



SOP: LFA 00079
SOP For Air Sampler

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1 Objective

To provide an operational guideline for air sampler "HIMEDIA"

2 Scope

Applicable to the operation of the air sampler "HIMEDIA"

3 Responsibility

By Microbiologist/Quality Control

4 Accountability

Manager of Quality Control

5 Procedure

5.1. Principle

- The air is aspirated at a fixed speed for a determined time and out through a cover with specially designed small holes. The laminar airflow that resulted is directed to the agar surface (contact plate) which contains a medium consistent of the microbiological examination that would be performed. When the pre-set sampling cycle is completed, the plate is removed and then incubated. The organisms are now visible to the naked eye and can be counted to determine the contamination level.
- For Fertility Test of Media: Use the Growth Promotion Test for each media lot using the environment monitoring as per the standard operating procedure.

5.2. Operation of Air Sampler

- 5.2.1. For environmental monitoring, use the Tryptone Soya Agar media plate.
- 5.2.2. Before use, incubate the media filled plates at 30 to 35°C for 48 hours.
- 5.2.3. Install media plate in air sampler.
- 5.2.4. Remove the micro perforated sieve from the tester.
- 5.2.5. Remove the sieve cover and autoclave it at 121°C for 20 minutes as per the validated cycle.
- 5.2.6. Sanitize the tester's external surface using 70% IPA v/v.
- 5.2.7. Position the media plate in the reuse area of the tester head. Make sure to retain the media plate in its position by holding on to it, lock the micro perforated sieve into the position.
- 5.2.8. Push the switch ON/OFF button. The old air sample value will appear on the display.
- 5.2.9. Press the "SET" key, "SPE" will display on the screen showing the previous speed setting
- 5.2.10. To set the speed, press the stop key on each of the stop key speed to change it from low-medium-high-low.

- 5.2.11. Press set key to save the appropriate speed setting.
 - 5.2.12. The display will show the old set time with the first number blinking. Use the start key to move between the digits, press the start key to change the number.
 - 5.2.13. Set the "ON" time value by pressing the stop key. The blinking digit will change with increments from 0-9-0.
 - 5.2.14. Press set key to save the "ON" time and display the chosen time.
 - 5.2.15. The time and speed should be set in such a way that it will suck 1000ltrs of air.
 - 5.2.16. Press start key for second time to turn the fan at the desired speed for the displayed ON time.
 - 5.2.17. The delay time will be shown on the screen. After the delay time, the fan will be turned on to the desired time.
 - 5.2.18. The ON time will decrease on the display.
 - 5.2.19. When the ON time displayed zero, the fan will turn off and a buzzer will be turned on.
 - 5.2.20. To stop the fan during the ON time, press the "STOP" key.
- 5.3. Remote Control Operations:
- 5.3.1. Press the "ON" key.
 - 5.3.2. Press the "ON" time and the fan speed will be displayed on the screen. To turn the "ON" fan at the displayed speed, press the "START" key.
 - 5.3.3. The "ON" time will decrease and once it reaches zero it will turn off; a buzzer will turn on to indicate that the process is complete.
 - 5.3.4. To stop the fan during the operation, press the "STOP" key.

6 Abbreviations

SOP Standard Operating Procedure

IPA Isopropyl Alcohol