastmilk of less than 2%,

wherein an at least 3-fold increase in the proportion of said viable ICs when compared to said reference indicates that said subject has an infection.

2. A method of diagnosing an infection in a lactating human subject, comprising the steps of

a) determining the proportion of viable immune cells (ICs) in mature breastmilk from said subject using a marker found on all human leucocytes; and

b) comparing said proportion of viable ICs with a reference, wherein said reference is the proportion of viable ICs in mature breastmilk from said same subject, determined using said same marker at a time when said subject did not have an infection as indicated by a proportion of viable ICs in said subject's breastmilk of less than 2%,

wherein an at least 3-fold increase in the proportion of said viable ICs when compared to said reference indicates that said subject has an infection

3. The method of claim 1 or claim 2, wherein said infection is selected from the group consisting of bacterial, viral and fungal infections.

4. The method of one of claims 1 to 3, wherein the infection is selected from the group consisting of systemic infections, infections of the breast, upper respiratory tract infections, ear infections, eye infections, gastrointestinal infections and vaginal infections.

5. The method of claim 3, wherein said systemic infection is an influenza infection.

6. The method of claim 3, wherein said upper respiratory tract infection is a common cold.

7. The method of claim 3, wherein said infection of the breast is mastitis.

8. The method of claim 3, wherein said infection of the breast is subclinical mastitis.

9. The method of claim 3, wherein said infection of the breast is clinical mastitis.