WE CLAIM:

1. A method for detecting an analyte in a sample, comprising
    - obtaining a baseline reading of a magnetic field strength carried out without the sample being present,
    - bringing a sample comprising a target analyte into contact with magnetisable particles, the magnetisable particles being coated with binding molecules complementary to the target analyte, resulting in bound and unbound binder complexes,
    - positioning the magnetisable particles using a magnetic field, 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 the magnetic field and 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, and wherein the measured changes in the magnetic signal correlate to the presence of the analyte in the sample, wherein the sample and magnetisable particles are processed by a microfluidic device.

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 any one of claims 1 or 2, 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.

4. A method of claim 1, wherein the microfluidic device facilitates binding between the magnetisable particles and analyte.

5. A method of any one of claims 1 to 4, wherein the magnetisable particles are magnetic particles.

6. A method of any one of claims 1 to 5, wherein the magnetisable particles are para-magnetic or ferro-magnetic.

7. A method of any one of claims 1 to 6, wherein the magnetisable particles have an average particle size of 5 to 5000 nm.

8. A method of any one of claims 1 to 7, wherein the microfluidic device positions the magnetisable particles and analyte into close proximity with the magnetic field sensor.

9. A method of any one of claims 1 to 8, wherein the magnetisable particles and analyte are brought within 1 to 5,000 μm from the sensing element of the magnetic field sensor.

10. A method of any one of claims 2 to 9, wherein the one or more magnets (or electromagnets) aligns the magnetisable particles.

11. A method of any one of claims 2 to 10, wherein the one or more magnets generates a magnetic field that changes over time.

12. A method of any one of claims 1 to 11, wherein the one or more magnets generate a continuity of magnitudes.

13. A method of any one of claims 1 to 12, wherein the one or more magnets alternate the magnetic field between on and off.

14. A method of any one of claims 1 to 13, wherein the magnetic field sensor measures the changes in magnetic field strength generated by the magnetisable particles over time.

15. A method of any one of claims 4 to 14, wherein data acquisition by the magnetic field sensor is synchronised with the microfluidic device.

16. A method of any one of claims 1 to 15, wherein data is continuously acquired from the sensor.

17. A method of claim 15 or 16 wherein acquired data is flagged as (1) environmental and/or ambient, or (2) sample data.

18. A method of any one of claims 15 to 17 wherein the method is calibrated based on the synchronisation of the signal acquisition with the operation of the microfluidic device.

19. A method of any one of claims 15 to 18 wherein the data is acquired over a period of 1 to 60 seconds.

20. A method of any one of claims 1 to 19 wherein magnetic signal output from the magnetic field sensor is amplified by a signal amplifier.

21. A method of any one of claims 1 to 20 wherein magnetic signal output from the magnetic field sensor is a voltage reading that is proportional to the magnetic field strength it senses.

22. A method of any one of claims 1 to 21 wherein voltage from the magnetic field sensor is boosted in magnitude to a higher voltage, with all changes kept in proportion to an original signal, into a range that is compatible with data processing and collecting electronics.

23. A method of any one of claims 20 to 22 wherein the amplified signal is converted from a voltage reading into digital bitstream and recorded and/or analysed by a computer.

24. A method of claim 23 wherein the conversion is performed by Analog to Digital Converter (ADC).

25. A method of any one of claims 1 to 24, 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 0.05 pg/mL, or

c) has a limit of quantification (LOQ) of at least 0.1 pg/mL, or

d) one or more of (a) to (c).

26. A device, when used in any one of claims 1 to 25, 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 close to or adjacent to the sample well surface 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.

27. The device of claim 26, wherein the device is operable in any orientation.

28. The device of claim 26 or 27 wherein the sample well(s) junction with two or more channels.

29. The device of any one of claims 26 to 28, wherein the one or more magnets are configured to exert a magnetic field strength of 0.01 to 100 Gauss at the sample.

30. The device of any one of claims 26 to 29, wherein the magnetic field sensor is configured to detect analytes from greater than 1 µm to 5,000 µm from the magnetic field sensor.