

into an instrument for operating the detection assay, for example, a detection device as disclosed in the present invention. The aptamers that specifically bind to a target allergen may be those disclosed in commonly owned U.S. Provisional Application Serial Nos.:

62/418,984, filed on November 8, 2016; and 62/435,106, filed on December 16, 2016;

5 62/512,299 filed on May 30, 2017; and the PCT application No. PCT/US2017/060487 filed on November 08 2017; the contents of each of which are incorporated herein by reference in their entirety.

[0006] The inventors of the present invention further developed detection systems which include a separate sampler, disposable cartridges/vessels and a detection instrument, for fast
10 and accurate detection of an allergen(s) in a sample using aptamer-based signal polynucleotides (SPNs). Particularly the aptamers and/or aptamer complement complexes are conjugated to magnetic beads and/or solid surfaces. The magnetic beads and solid surfaces coated with aptamer ligands are then used as detection sensors. The sensors may be integrated into the disposable cartridges of the present invention. They may also be used in
15 other detection systems. Such devices may be used by consumers in non-clinical settings, for example in the home, in restaurants and school cafeteria.

SUMMARY

[0007] The present disclosure provides systems, devices, disposable vessels/cartridges, optical modules and methods for use in allergen detection in various types of samples, in
20 particular, food samples. The allergen detection devices and systems are portable and handheld. In one example, the dimensions of the systems and devices may be less than 6 inches.

[0007a] In a first example, the present disclosure refers to a detection system for detecting the presence or absence of an allergen in a food sample, comprising (a) means for collecting a
25 food sample suspected of containing at least one allergen of interest; (b) a disposable detection cartridge configured for processing the food sample and contacting detection agents with said at least one allergen present in the food sample; and (c) a detection device configured for operating allergen detection, measuring and visualizing a signal from a binding interaction between the detection agents and the at least one allergen present in the
30 food sample, wherein the detection device comprises an optical system configured to measure absorbed light, scattered light, fluorescence or a combination thereof, which is a result of the

binding interaction between the detection agents and the at least one allergen.

[0007b] In a second example, the present disclosure refers to a method for calibrating an optical signal measuring system comprising (a) reading a baseline absorption signal of the system prior to any chemical reaction; (b) reading a first set of absorption, scatter and fluorescence signals after the addition of a reaction solution comprising magnetic particles, wherein the magnetic particles are coated with ligands labeled with one or more fluorophores; wherein the absorption signal indicates a signal decrease absorbed by the addition of the magnetic particles; the fluorescence signal represents the background auto-fluorescence signal from the reaction solution; and the scatter signal reflects the light signal scattered off the surface of the magnetic particles; (c) reading a second set of absorption, scatter and fluorescence signals after the addition of a test sample and the chemical reaction between the ligands and the test sample, wherein the second absorption signal indicates the presence of the magnetic particles; the second fluorescence signal indicates the gross fluorescence signal from the chemical reaction with the test sample; and the second scatter signal indicates the light signal scattered off the surface of the mixture of magnetic particles and the test sample; and (d) comparing signals read from steps (a), (b) and (c) to calibrate the optic signal measuring system.

[0007c] In a third example, the present disclosure refers to a method for measuring a signal to detect an allergen of interest in a test sample, comprising (a) reading a baseline absorption band signal of the system prior to any chemical reaction; (b) reading a first set of absorption, scatter and fluorescence signals after the addition of a reaction solution comprising magnetic beads, wherein the magnetic beads are coated with ligands which are labeled with one or more fluorophores; wherein the absorption signal indicates a signal decrease absorbed by the addition of the magnetic particles; the fluorescence signal represents the background auto-fluorescence signal from the reaction solution; and the scatter signal reflects the light signal scattered off the surface of the magnetic particles; (c) reading a second set of absorption, scatter and fluorescence signals after the addition of a test sample and the chemical reaction between the ligands and the test sample, wherein the second absorption signal indicates the presence of the magnetic particles; the second fluorescence signal indicates the gross fluorescence signal from the chemical reaction with test sample; and the second scatter signal indicates the light signal scattered off the surface of the mixture of magnetic particles and the test sample; (d) washing out the unbound compounds from the chemical reaction mixture, wherein the magnetic particles are held by the presence of a magnetic force; (e) reading a

third set of absorption, scatter and fluorescence signals after washing; wherein the third absorption signal indicates the presence of the magnetic particles; the third fluorescence signal represents signal from the complexes of the ligand and the allergen of interest; and the third scatter signal reflects the light signal scattered off the surface of the magnetic particles; and (f) measuring the presence, absence, and /or quantity of the allergen of interest in the test sample.

[0007d] In a fourth example, the present disclosure refers to a method for detecting the presence or absence of an allergen in a food sample comprising (a) collecting a food sample and processing the food sample, wherein the food sample is homogenized and proteins from the food sample are extracted in an extraction buffer; (b) transferring the processed sample into an optic detection chamber within a disposable cup, wherein the optic detection chamber is preloaded with detection agents, wherein the detection agents comprise magnetic beads coated with aptamers which are labeled with one or more fluorophores; (c) mixing the processed sample with the magnetic beads; (d) reading a first set of absorption, scatter and fluorescence signals; (e) washing out the unbound compounds from the mixture; (f) reading a second set of absorption, scatter and fluorescence signals; (g) comparing the first and second sets of absorption, scatter and fluorescence signals of steps (d) and (f) and to the absorption, scatter and fluorescence signals read prior to the transfer of the test sample to the optic detection chamber; and (h) detecting the presence or absence of the allergen in the food sample.

[0007e] In a fifth example, the present disclosure refers to a method for detecting the presence or absence of an allergen in a food sample comprising (a) collecting a food sample and processing the food sample, wherein the food sample is homogenized and proteins from the food sample are extracted in an extraction buffer; (b) transferring the processed sample into an optical detection chamber within a disposable cup, wherein the optical detection chamber comprises a glass chip which has a surface coated with aptamers labeled with one or more fluorophores; (c) mixing the processed sample with the aptamers immobilized on the glass chip; (d) reading fluorescence signals from a test area and two control areas of the glass chip; (e) washing out the unbound compounds from the mixture; (f) reading a second set of fluorescence signals from the test area and two control areas of the glass chip; (g) comparing the fluorescence signals of steps (d) and (f) and to fluorescence signals read prior to the transfer of the test sample to the optic detection chamber; and (h) detecting the presence or absence of the allergen in the food sample.

- [0007f]** In a sixth example, the present disclosure refers to a system for detecting the presence of an allergen in a sample, the system comprising: (a) a device comprising: an optical system configured to measure absorbed light, scattered light, fluorescence or a combination thereof, as a result of binding of a detection agent to the allergen; b) a test cartridge configured to
- 5 dock into a receptacle of the device, the test cartridge comprising (i) a homogenization chamber including a rotor for homogenizing the sample and extracting allergens; (ii) a wash buffer chamber; (iii) a waste chamber configured to receive waste; and (iv) a reaction and optical detection chamber in optical communication with the optical system, for detecting the binding of the detection agent to the allergen.
- 10 **[0007g]** In a seventh example, the present disclosure refers to a kit comprising one or more disposable cartridges as recited in the sixth example for use with the device as recited in the sixth example, the kit further comprising instructions for placement of the disposable cartridges into the receptacle of the device.
- [0007h]** In an eighth example, the present disclosure refers to an optical system for detecting
- 15 a signal comprising: (a) an optical detection chamber having a detector; (b) excitation optics comprising: (i) a light source having a spectral range, the light source configured to transmit an excitation light to an optical detection chamber; (ii) at least one excitation filter configured to allow specific wavelengths of excitation light to pass to the optical detection chamber, wherein the wavelengths may include: an absorption band for determining the presence of
- 20 detection agents in the optical detection chamber, the detection agents may be magnetic particles coated with ligands that bind to an allergen of interest; a scatter band for detecting light scattered of the surface of a test sample inside the optical detection chamber; and a fluorescent band configured to detect a fluorescence signal derived from an interaction between the ligands and the allergen of interest; and wherein the excitation optics may further
- 25 comprise optics capable of confining a light path; (c) emission optics capable of collecting fluorescence emissions from the test sample, the emissions optics comprising at least one emission filter configured to allow primarily light with wavelengths in the emission band to reach the detector; and wherein the emission optics may further comprise optics capable of confining a light path; (d) scatter optics capable of measuring scattering light signals; and (e)
- 30 absorption optics capable of measuring the light absorbance prior to an optical reading.
- [0007i]** In a first aspect, the present disclosure refers to a detection system for detecting the presence or absence of an allergen in a food sample, comprising (a) means for collecting a food sample suspected of containing at least one allergen of interest; (b) at least one

disposable detection cartridge configured for processing the food sample and contacting detection agents with said at least one allergen present in the food sample; and (c) a detection device configured for operating allergen detection, measuring and visualizing a signal from a binding interaction between the detection agents and the at least one allergen present in the food sample, wherein the detection device comprises an optical system composed of excitation optics, emission optics, scatter optics and absorption optics.

[0007j] In a second aspect, the present disclosure refers to a system for detecting the presence of an allergen in a sample, the system comprising: (a) a device comprising: an optical system composed of excitation optics, emission optics, scatter optics and absorption optics, wherein the optical system is configured to measure absorbed light, scattered light, fluorescence or a combination thereof, as a result of binding of a detection agent to the allergen; b) a disposable detection cartridge configured to dock into a mate plane of the device, the disposable detection cartridge comprising (i) a homogenization chamber including a rotor for homogenizing the sample and extracting allergens; (ii) a wash buffer chamber; (iii) a waste chamber configured to receive waste; and (iv) a reaction and optical detection chamber in optical communication with the optical system, for detecting the binding of the detection agent to the allergen; and (c) a sampling device for collecting the sample.

[0007k] In a third aspect, the present disclosure refers to a kit comprising one or more disposable detection cartridges as recited in the second aspect for use with the device as recited in the second aspect, the kit further comprising instructions for placement of the disposable detection cartridges into the mate plane of the device.

[0008] One example of the present disclosure is directed to an allergen detection system for detecting the presence and/or absence of one or more allergens in a food sample. In various embodiments, the system comprises: (a) means for collecting a test sample; (b) at least one disposable detection vessel/cartridge (as used herein, the terms “vessel” and “cartridge” and “test cup” are used interchangeably) for receiving and processing the test sample, and analyzing the interaction between an allergen(s) in the test sample and the detection agents; and (c) a detection device for reading detection signals and detecting the allergen(s) in the test sample. The detection device may be removably connected to the disposable cartridge. In some examples, the assay further comprises a step of washing and re-suspending the magnetic beads when they are used as the sensors for detecting the target allergen.

CLAIMS

1. A detection system for detecting the presence or absence of an allergen in a food sample, comprising:
 - (a) means for collecting a food sample suspected of containing at least one allergen of interest;
 - (b) at least one disposable detection cartridge configured for processing the food sample and contacting detection agents with said at least one allergen present in the food sample; and
 - (c) a detection device configured for operating allergen detection, measuring and visualizing a signal from a binding interaction between the detection agents and the at least one allergen present in the food sample, wherein the detection device comprises an optical system composed of excitation optics, emission optics, scatter optics and absorption optics.
2. The detection system of claim 1, wherein the detection device further comprises a mating plane for docking the at least one disposable detection cartridge.
3. The detection system of claim 2, wherein the means for collecting the food sample is a food corer, extending between a distal end and a proximal end, comprises a plunger, a skirt and a corer, wherein the proximal end of the corer includes a cutting edge for cutting the test sample.
4. The detection system of claim 3, wherein the plunger of the food corer comprises a seal at the proximal end.
5. The detection system of any one of claims 3-4, wherein the cutting edge is a blade, a flat edge, a sharp edge, a serrated edge with various numbers of teeth, a sharp serrated edge, or a thin wall edge.
6. The detection system of claim 3, wherein the disposable detection cartridge is a cup or a cup-like container comprising, a port for inserting the food corer;

a body part assembled with a cup top cover, a cup body and a cup bottom part providing interfaces to connecting to the mate plane of the detection device; and a homogenization rotor.

5 7. The detection system of claim 6, wherein the cup body comprises a plurality of chambers connected to one another, so that a fluid can flow between chambers, wherein the plurality of chambers includes:

- (1) a homogenization chamber, in which the test sample can be homogenized and proteins can be extracted from the test sample;
- 10 (2) a washing chamber, in which a processed sample solution and/or a mixture of the test sample and detection agents can be washed;
- (3) a waste chamber configured for holding waste from the detection system or a detection assay; and
- (4) a reaction and optical detection chamber, in which reaction signals and reference
15 signals can be read.

8. The detection system of claim 7, wherein the reaction and optical detection chamber further comprises:
magnetic beads conjugated with nucleic acid molecules that bind to the at least one
20 allergen, or
a solid support of which the surface is coated with nucleic acid molecules that bind to the at least one allergen.

9. The detection system of claim 8, wherein the nucleic acid molecules are aptamers or
25 aptamer-complement complexes which bind to the at least one allergen with high specificity and affinity.

10. The detection system of any of claims 8 and 9, wherein the magnetic beads are polystyrene beads comprising magnetite.

30 11. The detection system of claim 10, wherein the magnetic beads are lyophilized or in aqueous solution.

12. The detection system of claim 8, wherein the solid support is selected from a group consisting of a glass chip, silica, agarose beads, acrylic glass, a microwell and a microchip.
13. The detection system of claim 8, wherein the reaction and optical detection chamber
5 further comprises a first optical window and a secondary optical window, wherein the first and secondary optical windows are aligned with the optical system of the detection device when the test cup is inserted into the detection device.
14. The detection system of claim 6, wherein the homogenization rotor can be inserted into
10 the test cup body through a rotor interface at the cup bottom assembly.
15. The detection system of claim 6, wherein the homogenization rotor can be inserted into the test cup body through a rotor port at the cup top cover.
- 15 16. The detection system of claim 6, wherein the test cup further comprises a filter.
17. The detection system of claim 16, wherein the filter is attached to the cup top cover, and wherein the filter is a filter membrane or a filter assembly.
- 20 18. The detection system of claim 2, wherein the detection device comprises:
(a) an external housing configured for providing support for the components of the detection device;
(b) components integrated for operating an allergen detection testing; and
(c) a power supply;
25 wherein the components integrated for operating the detection testing comprise:
(i) means for driving and controlling the homogenization;
(ii) means for driving and controlling the flow of the processed sample solution during the process of the allergen detection testing;
(iii) means for collecting and retaining magnetic beads;
30 (iv) means for re-suspending magnetic beads;
(v) means for converting and digitizing the fluorescence signals; and
(vi) a display window for receiving the detected signals and indicating the presence and/or absence of the allergen in the test sample.

19. The detection system of claim 18, wherein the components of the detection device for operating the detection testing further comprise:

- (a) a motor coupled to the homogenization rotor;
- (b) a pump;
- (c) at least one magnetic bead collection actuator;
- (d) a vibratory re-suspension actuator;
- (e) a signal processor; and
- (f) a display interface.

20. The detection system of claim 19, wherein the excitation optics of the optical system comprises:

(a) a light source having a light spectral range configured to transmit an excitation light to an optical detection chamber;

(b) one or more excitation filters configured to select specific excitation wavelengths of light from the light source, wherein at least three different light wavelength bands can be selected:

one absorption band for determining the presence of detection agents in the optical detection chamber, wherein the detection agents are magnetic particles coated with signal polynucleotides (SPNs),

one scatter band for detecting light scattered off the food sample inside the optical detection chamber, and

one fluorescence band configured to detect a fluorescence signal derived from the interaction of the allergen of interest and SPNs; and

(c) optional optics capable of confining the light path.

21. The detection system of 20, wherein the emission optics of the optical system comprises:

(a) one or more emission filters operable to allow substantially light with wavelengths in an emission band to reach the detector;

(b) optics configured to collect and confine emitted light; and
wherein the detection device further comprises a detector capable of measuring signals.

22. The detection system of claim 19, wherein the magnetic bead collection actuator further comprises:

(a) a magnetic field generator which generates a magnetic field to hold and separate magnetic beads, and

5 (b) an actuator;

wherein the magnet field generator comprises a permanent magnet, or electromagnet.

23. A system for detecting the presence of an allergen in a sample, the system comprising:

10 (a) a device comprising: an optical system composed of excitation optics, emission optics, scatter optics and absorption optics, wherein the optical system is configured to measure absorbed light, scattered light, fluorescence or a combination thereof, as a result of binding of a detection agent to the allergen;

b) a disposable detection cartridge configured to dock into a mate plane of the device, the disposable detection cartridge comprising

15 (i) a homogenization chamber including a rotor for homogenizing the sample and extracting allergens;

(ii) a wash buffer chamber;

(iii) a waste chamber configured to receive waste; and

20 (iv) a reaction and optical detection chamber in optical communication with the optical system, for detecting the binding of the detection agent to the allergen; and

(c) a sampling device for collecting the sample.

24. The system of claim 23, wherein the reaction and optical detection chamber further
25 comprises magnetic beads conjugated with nucleic acid molecules that bind to the allergen, or a solid support having a surface coated with nucleic acid molecules that bind to the allergen.

25. The system of claim 24, wherein the nucleic acid molecules are aptamers or aptamer-complement complexes which bind to the allergen with high specificity and affinity.

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26. The system of claim 24, wherein the magnetic beads are polystyrene beads comprising magnetite.

27. The system of claim 24, wherein the magnetic beads are lyophilized or in aqueous solution.
- 5 28. The system of claim 24, wherein the solid support is selected from the group consisting of: a glass chip, silica, agarose beads, acrylic glass, a microwell, and a microchip.
29. The system of claim 23, wherein the reaction and optical detection chamber further comprises a first optical window and a secondary optical window, wherein the first and
10 secondary window are aligned with the optical system of the detection device when the test cartridge is inserted into the receptacle of the device.
30. The system of claim 23, wherein the rotor connects to a rotor-driving motor at an interface on the bottom of the cartridge.
- 15 31. The system of claim 23, wherein the homogenization chamber may include extraction buffer and the wash buffer chamber may include wash buffer.
32. The system of claim 31, wherein the homogenization chamber and the wash buffer
20 chamber each have passages with lower openings having seals which, when broken, permit fluid flow into a lower flow channel for transfer of homogenized sample and wash buffer to the reaction and optical detection chamber.
33. The system of claim 32, wherein the device includes upwardly extending pins for
25 breaking the seals when the cartridge is inserted into the receptacle.
34. The system of claim 33, wherein the seals are foil seals.
35. The system of claim 33, wherein the pins cooperate with an upper gasket to form a pinch
30 valve to open and close the passages.
36. The system of claim 24, wherein the device comprises a magnet movable between a first position for attracting the magnetic beads to an interior wall of the reaction and optical

detection chamber and a second position for allowing dispersal of the magnetic beads throughout the interior of the reaction and optical detection chamber.

37. The system of claim 23, wherein the absorbed light indicates the presence of magnetic
5 beads and/or sample in the reaction and optical detection chamber, the scattered light indicates the presence of sample in the chamber, and the fluorescence indicates detection of the allergen.

38. The system of claim 37, wherein the cartridge comprises a first optical window
10 configured for reading optical signals and a second optical window configured for reading light absorption or reading both light absorption and scattered light.

39. The system of claim 32, wherein the lower flow channel comprises an air port for
15 communication of the lower flow channel with atmospheric pressure via a gas permeable membrane.

40. The system of claim 32, further comprising at least one valve at the entrance and exit of
the reaction and optical detection chamber, wherein the entrance is at the end of the lower
flow channel and the exit leads to the waste chamber.

20 41. The system of claim 23, wherein a drive mechanism for the rotor is located in the device below the receptacle.

42. The system of claim 23, wherein the cartridge includes an upper opening configured for
25 insertion of a sampling device for addition of a sample to the homogenization chamber.

43. The system of claim 23, wherein the sampling device is configured for insertion in an
upper opening of the cartridge, for addition of a sample to the homogenization chamber.

30 44. The system of claim 42, wherein the sampling device includes an upper plunger for pushing the sample into the homogenization chamber.

45. The system of claim 44, wherein the sampling device is a food corer.

46. The system of claim 45, wherein a proximal end of the food corer includes a cutting edge for cutting the sample.
- 5 47. The system of claim 24, wherein the device further comprises a magnetic bead resuspension actuator in the receptacle, the resuspension actuator configured for contacting the cartridge to effect resuspension of the magnetic beads.
- 10 48. The system of claim 47, wherein the magnetic bead resuspension actuator is a vibratory actuator.
49. The system of claim 48, wherein the vibratory actuator is an ultrasonic wave generator or a low frequency vibrator.
- 15 50. The system of claim 24, wherein the magnetic beads are conjugated to a signaling polynucleotide.
51. The system of claim 24, wherein the reaction and optical detection chamber comprises a glass chip with a signaling polynucleotide conjugated thereto.
- 20 52. A kit comprising one or more disposable detection cartridges as recited in claim 23 for use with the device as recited in claim 23, the kit further comprising instructions for placement of the disposable detection cartridges into the mate plane of the device.

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