

Claims

1. A method for quantitative analysis of a sample, comprising:
 - (a) providing a singular marker representative of one or more features of the sample, the sample being a formalin-fixed paraffin-embedded (FFPE) tissue sample having a population of individual units of the marker;
 - (b) extracting markers from the tissue sample and measuring the marker with quantitative dot blot analysis (QDB), wherein the quantitation result is an absolute amount of the marker's population of individual units in the sample, normalized by the protein weight, and the marker standard curve is established to convert signals captured into absolute marker level; and (c) obtaining a determination of the one or more features of the sample based on the absolute quantitation result of the marker.
2. The method of claim 1, wherein the step (b) comprises:
 - (b1) incubating the sample with a solution comprising a binding agent, wherein:
 - the binding agent is capable of specifically binding to an individual unit of the marker, and
 - the binding agent is capable of being quantified by the dot blot analysis;
 - and
 - (b2) measuring the marker through QDB analysis of the binding agent.
3. The method of claim 2, wherein the marker is a protein marker and the binding agent is an antibody.
4. The method of claim 3, wherein the antibody is an analyte specific reagent (ASR) antibody.
5. The method of claim 3, wherein the antibody is an in vitro diagnostics (IVD) antibody.
6. The method of claim 3, wherein the antibody is capable of being assayed in immunohistochemistry.

7. The method of claim 1, wherein
the sample is a biopsy tissue from a subject.
- 5 8. The method of claim 7, wherein
the subject is a cancer patient.
9. The method of claim 8, further comprising
(d) evaluating the patient based on the quantitation result of the marker.
- 10 10. The method of claim 9, wherein,
in step (d), evaluating the patient comprises diagnosis and prognosis of a
cancer for the patient.
- 15 11. The method of claim 10, wherein
the diagnosis and prognosis of a cancer comprises disease-free survival, overall
survival, hazard ratio, or treatment prediction for the cancer.
- 20 12. A method for diagnosing cancer in a patient, comprising:
(a) obtaining a biopsy sample from the patient;
(b) measuring a marker in the biopsy sample with QDB analysis, wherein the
measured result is an absolute amount of the marker in the biopsy sample
normalized by protein weight and the marker standard curve is established to
convert signals captured into absolute level;
- 25 (c) comparing the quantitation result of the marker with that of a reference
profile stored in a reference database; wherein the reference profile database is
obtained by measuring the biomarker from samples of a known cancer
diagnosis using the same quantitative measurement of QDB analysis of step
(b); and
- 30 (d) identifying a reference profile in the reference database that has the best
match and administering therapeutics to said patient.
13. The method of claim 12, wherein
the cancer is a solid tumor cancer.