CLAIMS

1. A method for obtaining calibrated indicia of a level of at least one analyte in a sample comprising:

introducing a test sample possibly containing at least one analyte into a testing device;

processing said test sample in a test region of said testing device;

obtaining, as a result of said processing, a measurable indication of a level of said at least one analyte in said test sample;

processing at least two control samples containing said at least one analyte at mutually different, non-zero, predetermined concentrations in a control region of said testing device, said processing of said at least two control samples being carried out in at least near real time with respect to said processing of said test sample;

obtaining, as a result of said processing of said at least two control samples, at least one measurable indication of at least one level of said at least one analyte in each of said at least two control samples;

generating, from said at least one measurable indication of each of said at least two control samples, a standard curve correlating analyte concentration to measurable indication; and

calibrating said indication of said level of said at least one analyte in said test sample by applying said standard curve thereto, based on said at least one measurable indication of said level of said at least one analyte in said at least two control samples, to provide a calibrated indication of said level of said at least one analyte in said test sample.

2. A method according to claim 1, wherein each of said at least two control samples is separate to and different from said test sample.

3. A method according to claim 1 or claim 2, wherein said test sample comprises a bodily fluid obtained from a subject and said testing device is a single-use, disposable device, usable by said subject.

4. A method according to any one of claims 1-3, wherein said measurable indication of said level of said at least one analyte in said test sample and each of said at least two control samples comprises at least one of a colorimetric indication, an optical indication, an electrical indication and a chemical indication.

5. A method according to claim 4, wherein said calibrating comprises at least one of:

qualitative calibrating based on relative characteristics of said measurable indications of said test sample and said at least two control samples, and

quantitative calibrating based on relative concentrations of said at least one analyte as derived from said measurable indications of said test sample and said at least two control samples.

6. A method according to any one of claims 1-5, and also comprising, following said calibrating:

rating a level of said at least one analyte in said test sample based on said calibrating, and

providing a diagnosis of a subject from whom said test sample is obtained based on said rated level of said at least one analyte in said test sample.

7. A method according to claim 6, wherein said providing a diagnosis comprises providing one of a binary diagnosis and a probability of said subject having said diagnosis.

8. A method according to any one of claims 1 - 7, wherein said at least two control samples are formed within said control region by introducing thereinto a buffer, said control region comprising at least two control wells each having disposed therein a respective predetermined amount of said at least one analyte, said buffer re-suspending said respective

predetermined amounts so as to form said at least two control samples having said mutually different, non-zero, predetermined concentrations of said analyte therein.

9. A method according to claim 8, wherein said buffer is free of said at least one analyte.

10. A testing device comprising:

a test region configured to process therein a test sample obtained from a subject;

a first output region configured to display a measurable indication of a level of at least one analyte in said test sample;

a control region configured to process therein at least two control samples containing said at least one analyte at mutually different, non-zero, predetermined concentrations, said control samples being processed in at least near real time with respect to said test sample; and

a second output region configured to display, in at least near real time with respect to said display of said measurable indication of said level of said at least one analyte in said test sample, a measurable indication of at least one level of said at least one analyte in each of said at least two control samples,

said measurable indications of said at least one level of said at least one analyte in said at least two control samples providing a basis for generating a standard curve correlating analyte concentration to measurable indication and for calibration of said measurable indication of said level of said at least one analyte in said test sample by applying said standard curve thereto.

11. A system for diagnosing a subject comprising:

a testing device comprising:

a test sample receipt subsystem operative to receive a test sample from a subject, said test sample possibly containing at least one analyte;

a first processing subsystem operative to process said test sample in a test region of said testing device;

a first data output subsystem operative to output, as a result of said processing by said first processing subsystem, a measurable indication of a level of said at least one analyte in said test sample;

a second processing subsystem operative to process, in at least near real time with respect to said processing of said test sample by said first processing subsystem, at least two control samples containing said at least one analyte at mutually different, non-zero, predetermined concentrations, in a control region of said testing device; and

a second data output subsystem operative to output, as a result of said processing of said control samples, a measurable indication of at least one level of said at least one analyte in each of said at least two control samples,

an image acquisition device operative to capture said measurable indications of said levels of said at least one analyte in said test sample and said at least two control samples, and

a data analysis module operative to generate, from said captured measurable indications of said at least two control samples, a standard curve correlating analyte concentration to measurable indication, to calibrate said captured measurable indication of said level of said at least one analyte in said test sample by applying said standard curve thereto, based on said captured measurable indication of said at least one level of said at least one analyte in said at least two control samples and to output a diagnosis of said subject based on said calibrated level of said at least one analyte in said test sample.

12. A system according to claim 11, wherein each of said control samples is separate to and different from said test sample.

13. A system according to claim 11 or claim 12, wherein said test sample comprises a bodily fluid obtained from said subject.

14. A system according to any one of claims 11 - 13, wherein said testing device is a single-use, disposable device.

15. A system according to any one of claims 11 - 14, wherein said measurable indication of said level of said at least one analyte in said test sample and each of said control samples comprises at least one of a colorimetric indication, an optical indication, an electrical indication and a chemical indication.

16. A system according to claim 15, wherein said data analysis module is operative to perform at least one of:

qualitative calibration based on relative characteristics of said measurable indications of said test sample and said at least two control samples, and

quantitative calibration based on relative concentrations of said at least one analyte as derived from said measurable indications of said test sample and said at least two control samples.

17. A system according to claim 16, wherein said data analysis module is also operative to:

rate a level of said at least one analyte in said test sample based on said calibration, and

provide said diagnosis of said subject from whom said test sample is obtained based on said rated level of said at least one analyte in said test sample.

18. A system according to claim 17, wherein said diagnosis comprises one of a binary diagnosis and a probability of said subject having said diagnosis.

19. A system according to any one of claims 11 - 18, wherein said control region comprises at least two control wells each having disposed therein a respective predetermined amount of said at least one analyte, and said at least two control samples are formed within said control region by introduction thereinto of a buffer which re-suspends said respective

predetermined amounts so as to form said at least two control samples having said mutually different, non-zero, predetermined concentrations of said at least one analyte therein.

20. A system according to claim 19, wherein said buffer is free of said at least one analyte.