SurCapt™ Microbial Surface Detection Kit

FREQUENTLY ASKED QUESTIONS

1. What is the SurCapt™ Microbial Surface Detection Kit?

The SurCapt™ Microbial Surface Detection Kit is a single ready-to-use system for unique surface monitoring in aseptic areas. It is composed of a vial containing Tryptic Soy Broth (TSB) with an acute oxygen sensor and flocked swab (Copan FLOQSwab™) with ≥ 70% recovery of microbial surfaces. Inside the vial, the swab rests against a sponge containing the SRK™ solution (increases recovery of microorganisms) and all four neutralizers for disinfectants required by regulatory agencies.

Swabbing is a methodology that detects microorganisms typically on uneven or difficult to reach surfaces. This swab is designed to be used in critical areas like aseptic filling operations, etc.

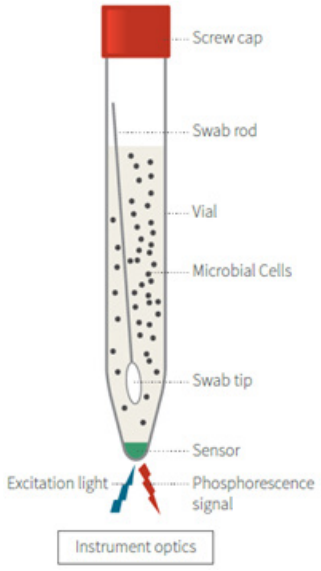


Figure 1

2. How does it work?

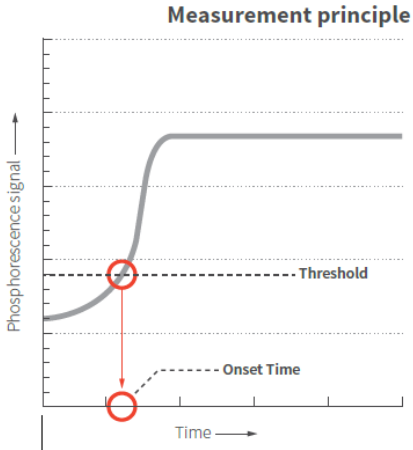
The SurCapt system uses optical fluorescence and the GreenLight® reader. When the probe sensor (see **Figure 1**) is initiated by the reader's LED light, it returns optical information regarding O_2 concentration inside the probe. Growth within the sample is continuously read in this way, with a decrease in O_2 inversely affecting the probe signal.

3. How is the initial microbial load determined?

The GreenLight soluble reagent is phosphorescent — it emits light. This light emission is quenched by dissolved oxygen in the test medium. The normal concentration of oxygen at the beginning of the test is close to 21% O_2 (typical environmental percentage).

As the bacteria grow and multiply, they consume more and more dissolved oxygen from the medium. The decrease in O_2 correlates with an increase in the probe's phosphorescent signal (see **Figure 2**).

21% of O_2 is equivalent to 22 - 23 µs (microseconds) of phosphorescent signal. 0% of O_2 is 40 µs.



Treshold is based on negative control determinations.

The time taken to reach a preset threshold signal (TTR [Time-to-Result]) is used to estimate initial microbial load.

Figure 2

4. What is the threshold?

Using the GreenLight software, a fixed threshold (in µs) is set that confirms microorganism growth. When the fluorescent signal reaches the threshold value, the test is finished.

Note: The threshold is used for both enumeration tests (see PQ 2) and Pass/Fail tests.

5. How do I set the threshold?

Particle Measuring Systems recommends a threshold of 25 µs, equivalent to 17% of O_2 inside the probe. The threshold can be lowered to speed up the test.

6. What is a Pass/Fail test?

A Pass/Fail determines the presence or absence of microorganisms on the critical surface using a flocked swab. Using the GreenLight software, choose the Time Method for Pass/Fail tests.

7. When should the test finish?

Microorganisms with the slowest growth must be taken into account based on their predetermined detection frequency (see PQ 2). The Pass/Fail Criteria is based on the time to grow < 5 CFU inside the SurCapt vial of the slowest-growing microorganisms. Determining the concentration of microorganisms inside the vial is necessary to inoculate the same amount at the same concentration on a normal TSA plate.

8. How many vials can be run at the same time in a Pass/Fail test?

There are three types of Pass/Fail methods (alternatively called the Time Method):

Continuous: Used with up to 24 vials (one carousel). The GreenLight will read each SurCapt vial for a set time between 2 and 15 minutes until the Pass/Fail Criteria is met. The growth curve is displayed in real-time.

Multipoint: Used with up to 9 carousels (216 vials) with external incubation, or 432 vials with two readers (only one PC is necessary). The GreenLight will read each carousel for a set time between 15 minutes and 72 hours until the Pass/Fail Criteria is met.

Pass/Fail: Used with up to 24 vials (one carousel). The GreenLight will read each SurCapt vial for a set time between 15 minutes and 72 hours until the Pass/Fail Criteria is met.

9. How are the results read?

At the end of the test, contaminated vials are marked with a red “F” (Fail).

Non-contaminated vials are marked with a green “P” (Pass).

At the end of each test, a final report is printed out and safely stored to the PC.

Figure 3

10. Is the double incubation temperature required (as specifed by GMP)?

No, it is demonstrated that most common microorganisms found on cleanroom surfaces in concentrations of < 5 CFU grow within 20 to 24 hours (see PQ 1).

11. Has the SurCapt Kit been validated?

Yes, the system has been validated by an external laboratory following the USP Chapter <1223> (Validation of Alternative Microbiological Methods) and EP Chapter 5.1.6 (Validation of Compendial Methods). All the documentation regarding the PQ 1 are provided to the customer that purchases the GreenLight.

12. Can I quantify my microorganisms?

Yes, the microbial load of the tested surface can be quantified after performing PQ 2.

13. What concentration of microorganisms do I need to perform PQ 2?

A concentration of 10^3 to 10^5 (< 5 CFU) should be made of environmental isolate microorganisms with the slowest growth rate based on detection frequency. Documenting the concentration of microorganisms inside the vial is necessary to successfully inoculate the same concentration on a TSA plate and Time-to-Threshold SurCapt vials, in addition to documenting the CFU found.

14. How many vials can be run at the same time with an enumeration test?

There are three types of enumeration tests (alternatively called the Test Method):

Continuous: Used with up to 24 vials (one carousel). The GreenLight will read each SurCapt vial for a set time between 2 and 15 minutes until the user-set Maximum Time, determined using the slowest-growing microorganism, has been reached. Pass/Fail criteria must also be set based on the cleanroom's CFU limit.

Multipoint: Used with up to 9 carousels (216 vials) with external incubation, or 432 vials with two GreenLight 930-15 readers (only one PC is necessary). The GreenLight will read each carousel for a set time between 15 minutes and 72 hours until the Maximum Time has been reached (based on PQ 2). It is recommended to set the Initial Incubation Time for 900 minutes (15 hours), with the expectation that 10 CFU will be found after 21 to 22 hours (for low-contamination areas).

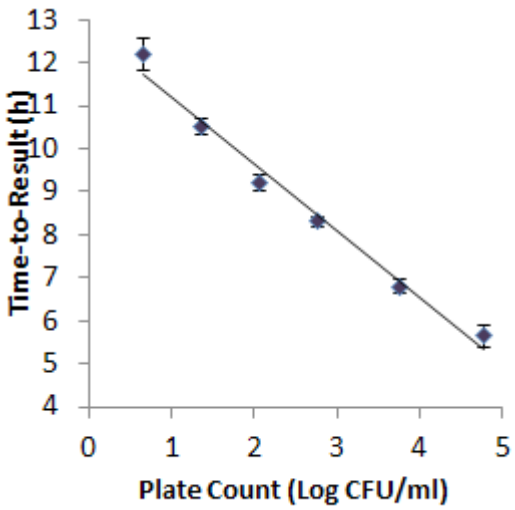


Figure 4

Pass/Fail: Used with up to 24 vials (one carousel). The GreenLight will read each SurCapt vial for a set time between 15 minutes and 72 hours until the Maximum Time is reached (based on the slowest microorganism growth).

The GreenLight compares the Time-to-Threshold of the SurCapt vial to the CFU found on the TSA plate during calibration (see **Figure 4** for a typical calibration curve).

15. Can any vials be replaced or added after testing has been initated?

No, each barcoded vial is associated with a specific carousel and its 24 positions. You will be unable to replace any vials if a test has been initated.

16. How often should the GreenLight reader be calibrated?

The GreenLight reader should be calibrated annually.

17. How do I set up a Demo Test?

- Open the GreenLight software. (GreenLight930.exe)
- Click on "Manage Methods" in the navigation panel.
- Click on "New", found towards the bottom of the window.
- Set your test parameters (see **Figure 5**).
- Click "Save".
- Start a "New Test" using your user-defined Demo Test.

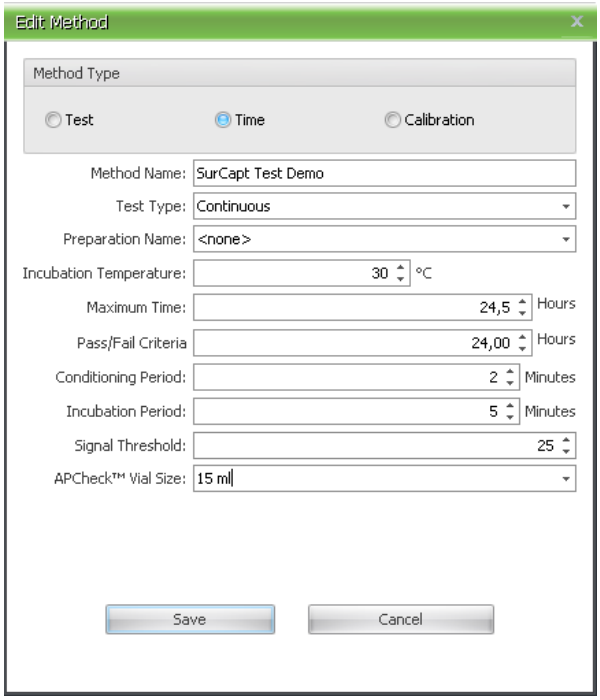


Figure 5

18. What are the applicable industries?

Examples of applicable industry sectors include:

- Pharmaceutical sterial products
- Cell factories
- Radiopharmaceutical
- Bulk sterile drug substances
- Sterile intermediates
- Excipients
- Medical devices
- Conventional cleanroom with unidirection airflow
- Blow/fill/seal machines
- Restricted Access Barrier Systems (RABS)
- Isolators

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