

CLAIMS

WHAT WE CLAIM IS:

1. A device for detecting an infection in a wound, comprising:
 - a) an indicator unit; wherein the indicator unit comprises:
 - i. a sensor tube having an open proximal end; and
 - ii. a sensor positioned in the sensor tube; and
 - b) a swab unit, wherein the swab unit comprises:
 - i. a swab shaft having a proximal end and a distal end;
 - ii. a swab tip positioned at the distal end of the swab shaft; and
 - iii. a swab handle connected to the swab shaft at the proximal end of the swab shaft, the swab handle being configured to sealingly engage the open proximal end of the sensor tube.
2. The device of claim 1, wherein the sensor comprises a carrier material and at least one substrate that is operable to undergo a visible color change in response to expression of a specific infection marker present in wound fluid.
3. The device of claim 2, wherein the sensor comprises at least two substrates, each substrate operable to undergo a visible color change in response to expression of a different marker present in wound fluid.
4. The device of claim 2 wherein the carrier material comprises at least one material selected from the group consisting of paper, cellulose, cellulose derivatives, viscose, polyamide, polyester, polyacrylate, fabric, sodium carboxymethylcellulose fiber, and cardboard.
5. The device of claim 1, wherein the indicator unit further comprises a sensor retaining insert sealingly engaged to a distal end of the sensor tube, and wherein the sensor is affixed to the sensor retaining insert.
6. The device of claim 5, wherein the sensor retaining insert defines a cavity configured to receive the swab tip when the swab unit is sealingly engaged to the indicator unit.
7. The device of claim 5, wherein the sensor retaining insert comprises at least one structural feature in or adjacent to the cavity to guide the swab tip as it enters the sensor retaining insert into a desired juxtaposition with the sensor.
8. The device of claim 7, wherein the at least one structural feature is selected from rib features, inclined cavity walls and combinations thereof.

9. The device of claim 1, wherein the swab tip comprises cellulose, modified cellulose, polyurethane foam, polyester, silk, wool, nylon, polypropylene, elastane, or mixtures thereof.
10. The device of claim 1, wherein the sensor comprises a member selected from the group consisting of an enzyme-reactive indicator, a reagent that is a source of peroxide, an enzyme that is able to transform color reactions, a pH indicator, a total protein-detecting reagent, a moisture-detecting reagent and combinations thereof.
11. The device of claim 10, wherein the pH indicator comprises a pH-sensitive reagent.
12. The device of claim 10, wherein the enzyme-reactive indicator comprises a moiety capable of producing a visible color or detectable electronic change upon interaction with one or more target enzymes.
13. The device of claim 12, wherein the moiety is selected from the group consisting of a peroxidase substrate, arylamine, an amino phenol, an indoxyl, a neutral dye, a charged dye, a nanoparticle, a colloidal gold particle, and combinations or analogs thereof.
14. The device of claim 1, wherein the swab handle defines a liquid chamber and wherein the swab handle is operable to contain a liquid in the liquid chamber and release the liquid into the sensor tube after the swab tip is positioned within the sensor tube.
15. The device of claim 14, wherein the swab handle is configured for manual release of the liquid from the liquid chamber.
16. The device of claim 15, wherein the swab handle comprises a retaining element configured to attach to the sensor tube, the retaining element defining a cavity, and a movable element retained within the cavity and movable relative to the retaining element.
17. The device of claim 16, wherein the liquid chamber is contained within the movable element.
18. The device of claim 17, wherein the movable element further comprises a liquid chamber seal, wherein the handle further comprises a piercing member fixedly attached to the retaining element, and wherein moving the movable element from a proximal position to a distal position causes the piercing member to pierce the liquid chamber seal to release the liquid into the sensor tube.
19. The device of claim 18 wherein the seal comprises a member selected from the group consisting of a metallic foil and a plastic film.

20. The device of claim 18, wherein the swab shaft is fixedly attached to the retaining element such that a proximal end of the swab shaft extends into the cavity, and wherein the piercing member comprises the proximal end of the swab shaft.
21. The device of claim 20, wherein the swab shaft comprises a tube defining a longitudinal passageway therethrough, and wherein, after the liquid chamber seal is pierced, the liquid chamber is in fluid communication with the sensor tube through the passageway.
22. The device of claim 21, wherein the swab shaft defines a radial aperture at its distal end near the swab tip, and wherein, after the liquid chamber seal is pierced, the liquid chamber is in fluid communication with the sensor tube through the passageway and the aperture.
23. The device of claim 18, further comprising a locking mechanism that is operable to prevent the movable element from moving in a proximal direction after the liquid chamber seal is pierced.
24. The device of claim 14, wherein the swab handle is configured for automatic release of the liquid from the liquid chamber when the handle of the swab unit is sealingly engaged to the open proximal end of the sensor tube.
25. The device of claim 24, wherein the swab handle comprises a liquid chamber seal positioned at a distal end of the liquid chamber, wherein the indicator unit further comprises a piercing member fixedly attached to the sensor tube at a location whereby the piercing member contacts the liquid chamber seal only when the distal end is inserted into the sensor tube, and wherein inserting the distal end into the sensor tube causes the piercing member to pierce the liquid chamber seal to release the liquid into the sensor tube.
26. The device of claim 25 wherein the piercing member is a piercing ring.
27. The device of claim 14, wherein the liquid chamber contains a liquid in an amount of about 500 uL, 1 mL, 1.5 mL, 2 mL, 2.5 mL, 3 mL, 3.5 mL, or 4 mL.
28. A method for detecting a marker in a wound, comprising:
- a) contacting the wound with the swab tip of the device of any of claims 1-25;
 - b) inserting the swab tip inside the sensor tube and sealingly engaging the swab unit to the indicator unit; and
 - c) observing a change in the sensor.
29. The method of claim 28, wherein the marker is a host biomarker.
30. The method of claim 28, wherein the change is a color change, a fluorescent signal, a luminescent signal, or an electrical change.

31. The method of claim 28, wherein the sensor comprises a carrier material and at least one substrate that is operable to undergo a visible color change in response to expression of a specific infection marker present in wound fluid released from the swab tip.
32. The method of claim 31, further comprising (d) comparing the signal to a reference or a control to determine a level of the marker.
33. The method of claim 28, wherein the device comprises a movable element, further comprising pressing the movable element following step (b).
34. The method of claim 28, wherein step (b) comprises placing the swab tip of the swab unit in contact with the sensor of the indicator unit.
35. The method of claim 28, wherein step (b) results in piercing of a liquid seal.
36. The method of claim 35, wherein the piercing of the liquid seal releases liquid into the sensor tube.