WE CLAIM:

1. A method for detecting an analyte in a sample, comprising
    - bringing a sample comprising a target analyte into contact with magnetisable particles, the particles being coated with binding molecules complementary to the target analyte, resulting in bound and unbound binder complexes,
    - positioning the magnetisable particles, comprising both bound and unbound binder complexes, in proximity to a magnetic field sensor,
    - changing the magnetic field sufficient to release at least a portion of the magnetisable particles, comprising both bound and unbound binder complexes, from their proximity to the magnetic field sensor, and
    - measuring changes in a magnetic signal detected from the net movement, being translational and/or rotational movement, of the magnetisable particles relative to the magnetic sensor.

2. A method of claim 1 wherein the method further comprises providing a sample testing device comprising:
    - a sample well or sample reservoir,
    - one or more magnets for generating a magnetic field in the sample well or sample reservoir, and
    - a magnetic field sensor for measuring changes over time in the magnetic field in the sample well or sample reservoir.

3. A method of claim 2 or 3 wherein the method further comprises providing a sample testing device comprising changing the magnetic field sufficient to release at least a portion of the magnetisable particles from their proximity to the magnetic sensor.

4. A method of any one of claims 1 to 3 wherein the detection and quantitation of the analyte in the sample is dependent on the amount of magnetisable particles detected via a magnetic field sensor.

5. A method of any one of claims 1 to 4 wherein the magnetisable particles are functionalised with molecules that specifically bind to the analyte.

6. A method of any one of claims 1 to 5 wherein the sample and magnetisable particles are processed by a microfluidic device.

7. A method of claim 6 wherein the microfluidic device facilitates binding between the magnetisable particles and analyte.

8. A method of any one of claims 1 to 7 wherein the magnetisable particles are magnetic particles.

9. A method of any one of claims 1 to 8 wherein the magnetisable particles are para-magnetic or ferro-magnetic.

10. A method of any one of claims 1 to 9 wherein the magnetisable particles have an average particle size of about 5 to about or 5000 nm.

11. A method of any one of claims 1 to 10 wherein the microfluidic device positions the magnetisable particles and analyte into close proximity with the magnetic sensor.

12. A method of any one of claims 1 to 11 wherein the magnetisable particles and analyte are brought within 1 to 5,000 μm from the sensing element of the magnetic sensor.

13. A method of any one of claims 1 to 12 wherein the one or more magnets (or electromagnets) aligns the magnetisable particles.

14. A method of any one of claims 1 to 13 wherein the one or more magnets generates a magnetic field that changes over time.

15. A method of any one of claims 1 to 14 wherein the magnetic field generator can generate a continuity of magnitudes.

16. A method of any one of claims 1 to 15 wherein the magnetic field generator can alternate the magnetic field between on and off.

17. A method of any one of claims 1 to 16 wherein the magnetic field is generated and positioned in such a way as to maximise its effect on the magnetisable particles but minimise its effect on the magnetic sensor.

18. A method of any one of claims 1 to 17 wherein the magnetic field sensor measures the changes in magnetic field strength generated by the magnetisable particles over time

19. A method of any one of claims 1 to 18 wherein the magnetic field sensor is adapted to maximise its sensing of the magnetisable particles and minimise the sensing from the magnet.

20. A method of any one of claims 1 to 19 wherein the data acquisition by the sensor is synchronised with the microfluidic device.

21. A method of any one of claims 1 to 20 wherein data is continuously acquired from the sensor.

22. A method of any one of claims 1 to 21 wherein acquired data is flagged as (1) environmental and/or ambient, or (2) sample data.

23. A method of any one of claims 1 to 22 wherein the method is calibrated based on the synchronisation of the signal acquisition with the operation of the microfluidic device.

24. A method of any one of claims 1 to 23 wherein the data is acquired over a period of about 1 to about 60 seconds.

25. A method of any one of claims 1 to 24 wherein the signal output from the magnetic field sensor is boosted by a signal amplifier.

26. A method of any one of claims 1 to 25 wherein the signal output from the magnetic field sensor is a voltage reading that is proportional to the magnetic field strength it senses.

27. A method of any one of claims 1 to 26 wherein the voltage from the magnetic field sensor is boosted in magnitude to a higher voltage, with all changes kept in proportion to the original signal, into a range that is compatible with data processing and collecting electronics.

28. A method of any one of claims 1 to 27 wherein the amplified signal is converted from a voltage reading into digital bitstream and recorded and/or analysed by a computer.

29. A method of any one of claims 1 to 28 wherein the conversion is performed by Analog to Digital Converter (ADC).

30. A method of any one of claims 1 to 29, wherein the method:

a) generates sufficient magnetic signal within 15 seconds to detect and/or measure an amount of target analyte in the sample, or
b) has a limit of detection (LOD) of at least about 0.05 pg/mL, or
c) has a limit of quantification (LOQ) of at least about 0.1 pg/mL, or
d) one or more of (a) to (c).

31. A device, when used in any one of claims 1 to 30, for detecting an analyte in a sample, comprising

- a passive microfluidic device comprising a sample insertion area, a non-sample well zone, and a sample well zone located therebetween, the sample well zone comprising one or more sample wells, and one or more channel(s) that juncture at the one or more sample well(s), the non-sample well zone having the one or more channels and absent any sample wells,
- one or more magnets for generating a magnetic field in the sample well, and

- a magnetic field sensor located at the sample well for measuring changes over time in the magnetic field proximate the sample well, and
- wherein the one or more magnets is adapted to control a position of the magnetisable particles relative to the magnetic field sensor, and the magnetic field sensor is adapted for use such that the magnetic sensor can detect a change in the net movement, being translational and/or rotational, of the magnetisable particles relative to the magnetic field sensor.

32. The device of claim 31, wherein the device is operable in any orientation.

33. The device of claim 31 or 32 wherein the sample well(s) junction with two or more channels.

34. The device of any one of claims 31 to 33, wherein the one or more magnets are configured to exert a magnetic field strength of about 0.01 to about 100 Gauss at the sample.

35. The device of any one of claims 31 to 33, wherein the magnetic field sensor is configured to detect analytes from greater than 1 µm to about 5,000 µm from the magnetic field sensor.