

CLAIMS

1. A method of detecting a cancer in an individual comprising:
 - a) extracting mitochondrial DNA, mtDNA, from a biological sample from the individual;
 - b) quantifying the amount of mtDNA in the sample having a deletion of approximately 3379 base pairs in the nucleic acid sequence spanning approximately residues 10744 to 14124 of the mtDNA genome;
 - c) comparing the amount of mtDNA in the sample having the deletion to at least one known reference value;wherein the cancer is breast cancer.
2. The method of claim 1, wherein the at least one known reference value is the amount of the deletion in a reference sample of mtDNA from known non-cancerous tissue or body fluid.
3. The method of claim 1, wherein the at least one known reference value is the amount of the deletion in a reference sample of mtDNA from known cancerous tissue or body fluid.
4. The method of claim 1, wherein the known reference value is the amount of the deletion in a reference sample of mtDNA from known non-cancerous tissue or body fluid,
wherein an elevated amount of the deletion in the biological sample compared to the reference sample is indicative of cancer.
5. The method of claim 4, further comprising the step of comparing the amount of mtDNA in the sample having the deletion to the amount of the deletion in a reference sample of mtDNA from known cancerous tissue or body fluid.
6. The method of claim 1, wherein the known reference value is the amount of the deletion in a reference sample of mtDNA from known cancerous tissue or body fluid,
wherein a similar level of the deletion in the biological sample compared to the reference sample is indicative of cancer.

7. The method of claim 6, further comprising the step of comparing the amount of mtDNA in the sample having the deletion to the amount of the deletion in a reference sample of mtDNA from known non-cancerous tissue or body fluid.
8. A method of monitoring an individual for the development of a cancer comprising:
- a) extracting mtDNA from a biological sample from the individual;
 - b) quantifying the amount of mtDNA in the sample having a deletion of approximately 3379 base pairs in the nucleic acid sequence spanning approximately residues 10744 to 14124 of the mtDNA genome;
 - c) repeating steps a) to b) over a duration of time, wherein an increasing level of the deletion over the duration of time is indicative of cancer;
- wherein the cancer is breast cancer.
9. The method of claim 8, further comprising at least one step selected from the group consisting of: (a) comparing the amount of mtDNA in the sample having the deletion to the amount of the deletion in a reference sample of mtDNA from known non-cancerous tissue or body fluid; and (b) comparing the amount of mtDNA in the sample having the deletion to the amount of the deletion in a reference sample of mtDNA from known cancerous tissue or body fluid.
10. The method of any one of claims 1 to 9, wherein the deletion has a nucleic acid sequence corresponding to the sequence identified in SEQ ID NO: 1.
11. The method of any one of claims 1 to 10, wherein the quantifying of the deletion includes first amplifying a target region of mtDNA that is indicative of the deletion, and quantifying the amount of the amplified target region.
12. The method according to claim 11, wherein the amplifying of the target region is conducted using a pair of amplification primers, one of the pair of amplification primers overlapping a splice joining regions on opposite ends of the deletion.

13. The method of any one of claims 1 to 12, wherein the step of quantifying is conducted using real-time PCR.
14. The method of claim 1, wherein the step of quantifying is conducted using real-time PCR and wherein the reference value is a cycle threshold.
15. The method of claim 11 or 14, wherein a PCR primer having a sequence corresponding to SEQ ID NO: 2 is used as part of a pair of amplification primers for amplifying the target region.
16. The method of claim 11 or 14, wherein one of a pair of PCR primers used in the amplifying of the target region overlaps a spliced region of mtDNA after deletion of the sequence corresponding to SEQ ID NO: 1.
17. The method of any one of claims 1 to 16, wherein the biological sample is a body tissue or body fluid.
18. The method of claim 17, wherein the biological sample is selected from breast tissue and urine.
19. A kit for detecting breast cancer in a subject, the kit comprising a pair of PCR primers for amplifying a target region of mitochondrial DNA, mtDNA, in a biological sample obtained from the subject, said target region comprising a region of the mtDNA having a deletion spanning nucleotides 10744 and 14124 of the mtDNA genome, the deletion being 3379 base pairs in length.
20. The kit of claim 19, wherein one primer of the pair of primers has a nucleic acid sequence of SEQ ID NO: 2 or SEQ ID NO: 3.
21. A kit for detecting breast cancer in a subject, the kit comprising a pair of PCR primers for amplifying a target sequence of mitochondrial DNA, mtDNA, in a biological sample obtained from the subject, the target sequence comprising a deleted region spanning nucleotides 10744 and 14124 of the mtDNA genome, the deleted region being 3379 base pairs in length.

22. The kit of claim 21, wherein the target sequence has a nucleic acid sequence of SEQ ID NO: 1.

23. The kit of claim 21, wherein one primer of the pair of primers has a nucleic acid sequence of SEQ ID NO: 9 or SEQ ID NO: 10.

24. The kit of any one of claims 19 to 23, further comprising at least one of reagents, instructions, and a means of extracting the biological sample from the subject.