

SYSTEMS AND METHODS FOR CONTROLLING AND MONITORING ENVIROMENTAL CONDITIONS OF A SEMEN SAMPLE DURING TRANSPORT

CROSS-REFERENCE

5 **[0001]** The present application claims priority to U.S. Provisional Patent Application No. 63/030,730 filed May 27, 2020, entitled, “Semen Analysis Kit”, which is entirely incorporated herein by reference for all purposes.

FIELD OF THE INVENTION

10 **[0002]** This description is generally directed toward systems, methods, and kits for controlling and monitoring environmental conditions of male fertility samples during transport and determining whether the male fertility samples are suitable for undergoing male fertility testing.

BACKGROUND

15 **[0003]** Currently, male fertility testing includes semen sample collection at a fertility clinic or doctor’s office. Samples are typically tested within one hour of collection at the same facility they were collected at.

[0004] Maintaining semen sample collection facilities at fertility clinics and doctor’s offices can be expensive and uncomfortable. Many fertility clinics and doctor’s offices are unable to dedicate
20 space to semen sample collection, so patients are required to produce samples in undesirable places such as public restrooms or nearby hotels to still enable the sample to be tested within the one-hour processing window.

[0005] Semen sample collection requires comfort and relaxation, whereas, clinics and doctor’s offices often foster discomfort and anxiety in people. As such, there is a need for systems,
25 methods, and kits allowing for sample collection for fertility testing to occur in one’s home while providing individualized transport in an environmentally controlled and monitored manner. The present disclosure addresses this and other needs.

SUMMARY

30 **[0006]** In ~~some aspects~~the present disclosure, an environmental control and monitoring system for transportation and analysis of a semen sample is disclosed. ~~In some embodiments, the~~The system may comprise a sample container, configured to contain a semen sample, an environmental control element configured to operate within an optimal range for semen viability, and a sensor system for monitoring

an environmental condition of the sample container, wherein the sensor system is in thermal contact with at least one of the sample container or the environmental control element.

[0006a] In one aspect, there is provided an environmental control and monitoring system for transportation and analysis of a semen sample, the system comprising: a sample container, configured to contain a semen sample; an environmental control element configured to operate within an optimal range for semen viability; and a sensor system for monitoring an environmental condition of the sample container, wherein the sensor system is in thermal contact with at least one of the sample container or the environmental control element.

[0007] In some exampleembodiments, the system further comprises a positioning retainer for restraining movement of the sample container, the environmental control element, and the sensor relative to one another. In some exampleembodiments, the positioning retainer comprises a packing material.

[0008] In some embodimentsexamples, the sensor system may further comprise a sensor for measuring the environmental condition, a data store in electronic communication with the sensor, wherein the data store is configured to store measurements from the sensor, and a data port in electronic communication with the data store. In some exampleembodiments, the sensor comprises a temperature sensor and the environmental condition comprises temperature. In some exampleembodiments, the sensor comprises a humidity sensor and the environmental condition comprises humidity. In some exampleembodiments, the sensor measures the environmental condition at least one time every minute.

[0009] In some exampleembodiments, the measurements from the sensor system may be stored on the data store. In some exampleembodiments, the data port may electronically communicate measurements from the sensor system to a remote server. In some exampleembodiments, the measurements may be stored on the data store prior to being transmitted to the remote server.

[0010] In some exampleembodiments, the remote server may comprise a server data port for sending and receiving data, wherein the data comprises the measurements, a server data store in electronic communication with the server data port for storing the data, and a sever processor for analyzing the data.

[0011] In some exampleembodiments, the environmental control element comprises a phase transition material. In some exampleembodiments, the phase transition material may be configured to go through a phase change within the optimal temperature range. In some exampleembodiments, the optimal range comprises temperatures ranging from 4°C to 37°C.

[0012] In some exampleembodiments, the environmental control and monitoring system may further comprise a container wall surrounding an internal cavity, wherein a positioning retainer fits within the internal cavity, wherein the cavity is surrounded by the container wall.

5 [0013] In some exampleembodiments, the sample container may hold a semen preservation solution.

[0014] In some exampleembodiments, the data port and the server data port each comprise a wireless adaptor.

10 [0015] In some exampleembodiments, the sensor system comprises a temperature indicator. In some exampleembodiments, the indicator may display a level of exposure. In some exampleembodiments, the temperature indicator may be in physical and thermal contact with an exterior surface. In some exampleembodiments, the temperature indicator may be in physical and thermal contact with an interior surface.

[0016] In some exampleembodiments, the temperature indicator may be in physical and thermal contact with a retainer surface.

[0017] In ~~some aspects~~the present disclosure, an environmental control and monitoring method for transportation and analysis of a semen sample is disclosed. In some embodiments examples, the method may comprise the steps of transporting a sensor system, an environmental control element, and a sample container, wherein the sensor system may be in thermal contact with at least one of the sample container or the environmental control element. In some embodiments examples, the method may comprise the step of controlling one or more environmental conditions of the sample container during transport using the environmental control element. In some embodiments examples, the method may comprise the step of recording a plurality of measurements of the one or more environmental conditions during transport of the sample container to a log. In some embodimentsexamples, the method may comprise the step of comparing the log to a reference to determine a condition of the sample container.

[0018] In some exampleembodiments, the method may further comprise the step of introducing a semen sample into the sample container prior to the transporting step.

[0019] In some exampleembodiments, the method may further the step of registering the semen sample with a laboratory to associate a subject with the semen sample. In some exampleembodiments, the one or more environmental conditions comprises temperature. In some exampleembodiments, the one or more environmental conditions comprises humidity. In some exampleembodiments, the plurality of measurements may be recorded every 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 minutes. In some exampleembodiments, the log comprises a plurality of temperature and timestamp pairs. In some exampleembodiments, the reference comprises off-target temperature values. In some exampleembodiments, the reference comprises exposure durations for the off-target temperature values. In some exampleembodiments, the reference is based on published research data. In some exampleembodiments, the reference is based on data acquired using the environmental control and monitoring method.

[0020] In some exampleembodiments, the condition determines whether the sample undergoes fertility testing and is based on sperm count, motility count, semen volume, or morphology.

[0021] In some exampleembodiments, the method further comprises causing a phase transition material of the environmental control element to undergo a phase transition. In some exampleembodiments, the phase transition may occur between 18-24°C. In some exampleembodiments, the environmental control element comprises a flexible material containing the phase transition material. In some exampleembodiments, the flexible material comprises a

0.5mm plastic film. In some examplesembodiments, the phase transition material comprises a salt solution. In some examplesembodiments, the phase transition material comprises a solution comprising sugar, NaCl, oil, glucose, water, mineral spirits, or a surfactant. In some examplesembodiments, the environmental control element comprises a mass between 90-110 grams.

[0022] In some exampleembodiments, the log comprises a temperature indicator. In some exampleembodiments, the temperature indicator comprises an adhesive strip including a temperature sensitive region, wherein the temperature sensitive region gradually changes appearance based on duration of exposure to off-target temperature values. In some exampleembodiments, the environmental control and monitoring method further comprising the steps of storing the log on a data store in digital format, transmitting the log from the data store to a remote server, and completing the comparing step on the remote server.

[0023] In some exampleembodiments, the step of transporting comprises traveling more than 10 miles. In some exampleembodiments, the step of transporting comprises traveling more than 10 minutes.

[0024] In some aspectsthe present disclosure, a kit for transporting a semen sample is disclosed. In some embodimentsexamples, the kit may comprise a sample container for storing a semen sample, an environmental control element for controlling a temperature of the sample container, and a sensor system for monitoring the temperature of the sample container.

[0025] In some exampleembodiments, the sensor system of the kit may comprise a temperature sensor, a data store for recording measurements produced by the temperature sensor, and a data port for transmitting the measurements.

[0026] In some exampleembodiments, the kit further comprises a positioning retainer for restraining movement of the sample container, the environmental control element, and the sensor system relative to one another.

[0027] In some exampleembodiments, the kit further comprises a preservation container comprising a preservation fluid.

[0028] In some exampleembodiments, the sensor system comprises an appearance changing temperature indicator.

[0029] In some exampleembodiments, the appearance change involves a material going through a chemical transition after exposure to an off-target temperature or pH.

[0030] In some exampleembodiments, the temperature control element comprises a phase transition material. In some exampleembodiments, the phase transition material has been optimized to operate within a validated range for semen sample viability.

[0031] In some exampleembodiments, the environmental control element may be a gel pack. In some exampleembodiments, the phase change occurs between 18-24°C. In some exampleembodiments, the environmental control element comprises a flexible material containing the phase transition material. In some exampleembodiments, the flexible material comprises a 0.5mm plastic film. In some exampleembodiments, the phase transition material comprises a salt solution. In some exampleembodiments, the phase transition material

comprises a solution comprising sugar, NaCl, oil, glucose, water, mineral spirits, or a surfactant. In some example embodiments, the environmental control element comprises a mass between 90-110 grams.

5 **INCORPORATION BY REFERENCE**

[0032] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference. To the extent publications and patents or patent applications incorporated by reference contradict the disclosure
10 contained in the specification, the specification is intended to supersede and/or take precedence over any such contradictory material.

BRIEF DESCRIPTION OF FIGURES

[0033] The novel features of the technology are set forth with particularity in the appended
15 claims. A better understanding of the features and advantages of the present technology will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the technology are utilized, and the accompanying drawings (also “Figure” and “FIG.” herein). The accompanying drawings are not intended to be drawn to scale. Like reference numbers and designations in the various drawings indicate like elements. For purposes of clarity, not every
20 component can be labeled in every drawing. In the drawings:

[0034] FIG. 1 is a top down view of an environmental control and monitoring system according to some embodiments.

[0035] FIG. 2 is a side view (wall removed for visibility) of an environmental control and monitoring system with a sensor system in thermal contact with an environmental control element
25 according to some embodiments.

[0036] FIG. 3 shows a schematic diagram of a data and analysis system according to some embodiments.

[0037] FIG. 4 shows a schematic diagram of a sensor system according to some embodiments.

30 [0038] FIG. 5 shows a schematic diagram of a computer system according to some embodiments.

[0039] FIG. 6 is a side view (wall removed for visibility) of an environmental control and monitoring system with a sensor system on an exterior surface according to some embodiments.

CLAIMS:

1. An environmental control and monitoring system for transportation and analysis of a semen sample, the system comprising:
 - a sample container, configured to contain a semen sample;
 - an environmental control element configured to operate within an optimal range for semen viability; and
 - a sensor system for monitoring an environmental condition of the sample container, wherein the sensor system is in thermal contact with at least one of the sample container or the environmental control element.
2. The environmental control and monitoring system of claim 1, wherein the system further comprises:
 - a positioning retainer for restraining movement of the sample container, the environmental control element, and the sensor relative to one another.
3. The environmental control and monitoring system of claim 2, wherein the positioning retainer comprises a packing material.
4. The environmental control and monitoring system of claim 1, wherein the sensor system further comprises:
 - a sensor for measuring the environmental condition;
 - a data store in electronic communication with the sensor, wherein the data store is configured to store measurements from the sensor; and
 - a data port in electronic communication with the data store.
5. The environmental control and monitoring system of claim 4, wherein the sensor comprises a temperature sensor and the environmental condition comprises temperature.
6. The environmental control and monitoring system of claim 4 ~~according to any one of claims 4-5~~, wherein the sensor comprises a humidity sensor and the environmental condition comprises humidity.
7. The environmental control and monitoring system of claim 4 ~~according to any one of claims 4-6~~, wherein the sensor measures the environmental condition at least one time every minute.

8. The environmental control and monitoring system ~~of claim 4 according to any one of the preceding claims~~, wherein measurements from the sensor system are stored on the data store.
9. The environmental control and monitoring system ~~of claim 4 according to any one of the preceding claims~~, wherein the data port electronically communicates measurements from the sensor system to a remote server.
10. The environmental control and monitoring system of claim 9, wherein the measurements are stored on the data store prior to being transmitted to the remote server.
11. The environmental control and monitoring system of claim 10, wherein the remote server comprises:
 - a server data port for sending and receiving data, wherein the data comprises the measurements;
 - a server data store in electronic communication with the server data port for storing the data; and
 - a sever processor for analyzing the data.
12. The environmental control and monitoring system ~~of claim 1 according to any one of the preceding claims~~, wherein the environmental control element comprises a phase transition material.
13. The environmental control and monitoring system of claim 12, wherein the phase transition material is configured to go through a phase change within the optimal temperature range.
14. The environmental control and monitoring system ~~of claim 1 according to any one of the preceding claims~~, wherein the optimal range comprises temperatures ranging from 4°C to 37°C.
15. The environmental control and monitoring system ~~of claim 2 according to any one of the preceding claims~~, further comprising a container wall surrounding an internal cavity, wherein the positioning retainer fits within the internal cavity, wherein the cavity is surrounded by the container wall.
16. The environmental control and monitoring system ~~of claim 1 according to any one of the preceding claims~~, wherein the sample container holds a semen preservation solution.

17. The environmental control and monitoring system of claim 11~~according to any one of claims 4-16 the preceding claims~~, wherein the data port and the server data port each comprise a wireless adaptor.

18. The environmental control and monitoring system of claim 1, wherein the sensor system comprises a temperature indicator.

19. The environmental control and monitoring system of claim 18, wherein the indicator displays a level of exposure.

20. The environmental control and monitoring system of claim 18~~according to any one of claims 18-19~~, wherein the temperature indicator is in physical and thermal contact with an exterior surface.

21. The environmental control and monitoring system of claim 18~~according to any one of claims 18-19~~, wherein the temperature indicator is in physical and thermal contact with an interior surface.

22. The environmental control and monitoring system of claim 18~~according to any one of claims 18-19~~, wherein the temperature indicator is in physical and thermal contact with a retainer surface.

~~23. — An environmental control and monitoring method for transportation and analysis of a semen sample, the method comprising:~~
~~transporting a sensor system, an environmental control element, and a sample container, wherein the sensor system is in thermal contact with at least one of the sample container or the environmental control element;~~
~~controlling one or more environmental conditions of the sample container during transport using the environmental control element;~~
~~recording a plurality of measurements of the one or more environmental conditions during transport of the sample container to a log; and~~
~~comparing the log to a reference to determine a condition of the sample container.~~

~~24. — The environmental control and monitoring method of claim 23, further comprising the step of introducing a semen sample into the sample container prior to the transporting step.~~

~~25.——The environmental control and monitoring method of claim 24, further comprising the step of registering the semen sample with a laboratory to associate a subject with the semen sample.~~

~~26.——The environmental control and monitoring method according to any one of claims 23-25, wherein the one or more environmental conditions comprises temperature.~~

~~27.——The environmental control and monitoring method according to any one of claims 23-26, wherein the one or more environmental conditions comprises humidity.~~

~~28.——The environmental control and monitoring method according to any one of claims 23-27, wherein the plurality of measurements are recorded every 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 minutes.~~

~~29.——The environmental control and monitoring method according to any one of claims 23-28, wherein the log comprises a plurality of temperature and timestamp pairs.~~

~~30.——The environmental control and monitoring method according to any one of claims 23-29, wherein the reference comprises off-target temperature values.~~

~~31.——The environmental control and monitoring method of claim 30, wherein the reference comprises exposure durations for the off-target temperature values.~~

~~32.——The environmental control and monitoring method according to any one of claims 30-31, wherein the reference is based on published research data.~~

~~33.——The environmental control and monitoring method according to any one of claims 30-31, wherein the reference is based on data acquired using the environmental control and monitoring method.~~

~~34.——The environmental control and monitoring method according to any one of claims 23-33, wherein the condition determines whether the sample undergoes fertility testing and is based on sperm count, motility count, semen volume, or morphology.~~

35.——The environmental control and monitoring method according to any one of claims 23-35, wherein the step of controlling comprises causing a phase transition material of the environmental control element to undergo a phase transition.

36.——The environmental control and monitoring method of claim 35, wherein the phase transition occurs between 18-24°C

37.——The environmental control and monitoring method according to any one of claims 35-37, wherein the environmental control element comprises a flexible material containing the phase transition material.

38.——The environmental control and monitoring method of claim 37, wherein the flexible material comprises a 0.5mm plastic film.

39.——The environmental control and monitoring method according to any one of claims 35-38, wherein the phase transition material comprises a salt solution.

40.——The environmental control and monitoring method according to any one of claims 35-39, wherein the phase transition material comprises a solution comprising sugar, NaCl, oil, glucose, water, mineral spirits, or a surfactant.

41.——The environmental control and monitoring method according to any one of claims 23-40 wherein the environmental control element comprises a mass between 90-110 grams.

42.——The environmental control and monitoring method according to any one of claims 23-41, wherein the log comprises a temperature indicator.

43.——The environmental control and monitoring method of claim 42, wherein the temperature indicator comprises an adhesive strip including a temperature sensitive region, wherein the temperature sensitive region gradually changes appearance based on duration of exposure to off-target temperature values.

~~44. The environmental control and monitoring method according to any one of claims 23-43, further comprising the steps of:~~

~~storing the log on a data store in digital format;~~

~~transmitting the log from the data store to a remote server; and~~

~~completing the comparing step on the remote server.~~

~~45. The environmental control and monitoring method according to any one of claims 23-44, wherein the step of transporting comprises traveling more than 10 miles.~~

~~46. The environmental control and monitoring method according to any one of claims 23-45, wherein the step of transporting comprises traveling more than 10 minutes.~~

~~47. A kit for transporting a semen sample, comprising:~~

~~a sample container for storing a semen sample;~~

~~an environmental control element for controlling a temperature of the sample container; and~~

~~a sensor system for monitoring the temperature of the sample container.~~

~~48. The kit of claim 47, wherein the sensor system comprises:~~

~~a temperature sensor;~~

~~a data store for recording measurements produced by the temperature sensor; and~~

~~a data port for transmitting the measurements.~~

~~49. The kit according to any one of claims 47-48, wherein the kit further comprises a positioning retainer for restraining movement of the sample container, the environmental control element, and the sensor system relative to one another.~~

~~50. The kit according to any one of claims 47-49, wherein the kit further comprises a preservation container comprising a preservation fluid.~~

~~51. The kit according to any one of claims 47-50, wherein the sensor system comprises an appearance-changing temperature indicator.~~

~~52. The kit of claim 51, wherein the appearance change involves a material going through a chemical transition after exposure to an off-target temperature or pH.~~

~~53. The kit according to any one of claims 47-52, wherein the temperature control element comprises a phase transition material.~~

~~54. The kit of claim 53, wherein the phase transition material has been optimized to operate within a validated range for semen sample viability.~~

~~55. The kit according to any one of claims 47-54, wherein the environmental control element is a gel pack.~~

~~56. The environmental control and monitoring system of claim 13, wherein the phase change occurs between 18-24°C.~~

~~57. The environmental control and monitoring system of claim 56, wherein the environmental control element comprises a flexible material containing the phase transition material.~~

~~58. The environmental control and monitoring system of claim 57, wherein the flexible material comprises a 0.5mm plastic film.~~

~~59. The environmental control and monitoring system according to any one of claims 57-58, wherein the phase transition material comprises a salt solution.~~

~~60. The environmental control and monitoring system according to any one of claims 57-58, wherein the phase transition material comprises a solution comprising sugar, NaCl, oil, glucose, water, mineral spirits, or a surfactant.~~

~~61. The environmental control and monitoring system according to any one of claims 1-22 and 56-60, wherein the environmental control element comprises a mass between 90-110 grams.~~