

- 30 -

WHAT IS CLAIMED IS:

1. A cartridge for determining the presence and/or amount of a microbial contaminant in a sample, the cartridge comprising:
 - a. a housing including an optical sample well, a fluid inlet port and a conduit fluidly connecting the fluid inlet port and the optical sample well;
 - b. a pump mechanism associated with the housing and fluidly connected to the fluid inlet port, the conduit and the optical sample well;
 - c. a mixing zone located along the conduit configured to include a dried composition including a hemocyte lysate.
2. The cartridge of claim 1, wherein the housing includes four optical sample wells, wherein two of the four optical sample wells are configured to include an agent representative of the microbial contaminant dried in the optical sample wells.
3. The cartridge of claim 1 or claim 2, further comprising a chromogenic substrate dried in the mixing zone.
4. The cartridge of any one of claims 1-3, wherein the housing includes a cover section and a base section, mechanically connected to each other.
5. The cartridge of claim 4, wherein the housing further includes a manifold section mechanically connected to the base section, and wherein the dried composition is dried on a mixing portion of the manifold section.
6. The cartridge of claim 5, wherein the mixing portion further includes the chromogenic substrate dried thereon.

- 31 -

7. The cartridge of claim 5 or claim 6, wherein the manifold section further includes the agent representative of the microbial contaminant dried on a sample well portion of the manifold section.
8. The cartridge of any one of claims 1-7, wherein the mixing zone includes a magnetic stirring element contained therein.
9. The cartridge of any one of claim 1-8, wherein the conduit includes an aspiration zone and a fluid restrictor, located between the fluid inlet port and the mixing zone.
10. The cartridge of any one of claims 1-9, wherein the hemocyte lysate is limulus amoebocyte lysate.
11. The cartridge of claim 2, wherein the agent representative of the microbial contaminant is a bacterial endotoxin.
12. The cartridge of any of claims 9-11, wherein the pump mechanism is a three-position syringe, wherein a first position creates a vacuum to introduce the sample into the aspiration zone, a second position provides transport from the aspiration zone, through the fluid restrictor, to the mixing zone, and a third position provides transport from the mixing zone to the sample well.
13. A cartridge for determining the presence and/or amount of a microbial contaminant in a sample, the cartridge comprising:
 - a. a housing including a cover section, a base section mechanically connected to the cover section, and a manifold section mechanically connected to the base section;

- 32 -

- i. the base section including two optical sample wells, a fluid inlet port and a conduit fluidly connecting the fluid inlet port and the optical sample well;
 - ii. the conduit including an aspiration zone, a fluid restrictor, and a mixing zone;
 - iii. the manifold section including a mixing portion configured to include a dried composition comprising a hemocyte lysate, the mixing portion corresponding to the mixing zone of the conduit; and
 - b. a pump mechanism associated with the housing and fluidly connected to the fluid inlet port, the conduit and the two optical sample wells.
14. The cartridge of claim 13, wherein the base section includes four optical sample wells, wherein two of the four optical sample wells are configured to include an agent representative of the microbial contaminant dried in the optical sample wells.
15. The cartridge of claim 14, wherein the manifold section further includes the agent representative of the microbial contaminant dried on a sample well portion of the manifold section.
16. The cartridge of any of claims 13-15, further comprising a chromogenic substrate dried on the mixing portion of the manifold section.
17. The cartridge of any one of claims 13-16, wherein the pump mechanism is integrated into the base section, and the pump mechanism is a three-position syringe, wherein a first position creates a vacuum to introduce the sample into the aspiration zone, a second position provides transport from the aspiration zone, through the fluid restrictor, to the

- 33 -

mixing zone, and a third position provides transport from the mixing zone to the sample wells.

18. The cartridge of any of claims 13-17, wherein the hemocyte lysate is limulus amoebocyte lysate.

19. The cartridge of any of claims 14-18, wherein the agent is a bacterial endotoxin.

20. A method for detecting the presence of a microbial contaminant in a sample, the method comprising:

- a. introducing the sample into the fluid inlet port of the cartridge of claim 3, and transferring the sample to the conduit;
- b. transferring the sample into the mixing zone of the conduit;
- c. mixing the sample with the hemocyte lysate and the chromogenic substrate to generate a mixed sample;
- d. transferring the mixed sample from the mixing zone to the sample well; and
- e. measuring an optical property of the mixed sample in the optical sample well, wherein a change in the optical property is indicative of the presence of the microbial contaminant in the sample.

21. The method of claim 20, wherein the measuring the optical property is a change in absorbance of light at a preselected wavelength.

22. The method of claim 21, wherein the change in absorbance of light at a preselected wavelength is compared to a standard curve.

- 34 -

23. The method of claim 22, wherein the standard curve is an archived standard curve.
24. The method of any of claims 20-23, wherein the introducing the sample comprises creating a vacuum via the pump mechanism to introduce the sample into the fluid inlet port and the conduit.
25. The method of any of claims 20-24, wherein the transferring comprises transporting via the pump mechanism the sample from mixing zone to the optical sample well.
26. A method for detecting the presence of a microbial contaminant in a sample, the method comprising:
- a. introducing the sample into the fluid inlet port of the cartridge of claim 16, and transferring the sample to the aspiration zone;
 - b. transferring the sample from the aspiration zone, through the fluid restrictor, to the mixing zone;
 - c. mixing the sample with the hemocyte lysate and the chromogenic substrate to generate a mixed sample;
 - d. transferring the mixed sample to the optical sample wells; and
 - e. measuring an optical property of the mixed sample in the optical sample wells, wherein a change in the optical property is indicative of the presence of the microbial contaminant in the sample.
27. The method of claim 26, wherein the measuring the optical property is a change in absorbance of light at a preselected wavelength.

- 35 -

28. The method of claim 27, wherein the change in absorbance of light at a preselected wavelength is compared to a standard curve.
29. The method of claim 28, wherein the standard curve is an archived standard curve.
30. The method of any of claims 26-29, wherein the introducing the sample comprises creating a vacuum via the pump mechanism to introduce the sample into the fluid inlet port and the aspiration zone, the transferring in b) comprising transporting via the pump mechanism the sample from the aspiration zone to the mixing zone; and the transferring in d) comprises transporting via the pump mechanism the mixed sample from mixing zone to the optical sample wells.