CLAIMS

1. A method of determining the quantity or concentration of a bacterium in a sample, said method including the steps of:

(a) amplifying a target nucleic acid of the bacterium from genetic material obtained from the sample to form an amplification product, wherein the target nucleic acid comprises at least a portion of a bacterial 16S rRNA gene and wherein the target nucleic acid comprises one or a plurality of single nucleotide polymorphisms (SNPs) in the bacterial 16S rRNA gene;

(b) identifying the bacterium in the sample and measuring a quantity or concentration of the amplification product in a single process, wherein the step of identifying the bacterium comprises analysing the amplification product for the presence or absence of one or a plurality of SNPs;

(c) calculating a quantity or concentration of the target nucleic acid in the sample by comparing the quantity or concentration of the amplification product with a reference level thereof; and

(d) determining a copy number of the bacterial 16S rRNA gene in the sample from the quantity or concentration of the target nucleic acid therein, the copy number being a function of or correlated to the quantity of the bacterium in the sample.

2. The method of claim 2, wherein the one or plurality of SNPs corresponding to at least one of positions 273, 378, 408, 412, 440, 488, 647, 653, 737, 755, 762 and 776 of the 16S rRNA gene set forth in SEQ ID NO: 1.

3. The method of either one of claims 1 or 2, further including the step of generating the reference level from one or a plurality of control samples.

4. The method of claim 3, wherein the step of generating the reference level comprises amplifying the target nucleic acid from the one or plurality of control samples, wherein the control samples comprise genetic material of a known quantity or concentration.

5. The method of either one of claims 3 or 4, wherein amplifying the target nucleic acid from the one or plurality of control samples is performed substantially simultaneously or in parallel with step (a).

6. The method of any one of claims 3 to 5, wherein the one or plurality of control samples further comprise genetic material from one or a plurality of further bacteria.

7. The method of any one of the preceding claims, wherein amplifying the target nucleic acid from genetic material of the sample and/or the one or plurality of control samples is conducted with a pair of primers that comprise at least one of SEQ ID NOs: 16-37 and 48-51.

8. The method of any one of the preceding claims, wherein the step of analysing the amplification product for the presence or the absence of the at least one SNP comprises the use of high resolution melt analysis, 5' nuclease digestion, molecular beacons, oligonucleotide ligation, microarray, restriction fragment length polymorphism, antibody detection methods, direct sequencing or any combination thereof.

9. The method of any one of the preceding claims, wherein the copy number of the bacterial 16S rRNA gene is determined using the formula:

$$copy\ number = \frac{X\ \text{ng} * 6.0221\text{x}10^{23}\ \text{molecules/mole}}{(\text{N} * 660\text{g/mole}) * 1\text{x}10^{9}\text{ng/g}}$$

wherein X is the quantity of the amplification product and N is the length in nucleotides of the target nucleic acid.

10. The method of any one of the preceding claims, wherein the sample is a biological sample, such as sputum, blood, cerebrospinal fluid or urine, to be taken from a subject.

11. The method of claim 10, wherein the subject has an infection by the bacterium.

12. A method of determining a prognosis for an infection by a bacterium in a subject, including the step of quantifying the bacterium in a biological sample from the subject according to the method of any one of claims 1 to 11 to thereby evaluate the prognosis of the infection in the subject.

13. A method of evaluating treatment efficacy of an infection by a bacterium in a subject including:

quantifying the bacterium in a biological sample from the subject according to the method of any one of claims 1 to 11; and

determining whether or not the treatment is efficacious according to whether said quantity of the bacterium in the subject's biological sample is reduced or absent.

14. The method of any one of claims 12 to 13, wherein the subject has sepsis.

15. A kit or assay for quantifying a bacterium in a sample or biological sample, said kit or assay comprising one or more reagents for performing the method according to any one of claims 1 to 14 and instructions for use.